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IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 15 May 2014

Before :

THE HON MR JUSTICE ARNOLD

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Between :

	(1) ACTAVIS UK LIMITED **(2) ACTAVIS GROUP EHF (FORMERLY ACTAVIS GROUP HF)** **(3) ACTAVIS GROUP PTC EHF** **(4) MEDIS EHF** **(5) ACTAVIS DEUTSCHLAND GMBH & CO. KG** **(6) MEDIS PHARMA GMBH** **(7) MEDIS PHARMA FRANCE SAS** **(8) ACTAVIS FRANCE SAS** **(9) ACTAVIS SPAIN S.A.** **(10) ACTAVIS ITALY SPA A SOCIO UNICO**	**Claimants**
	- and -	
	ELI LILLY & COMPANY	**Defendant**

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Richard Meade QC, **Thomas Raphael** and **Isabel Jamal** (instructed by **Bird & Bird LLP**) for the **Claimants**
Simon Thorley QC, **Thomas Mitcheson QC** and **Stuart Baran** (instructed by **Hogan Lovells International LLP**) for the **Defendant**

Hearing dates: 9-10, 15-16 April 2014

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Approved Redacted Judgment

MR JUSTICE ARNOLD :

Contents

Introduction

1. 1. Pemetrexed disodium is a cancer treatment which has been marketed by the Defendant ("Lilly") or its subsidiaries under the brand name Alimta since 2004. Pemetrexed and its pharmaceutically acceptable salts were protected by European Patent No. 0 432 677 ("677"), which expired on 10 December 2010. The protection conferred by that patent has been extended by Supplementary Protection Certificates ("the SPCs") which will expire on 10 December 2015. Lilly also owns European Patent No. 1 313 508 ("the Patent"), which will not expire until June 2021, for the use of pemetrexed disodium in combination with vitamin B12 or a pharmaceutical derivative thereof and optionally a folic protein binding agent. The Claimants (whom I will refer to as "Actavis" save when it is necessary to distinguish between them) intend to launch a generic pemetrexed product the active ingredient in which will be either pemetrexed diacid, pemetrexed dipotassium or pemetrexed ditromethamine. Actavis intend to obtain regulatory approval for their product by reference to Alimta. Actavis contend that dealings in their product will not infringe the Patent. Lilly disputes this. Actavis would like a resolution of this issue in good time for them to enter the market on expiry of the SPCs. Furthermore, Actavis wanted the issue to be determined with respect to the French, German, Italian, Spanish and United Kingdom designations of the Patent, which cover the major pharmaceutical markets in Europe, in a single trial. Accordingly, Actavis commenced these proceedings seeking declarations of non-infringement ("DNIs") in respect of each

of those designations of the Patent. Lilly has counterclaimed for threatened infringement only of the UK designation.

2. 2. At an early stage of these proceedings, I heard a jurisdictional challenge by Lilly in relation to the French, German, Italian and Spanish designations which I rejected for the reasons given in my judgment dated 27 November 2012, [2012] EWHC 3316 (Pat) (affirmed [2013] EWCA Civ 517, [2013] RPC 37). Since then, there have been a number of developments, of which the following are the most significant for present purposes. A detailed procedural timetable is set out in paragraphs 237-292 below.

3. 3. First, as indicated in paragraph 1 above, Actavis now seek DNIs in relation to pemetrexed diacid and ditromethamine as well as dipotassium. Indeed, the diacid is currently Actavis' lead candidate.

4. 4. Secondly, a number of additional Actavis subsidiaries have been joined as claimants. Recently, however, Actavis Deutschland GmbH & Co KG, Actavis France SAS and Actavis Spain SA have ceased to be claimants consequential upon the sale of those companies to the Aurobindo Group.

5. 5. Thirdly, as explained in more detail below, Lilly brought proceedings against Actavis for threatened infringement of the German designation of the Patent before the Düsseldorf Landgericht (Regional Court). Despite the fact that this court was first seized, Actavis' jurisdictional challenge was rejected and on 3 April 2014 the Düsseldorf Regional Court gave judgment on the merits of Lilly's claim. In those circumstances, Actavis decided to discontinue the present proceedings so far as they relate to the German designation.

6. 6. Fourthly, whereas it was common ground at the time of the hearing before me in November 2012, as I recorded in my judgment at [30], that the law applicable to the question of whether this Court has power to grant DNIs with regard to the non-UK designations of the Patent was English law as the *lex fori*, since this was a question of procedure or remedy, Lilly subsequently changed its position and now contends that the applicable law is the law of the country in question. Furthermore, Lilly contends that Actavis have not satisfied certain requirements, which Lilly characterises as requirements of *locus standi* and Actavis characterise as procedural requirements, under French, Italian and Spanish law.

7. 7. Fifthly, in an attempt to circumvent Lilly's objections under the foreign laws, Actavis have brought a series of further claims. In essence, Actavis say that, even if Lilly's procedural objections were well founded as at the date of the first and second actions, the relevant procedural requirements had been satisfied by the date of one or more of the later actions. Lilly contend that the bringing of the later actions amounts to an abuse of the process of the court. In a judgment given on 27 November 2013 ([2013] EWHC 3749 (Pat)) I dismissed an application by Lilly to strike out the fourth and fifth actions as an abuse of process, primarily on the ground that, for the reasons given in that judgment, the application was premature.

8. 8. Sixthly, at a pre-trial review on 20 March 2014, I ruled, for the reasons given in my first judgment of that date ([2014] EWHC 838 (Pat)), that there should be no cross-examination of the foreign law experts upon their reports. I also ruled, for the reasons

given in my second judgment of that date ([2014] EWHC 839 (Pat)), that there should no cross-examination of Dr Maria Rotaru of Sindan Pharma SRL ("Sindan"), who had verified a Product and Process Description ("PPD") served by Actavis in lieu of giving disclosure with regard to relevant properties of pemetrexed diacid, dipotassium and ditromethamine. As a result, and thanks to the industry and efficiency of counsel on both sides, the hearing was completed in less than four days. Indeed, the cross-examination of all five witnesses was completed in only just over one court day.

9. 9. I make no apologies for the length of this judgment. There are many significant issues between the parties, I must consider and apply the laws of four different countries and a great deal of money is at stake. I was provided by the parties with 546 pages of written submissions and 41 files of evidence and other materials, which I have done my best to assimilate. Nevertheless, I shall endeavour to express my findings and reasoning as succinctly as I can.

The witnesses

Fact witness

1. 10. The only factual witness who gave evidence was Dr Stefán Stefánsson, Director of IP for the Actavis Group, who gave evidence about Actavis' preparations to launch a generic pemetrexed product. He was a straightforward witness.

Technical experts

1. 11. *Actavis' experts*. Professor Michael Seckl is currently Professor of Molecular Oncology at Imperial College London, where he is head of the Lung Cancer Research Group and of the Experimental Cancer Medicine Research Centre, and an honorary Consultant Medical Oncologist at Imperial College NHS Healthcare Trust. In addition, he is director of the Charing Cross Gestational Trophoblastic Disease ("GTD") Centre. He obtained a BSc in Immunology from University College London in 1983, an MBBS in 1986 and a PhD on the development of novel therapies for small cell lung cancer in 1995. He was appointed as a Senior Lecturer and honorary Consultant by Imperial in 1995, Reader in 2000 and Professor in 2002. His principal research interests are in the fields of small cell lung cancer and GTD. He has used pemetrexed since 2007.

2. 12. Dr Peter Spargo is currently an independent consultant whose areas of expertise are in Chemistry, Manufacturing and Controls ("CMC") associated with research and development in the pharmaceutical industry. He obtained a BA in Natural Sciences (Chemistry) from Cambridge University in 1983 and a PhD in Synthetic Organic Chemistry from Cambridge in 1986. From 1986 to 1988 he was a Post-Doctoral Research Fellow at Columbia University. From 1988 to 2003 he was employed by Pfizer successively as Medicinal Chemistry Team Leader, Process Chemistry Team Leader, then Section Head, Manager and Director of Process Research and Development and finally Head of Chemical R & D. In these capacities he was involved in numerous drug discovery and development projects. From 2003 to 2006 he was employed by Scientific Update LLP, becoming its Managing Director towards the end of that period. From 2007 to 2008 he was Vice President and then Senior Vice President of Novexel SA and from 2011 to 2013 he was Senior Vice President of Creabilis.

3. 13. *Lilly's experts*. Until very recently, Professor David Ferry was Professor of Medical Oncology at Wolverhampton University and a Consultant Medical Oncologist at New Cross Hospital, Wolverhampton and Clinical Director of the Greater Midlands Cancer Research Network. He obtained a BSc in Molecular Pharmacology from the University of Leicester in 1984, a PhD in Molecular Pharmacology from the University of Geissen in 1984 and an MBBS from Leicester in 1987. From 1990 to 1995 he was a Pulmonary Oncology Research Registrar at the Cancer Research Campaign. He was appointed as Senior Lecturer in Medical Oncology at the University of Birmingham and Heartlands NHS Trust in 1995. He was appointed as Consultant Medical Oncologist at the Royal Wolverhampton Hospitals NHS Trust in 2001 and was appointed as Professor in 2003. Coincidentally, he was recently recruited by Lilly to be Senior Director, Strategy and Clinical Development for GI tumours. I am satisfied that this did not influence his evidence before me in any way.

4. 14. Professor David Thurston is currently Professor of Drug Discovery in the Department of Pharmacy and the Institute of Pharmaceutical Sciences at King's College London. He obtained a BSc in Pharmacy from University of Portsmouth in 1976, qualified as a pharmacist in 1977 and obtained an MSc in Community Pharmacy Practice in 2010. He obtained a PhD from Portsmouth in 1980. From 1980 to 1983 he was a Post-Doctoral Fellow at the Universities of Kentucky and Texas at Austin. From 1983 to 1986 he was a junior faculty member at Texas. From 1987 to 1999 he was at Portsmouth, from 1999 to 2001 at Nottingham University and from 2001 to 2011 at University College London. He is the author of a standard work of reference *Chemistry and Pharmacology of Anticancer Drugs* (CRC Press, 2006), a second edition of which is in preparation.

5. 15. *Assessment*. All of the technical experts were good witnesses who did their best to assist the court. The only points about their evidence that merit comment are as follows. First, Prof Ferry struggled to put himself in the position of the skilled team. Secondly, and more importantly, there was some divergence between what Prof Ferry said in his oral evidence and what he had stated in his written reports both for these proceedings and for the German proceedings. In the end, there was little disagreement between him and Prof Seckl. Thirdly, Prof Thurston's area of expertise was of much less relevance to this case than that of Dr Spargo. Indeed, Prof Thurston had not come across either Berge or Stahl & Wermuth (as to which, see below) before. When it came to questions about salt formation and selection, in general Prof Thurston agreed with Dr Spargo's evidence or deferred to Dr Spargo's experience. To the extent that he differed, I prefer Dr Spargo's evidence.

French law experts

1. 16. Actavis' expert on French law is Professor Jean-Christophe Galloux. Since 2000 he has been Professor of Private Law at the University of Panthéon-Assas (Paris II), where he has directed the Masters program in Industrial Property Law since 2008. He is also a professor at the International Center for Industrial Property Studies (CEIPI) in Strasbourg and a visiting professor at several universities, including Montreal, Budapest, Munich, Columbia, Tokyo, Moscow and Saint Petersburg. Since 2010 he has been the President of the Research Institute in Intellectual Property of Paris. Since 2013 he has been a member of the French National Pharmaceutical Academy. He is also a member of the Scientific Advisory Board at the Munich Intellectual Property Law Centre. He is the author of several books, including *Droit de la Propriété Industrielle* (*Industrial Property Law*) (Précis Dalloz, 7th edition, 2012) with Prof Azema. In addition to his academic

work, Prof Galloux has been a member of the Paris Bar since 1984 and is an arbitrator and mediator.

2. 17. Lilly's expert on French law is Professor Jacques Azéma. He is currently Professor Emeritus at Jean Moulin University (Lyon III), Honorary Director of the Paul Roubier Centre, an intellectual property training institute set up jointly by the Law Faculty of Lyon III and the Lyon Chamber of Commerce, and Honorary Chairman of the French Group of the International Association for the Protection of Intellectual Property (AIPPI). He is the author of several books, including the book he has co-authored with Prof Galloux. From 1990 to 2006 he was a member of the Paris Bar.

Italian law experts

1. 18. Actavis' expert on Italian law is Professor Mario Franzosi. From 1963 to 1994 he was Professor of Intellectual Property Law and then of Business Law at the University of Parma. He is currently a visiting Professor of European Patent Law at the University of Washington. He has been a member of the Italian Bar since 1959 and a member of the Supreme Court Bar since 1974. In 1963 he founded the law firm which is now Avvocati Franzosi Dal Negro Setti. He is the author of, or a contributor to, a number of books on intellectual property law.

2. 19. Lilly's expert on Italian law is Professor Giovanni Guglielmetti. He has been Professor of Intellectual Property Law at the University of Milano-Bicocca since 2008, having previously been an associate professor and adjunct professor at the same institution since 1998. He has been a member of the Italian Bar since 1990. Since 2006 he has been head of the intellectual property department in the law firm Bonelli Erede Pappalardo. He is the author of a book on patents and copyrights in computer software.

Spanish law experts

1. 20. Actavis' expert on Spanish law is Professor Manuel Desantes Real. He has been Head of the Department of Philosophy of Law and Private International Law at the University of Alicante since 2011. From 1985 to 1998 he was employed by the Spanish Ministry of Justice to negotiate the Brussels and Lugano Conventions. From 1993 to 1998 he was Professor of Private International Law at the University of Alicante, where he was director of the Masters in Intellectual Property from 1994 to 1998. From 1998 to 2001 he was a national expert in the Legal Service of the European Commission. From 2001 to 2008 he was Vice-President (Directorate General 5 – Legal and International Affairs) of the European Patent Office. He returned to the University of Alicante in 2008. Since 2010 he has also worked for the law firm Elzaburu. He is the author of five books.

2. 21. Lilly adduced evidence from two experts on Spanish law, Professor Rafael Arenas Garcia and Professor Alberto Bercovitz. Since 2005 Prof Arenas has been Professor of Private International Law at the Autonomous University of Barcelona, where he had been a lecturer since 1996. He was a member of the Catalan Codification Commission between 2007 and 2010. He is co-author of a book on international business law. Prof Bercovitz is currently Emeritus Professor of Commercial Law at the Spanish National Distance Education University, where he has been a professor since 1978. Since 1970 he has been a member of, and since 2006 he has been President of the Commercial Law Section of, the Spanish Codification Commission. From 2004 to 2011 he was a member

of the Scientific Advisory Board at the Munich Intellectual Property Law Centre. He is the author of several books, including three monographs on aspects of patent law.

3. 22. By an order dated 17 October 2013, I gave each party permission to adduce reports from one expert witness on each of (i) the patent laws of France, Germany, Italy and Spain and (ii) the conditions for DNIs and the burden of proof under the laws of those countries. Save in the case of Lilly and Spain, both parties managed to find a single expert from each country to deal with both topics. While Lilly cannot be criticised for adducing evidence from two experts, it is regrettable that there was a substantial degree of overlap, and hence duplication, between the reports of Prof Arenas and Prof Bercovitz with regard to topic (ii). I have not accorded Lilly's evidence any greater weight because some of the points made were supported by two experts rather than one.

General comments on the evidence of foreign law

1. 23. All of the foreign law experts are distinguished experts in their fields who appear to have discharged their responsibilities as expert witnesses in an exemplary manner. Their reports are generally clear and comprehensive. As directed by the order dated 17 October 2013, they prepared memoranda setting out points of agreement and disagreement. Points that are agreed I shall recite without further comment. Where the experts have disagreed, it is generally because the law in their respective countries is not settled. The experts have supported their opinions by extensive reference to legislation, case law and commentaries. It would considerably lengthen what is already a lengthy judgment, and further delay its delivery, if I were to set out in detail the experts' views, all the supporting materials they rely upon and my analysis of those views and materials on every issue. I shall therefore concentrate on setting out my conclusions as to the foreign law and identifying the principal materials those conclusions are based on, with only brief explanations of why I have preferred one expert's view to another's. Furthermore, I shall concentrate on the main points which are necessary for my decision, ignoring points which are not necessary for my decision or are peripheral. I shall quote the foreign law sources only in English translation. Where there is an agreed translation, I shall quote that. Where there are rival translations, I shall quote the one which appears to me to be most accurate.

<u>Burden of proof</u>

1. 24. I do not understand there to be any real dispute between the parties as to the incidence of the burden of proof. So far as the UK designation of the Patent is concerned, as noted above, Lilly has counterclaimed for threatened infringement by Actavis, and thus the burden of proving infringement lies on Lilly. Actavis admit that they intend, if it is lawful to do so, to market a generic pemetrexed product which will be pemetrexed diacid, dipotassium or ditromethamine. Furthermore, Actavis admit that the product is to be administered in combination with vitamin B12 and folic acid. Accordingly Lilly only needs to show either that the proposed products fall within the scope of the claims of the Patent or that the supply of the proposed products would amount to indirect infringement of the Patent. If Lilly fails to establish infringement, the burden of proving it is appropriate to make a DNI lies on Actavis. So far as the French, Italian and Spanish designations are concerned, the burden lies on Actavis to establish that the proposed products do not fall within the scope of the claims of the Patent, that the supply of the proposed products would not amount to indirect infringement and that the applicable criteria for making DNIs are satisfied, although the burden lies on Lilly to prove any positive allegations it makes. As will appear, however, I have not found it

necessary to resort to the burden of proof in order to resolve any of the issues between the parties.

The Patent

1. 25. The Patent has an earliest claimed priority date of 30 June 2000, was applied for on 15 June 2001, and was granted on 18 April 2007. As explained in my first judgment, there is no challenge to the validity of the Patent in these proceedings. The Patent was opposed before the European Patent Office by Teva Pharmaceutical Industries Ltd ("Teva"). The Opposition Division rejected the opposition in a decision dated 27 December 2010, but Teva has appealed to the Technical Board of Appeal. At the time of the hearing before me, no date had been set for the hearing before the Board of Appeal.

2. 26. The title of the Patent is "Combination containing an antifolate and methylmalonic acid lowering agent". The specification begins at [0001] by stating that "Potentially, life-threatening toxicity remains a major limitation to the optimal administration of antifolates".

3. 27. The specification goes on at [0002] to say that "Antifolates represent one of the most thoroughly studied classes of antineoplastic agents, with aminopterin initially demonstrating clinical activity approximately 50 years ago". Having explained that "Antifolates inhibit one or several key folate-requiring enzymes of the thymidine and purine biosynthetic pathways, in particular, thymidylate synthase (TS), dihydrofolate reductase (DHFR), and glycinamide ribonucleotide formyltransferase (GARFT), by competing with reduced folates for binding sites of these enzymes", it identifies several antifolate drugs as being in development. In this context, it states:

> "… pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, IN) has demonstrated thymidylate synthase, dihydrofolate reductase, and glycinamide ribonucleotide formyltransferase inhibition."

1. 28. The specification then explains at [0003] that a limitation to the development of these drugs is that the cytotoxic activity and subsequent effectiveness of antifolates may be associated with substantial toxicity for some patients.

2. 29. In [0004] the specification discusses previous work on the use of folic acid as a treatment for toxicities associated with GARFT and on vitamin B12 as a predictor of cytotoxic events related to the use of GARFT inhibitors. In this context, it states:

> "The role of folic acid in modulating the toxicity and efficacy of the multitargeted antifolate LY 231514 (pemetrexed) was discussed in Worzalla *et al.* (Anticancer Research 18: 3235-3240 (1998) Worzalla JF, Chuan S and Schultz RM)."

1. 30. The specification then explains the broad idea underlying the invention in the following terms:

> "[0005] Surprisingly and unexpectedly, we have now discovered that certain toxic effects such as mortality and nonhematologic events, such as skin rashes and fatigue, caused by antifolates, as a

class, can be significantly reduced by the presence of a methylmalonic acid lowering agent as vitamin B12, without adverse adversely affecting therapeutic efficacy. The present invention thus generally relates to a use in the manufacture of a medicament for improving the therapeutic utility of antifolate drugs by administering to the host undergoing treatment with a methylmalonic acid lowering agent as vitamin B12. We have discovered that increased levels of methylmalonic acid is a predictor of toxic events in patients that receive an antifolate drug and that treatment for the increased methylmalonic acid, such as treatment with vitamin B12, reduces mortality and nonhematologic events, such as skin rashes and fatigue events previously associated with the antifolate drugs. Thus, the present invention generally relates to a use in the manufacture of a medicament for reducing the toxicity associated with the administration of an antifolate to a mammal by administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent as vitamin B12.

[0006] Additionally, we have discovered that the combination of a methylmalonic acid lowering agent as vitamin B12 and folic acid synergistically reduces the toxic events associated with the administration of antifolate drugs. Although, the treatment and prevention of cardiovascular disease with folic acid in combination with vitamin B12 is known, the use of the combination for the treatment of toxicity associated with the administration of antifolate drugs was unknown heretofore."

1. 31. Paragraphs [0007]-[0009] are consistory clauses expressed in terms of "an antifolate". Paragraphs [0010]-[0015] are consistory clauses expressed in terms of "the antifolate pemetrexed disodium".

2. 32. At [0016] the specification states:

> "The current invention concerns the discovery that administration of a methylmalonic acid lowering agent such as vitamin B12 or a pharmaceutical derivative thereof, in combination with an antifolate drug such as pemetrexed disodium reduces the toxicity of the said antifolate drug."

1. 33. Paragraphs [0017]-[0022] and [0028]-[0029] contain a number of definitions, including the following:

"[0021] As used herein, the term 'in combination with' refers to the administration of the vitamin B12 or pharmaceutical derivative, pemetrexed disodium, and optionally the folic acid; in any order such that sufficient levels of methylmalonic acid lowering agent and optionally folic acid are present to reduce the toxicity of an antifolate in a mammal. The administration of the compounds maybe simultaneous as a single composition or as two separate compositions or can be administered sequentially as separate compositions such that an effective amount of the agent first

administered is in the patient's body when the second and/or third agent is administered. …

[0022] The terms 'antifolate' and 'antifolate drug' generally refer to a chemical compound which inhibits at least one key folate-requiring enzyme of the thymidine or purine biosynthetic pathways, preferably thymidylate synthase ('TS'), dihydrofolate reductase ('DHFR'), or glycinamide ribonucleotide formyltransferase ('GARFT'), by competing with reduced folates for binding sites of these enzymes. The 'antifolate' or 'antifolate drug' for use in this invention is Pemetrexed Disodium (ALIMTA®), as manufactured by Eli Lilly & Co.

[0028] The term 'FBP binding agent' as used herein refers to a folic binding protein binding agent which includes folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid, and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically-available salt or ester thereof. …

[0029] **'**Physiologically-available salt' refers to potassium, sodium, lithium, magnesium, or preferably a calcium salt of the FBP binding agent. 'Physiologically-available...ester' refers to esters which are easily hydrolyzed upon administration to a mammal to provide the corresponding FBP binding agent free acid, such as for example C1-C4 alkyl esters, and mixed anhydrides."

1. 34. Methods of administration are described in [0026]. Dosages are discussed in [0027]. From [0034] to [0056] the specification describes a number of examples, which relate to animal and human tests. The details of these do not matter, but two points should be noted. First, the only antifolate used is pemetrexed disodium, which is consistently referred to in this part of the specification (24 times) as "pemetrexed disodium (ALIMTA®)". Secondly, the specification indicates at [0044] that, in a typical cancer evaluation, the antifolate is to be administered in four doses over a two week period by rapid intravenous injection followed by two weeks of non-therapy.

<u>The claims</u>

1. 35. Claims 1-11 of the Patent are Swiss form claims and claims 12-14 are product claims. It is only necessary to refer to claims 1, 2 and 12, which are as follows:

"1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.

2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-

chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-forinyl-5,6,7,8-tetrahydrofolic acid or a physiologically available salt or ester thereof.

12. A product containing pemetrexed disodium, vitamin B 12 or a pharmaceutical derivative thereof said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and, optionally, a folic binding protein binding agent selected from the group consisting of folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically available salt or ester thereof, as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumor growth."

The prosecution history of the Patent

1. 36. The Patent was applied for by an International Application under the Patent Co-operation Treaty filed on 15 June 2001 and published on 10 January 2002 under number WO 02/02093 ("the PCT"). The PCT included 28 claims: claims 1-10 were directed to a method of treatment, claims 11-24 were Swiss form claims and claims 25-28 were purpose-bound product claims.

2. 37. When the PCT entered the European regional phase, Dr Ivan Burnside, Lilly's in-house European Patent Attorney, filed a revised set of claims which omitted the method of treatment claims under cover of a letter dated 8 January 2003. Claims 1 and 2 were as follows:

"1. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate.

2. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate and a FBP binding agent."

Claim 10 was a dependent claim "wherein the antifolate is ALIMTA". Claims 13-17 were purpose-bound product claims, with claim 15 being a dependent claim "wherein the antifolate is ALIMTA". None of the claims was directed to a use or product wherein the antifolate was pemetrexed.

1. 38. On 9 March 2004 the EPO examiner issued an official communication which raised objections under Article 52(4) of the European Patent Convention (patentability), Article 54 EPC (novelty), Article 56 EPC (inventive step), Article 83 EPC (disclosure) and Article 84 EPC (clarity). The clarity and lack of disclosure objections were expressed as follows:

"Present claims 1-11, 13-16 relate to an extremely large number of possible combinations of compounds defined as 'antifolate', 'methylmalonic acid lowering agent', 'FBP binding agent'.

In fact, the claims contain so many options and variables that a lack of clarity (and conciseness) within the meaning of Article 84 EPC arises.

Moreover claims 1-11, 13-16 relate to a compounds defined by reference to desirable characteristics or properties, namely 'antifolate', 'methylmalonic acid lowering agent', 'FBP binding agent'.

The claims cover all compounds having these characteristics or properties, whereas the application provides support within the meaning of Article 84 EPC and disclosure within the meaning of Article 83 EPC for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure. Support is only to be found in the present application for those parts relating to the compounds/compositions prepared in the examples and those specifically defined by chemical name in claims 8-10, 12, 14-17.

Independent of the above reasoning, claims 1-3, 6-12 also lack clarity (Article 84 EPC):

A therapeutic application is defined in terms of a result to be achieved: 'reducing toxicity' (claims 1-3). No therapeutically defined use or disease is clearly encompassed under such wording.

Again, this lack of clarity in the present case does not comply with Art 84 EPC. (See also Decision of the Board of Appeal T1048/98).

Furthermore the abbreviations 'FBP' expressed on claims 2, 6, 7, 9, 13, 16 and 'ALIMTA' expressed on claims 10, 12, 15, 17 are unclear (Art 84 EPC). They should be replaced by the appropriate wording.

…."

1. 39. Dr Burnside replied to the official communication in a letter dated 23 December 2004, under cover of which he filed new claims 1-16 to replace claims 1-17 previously on file. New claims 1 and 2 were as follows:

"1. Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.

2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic

acid or a physiologically available salt or ester thereof."

Claims 13-16 were purpose-bound product claims with claim 13 similarly limited to pemetrexed.

1. 40. In support of the new claims, Dr Burnside argued *inter alia* as follows:

> "The Applicant, having reviewed the scope of the application and in order to expedite the application proceeding to grant, has elected to amend the claims so as to more closely reflect the specific examples provided. The present amendments are made without prejudice to the Applicant's right to obtain protection for other patentable subject matter in one or more divisional applications.
>
> Claims 1-12 have been refocused on the use of the antifolate compound pemetrexed. Basis can be found at page 2 line 6-7 and page 6 line 16 of the application as filed. The term 'methylmalonic acid lowering agent' has been replaced by 'vitamin B12 or a pharmaceutical derivative thereof'. Basis for this can be found page 6 lines 19-21 and page 7 line 5 of the application as filed.
>
> …
>
> In claim 2 the term 'FBP binding agent' has been expounded in full following page 8 lines 6-7. Additionally, this term has been further refined according to page 8 lines 7-9 of the application as filed.
>
> …"

1. 41. On 17 May 2005 the EPO examiner issued a further official communication objecting to the admissibility of the new claims on the following grounds:

> "**Amendments (Art. 123 (2) EPC)**
>
> The amendments filed with letter 23.12.2004 do not comply with the requirements of Art. 123(2) EPC in so far as they introduce subject matter beyond the content of the originally filed documents.
>
> The amendments concerned are the following:
>
> The subject matter of claims 1-16 and description pages 4, line 18- page 4a.
>
> The subject matter of present claims 1 reading 'use of pemetrexed... ' and claim 13 "a product containing pemetrexed... ' do not find base in the application documents as filed. The term 'pemetrexed' in the wording of these claims and the corresponding passages on amended description is certainly a distinct compound (CAS Registry number 137281-23-3) of the 'pemetrexed disodium' (CAS Registry number 150399-23-8)

> expressed on original document description page 2, line 6 and page 6, line 16. Said amendment beyond the content of the original document is therefore not allowable (Art. 123 (2) EPC).
>
> Dependent claims 2-12, 14-16 in so far as related to 'pemetrexed' are consequently not allowable according to Art. 123(2) EPC. "

1. 42. The examiner also raised a number of other objections to the new claims, including an objection under Article 56 EPC premised on the ground that "the problem underlying the present invention is to reduce the toxic events associated with the administration of the antifolate drug pemetrexed disodium (namely ALIMTA, LY 231514 or MTA)."

2. 43. Dr Burnside replied to the official communication in a letter dated 8 March 2006, under cover of which he filed new claims 1-14 to replace claims 1-16 previously on file. The new claims were limited to pemetrexed disodium.

3. 44. In support of the new claims, Dr Burnside argued *inter alia* as follows:

> "The Claims have been amended to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug. The Claims have also been amended to incorporate the list of vitamin B12 derivatives set out on page 7 lines 6-7 of the application as filed."

1. 45. The examiner accepted the new claims, and the application proceeded to grant. Three additional points should be noted. First, Lilly did not challenge the examiner's objections, still less appeal against them. Secondly, Lilly has admitted that making the amendments was "a deliberate and conscious act on the part of Lilly". Thirdly, although Lilly reserved the right to file divisional applications, no divisional application has been published or granted.

<u>The skilled person or team</u>

1. 46. There is a significant dispute between the parties as to the correct identification of the person or team skilled in the art to whom the Patent is addressed. Both parties addressed me by reference to UK law on this subject, which is intended to be consistent with the jurisprudence of the EPO Boards of Appeal. Neither party relied on any evidence as to what the foreign laws have to say on this topic, if anything.

UK law: general

1. 47. A patent specification is addressed to those likely to have a practical interest in the subject matter of the invention, and such persons are those with practical knowledge and experience of the kind of work in which the invention is intended to be used. The addressee comes to a reading of the specification with the common general knowledge of persons skilled in the relevant art, and he (or she) reads it knowing that its purpose is to describe and demarcate an invention. He is unimaginative and has no inventive capacity. In some cases the patent may be addressed to a team of persons having different skills.

2. 48. Jacob LJ, with whom Waller and Sullivan LJJ agreed, reviewed the law with regard to the correct identification of the skilled person or team in *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819, [2010] RPC 33 at [30]-[65]. He held that the person skilled in the art was not necessarily the same when considering pre-grant issues such as obviousness (inventive step) as when considering post-grant issues such as sufficiency and infringement. In essence, this was for two reasons. First, because in the post-grant scenario the skilled person was deemed to have read the patent whereas in the pre-grant scenario he was not. Secondly, because the making of the invention could in itself change the art. Furthermore, he held at [42] that, at least when considering obviousness, the court should have regard to "the combined skills (and mind-sets) of real research teams in the art".

3. 49. In the situation where the specification is clearly aimed at a set of skills that would be possessed by a team of people as opposed to a single individual, in general the team has no boss and each member of the team is assumed to play his/her own part: see *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] EWCA Civ 1715 at [14] (Jacob LJ delivering the judgment of the Court of Appeal). There may, however be cases where the skilled team is led by a particular member, who would take advice from other members of the team: see e.g. *KCI Licensing Inc v Smith & Nephew plc* [2010] EWHC 1487 (Pat), [2010] FSR 31 at [103]. In the latter situation, however, one cannot ignore the supporting team members when considering the relevant common general knowledge.

UK law: Swiss form claims

1. 50. A significant aspect of the dispute which emerged in the course of counsel's submissions concerns the proper identification of the addressee of Swiss form claims i.e. claims in the form "use of substance X in the manufacture of a medicament for therapeutic use Y". The history of, and rationale for, granting patents with claims in this form was considered in detail by Jacob LJ giving the judgment of the Court of Appeal in *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186 at [7]-[49] and by Kitchin J (as he then was) in *Ranbaxy (UK) Ltd v AstraZeneca AB* [2011] EWHC 1831 (Pat), [2011] FSR 45 at [42]-[56].

2. 51. As those judgments explain, the purpose for which Swiss form claims were devised was in order to provide protection for second medical uses of known substances while avoiding the problems of (i) lack of novelty and (ii) the prohibition on patenting methods of treatment which was formerly contained in Article 52(4) EPC 1973: see G 05/83 *Eisai/Second medical indication* [1985] OJ EPO 64.

3. 52. For present purposes, the following points may be noted. First, in the course of analysing G 05/83, Jacob LJ commented at [21]:

> ".. The board is clearly saying that this form of claim does *not* fall foul of article 52(4). Making up the substance for administration is not in itself administration—is not treatment. That would seem to be the case whether the substance is made up in a factory … or in a pharmacy (where it may even be patient-specific). We emphasise this because sometimes in the discussion there is a tendency to conflate the novelty and therapeutic treatment objections, as though one followed from the other. What worried the board was only novelty."

1. 53. Jacob LJ went on at [75] to hold that the claim under consideration in that case was not a claim to a method of treatment for reasons he encapsulated as follows:

> "… There is nowhere near the degree of involvement of medical personnel which turned the case in the *Bristol-Myers Squibb* case. In its essence the claim here is to the use of finasteride for the preparation of a medicament of the specified dosages. It is not aimed at and does not touch the doctor—it is directed at the manufacturer. …"

1. 54. Secondly, again in the course of analysing G 05/83, Kitchin J commented:

> "54. It is, I think, inherent in all this reasoning that the skilled person would generally understand a Swiss form claim to mean that the medicament must contain the active ingredient for which the new and inventive use has been found. But for the exclusion contained in art.52(4) EPC 1973, the claim would have been directed to the new and non obvious use of that ingredient.
>
> 55. I do not go so far as to suggest that a claim cast in Swiss form must always be construed as being directed to the use of an active ingredient for the manufacture of a medicament which contains that ingredient. The proper meaning of the claim must be determined having regard to the words of the claim when construed purposively in the light of the specification and the common general knowledge, as the Court of Appeal emphasised in *Monsanto & Co v Merck & Co Inc (No.1)* [2000] R.P.C. 77. However, it seems to me that is how it would normally be understood. Moreover, the skilled person would appreciate that to construe it otherwise would render the claim vulnerable to an attack of insufficiency."

1. 55. As Kitchin J explained at [57]-[61], the coming into force of EPC 2000 amended the relevant provisions so that what was Article 52(4) EPC 1973 is now Article 53(c) EPC 2000 and Article 54(5) now permits the granting of patents for known substances for use in a method referred to in Article 53(c) provided that it is novel. It follows that the legal fiction involved in Swiss form claims is no longer required, and instead it is possible for the patentee to obtain a claim to "Substance X for use in method of treatment Y". Accordingly, the Enlarged Board of Appeal has held that it is no longer appropriate to grant claims in the Swiss form: see G 02/08 *Abbott Respiratory/Dosage regime* [2010] EPOR 26.

Assessment

1. 56. Actavis contend that, at least for the purpose of post-grant issues such as infringement, the Patent is addressed to a team consisting of a number of persons with a range of skills, but in particular (i) a medical oncologist and (ii) someone with experience in pre-formulation work, who could be a process chemist or a formulation scientist (and who I will refer to for brevity as a chemist), supported by an analytical chemist. Lilly's original position, as pleaded in its Statement of Case on Common General Knowledge and stated in its opening skeleton argument at trial, was that the Patent was directed solely, or at least primarily, to a medical oncologist. In closing submissions, however, Lilly modified its position to some extent, as described below.

2. 57. In assessing the rival contentions, it is convenient to begin with the fact that claim 1 of the Patent is in Swiss form, whereas claim 12 is a purpose-bound product claim. Apart from that slight difference, the scope of claim 12 is the same as that of claim 1. Counsel for Lilly suggested that there was a difference in scope. If I understood him correctly, this was for one of two reasons. The first was that claim 12 corresponded to claim 2. This overlooks the fact that in claim 12 the folic protein binding agent is optional, however. The second is that claim 12 was limited to a single combined preparation of the two or three ingredients. This overlooks the definition in [0021] and the fact that claim 12 expressly refers to "simultaneous, separate or sequential use", however.

3. 58. Despite this, counsel for Lilly submitted in his closing submissions that claim 1 was directed to a medical oncologist, whereas he accepted that claim 12 was directed to a team consisting of a medical oncologist and a chemist. I do not accept that claim 1 and claim 12 are directed to different addressees. Counsel for Lilly cited no authority in support of the proposition that different claims of the same scope in the same patent may be addressed to different skilled persons even for the purposes of the same issue. I am aware of no such authority and in my judgment such an approach would be contrary to principle.

4. 59. Counsel for Lilly sought to support his submission by arguing that what mattered was claim 1, since Lilly could apply to delete claim 12 and did not assert claim 12 for the purposes of its counterclaim for threatened infringement of the UK designation. Lilly has not applied to delete claim 12, however, and Actavis seek a declaration of non-infringement in respect of all claims of the Patent. (I would add that, as counsel for Lilly accepted, it is clear that Actavis' proposed product will infringe claim 2, as well as claim 1, if those claims extend to pemetrexed diacid, dipotassium and ditromethamine, since Actavis intend to seek regulatory approval by reference to Lilly's product which is administered together with both vitamin B12 and folic acid.)

5. 60. Counsel for Lilly also suggested that the addressee of the Patent could be different for the purposes of considering the scope of the claim (and hence infringement) and for the purpose of considering sufficiency. In the alternative, he suggested that the addressee could be different for the purposes of considering *Improver* question 1 on the one hand and *Improver* questions 2 and 3 on the other hand. Again, he cited no authority for these propositions and in my judgment they are contrary to principle.

6. 61. In my view counsel for Lilly was correct to accept that claim 12 is addressed to a team comprising a medical oncologist and a chemist. It is clear from the evidence of both Prof Ferry and Prof Seckl that a medical oncologist would be unable to make a single combined preparation for simultaneous use falling within claim 12, whether the combination consisted just of pemetrexed disodium and vitamin B12 (or derivative) or all three components, and would require the assistance of a chemist for this purpose. In my judgment it follows that claim 1 is also addressed to the same team.

7. 62. I would reach the same conclusion if claim 1 stood on its own. I do not accept the argument advanced by counsel for Lilly that, because claim 1 is a Swiss form claim which was a legal fiction designed to circumvent Article 52(4) EPC 1973, therefore it should be interpreted as if it were a claim to a method of treatment. I accept that, as indicated by *Virgin v Premium*, the skilled person interpreting the claim is deemed to have some understanding of relevant drafting conventions, but that does not warrant interpreting claim 1 as if it was to a method of treatment. Even under the EPC 2000, the method of treatment would not be patentable. Claim 1 is directed at the manufacturer of

the pemetrexed disodium medicament, and it embraces a single combined preparation for simultaneous use. Furthermore, it is clear from the evidence of Dr Spargo that in the real world the teams who deal with developing and making medicaments for use in treatment comprise a range of disciplines, and in this context would comprise both a medical oncologist and a chemist.

8. 63. I would add that, if Lilly is correct that, in addition to pemetrexed disodium, other forms of pemetrexed may fall within the scope of the claims, then it necessarily follows that the skilled team must include a chemist. As Prof Ferry accepted, the choice of an appropriate alternative salt would not be something that the medical oncologist could assist with. To put it another way, if the skilled team did not include a chemist and the claim extended to alternative salts, the claim would be insufficient for that reason alone.

9. 64. Finally, counsel for Lilly relied on the decision of the Opposition Division, in which the Opposition Division considered inventive step from the perspective of a medical oncologist, as supporting Lilly's case as to the addressee. Even assuming that that assessment is correct, however, for the reasons given in *Schlumberger*, it does not follow that the skilled team is the same for the purposes of sufficiency and infringement.

Common general knowledge

1. 65. Again, both parties addressed me by reference to UK law on this subject, which is intended to be consistent with the jurisprudence of the EPO Boards of Appeal. Neither party relied on any evidence as to what the foreign laws have to say on this topic, if anything.

UK law

1. 66. I reviewed the law as to common general knowledge in *KCI Licensing Inc v Smith & Nephew Ltd* [2010] EWHC 1487 (Pat) at [105]-[115]. That statement of the law was approved by the Court of Appeal [2010] EWCA Civ 1260, [2011] FSR 8 at [6]. Counsel for Lilly relied on what I said at [112]:

> "… even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain the information, not because it is common general knowledge."

1. 67. A point which I did not address in KCI was the relevant date at which to assess the

common general knowledge. It is settled that, when considering validity, the relevant date is the filing date or the priority date if there is a valid claim to an earlier priority date. Although the matter is not settled, the weight of authority supports assessment as at the publication date for the purposes of infringement: see *Terrell on the Law of Patents* (17th ed) at §§9-10 to 9-11. In practice, however, English courts tend to assess the common general knowledge as at the filing or priority date for this purpose as well.

Assessment: common general knowledge of the oncologist in 2000/2001

1. 68. There is little dispute as to the relevant common general knowledge of the oncologist in 2000/2001. It may be summarised as follows.

2. 69. *Antifolates.* It was well known that antifolates were a class of drugs which were used in cancer chemotherapy. Some drugs in this class, such as methotrexate, had been used for a considerable period of time, but others were under development. There was some understanding of the mechanism of action of antifolates. It was well known that the use of antifolates in chemotherapy caused toxic side effects which it would be desirable to avoid or reduce if possible.

3. 70. *Pemetrexed*. It was known that an antifolate called pemetrexed was the subject of clinical trials for use in chemotherapy, that it targeted multiple enzymes and that it was administered intravenously, but that it had not yet received regulatory approval. The only form of pemetrexed which had been shown to be effective and safe, to the extent that this had been shown, was pemetrexed disodium, which was manufactured by Lilly under the trade mark Alimta.

4. 71. Prof Seckl's view was that in 2000/2001 an oncologist who had not been personally involved in the Alimta clinical trials would only have had a limited knowledge of pemetrexed, whereas Prof Ferry thought that the oncologist would have had a greater degree of knowledge about pemetrexed. This difference of opinion is immaterial, because it is common ground that, before embarking on any research involving pemetrexed, an oncologist who did not know much about it would carry out a literature search and find out what was known about it.

5. 72. *Vitamin B12 and folic acid.* Both vitamin B12 and folic acid had been well known for a considerable period of time, and their characteristics, structure and functions were well understood. In particular, it was known that vitamin B12 and folic acid were both involved in DNA synthesis repair. It was well known that there were a number of different safe and effective forms of both vitamin B12 and folic acid available.

6. 73. *Salt forms and counter-ions*. It is clear from the evidence of both Prof Seckl and Prof Ferry that skilled oncologists (even research clinicians) do not think about drugs like pemetrexed in their ionic form, nor do they consider issues regarding the choice of counter-ion or the effect, if any, of counter-ions on the efficacy, safety or other properties of the drug. Importantly, Prof Ferry agreed with Prof Seckl that the choice of salt form was really the province of the chemist and that the oncologist would not be involved in this. He also agreed that the properties of salt forms and free acids were difficult to predict and that the chemist would need to address this problem by conducting experiments.

Common general knowledge of the oncologist in 2007

1. 74. It is common ground that, by 2007, the oncologist would have been far more familiar with pemetrexed than in 2000/2001. Neither side suggested that this made any real difference to the issues in the case, however.

Common general knowledge of the chemist in 2000/2001 and in 2007

1. 75. Again, there is little dispute as to the common general knowledge of the chemist. Furthermore, it is common ground that there was no material difference between 2000/2001 and 2007. It may be summarised as follows.

2. 76. *Salts and counter-ions*. Drugs frequently contain one or more acidic or basic groups. Where this is the case, it is generally possible to form different salts of the parent molecule by reacting it with a complementary base or acid. The salt will typically have different properties from the parent molecule. For example, a salt may be a solid at room temperature, whereas the parent molecule is a liquid; a salt may be soluble in water, whereas the parent molecule is not; and so on. Furthermore, different salts will typically have different properties from each other. For these reasons, salt screening is a routine, but important, part of the process of determining the most suitable form of a drug for formulation.

3. 77. Formation of a salt involves the transfer of one or more protons (hydrogen ions) from the acid to the base, resulting in a negatively charged species (an anion) and a positively charged species (a cation). The ion which is not derived from the parent molecule is generally referred to as the “counter-ion”. Where the parent molecule is an acid, it will form an anion when reacted with a base. The base will provide the counter-ion. Thus pemetrexed diacid reacts with sodium hydroxide to form pemetrexed disodium salt. In this case the counter-ion is sodium, which is a cation.

4. 78. Solid salts consist of the anions and cations regularly arranged in a fixed lattice structure. In sodium chloride, for example, each ion is surrounded by six ions of the opposite charge in a structure known as a face-centered cubic lattice. It is possible to draw a cube containing a number of ions which is a repeating element in an infinite array. In a salt consisting of a single cation and a single anion, there are equal numbers of alternating cations and anions in the lattice. Where there are different ratios of cations and anions, this gives rise to different lattice structures. The different lattice structures in turn give rise to different crystal structures. Although lattices contain infinite numbers of cations and anions, the fact that the cations and anions are present not only in fixed proportions, but also fixed relative positions, means that it is possible to speak meaningfully of the salt as being present in solid form.

5. 79. It is important to appreciate that, when a salt like pemetrexed disodium is dissolved in a solvent like water, the ions dissociate from each other and become surrounded by solvent molecules. The result is free cations and anions in solution. It follows that the salt does not exist as such in the solution, but rather there is a solution containing the separate constituent cations and anions. Thus a solution of sodium chloride does not contain sodium chloride, it contains sodium cations and chloride anions. It is commonplace to refer to “a salt solution” or “a salt in solution”, but this is a convenient shorthand which is not technically entirely accurate.

6. 80. *The impact of the salt form on a drug and the difficulties in making salts*. The evidence of Dr Spargo and Prof Thurston on these topics can be summarised as follows:

i. i) the salt form can have a significant impact on the effectiveness of a drug;

ii. ii) salt forms can modify the solubility, therapeutic use, pharmaceutical dosage forms, pharmacokinetic properties (e.g. absorption, distribution, metabolism and excretion of the parent molecule in the body) and the chemical and physical stability of the drug, and its suitability for industrial processing;

iii. iii)in particular, in relation to solubility, if a salt form has poor solubility and dissolution, this can result in poor bioavailability, as good solubility and/or dissolution are indicators of how likely it is that the drug will be absorbed in the gut. When considering a drug for intravenous chemotherapy, the solubility of the salt form is crucial;

iv. iv)by contrast, if a salt is too soluble, then it may not result in direct crystallization or precipitation of the desired salt, and therefore the salt cannot be made in solid form in the first place;

v. v) there can be other problems trying to make salts before one can consider testing them further, including solvents or other impurities being trapped in the lattice. In such cases, although a salt has been made, the solid form would rarely be robust or commercialisable;

vi. vi)in general, there can be many dead-ends and false leads when attempting to prepare salts of a parent molecule for the first time.

i. 81. *Salt screening*. When deciding which counter-ions to test in a salt screening process, the chemist would routinely refer to the lists of commonly used counter-ions which had been identified in standard texts. The two most common standard texts were Berge, Bighly and Monkhouse, "Pharmaceutical Salts", *J. Pharm. Sci.*, 66, 1-19 (1977) ("Berge") and Stahl and Wermuth (eds), *Handbook of Pharmaceutical Salts: Properties, Selection and Use* (Wiley-VCH, 2002) ("Stahl & Wermuth"). Both of these texts contain tables showing the most common counter-ions found in approved pharmaceuticals. At the time of Berge, the most common counter-ion for acidic parent molecules was sodium, followed by potassium, calcium, zinc, lithium, magnesium and aluminium. By the time of Stahl & Wermuth, sodium was still the most common, now followed by calcium, potassium, magnesium, meglumine, lysine and a variety of others.

ii. 82. *Predictability of the viability of salts*. It was common ground between the experts that one could not predict in advance (a) whether one could make a particular salt form of a parent molecule, (b) what its properties would be once the salt form was made or (c) whether it would affect the efficacy of the drug. As Dr Spargo explained in his reports, the screening and selection process for salt forms is an empirical one involving trial and error. As Prof Thurston agreed, this remains the case even if one has already identified a suitable salt (such as the sodium salt) and is looking for an alternative. In particular, one cannot predict the solubility of any particular salt form in advance of making and testing it. A typical approach would be to screen a handful of potential candidates. Once these

had been made (assuming this could be achieved), they would be tested for solubility, stability and so forth. Thus, while the chemist tasked with finding an alternative salt to pemetrexed disodium would have a reasonable expectation of being able to find a suitable alternative, he would not be confident that any particular salt would be suitable before making and testing it. I would add that Dr Stefánsson's evidence is entirely consistent with this.

iii. 83. *Sodium salts*. It was well known that sodium was the most preferred counter-ion. Thus sodium would be the chemist's first choice. It was known that sodium salts were generally not toxic. Sodium salts would generally be expected to be reasonably soluble, but they were not always easy to make.

iv. 84. *Potassium salts*. Potassium was known to be used in pharmaceutical compositions. Although it had a general tendency to be in the "more soluble" class of salt with sodium, there were exceptions to this tendency. It was known that there were some concerns about the potential toxicity of potassium salts in terms of cardiac side effects. This is something which would require particular consideration if large quantities of the drug (such as gram quantities) were to be administered.

v. 85. *Tromethamine salts*. Tromethamine salts were very much in the minority in 2000/2001 and there were only a small handful of examples of its use. It is still not particularly high on the list to be used as a counter-ion even now. It was known that tromethamine salts might well be too soluble, such that one would not be able to make and harvest the solid form.

vi. 86. *Free acids*. In principle, an acidic parent molecule could be administered in the form of the free acid, and this is something that the chemist would consider. It was often the case, however, that there was a need or desire to change from the free acid to a salt form in order to improve kinetics, absorption or physicochemical properties. In particular, the free acid might not be adequately soluble, and a common way to try to address that was through salt formation.

Article 69 and the Protocol

i. 87. France, Germany, Italy, Spain and the UK are all parties to the European Patent Convention 2000. Article 69(1) EPC provides:

> "The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

i. 88. The Protocol on the Interpretation of Article 69 of the Convention provides:

> "**Article 1**
>
> *General principles*
>
> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used

> in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.
>
> **Article 2**
>
> *Equivalents*
>
> For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

Construction of the UK Patent

UK law: general

i. 89. Although UK law as to the construction of patent claims is fairly well settled, it is appropriate to set out a much fuller exposition than I normally would. This is both because of the nature of the issue in the present case, and to facilitate comparison with the foreign laws and with the judgment of the Düsseldorf Regional Court.

ii. 90. The modern UK law of patent claim construction begins with the famous passage in the speech of Lord Diplock, with whom the other members of the House of Lords agreed, in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 at 242-243:

> "My Lords, a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. 'skilled in the art'), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called 'pith and marrow' of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

> The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked."

i. 91. *Catnic* was a decision on a patent granted under the Patents Act 1949, but it was subsequently taken by the English courts to represent the correct approach to patents granted under the Patents Act 1977, and hence to comply with Article 69 EPC 1973 and the Protocol.

ii. 92. In *Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181 at 289 the then Hoffmann J analysed the guidance given by Lord Diplock in *Catnic* with regard to equivalents as follows:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim ('a variant') was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
>
> (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?
>
> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.
>
> On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

i. 93. These questions, referred to initially as "the *Improver* questions" and latterly as "the Protocol questions", were routinely used by first instance judges and the Court of Appeal for some 15 years. One of the important cases decided by the Court of Appeal during this period was *American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8. In that case the patentee argued that the word "rapamycin" in the claim meant "rapamycin itself and derivatives thereof which exhibit the same type of inhibition to organ rejection as rapamycin". The Court of Appeal rejected that construction, and in doing so considered it relevant that the specification gave no indication that any derivatives of rapamycin would in fact work (see [20]). The Court also held that the patentee could not adopt a construction which included "all variants that did not materially affect the invention" and therefore effectively by-pass *Improver* questions 1 and 2 (see [23]-[24]). In relation to *Improver* question 3 the Court considered it important that, if the words of the claims were not complied with strictly and instead covered derivatives of rapamycin that worked, then such a claim would not have been allowed by the European Patent Office as it would have lacked support and would have been speculative (see [31]).

ii. 94. The UK approach to patent claim construction was reviewed nearly 10 years ago by the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9. In a magisterial speech which continues to repay close study, the then Lord Hoffmann, with whom the other members of the House agreed, considered almost every facet of the question. For present purposes, five aspects of Lord Hoffmann's analysis merit emphasis.

iii. 95. First, Lord Hoffman made some general observations about construction:

> "32. …. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, 'the meaning of the words the author used', but rather what the notional addressee would have understood the author to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of, and background to, the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience. ...
>
> 33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention—a practical idea which the patentee has had for a new product or process—and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of 'purposive construction'. … The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one

uses to ascertain the meaning. But purpose and meaning are different. … There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.

34. ‘Purposive construction’ does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.

35. One of the reasons why it will be unusual for the notional skilled man to conclude, after construing the claim purposively in the context of the specification and drawings, that the patentee must nevertheless have meant something different from what he appears to have meant, is that there are necessarily gaps in our knowledge of the background which led him to express himself in that particular way. The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent

> office. I do not think that it is sensible to have presumptions about what people must be taken to have meant, but a conclusion that they have departed from conventional usage obviously needs some rational basis."

i. 96. Secondly, Lord Hoffman concluded that the *Catnic* principle of purposive construction was precisely in accordance with the Protocol for reasons he encapsulated at [47] as follows:

> "The Protocol, as I have said, is a Protocol for the construction of art.69 and does not expressly lay down any principle for the construction of claims. It does say what principle should not be followed, namely the old English literalism, but otherwise it says only that one should not go outside the claims. It does however say that the object is to combine a fair protection for the patentee with a reasonable degree of certainty for third parties. How is this to be achieved? The claims must be construed in a way which attempts, so far as is possible in an imperfect world, not to disappoint the reasonable expectations of either side. What principle of interpretation would give fair protection to the patentee? Surely, a principle which would give him the full extent of the monopoly which the person skilled in the art would think he was intending to claim. And what principle would provide a reasonable degree of protection for third parties? Surely again, a principle which would not give the patentee more than the full extent of the monopoly which the person skilled in the art would think that he was intending to claim. Indeed, any other principle would also be unfair to the patentee, because it would unreasonably expose the patent to claims of invalidity on grounds of anticipation or insufficiency."

i. 97. Thirdly, Lord Hoffmann gave careful consideration to the question of equivalents:

> "41. There is often discussion about whether we have a European doctrine of equivalents and, if not, whether we should. It seems to me that both the doctrine of equivalents in the United States and the pith and marrow doctrine in the United Kingdom were born of despair. The courts felt unable to escape from interpretations which 'unsparing logic' appeared to require and which prevented them from according the patentee the full extent of the monopoly which the person skilled in the art would reasonably have thought he was claiming. The background was the tendency to literalism which then characterised the approach of the courts to the interpretation of documents generally and the fact that patents are likely to attract the skills of lawyers seeking to exploit literalism to find loopholes in the monopoly they create. (Similar skills are devoted to revenue statutes.)
>
> 42. If literalism stands in the way of construing patent claims so as to give fair protection to the patentee, there are two things that you can do. One is to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents. That is what the Americans have done. The other is to abandon literalism. That is what the House of

Lords did in the *Catnic* case …

44. Since the *Catnic* case we have art.69 which, as it seems to me, firmly shuts the door on any doctrine which extends protection outside the claims. …

49. Although art.69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense. It is also expressly provided by the new art.2 added to the Protocol by the Munich Act revising the EPC, dated November 29, 2000 …

52. … When speaking of the '*Catnic* principle' it is important to distinguish between, on the one hand, the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines for applying that principle to equivalents, which are encapsulated in the Protocol questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others. …. "

i. 98. Fourthly, Lord Hoffman discussed the approaches of the Dutch and German courts to Article 69 and the Protocol. In this context he observed at [75]:

> "The German courts have their own guidelines for dealing with equivalents, which have some resemblance to the Protocol questions. In the 'quintet' of cases before the Bundesgerichtshof (see, for example, *Kunstoffrohrteil* [2002] G.R.U.R. 511 and *Schneidemesser 1* [2003] E.N.P.R. 12 309) which concerned questions of whether figures or measurements in a claim allow some degree of approximation (and, if so, what degree), the court expressly said that its approach was similar to that adopted in *Catnic*. But there are differences from the Protocol questions which are lucidly explained by Dr Peter Meier-Beck (currently a judge of the 10th Senate) in a paper to be published in the International Review of Intellectual Property and Competition Law (IIC). For example, German judges do not ask whether a variant 'works in the same way' but whether it solves the problem underlying the invention by means which have the same technical effect. That may be a better way of putting the question because it avoids the ambiguity illustrated by *American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] R.P.C. 8 over whether 'works in the same way' involves an assumption that it works at all. On the other hand, as is illustrated by the present case, everything will depend upon what you regard as 'the problem underlying the invention.' It seems to me, however, that the German courts are also approaching the question of equivalents with a view to answering the same ultimate question as that which I have suggested is raised by Art.69, namely what a person skilled in the art would have thought the patentee was using the language of the claim to mean."

i. 99. Fifthly, Lord Hoffmann discussed the impact of new technology, and the problems that this gave rise to in answering the second *Improver* question. In this context he observed at [80]:

> "I do not dispute that a claim may, upon its proper construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing 'carriage' in a 19th century statute to include a motor car. In such cases it is particularly important not to be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result. …."

He went on to refer again to *AHP v Novartis* at [82] as an example of the difficulty of applying the second *Improver* question to new technology.

i. 100. Since *Kirin-Amgen*, the *Improver* questions have fallen out of fashion and have rarely been referred to in judgments of the English courts in the last 10 years. This may be regarded as unfortunate given that, although the *Improver* questions have their limitations for the reasons given by Lord Hoffmann, they do provide a structured approach to the question of equivalents and they have been influential across Europe.

ii. 101. The principles established by *Kirin-Amgen* were summarised by Jacob LJ giving the judgment of the Court of Appeal in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062, [2010] RPC 8 at [5] as follows.

> "(i) The first overarching principle is that contained in Article 69 of the European Patent Convention.
>
> (ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.
>
> (iii) It follows that the claims are to be construed purposively - the inventor's purpose being ascertained from the description and drawings.
>
> (iv) It further follows that the claims must not be construed as if they stood alone - the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.
>
> (v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor

may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.

(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol - a mere guideline - is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.

(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.

(viii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.

(ix) It further follows that there is no general 'doctrine of equivalents.'

(x) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.

(xi) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge."

i. 102. Jacob LJ went on at [6]-[22] to hold that the skilled reader is to be taken to know (i) the purpose of including reference numerals in patent claims, (ii) the purpose of dividing claims into pre-characterising and characterising portions and (iii) the practice of filing divisional applications, and to bring that knowledge to bear when he considers the scope of the claim. In this context, Jacob LJ said at [15]:

> "We think it would unrealistic – indeed perverse – for the law to say that the notional skilled reader, probably with the benefit of skilled advice, would not know and take into account the explicit drafting conventions by which the patent and its claims were framed. Likewise when there is a reference to the patent being a divisional application, it would be perverse to work on the basis that the skilled man would not know what that means. A real skilled man reading a patent which, as in the case of the Patent, refers to 'the parent application' would surely say 'what's a parent application?' – and he would go on to ask a man who knows, probably a patent agent."

i. 103. I would add the following observations on two aspects of the question of equivalents. The first point is that it is vital not to lose sight of the fact that the claim

must be construed in the same manner for the purpose of considering both infringement and validity. Article 69 and the Protocol govern the interpretation of the claim for both purposes. It follows that, once due account has been taken of equivalents in determining the scope of the claim in accordance with Article 2 of the Protocol, that claim scope is determinative of questions of both of infringement and validity. To put it bluntly, one cannot use equivalents to extend the scope of the claim just for infringement and not for validity. Still less can one use equivalents to extend protection outside the claims for the purposes of infringement, but confine attention to the claims when considering validity.

ii. 104. The second point is that experience shows that patentees resort to arguments about equivalents in three main classes of case. The first is where, with the benefit of hindsight, it can be seen that the patent was unfortunately drafted, whether because of poor instructions from the inventor or poor drafting by his patent attorney or a combination of these things. *Improver* might perhaps be regarded as an example of this. The second class is where technology has moved on since the priority or filing date of the patent. *Kirin-Amgen* might perhaps be regarded as an example of this. The third class is where the patentee now regrets a decision taken during the course of prosecution of the patent application, whether by himself or by the examiner, and is trying to avoid the consequences of that decision. As will appear, in my view the present case is a clear example of this.

iii. 105. In the first class of case, the law recognises that drafting patent claims is a difficult and imprecise art and that third parties should not be allowed to exploit infelicities of drafting where it is reasonably clear that those infelicities should not affect the scope of the claim. This is in order to provide "fair protection for the patent proprietor". The law also recognises, however, the countervailing consideration that third parties are entitled to rely on the drafting of the claim when deciding on a commercial course of action. There is no tort of avoiding a patent claim. Thus it is also necessary to provide "a reasonable degree of legal certainty for third parties". The problem, of course, is that what is fair protection to one person is legal uncertainty to another. Conversely, what is reasonable legal certainty to the second person is a denial of protection to the first. The courts have to strike a balance. In striking that balance, it is important to bear in mind that, as Lord Hoffman and Jacob LJ have pointed out, both the patentee and the third party will generally rely on skilled professional advice (and may have a remedy if the advice is incompetent).

iv. 106. In the second class of case, the problem is more acute. It is difficult for an applicant for a patent to anticipate how technology may evolve during the 20 year life of the patent. The law is sympathetic to the proposition that third parties should not be able to avoid infringement merely by employing new technical means to implement the invention. But on the other hand, a claim may be drafted in a manner which is inescapably tied to the old technology. There is no easy answer to this conundrum. It is not necessary to explore this question any further for the purposes of the present case, however.

v. 107. In the third class of case, there is no reason why the law should be sympathetic to the patentee. Not only do applicants generally rely on skilled professional advice, but also they can appeal against adverse decisions of examiners during the course of prosecution if they consider that those decisions are wrong. If the courts allow decisions as to claim scope made by the examiner during the course of prosecution which have not been successfully appealed effectively to be overturned by decisions on claim construction, the courts undermine the important role of the examiner. This is still

more so if the courts allow decisions as to claim scope made by the applicant during the course of prosecution effectively to be reversed by decisions on claim construction.

UK law: prosecution history as an aid to construction

i. 108. As is well known, US patent law has a doctrine of equivalents and, to counterbalance it, a doctrine of "file wrapper estoppel". It is common ground that the UK has no doctrine of prosecution history estoppel. It is also common ground, however, that the prosecution history is admissible as an aid to construction. Actavis contend that in an appropriate case, of which this is an example, the prosecution history can be illuminating as to the correct construction of the claim, in particular because it may shed light on the answer to *Improver* question 3. Lilly contend that, as a general rule, the prosecution history is rarely useful as an aid to construction and that the present case is no exception to that general rule.

ii. 109. Most of the relevant case law is helpfully summarised in *Terrell* at §§9-100 to 9-103. The main cases where consideration has been given to the issue are *Bristol Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, *Rohm & Haas Co v Collag Ltd* [2002] FSR 28 and *Kirin-Amgen* (see the passage at [35] quoted above). Strictly speaking, the statements about prosecution history in those and the other cases cited in *Terrell* are *obiter* because either the issue did not arise and was merely commented upon in passing (*Bristol Myers*, *Kirin-Amgen*) or because the decision was reached on other grounds (*Rohm & Haas*). Furthermore, the decision in *Rohm & Haas* pre-dated *Kirin-Amgen.*

iii. 110.Counsel for Actavis nevertheless submitted that the relevant passage in the judgment of Robert Walker LJ in *Rohm & Haas* was persuasive:

> "40. There seens to be no clear English authority on the point, even at first instance. In *Bristol-Myers Squibb Co. v. Baker Norton Inc.* [1999] R.P.C. 253 at pp. 274–275 Jacob J. has given a useful summary of the problems associated with taking account of what he called prosecution history—that is, the vicissitudes of an application file's progress through the official system—as an aid to construction of the final specification. But Jacob J. said that he did not have to decide anything about the point.
>
> 41. This court was shown a decision of the Supreme Court of the Netherlands, *Ciba-Geigy v. Oté Optics* (January 13, 1995) which contains a helpful statement of principle. In explaining that the Court of Appeal had gone too far in excluding all reference to the file, the Supreme Court said:
>
> > 'Article 69, paragraph 1 of the EPC as interpreted in accordance with the Protocol relating thereto does indeed purport (among other things) to ensure reasonable certainty for third parties, but it does not follow that the information from the granting file that is available to third parties may never be used in support of the interpretation given by the patentee to his patent. The requirement of reasonable certainty for third parties does, however, call for restraint in using arguments derived from the granting file in favour of the patentee.

> Consequently, a court will only be justified in using clarifying information from the public part of the granting file, when it holds that even after the average person skilled in the art has considered the description and the drawings, it is still open to question how the contents of the claims must be interpreted. In this connection must also take into consideration that the risk of any ambiguities due to careless wording of the patent specification must in principle lie with the patentee.'

> 42. Apart from the last sentence (which raises a different point, and on which Mr Floyd did not rely) I would treat this as persuasive guidance. The letter to the European Patent office did not have the same status as published prior art identified in a specification, which is readily admissible. But it did contain objective information about and commentary on experiments which were conducted in response to official observations, and it could be of assistance in resolving some puzzling features of the specification. Although the prosecution process may sometimes superficially resemble a process of negotiation between the applicant and its advisers and the officials who scrutinise the file, it is not the sort of commercial negotiation which is still rigidly excluded in the construction of a written contract (see *Investors Compensation Scheme v. West Bromwich Building Society* [1998] 1 W.L.R. 896 at 913). Had it been necessary for the judge to take account of the letter in order to resolve the issue of construction, I consider that he would have been entitled to do so."

i. 111.In my judgment this reasoning is persuasive, and it is supported by the subsequent judgment of the Court of Appeal in *Virgin v Premium*. I accept that, for the reasons explained by Jacob J in *Bristol-Myers Squibb* and Lord Hoffmann in *Kirin-Amgen*, courts should be cautious before relying upon prosecution history as an aid to construction. In the real world, however, anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection) and will consider it to see if it sheds light on the matter. In some cases, perhaps not very many, the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in some broader manner. In such a situation, there is no good reason why the court should shut its eyes to the story told by the prosecution file. On the contrary, consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement. For the reasons discussed below, I consider that the present case provides a good illustration of this.

ii. 112.Counsel for Lilly submitted that, if the prosecution history was useful as an aid to construction at all, this was only if the claims had been limited during prosecution to avoid objections of novelty or obviousness over prior art, and not where the claims had been limited to avoid objections of lack of support/added matter or clarity. I do not accept this. As a matter of principle, I can see no good reason why the prosecution history should only be useful as an aid to construction in the former type of case and not in the latter. Counsel for Lilly argued that an amendment made in order to address an objection of lack of support/added matter could not shed any light on the meaning which the applicant (subsequently the patentee) intended, because there was a distinction

between the disclosure of a specification and the scope of a claim. I entirely accept that there is such a distinction. I also accept that it follows that, in some cases, a claim can be broadened during prosecution without adding subject matter. I do not accept that it follows that a limitation made to a claim during prosecution in order to avoid an objection of lack of support for a broader claim cannot shed light on the patentee's purpose in framing the claim in the manner that he did and hence upon the meaning that the skilled person would have understood the patentee to have been intending to convey by that choice of language.

Assessment

i. 113.The key issue in this case is as to the scope of claims 1 and 12, and in particular as to the meaning of the expression "pemetrexed disodium" in those claims when interpreted in the context of the specification and taking into account the common general knowledge of the skilled team to whom the Patent is addressed.

ii. 114.Actavis' construction is that the skilled team would understand the expression "pemetrexed disodium" to mean pemetrexed disodium and nothing else. In brief summary, Actavis contend that this is a precise chemical expression with a clear meaning, that the skilled team would understand that the inventor's purpose in choosing this expression was to identify a specific chemical for use in the invention, that this understanding would be confirmed by the contrast between the reference to pemetrexed disodium on the one hand and the references to vitamin B12 (or a pharmaceutical derivative thereof) and a selected folic protein binding agent on the other, that consideration of the prosecution history confirms that the limitation to pemetrexed disodium was both intentional and made for good reason and that the claims would be invalid if construed more broadly.

iii. 115.Lilly's construction is that the skilled team would understand the expression "pemetrexed disodium" to mean (at least) pemetrexed diacid and any salt of pemetrexed which is pharmaceutically acceptable (i.e. is able to be made, is safe, sufficiently stable and does not affect the efficacy of the drug) and sufficiently soluble. As counsel for Lilly made clear, Lilly reserves the right to contend that the meaning of the expression is broader still, and embraces e.g. analogues of pemetrexed; but it is not necessary for Lilly to go that far for the purposes of the present case. In brief summary, Lilly contends that it would be obvious to the skilled team that substitution of the free acid or a different salt would have no material effect on the way in which the invention works, in particular because (a) the invention is about reducing the toxicity, while maintaining the efficacy, of pemetrexed and (b) the active chemotherapeutic principle is the pemetrexed anion, and the skilled team would therefore conclude that "pemetrexed disodium" was being used in a figurative sense which was exemplary of the means of obtaining the benefits of the invention.

iv. 116.I shall concentrate on the question whether the scope of the claim extends to pemetrexed diacid, both because that is Actavis' lead candidate and because, if it does, then it must also embrace the dipotassium and ditromethamine salts, whereas the converse does not necessarily follow.

v. 117.There can be no dispute that pemetrexed diacid is not pemetrexed disodium according to its "primary, literal or acontextual meaning". To use the terminology of *Improver*, it is a variant. Partly for this reason and partly for consistency with their

arguments in respect of the French, Spanish and Italian designations, both parties argued their positions at least partly by reference to the *Improver* questions. I agree that these provide a helpful framework for consideration of the issue.

vi. 118.*Improver question 1*. Actavis accept that *Improver* question 1 should be answered yes with regard to each of pemetrexed diacid, dipotassium and ditromethamine. It is important to be clear, however, as to why Actavis accept this. It is for a combination of two reasons. First, looking at the invention from the oncologist's perspective, the active anti-cancer principle in an aqueous solution of pemetrexed disodium for intravenous administration is the pemetrexed anion. From the oncologist's perspective, the source of the pemetrexed anion is immaterial, since it will not affect the efficacy or safety of pemetrexed as a treatment for cancer. Nor will it affect the efficacy of co-administration of vitamin B12 (or a derivative) and a folic protein binding agent as a means of the reducing toxic side effects of pemetrexed.

vii. 119.Secondly, looking at the invention from the chemist's perspective, it must be assumed for this purpose that pemetrexed diacid, dipotassium and ditromethamine are in fact all pharmaceutically acceptable and sufficiently soluble. This is because Actavis will not obtain regulatory approval to market products containing these active ingredients if that is not the case. In order to obtain regulatory approval, Actavis will need to establish that its product is bioequivalent to Alimta. Furthermore, as described below, Actavis has done some work on establishing the pharmaceutical acceptability and solubility of each form, and so far has not encountered any fundamental obstacles.

viii. 120. *Improver question 2*. Actavis contend that *Improver* question 2 should be answered no, whereas Lilly contends that it should be answered yes. As is so often the case, resolving this question depends crucially on what one means by "the way in which the invention works", and in particular the level of generality at which that is assessed. The problem is much the same if one asks whether the variant solves the problem underlying the invention by means which have the same technical effect.

ix. 121. As I see it, Actavis do not seriously dispute that, considering the matter from the oncologist's perspective, it would be obvious that, *provided the diacid yielded a sufficient concentration of pemetrexed anions in solution and did not introduce side effects which were not obtained with the disodium salt or other complications*, then using the diacid would have no material effect on the invention. This is because, as explained above, it would not affect the efficacy or safety of pemetrexed as an anti-cancer agent, nor would it affect the benefit to be obtained by co-administration of vitamin B12 (or a derivative) and a folic protein binding agent.

x. 122. Actavis say that this is not the end of the matter, however, because, as is clear from the evidence of Prof Seckl and Prof Ferry, the oncologist would have no idea what the effect of substituting the diacid for the disodium salt would be on the solubility or pharmaceutical acceptability of the source of pemetrexed anions. Accordingly, the oncologist would ask the chemist. It is clear from the evidence of Dr Spargo and Prof Thurston that the chemist's answer would be, in short, "I do not know until I have tested it". It appears that the chemist's uncertainty would be greatest in relation to the diacid, less in relation to the ditromethamine salt and lowest in relation to the dipotassium salt; but even in relation to the dipotassium salt the chemist would not be confident of success before testing it (in particular because of the potential toxicity of potassium given the quantities of pemetrexed required). This is far from the level of confidence required for an affirmative answer to *Improver* question 2: see *Merck & Co Inc v Generics (UK) Ltd*

[2003] 2842 (Pat), [2004] RPC 31 at [78] (Laddie J).

xi. 123. As counsel for Actavis pointed out, the uncertainty is illustrated by the position concerning pemetrexed calcium. Based on the tables in Berge and in Stahl & Wermuth, calcium would be high on the list of potential alternative counter-ions. It turns out, however, that pemetrexed calcium is not sufficiently soluble. As described below, it is for this very reason that Actavis have not pursued pemetrexed calcium although it was one of their original candidates.

xii. 124. As counsel for Actavis also submitted, it is irrelevant that, as is clear from the evidence of Dr Spargo and Prof Thurston, the chemist would be reasonably confident that he could come up with an alternative counter-ion to sodium. That is not the question.

xiii. 125. Lilly has three different answers to this argument. The first I have already considered and rejected, namely that the Patent is solely addressed to the medical oncologist.

xiv. 126. Lilly's second answer is that the question should be approached on the basis the skilled team knows that the variant has received regulatory approval, and hence that they know it is pharmaceutically acceptable and sufficiently soluble. I do not accept that this is the correct way in which to approach *Improver* question 2. The correct approach is to ask whether it is obvious from the skilled team's common general knowledge. As counsel for Actavis submitted, assuming that the skilled team knows that the variant has received regulatory approval is really an attempt to short circuit the analysis by providing the skilled team with the answer to the question in advance. The skilled team must be able to ask and answer question 2 before investing what may be four years' effort and considerable expense to obtain regulatory approval even on the basis of bioequivalence.

xv. 127. Lilly's third and most important answer is that Actavis' argument involves mischaracterising the invention. The invention, Lilly argues, is all about reducing the toxic side effects of pemetrexed by co-administration of vitamin B12 (or a derivative) and a folic protein binding agent. It is not about providing a convenient and safe source of pemetrexed anions in solution. The source of the pemetrexed anions makes no difference at all to the reduction in toxic side effects achieved by such co-administration. The problem is solved by means which have precisely the same technical effect as pemetrexed disodium.

xvi. 128. This is a powerful argument. In the end, however, and not without considerable hesitation, I do not feel able to accept it. My reasons are similar to those I have given in relation to the question of the identity of the addressee. Although it is true to say that the underlying invention is an improved method of treatment, that invention was not and is not patentable as such. The only patentable invention is the use of the drug for the manufacture of a medicament for use in the combination therapy (claim 1) or a product containing the drug in combination with the other ingredient(s) for use in therapy (claim 12), depending on whether one is looking at it from the perspective of EPC 1973 or EPC 2000. Either way, the patentable invention involves the making of the medicament or the product. If the proposed source of pemetrexed anions is not sufficiently soluble or is not pharmaceutically acceptable for some other reason, then as a practical matter the skilled team cannot make that medicament or product and therefore cannot obtain the benefit of the patented invention. To that extent, therefore, it would not

be obvious to the skilled team that pemetrexed diacid would have no material effect on the way the invention works. The same goes for pemetrexed dipotassium and ditromethamine.

xvii. 129. *Improver question 3*. Even if question 2 is answered yes, Actavis contend that *Improver* question 3 should be answered yes, whereas Lilly contends that it should be answered no. In considering this question I shall assume that, contrary to the conclusion I have just reached, question 2 is to be answered yes.

xviii. 130. Actavis rely on a number of considerations as showing that the skilled team would nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the "primary, literal or acontextual meaning" of pemetrexed disodium was an essential requirement of the invention.

xix. 131. First, Actavis rely on the nature of the expression in issue. Pemetrexed disodium is the name of a specific, known chemical compound with a specific atomic formula and molecular structure. There is no sense in which it can be regarded as a figurative expression. It is not as if the expression used was "pemetrexed", which might well cover any suitable form of pemetrexed. Pemetrexed diacid, dipotassium and ditromethamine are all different chemical compounds with different atomic formulae and molecular structures. As a matter of language, therefore, this integer of the claims means only one thing and does not mean other, different things.

xx. 132. Secondly, Actavis contend that the specification is supportive of this reading. As Actavis point out, the specification begins with very broad general statements of the inventive concept expressed in terms of "an antifolate", but thereafter it concentrates specifically on pemetrexed disodium. Further, the only data contained in the specification relate to pemetrexed disodium.

xxi. 133. Thirdly, Actavis rely on the fact that the claims are explicit that the pemetrexed disodium may be combined with a selected pharmaceutical derivative of vitamin B12 or a selected folic protein binding agent. Furthermore, in the latter case the claims explicitly contemplate the use of "a physiological salt or ester thereof". Actavis contend that the skilled team would not only notice this difference in language, but also would regard it as explicable by reference to the fact that no other form of pemetrexed was known to be efficacious and safe whereas other forms of vitamin B12 and folic acid were known.

xxii. 134. Fourthly, Actavis contend that this reading is supported by the expert evidence. Prof Seckl's unchallenged evidence was that the oncologist member of the skilled team, when faced with the Patent, would have assumed that the chemist involved had specifically chosen pemetrexed disodium for a reason, would not have made any assumptions one way or another regarding the adequacy of any other salt form of pemetrexed, and would have deferred to a chemist with expertise in such matters. Importantly, Prof Ferry entirely agreed with this in cross-examination. It is clear from the evidence of Dr Spargo and Prof Thurston that the chemist member of the team would not assume that any other form of pemetrexed was equivalent to pemetrexed disodium, but would appreciate that any alternative form would have to be tested for solubility and pharmaceutical acceptability. Accordingly, as Prof Thurston agreed, it would be reasonable for the chemist to assume that the patentee meant specifically that chemical form because it was the only form which had been made and tested.

xxiii. 135. Fifthly, Actavis contend that the skilled team would appreciate that there were a number of other reasons why the patentee might have wished to limit the claims to pemetrexed disodium even if the use of other forms of pemetrexed had no material effect on the way in which the invention worked. These include the following: so as precisely to cover the commercial embodiment, Alimta; because broader claims would lack support or be unclear; because the patentee opted for narrow claims in order to get the Patent granted rapidly; or for some other reason known only to the patentee.

xxiv. 136. Sixthly, Actavis ask rhetorically: if the claims are not limited to pemetrexed disodium, what are the boundaries of the claims? In essence, Lilly's construction amounts to "anything that works". As noted above, Lilly reserves the right to argue that the claims embrace pemetrexed analogues. But why stop there? If "pemetrexed disodium" is being used figuratively, why does the claim not extend to any antifolate whose toxicity is reduced by co-administration with vitamin B12 and folic acid?

xxv. 137. Seventhly, Actavis rely on the prosecution history which I have set out in paragraphs 36-45 above. It is very clear from this why the claims are limited to pemetrexed disodium. In short, Lilly attempted to obtain broader claims, first to an antifolate and secondly to pemetrexed, but the examiner objected to those claims. In particular, the examiner objected that the amendment to introduce claims to pemetrexed lacked support in the description and therefore constituted added matter. The description contained textual support (but not supporting data) for broad claims to an antifolate, but it did not even contain textual support for claims to pemetrexed. Rather than argue the point, Lilly opted for narrow claims to pemetrexed disodium in order to obtain rapid grant of a patent. It also reserved the right to file a divisional application, but apparently did not do so.

xxvi. 138. Eighthly, Actavis contend that, if claims 1 and 12 are construed as Lilly contend, then it follows that they are invalid for added matter and/or for insufficiency for the reasons given by the examiner.

xxvii. 139. Lilly's answer to Actavis' first three points is that these all involve the sins of literalism and meticulous verbal analysis. The correct approach, Lilly says, is to ask what technical purpose the skilled team would think there was for specifying pemetrexed disodium in the claims and whether the skilled team would think that pemetrexed disodium was being specified in contradistinction to other suitable forms of pemetrexed.

xxviii. 140. Lilly's answer to Actavis' fourth point is to rely upon the fact (which must be assumed to be the case for this purpose) that it would be obvious to the skilled team that the use of a different suitable form of pemetrexed made no difference to the way in which the invention worked.

xxix. 141. With respect to Actavis' fifth point, Lilly argues that none of the suggested considerations provides a cogent reason for giving a negative answer to Lord Diplock's nutshell question, which in the circumstances of the present case may be expressed as follows:

> "Does the specification make it obvious to the skilled addressee that the reference to pemetrexed disodium as being the source of pemetrexed in an intravenous solution could not have been intended to exclude some other source of pemetrexed which

made no material difference to the way pemetrexed worked when administered in conjunction with vitamin B12?"

i. 142. As for Actavis' sixth point, Lilly says that it does not matter where the boundary of the claims might or might not be. All that has to be decided is whether the scope of the claims is sufficiently broad to encompass pemetrexed diacid, dipotassium and ditromethamine.

ii. 143. With regard to the prosecution history, Lilly contends that this does not assist Actavis because the application always included claims in which the antifolate was pemetrexed disodium (or Alimta, which amounts to the same thing). Counsel for Lilly argued that the fact that broader claims were abandoned during prosecution sheds no light on the meaning of "pemetrexed disodium", particularly given that the reason for the amendments was to avoid objections of lack of support/added matter.

iii. 144. As to Actavis' eighth point, Lilly points out that the validity of the Patent is not in issue in these proceedings.

iv. 145. In my judgment Actavis' arguments are more persuasive than those of Lilly. I consider that all of Actavis' points have force, but I would add the following comments with respect to points six, seven and eight.

v. 146. So far as the sixth point is concerned, while Lilly is correct that it is only necessary to decide whether the claim extends to pemetrexed diacid, dipotassium and ditromethamine, it is relevant to consider where the logic of Lilly's argument leads.

vi. 147. With regard to the prosecution history, I consider that this supplies a clear answer to the question why the claims are limited to pemetrexed disodium and that this does shed light on the correct interpretation of the claims. I disagree with Lilly's argument for the reasons I have already given.

vii. 148. Lilly is correct that validity is not in issue in these proceedings, but it does not follow that the court cannot consider what the consequences of Lilly's construction would be for the validity of the Patent: see e.g. *AHP v Novartis*. Furthermore, counsel for Lilly expressly accepted that (i) there was no basis in the application as filed for a claim to pemetrexed or any pharmaceutically acceptable (and sufficiently soluble) salt thereof and (ii) Lilly would have been unlikely to have succeeded in obtaining a claim framed in that manner, because it would have been rejected by the EPO on the grounds of added matter. If Lilly could not have obtained claims which explicitly referred to pemetrexed or any pharmaceutically acceptable and sufficiently soluble salt thereof because such claims would have been invalid, I cannot see how it can be right to construe "pemetrexed disodium" in claims 1 and 12 as granted as having that meaning for the purposes of infringement.

viii. 149. Having considered all of the points individually, it remains necessary to stand back and to consider overall which construction of the expression "pemetrexed disodium" accords with the Protocol and combines fair protection for the patentee and reasonable certainty for third parties. In my judgment this is Actavis' construction. Lilly deliberately limited the claims of the Patent to pemetrexed disodium. There was nothing

to prevent Lilly seeking broader claims if it thought it was entitled to them. There is nothing in the specification or the common general knowledge of the skilled team to suggest to the skilled team that Lilly intended to use the expression "pemetrexed disodium" in anything other than its conventional sense or that it made some mistake in using that expression, and the prosecution history shows that the opposite is the case. Confining Lilly to the scope of claim that it chose with the benefit of skilled professional advice provides Lilly with fair protection, and does not expose Lilly to the risk of the Patent being invalid on the grounds of added matter and/or insufficiency. Construing the claim as extending to (at least) any form of pemetrexed which is pharmaceutically acceptable and sufficiently soluble would not provide a reasonable degree of certainty for third parties. Any other conclusion would fail to give effect to the Protocol and would be tantamount to treating the claims as a mere guideline.

The judgment of the Düsseldorf Regional Court

i. 150. Lilly issued proceedings against Actavis Group PTC ehf (the Third Claimant in these proceedings) and Actavis Deutschland GmbH & Co KG (the Fifth Claimant until recently) before the Düsseldorf Regional Court on 20 July 2012. These proceedings were served on Actavis on 9 August 2013. At that time, Lilly's only claim was in respect of pemetrexed dipotassium, since that was the only salt which had been mentioned in Bird & Bird's letter dated 12 July 2012. Actavis challenged the jurisdiction of the German court on the ground that the English court was first seized of the dispute, but that challenge was rejected both by the Düsseldorf Regional Court and by the Düsseldorf Oberlandesgericht (Court of Appeal). On 14 June 2013 Lilly joined Kálmán Petró, the managing director of Actavis Management GmbH (the parent company of Actavis Deutschland GmbH & Co KG and not a claimant in these proceedings) as a defendant to the German proceedings and added claims in respect of pemetrexed diacid and ditromethamine.

ii. 151. In its judgment dated 3 April 2014 the Düsseldorf Regional Court (Judges Dr Voss, Dr Reimnitz and Dr Thom) held that the use of pemetrexed dispotassium would infringe claim 1 of the German designation of the Patent. In essence, it held that there was no literal infringement, but that there was infringement on the basis of the doctrine of equivalents. It went on to hold that there was a threat by Actavis Group PTC ehf to infringe the Patent by dealings in pemetrexed dispotassium, but not by Actavis Deutschland GmbH & Co KG or Mr Petró. By contrast, it held that there was no threat by the defendants in relation to pemetrexed diacid or ditromethamine. Accordingly, it did not consider whether the diacid or ditromethamine fell within claim 1.

iii. 152. The Düsseldorf Regional Court is an experienced patent court, and its judgments are entitled to considerable respect. Furthermore, its judgment is detailed, careful and clearly reasoned. Nevertheless, I am unable to agree with its conclusion with regard to pemetrexed dipotassium. I will not lengthen this judgment still further by giving an exhaustive explanation of my reasons for this disagreement. Most of them will be apparent from a comparison of my reasoning with that of the Düsseldorf Regional Court. I would, however, draw attention to the following points.

iv. 153. First, the evidence before me was different to the evidence before the Düsseldorf Regional Court. In particular, although the Düsseldorf Regional Court had written evidence from Prof Ferry before it, it did not have the advantage which I had of hearing Prof Ferry being cross-examined on his written evidence. As I have observed above, there was some divergence between Prof Ferry's oral evidence and his written

evidence. Likewise, the Düsseldorf Regional Court did not have the benefit of the hearing the chemists cross-examined on their reports.

v. 154. Secondly, it appears that the arguments on both sides differed in some respects from those before me. In particular, Lilly relied on the fact that 677 disclosed that pemetrexed could be used in the form of a pharmaceutically acceptable salt, including specifically potassium, as supporting its case. Furthermore, the Düsseldorf Regional Court accepted this argument (see page 42 of the translation). By contrast, Lilly placed no reliance upon 677 before me, no doubt anticipating the riposte that the skilled team would notice the contrast between 677 and the Patent and draw the conclusion that limitation of the latter to pemetrexed disodium was intentional.

vi. 155. Thirdly, the Düsseldorf Regional Court considered the matter solely from the perspective of the oncologist. I have explained above why I do not agree with this.

vii. 156. Fourthly, in finding infringement by reason of equivalence alone, I respectfully consider that the Düsseldorf Regional Court has not given proper effect to the Protocol, but rather has treated the claims as a mere guideline. As the evidence of the German law experts (Uwe Scharen, a former judge of the Düsseldorf Regional Court, Court of Appeal and Bundesgerichsthof (Federal Supreme Court) and Professor Dr Klaus Melullis of Karlruhe Institute of Techology) filed by the parties before me confirms, German law addresses the question of equivalence by asking the three questions identified in the quintet of cases decided by the Federal Supreme Court on 14 March 2002 to which Lord Hoffmann referred in *Kirin-Amgen* at [75]. These questions are similar to the *Improver* questions, although, as Lord Hoffmann noted, there is a difference in the way in which the German courts formulate the second question. In particular, as the Federal Supreme Court (Judges Prof Dr Meier-Beck, Keukenschrijver, Mühlens, Dr Grabinski and Schuster) recently confirmed in its judgment dated 10 May 2011 in Case X ZR 16/09 *Occlusion Device* at [36], German law does have the equivalent of *Improver* question 3 (as the late Laddie J had concluded in *Celltech R & S Ltd v MedImmune Inc* [2004] EWHC 1124 (Pat) at [59]-[63]). In the present case, it seems to me that the Düsseldorf Regional Court's answer to question 3 simply reiterates its reasoning in answering question 2.

viii. 157. Fifthly, the Düsseldorf Regional Court did not have regard to the prosecution history (see page 52 of the translation). As I understand it, the position in German law with regard to use of the prosecution history is similar to that in UK law: the prosecution history is admissible as an aid to construction, but reference to it is generally discouraged. For the reasons I have explained, I consider that in the present case the prosecution history is directly relevant to, and helpful in determining, the issue of interpretation.

ix. 158. Finally, the Düsseldorf Regional Court did not consider the consequences of its construction for the validity of the Patent.

<u>Construction of the French designation of the Patent</u>

French law

i. 159. There is little dispute as to the applicable principles of French law. It is convenient to quote from the joint memorandum prepared by Prof Galloux and Prof Azéma:

> "**General comments on the French legal system**
>
> After discussion, neither of the two experts noted any disagreement on this section.
>
> They also agreed, in particular, on the following conclusions:
>
> - They reiterate that case-law does not constitute a real source of law: Only legislation (whether or not codified, and administrative texts such as decrees) is applied by the Courts which never refer to previous case rulings.
>
> - The '*cours*' and '*tribunaux*' (Courts) are indeed prohibited from handing down '*arrest de règlement*', i.e. from giving a general and impersonal solution in the particular case on which they are ruling.
>
> - It is nonetheless true that homogeneous sets of case-law, referred to as '*jurisprudence constante*' may have an influence on the way the Courts rule, as do the rulings of the Supreme Court (*Cour de cassation*), since the role of said Court is, precisely, to harmonise the case-law of the lower Courts.
>
> **Doctrine of equivalents**
>
> After discussion, neither of the two experts noted disagreement on this section either.
>
> They comment in particular:
>
> - France is bound by Article 69 of the European Patent Convention (EPC) and by its Protocol on Interpretation, amended on revision of the EPC in 2000. Article L.613-2 of the Intellectual Property Code (IPC) introduced Article 69 of the EPC into French law.
>
> Regarding European patents designating France, said provisions are directly applied by the Courts.
>
> - However, the doctrine of equivalents is not, as such, enshrined in French law. It is the subject of a doctrinal definition which has been widely adopted by the Courts, in particular the Supreme Court, according to which means which are different in form but perform the same function to achieve a similar result, are equivalent. Thus equivalence is characterised by identical function.
>
> - For this doctrine to apply, there is no need for the claim to be unclear or for it to be widely worded (thus referring to 'general means')
>
> - On the other hand, where the claim is narrowly worded, the doctrine of equivalents only applies on condition that the function

is a new one. Should the function of the means be known, the scope of the claim shall be limited to the claimed structure. Should the function be new, any means which perform the same function with a view to the same result shall be considered to be equivalent to the claimed means, even if the latter is precisely claimed.

- Equivalents are distinguished from simple embodiment variations ('*variants d'exécution*') which are insignificant changes affecting non-essential means of the invention, i.e. which do not produce or do not contribute to producing a technical effect.

Use of the prosecution history before the EPO

After discussion, neither of the two experts noted any disagreement on this section. In particular, they agree:

- That the French Courts quite often refer to the prosecution history file where interpretation of the claims is concerned, and to assess the scope of protection granted. The Supreme Court accepts such a consideration so long as the claims remain the source of interpretation.

- Said documents are considered as being factual data amongst all such data subject to the Court's assessment. From this point of view, the French Courts do not distinguish between the different types of document arising from the prosecution file (letters from the examiner, statements by the patentee or by third parties etc.): all these documents have the same probative value.

- Reference to said file is not restricted to cases where infringement by equivalence is alleged."

i. 160. It is worth elaborating on two points. The first is the penultimate point made by the experts under the heading "Doctrine of equivalents". Where the claim is narrowly worded to cover specific means ("*moyens particuliers*") rather than general means ("*moyens généreaux*"), then the court must consider the function of that means and consider whether it is a novel function. If the function of the means is not novel then the claim monopoly is limited to the particular claimed structure. An example of this principle being applied is in the judgment of the Cour de Cassation (Supreme Court) in Appeal S 09-15668 *Institut Pasteur v Chiron Healthcare* of 23 November 2010. In that case the means in question was a specific means of DNA/RNA hybridization to detect HIV with a probe composed of a particular DNA fragment. The function of the specific means was known at the priority date and so the claim integer could not be extended to cover any other method of hybridization that achieved the same function. Another example of this principle being applied is in the judgment of the Tribunal de Grande Instance (High Court) of Paris in Case 09/01863 *Mundipharma Laboratories GmbH v Sandoz SAS* of 2 July 2010. In that case the integer that was said to be infringed by equivalence was the use of cellulose ether (the alleged equivalent being xanthan gum). The function of the cellulose ether was not novel at the priority date and as such the scope of the claim could not be extended to cover any means which achieved that function.

ii. 161. Conversely, if the function of the particular claimed means is novel, then even

though the claim is explicitly drafted in a narrow sense, the claim will be treated as covering a means which performs the same function and which achieves a similar result. Thus in the judgment of the Supreme Court in Appeal No. 06-17915 *B2M Industries v Acome* of 20 November 2007 the function of the particular integer that was said to be infringed pursuant to an equivalent was held to be novel, and therefore because the means that was said to be equivalent to that integer performed the same function and produced the result sought by the invention the means was equivalent to that integer.

iii. 162. Secondly, the prosecution history is of particular relevance when the scope of the claims have been narrowed during the prosecution process, in particular where that narrowing was necessary to obtain the grant of the patent at issue. Both experts cited the judgment of the Cour d'Appel (Court of Appeal) of Paris in Case No. 08/00882 *Hewlett Packard GmbH v Agilent Technologies Deutschland GmbH* of 27 January 2010 as illustrating this principle. In that case the patentee argued that its claim to a pumping apparatus covered all devices whose volume per stroke of the pistons was controlled in response to the desired flow, because the patent was the first to teach such a device. The Court of Appeal rejected this argument, and held as follows:

> "But whereas if it is accepted, in the presence of a groundbreaking invention, that the patent can describe a way of carrying out the invention and claim any other possible way of carrying it out, it cannot be given a general scope, even if it is groundbreaking, if its claims are drafted in restrictive terms;
>
> Whereas more specifically, a non-ambiguous claim with narrow scope cannot through interpretation be given a general scope, in particular when the patentee has been forced, in order to distinguish the invention from the prior art, to limit the scope of the claim in the context of the granting process;
>
> …
>
> Yet whereas the patentee who amended its clauses to give them a limited scope may not, without putting the safety of third parties at risk, claim that the amendments were not necessary, nor that the limited claims have the same scope as the broader claims;
>
> …"

Assessment

i. 163. As I understand it, it is common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

ii. 164. In my judgment they are not within the scope of the claims for two main reasons. First, the doctrine of equivalents does not apply in the circumstances of the present case. The means in issue is "pemetrexed disodium", which is a specific means (*moyen particulier*). The function of that means was not novel: its function was its efficacy in inhibiting tumour growth, and that was known at the date of the Patent. It follows that the expression "pemetrexed disodium" must be interpreted as being limited to the particular compound specified by that expression.

iii. 165. Secondly, the prosecution history shows that the claims were limited to pemetrexed disodium in order to obtain the grant of the Patent. In those circumstances it would not be appropriate to interpret the claims as having a broader scope.

Construction of the Italian designation of the Patent

Italian law

i. 166. There is some common ground between the experts as to Italian law, but also some disagreement. As in France, the law is contained in the relevant statutory provisions. Case law illustrates how the courts apply those provisions, but even decisions of the Corte Suprema di Cassazione (Supreme Court) are not binding, although they are normally followed. The following matters were agreed by the experts in their joint memorandum:

> "Articles 69 EPC and Protocol are directly applicable in Italy.
>
> There is in Italy a doctrine of equivalence which applies when not all the claimed features are reproduced literally by the accused product or process.
>
> No specific rules are set forth by Italian law on the relevance of the file history to the purpose of claim construction.
>
> No decisions of the Supreme Court have been delivered acknowledging the relevance of the file history.
>
> …
>
> The Supreme Court starting from the *Barilla*'s case has broadened the scope of the doctrine of equivalence also to solutions which are inventive, even though Prof. Franzosi believes that the issue is not the inventive step of the infringing solution but the relation of the accused infringement and the claims.
>
> On the equivalence, Prof. Franzosi agrees with the summary of the principles of the case law of the Supreme Court in paragraph 70 of Prof. Guglielmetti's report, even though Prof. Franzosi believes that such case law does not properly reflect the present law.
>
> …
>
> As to the date to be considered for determining the common general knowledge available to the skilled person in order to assess the infringement, Prof. Franzosi and Guglielmetti agree that the date to be considered is that on which the infringement is to be assessed, although Prof. Franzosi thinks that the case law is not entirely clear."

i. 167. The statutory provision currently in force in Italy regarding the scope of protection of patent claims is Article 52 of the Code of Industrial Property ("CIP"), which states as follows:

> "1. Claims indicate, specifically, what is intended to form the object of the patent.
>
> 2. The limits of protection are determined by the claims; however description and drawings serve to interpret (have the function of interpretation) the claims.
>
> 3. The rule of sect. 2, above, has to be understood so as to guarantee at the same time a fair (equitable) protection to the owner and a reasonable legal security for third parties.
>
> 3*bis*. For determining the scope of protection conferred by a patent, due consideration is given to every element equivalent to an element indicated in the claims."

i. 168. With the exception of section 3*bis*, this provision came into force on 19 March 2005. Section 3*bis* was added by Legislative Decree No. 131/2010 with effect from 13 August 2010 to give effect to the revised Protocol to Article 69 in EPC 2000. It is common ground that there have been no Supreme Court decisions addressing issues of infringement by equivalence since Article 52 CIP came into force. Although there have been Supreme Court judgments addressing equivalence since 2010, these are all cases that were applying the law in force before the CIP, namely Royal Decree No. 1127 dated 29 June 1939 (the "LI"), and its implementing regulation Royal Decree No. 244 of 5 February 1940 ("the RI"), as amended by the Decree of the President of the Republic No. 338 dated 22 June 1979 ("the DPR"). Article 5 of the RI stated that:

> "The description, including the indications laid down by Art.28 of [the LI] must begin with a summary that is for technical information purposes only, and must end with one or more claims in which it must be specifically indicated what is intended to form the subject matter of the patent."

i. 169. There is a debate between the experts as to whether or not the enactment of Article 52 CIP changed the previous law. Prof Franzosi considers that it did, whereas Prof Guglielmetti considers that it did not. Both experts refer to the fact that the DPR was drafted by a commission chaired by Professor Giorgio Floridia following the ratification of the EPC 1973 by Italy in order to adapt Italian law to the Convention. The Floridia Commission considered that it was not necessary to amend the final part of the original wording of Article 5 of the RI in order to make it consistent with Article 69 EPC. On the other hand, Prof Franzosi states that Article 52 CIP was inserted as a result of his personal insistence with the commission which drafted the CIP because of the reluctance of Italian legal culture to accept the controlling role of the claims.

ii. 170. In my judgment it cannot be assumed that the enactment by the Italian legislature of a new statutory provision which more clearly reflects Article 69 and the Protocol than the old provision will have no effect on the law. On the contrary, it seems to me to be calculated to require Italian courts to focus more closely on what is required by Article 69 and the Protocol. This is particularly true with the recent addition of section 3*bis* to Article 52 CIP. As Prof Franzosi points out, this requires the court to consider equivalence on an element by element basis, dividing the claim into integers and considering whether or not each integer is present either literally or by equivalence. As is stated in an article commenting on the 2010 reform cited by Prof Guglielmetti in paragraph 38 of his first report, "The centrality of the claims is confirmed by these regulations".

iii. 171. With regard to the question of equivalents, as can be seen from the joint memorandum, Prof Franzosi accepts that Prof Guglielmetti has accurately summarised the existing jurisprudence of the Supreme Court in cases such as Case No. 257 *Forel SpA v Lisac* (13 January 2004), Case No. 30234 *Barilla GER Fratelli SpA v Pastifico Fazion SpA* (30 December 2012) and Case No. 622 *Entsorga Italia Srl v Ecodeco Srl* (11 January 2013) in paragraph 70 of his first report:

> "(i) the '*inventive core*' of the patent must first be identified;
>
> (ii) the contested device infringes the patent if it reproduces the '*inventive core*' of the patent, unless it is non-obvious in respect of the '*inventive core*';
>
> (iii) when some elements of the infringing device include non-obvious modifications, it does not automatically exclude infringement by equivalence if the modifications do not exclude the use, even in part, of the patent; and
>
> (iv) the mere lack of some elements of the patented device in the contested device does not automatically exclude infringement if the '*inventive core*' of the idea protected by the patent is reproduced in the contested device, and if the removal of those elements in the contested device is not inventive."

i. 172. It is also common ground between the experts that, in addition or in the alternative to the "obviousness" test outlined above, Italian courts frequently apply a "triple identity" test: does the variant (i) perform substantially the same function (ii) in substantially the same way (iii) to achieve substantially the same result?

ii. 173. Nevertheless, Prof Franzosi expresses the opinion that this jurisprudence does not correctly reflect the current statutory provisions because it pays insufficient regard to the role of the claims. In particular, it is his view that, if it is evident that there has been a conscious limitation to the claim, then the doctrine of equivalence is excluded. For the reasons given above, I consider that in future the Italian courts will be bound by Article 52 CIP to pay closer attention to the wording of the claims. Furthermore, Prof Franzosi was able to point to some recent lower court decisions which support this point of view. An example is Case 4114/2011 *EG SpA v AstraZeneca AB* (Ordinary Court of Turin, 1 April 2011), where the court held that EG's product did not infringe a claim requiring a minimum of 99.8% enantiomeric excess of magnesium esomeprazole because this was clear limitation in the claim and the accused product did not have the required purity level (consistently with the decision of Kitchin J in *Ranbaxy v AstraZeneca*). Accordingly, I accept Prof Franzosi's opinion on this point.

iii. 174. So far as the prosecution history is concerned, it is common ground between the experts that (i) there is no doctrine of prosecution history estoppel and (ii) there is no clear rule as to the relevance, if any, of the prosecution history as an aid to interpretation of the claims. The Supreme Court has not opined on the latter point, and decisions of lower courts can be found going both ways. Prof Guglielmetti considers that the weight of authority points away from reliance on the prosecution history, whereas Prof Franzosi considers that there is a recent trend towards reliance upon it. Again, *EG v AstraZeneca* is an example of this.

iv. 175. In my judgment the Supreme Court can be expected, when called upon to

consider this question, to adopt a similar position to that adopted by other European appellate courts on this issue. In short, I consider that the Supreme Court will not encourage reference to the prosecution history, but nevertheless will hold that, in an appropriate case, the prosecution history can be relied upon as an aid to construction of the claims, particularly where it is clear the applicant has intentionally limited the scope of the claims during the course of prosecution. This would accord with the argument advanced by Prof Guglielmetti in an article which he acknowledges in paragraph 29 of his first report.

Assessment

i. 176. As I understand it, it is again common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

ii. 177. Lilly contends that it is clear that pemetrexed diacid, dipotassium and ditromethamine are equivalent to pemetrexed disodium whether one applies the "obviousness" or "triple identity" tests, and accordingly they fall within the scope of the claim.

iii. 178. Counsel for Actavis did not argue that pemetrexed diacid, dipotassium and ditromethamine were not equivalent to pemetrexed disodium under Italian law. Rather he argued that the correct interpretation of the claims was that such equivalents were nevertheless excluded from the scope of protection. This was for two reasons. First, because on its face the Patent clearly demonstrated a conscious intention of the patentee to limit the claims to pemetrexed disodium. Secondly, because if there was any doubt about that, it was amply confirmed by the prosecution history.

iv. 179. With some hesitation in respect of the first of these points, but rather less in respect of the second, I accept both these points. Accordingly, I conclude that pemetrexed diacid, dipotassium and ditromethamine are not within the scope of the claims.

<u>Construction of the Spanish designation of the Patent</u>

Spanish law

i. 180. Again, there is some common ground between the experts as to Spanish law, but also some disagreement. So far as precedent is concerned, the experts are agreed that only reiterated decisions of the Tribunal Supremo (Supreme Court) are binding on the lower courts. In the lower courts, the majority of patent cases are heard by the courts of Madrid and Barcelona, with the latter tending to handle the pharmaceutical cases. Accordingly the judgments of those courts are particularly persuasive.

ii. 181. With regard to substantive law, the following matters were agreed by the experts in their joint memorandum:

"**a. General issues on Spanish Law (questions addressed in the**

reports issued by Prof. Bercovitz and Desantes)

1. The sources of Spanish Law.

2. The scope of binding effect of Spanish jurisprudence.

3. The direct effect and direct applicability in Spain of International Treaties, including the European Patent Convention (EPC).

4. The primacy of the EPC over national Law in Spain.

5. The EPC should be the basis for the interpretation of the corresponding Spanish patent Law.

6. The direct effect, direct applicability and primacy in Spain of Article 69 EPC and the Protocol on its Interpretation.

7. Art. 1 of the Protocol of Interpretation constitutes a compromise between the extremes of strictly literal claim construction and the relegation of the claims to the status of guidelines.

8. Art. 69 EPC and its Protocol of Interpretation have played an important role in Spain for extending the protection of the patent to infringement by equivalence cases.

b. Direct patent infringement. Equivalents (questions addressed in the reports issued by Prof. Bercovitz and Desantes)

1. The notion of equivalence.

2. The Spanish Courts understand that the scope of the patent should be objectively based on claim content regardless of the subjective intention of the patentee.

3. The scope of protection of the patent extends to equivalents.

4. In Spain, the doctrine of equivalents is not applied to the invention as a whole but to each of the elements described in the claims - element by element analysis.

5. In Spain, the scope of protection of the claims must in all cases be construed in the light of the description and the drawings.

6. The EPC does not impose on national courts any specific and closed definition of equivalents.

c. Application of the doctrine of equivalents by Spanish Courts (question addressed in the reports issued by Prof. Bercovitz and Desantes)

1. The doctrine of equivalents cannot be used to extend the scope of the patent beyond what the applicant has protected nor should equivalence be used to allow the patentee to portray a claimed feature as ‘irrelevant’ or to compensate for mistakes.

2. Spanish Courts have been alternating various types of tests, as shown by the Supreme Court judgment dated 10 May 2011 (Olanzapine case).

3. The relevance of the test of obviousness, amongst others, in pharmaceutical cases (Olanzapine case)

4. Spanish Courts in fact apply the doctrine of one's own acts (*doctrina de los actos propios*) while sometimes they refer erroneously to the 'prosecution history estoppel' doctrine, which is not applied as such.

5. The doctrine of one's own acts is a general civil law doctrine which applies not only to patent claim construction but also to any other civil law issue.

6. An own act can be something different than a change of a claim.

7. The requirements for the application of the doctrine of one's own acts.

8. None of the judgments quoted in paragraph 60 of the Expert Report by Prof. Bercovitz refer to patents but to general civil law cases and there are cases where the doctrine has been applied to patents.

9. Limitations are also possible in other areas further than prior art.

10. The Spanish Courts have never considered whether the relevant date is the priority date or the publication date in a case on which this issue was relevant for the outcome of the case."

i. 182. As appears from this, the leading case on equivalents is the Supreme Court's decision in Judgment No. 309/2011 *Laboratorios Cinfa SA v Eli Lilly & Co Ltd* ("Olanzapine") of 10 May 2011. In that case the Supreme Court considered a number of tests that had previously been applied, but did not settle on a definitive test. The experts are agreed that in a pharmaceutical case a test that is particularly likely to be applied is an adapted *Improver* test which is sometimes referred to as the "obviousness" test. This involves asking the following questions:

"1. Does the variant alter the functioning of the invention? If the answer is yes, equivalence does not exist. If the answer is no, i.e. the functioning of the invention is not altered, it is necessary to ask the next question.

2. Would the variant have been obvious to a skilled person who read the patent on the date when it was published? If the variant was not obvious i.e. it is inventive, there is no equivalence. If the answer is yes, it is still necessary to ask the third question.

3. Would the person skilled in the art who read the patent have understood, given the terms used in the claim, that the patent holder intended that strict compliance with the literal wording was an essential requirement of the invention? If the answer is yes then there can be no equivalence. But if strict compliance is not essential then the variant may be equivalent."

i. 183. Despite the phraseology of the second question, the experts agree that this does not involve the same test as the step of inventive step for validity purposes. Rather

the question is whether it is obvious to the skilled person or team that the variant is equivalent to the claimed integer. It is only obvious if this would be predictable: see the decision of Audiencia Provincial (Court of Appeal) of Barcelona in Judgment No. 434/2012 *H. Lundbeck A/S v Laboratorios Cinfa SA* of 19 December 2012.

ii. 184. As indicated in the joint memorandum, the experts agree that the "doctrine of one's own acts" should be applied if there is relevant material in the prosecution history. An "own act" can include an amendment to a claim, but it is not limited to amendments. It is agreed that this doctrine is applied restrictively, but there is a slight disagreement as to how restrictively. I shall adopt the summary given by the Spanish national group in its response to AIPPI Question 229 regarding the use of prosecution history in post-grant patent proceedings which is quoted by Prof Bercovitz in paragraph 72 of his second report:

> "The '*actos proprios*' doctrine, as established in Spanish case law, is very clear on the requirement whereby the 'statements' must be unequivocal, clear, precise, conclusive, undoubted and must not reflect any kind of ambiguity. From that perspective, only explicit statements would have to be considered."

i. 185. More importantly, the experts do not agree as to whether or not the doctrine is only applicable where the patentee has expressly limited the claim to overcome a prior art objection. In my judgment the evidence shows that the doctrine is most likely to be applied in such a situation, but does not establish that it is limited to that situation. Thus the Spanish national group's response to AIPPI Question 229 was that it did not matter why the amendments or arguments were made. Counsel for Lilly relied in particular on a passage from the decision of the Court of Appeal of Madrid in Judgment No. 292/2008 *Ros Roca Group SL v Sistemas y Vehícuols de Alta Technología SA* of 1 December 2009, where reference was made to amendments to overcome prior art objections, as in the case under consideration. The Court went on, however, to state the applicable principle in the following way:

> "The Chamber deems it a contradiction with his own acts for the patent's applicant to have renounced a broader scope of protection during the patent's application proceedings, by introducing technical features which reduce the scope protected by its claims, and, subsequently, after the registration, to have attempted to broaden the scope of protection to include in its features that had been excluded from it by virtue of restrictions added by the applicant himself."

Assessment

i. 186. As I understand it, it is again common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

ii. 187. Applying the adapted *Improver* questions, Actavis do not dispute that the answer to question 1 is yes. In my judgment the answer to question 2 is no for the reasons I have given when answering the equivalent question under UK law. Even if the answer to question 2 is yes, I consider that the answer to question 3 is yes for the reasons

I have given when answering the equivalent question under UK law. In so far as those reasons involve considering the prosecution history, I consider that the requirements for application of the "own acts" doctrine are met. The amendments to the claims made by Lilly, and the reasons for making those amendments, are explicit, unequivocal, clear, precise, conclusive, undoubted and do not reflect any kind of ambiguity. The principle stated by the Madrid Court of Appeal in the *Ros Roca* case applies here. Accordingly, I conclude that pemetrexed diacid, dipotassium and ditromethamine are not within the scope of the claims.

Actavis' proposed products

i. 188. In a confidential letter dated 10 December 2013 Actavis set out details of the formulations of their proposed products on which Actavis were focussing. The precise details of these proposed formulations are confidential and are not important. In summary, the proposed products are as follows:

i. i) pemetrexed diacid supplied as a concentrated aqueous solution for dilution [REDACTED];

ii. ii) pemetrexed dipotassium as a lyophilised (i.e. freeze-dried) powder;

iii. iii)pemetrexed ditromethamine as a lyophilised powder [REDACTED].

Direct infringement

i. 189. For the reasons given above, I have concluded that neither pemetrexed diacid, nor pemetrexed dipotassium nor pemetrexed ditromethamine falls within the scope of the claims 1 or 12 of the UK, French, Italian or Spanish designations of the Patent. It is common ground that it follows that dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will not constitute direct infringement of the UK, French, Italian or Spanish designations of the Patent. Accordingly, it is not necessary for me to set out the details of the relevant French, Italian or Spanish law.

Indirect infringement

Infringement of the UK designation

i. 190. *The law*. Section 60 of the Patents Act 1977 provides, so far as is relevant, as follows:

> "(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting,

and are intended to put, the invention into effect in the United Kingdom.

(3) Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above."

i. 191. Section 130(7) declares that a number of sections in the 1977 Act, including section 60, "are so framed as to have, as nearly as practicable, the same effect in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply." Section 130(6) provides that references to the CPC are to "that convention as amended or supplemented".

ii. 192. Article 26 of the CPC, as revised in 1989, provides as follows:

"*Prohibition of indirect use of the invention*

1. A Community patent shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply within the territories of the Contracting States a person, other than a party entitled to exploit the patented invention, with means relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances, that these means are suitable and intended for putting that invention into effect.

2. Paragraph 1 shall not apply when the means are staple commercial products, except when the third party induces the person supplied to commit acts prohibited by Article 25.

3. Persons performing the acts referred to in Article 27(a) to (c) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1."

i. 193. The background to Article 26 CPC, and hence section 60(2) of the 1977 Act, was explained by Jacob LJ in *Grimme Landmaschinefabrik GmbH v Scott* [2010] EWCA Civ 1110, [2011] FSR 7 at [82]-[98].

ii. 194. *The facts*. These are not in dispute. Section 6.6 of the Summary of Product Characteristics for Alimta states as follows:

"3. Reconstitute 500mg vials with 20 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed. Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely affecting product quality. The pH of the reconstituted solution is between 6.6 and 7.8. **Further dilution is required**.

4. The appropriate volume of reconstituted pemetrexed solution

must be further diluted to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes."

i. 195. The effect of this reconstitution and dilution is that there will be present in a solution of Alimta used for the infusion both pemetrexed ions and sodium ions which emanate both from the pemetrexed disodium and from the saline solution. Thus there will be an excess of sodium ions. The solution will also contain chloride ions from the saline.

ii. 196. Actavis admit that their product will be reconstituted and diluted in the same way, save that in the case of the diacid it will simply be diluted. The result will be a solution containing pemetrexed ions, sodium ions and chloride ions. Again, there will be an excess of sodium ions present, albeit that they are all derived from the saline. If the product is pemetrexed dipotassium, there will also be potassium ions present. If it is pemetrexed ditromethamine, ditromethamine ions will be present.

iii. 197. Actavis also admit that it would be obvious to the skilled team that this will occur.

iv. 198. Finally, Actavis also admit that the product will be administered in combination with vitamin B12 and folic acid, and that they know this.

v. 199. *Assessment*. Lilly contends that, even if pemetrexed diacid, dipotassium and ditromethamine do not fall within claim 1 of the Patent and therefore dealings in those products by Actavis will not constitute direct infringement, such dealings will amount to indirect infringement under section 60(2). (As noted above, Lilly does not rely on claim 12. In any event, Lilly cannot be in a better position with regard to claim 12.) In summary, Lilly's argument runs as follows:

i. i) Pemetrexed diacid, dipotassium and ditromethamine are means relating to an essential element of the invention since they provide a source of pemetrexed ions.

ii. ii) The means is for putting the invention into effect. The reconstituted and diluted solution of Actavis' product (or the diluted solution in the case of the diacid) will put the invention into effect in precisely the same manner as a reconstituted and diluted solution of Alimta, since both will contain pemetrexed ions (and sodium ions for that matter).

iii. iii)Actavis have the requisite knowledge.

iv. iv)The persons to whom Actavis' product will be supplied are not entitled to work the invention.

i. 200. Actavis deny indirect infringement. Actavis point out that the issue only arises if the expression "pemetrexed disodium" in claim 1 of the Patent means pemetrexed disodium and not any form of pemetrexed that is pharmaceutically acceptable and

sufficiently soluble. Accordingly, Actavis contend that they cannot be liable for indirect infringement because at no point is pemetrexed disodium used in the manufacture of a medicament by anyone. The fact that, when Actavis supply their product to third parties who reconstitute (or in the case of diacid, dilute) the Products with saline, there will be sodium ions and pemetrexed ions floating around, does not mean that those third parties are implementing the invention; they have not used pemetrexed disodium in the manufacture of a medicament as required under claim 1. It is no answer to this to say that pemetrexed ions on their own constitute an essential element of the invention, as this is just another way of saying that the claim does not require pemetrexed disodium, but merely requires any form of pemetrexed which makes pemetrexed ions available.

ii. 201. I agree with Actavis' analysis. Accordingly, I conclude that there will be no indirect infringement by Actavis of the UK designation of the Patent.

Infringement of the French, Italian and Spanish designations

i. 202. The experts considered the French, Italian and Spanish laws in their respective reports. There was a substantial measure of agreement in each case. In very brief summary:

i. i) In France, Article L 613-4 of the Intellectual Property Code ("IPC") is very similar to section 60(2). As I understand it, it is also intended to implement Article 26 CPC.

ii. ii) In Italy, it does not appear that there is any specific statutory provision for indirect infringement derived from Article 26 CPC. Rather, Italian law provides for contributory infringement applying the general rules on tortuous liability. The effect of the case law is broadly similar to the law in the other countries.

iii. iii)In Spain, Article 51 of the Spanish Patents Act ("SPA") is very similar to section 60(2). As I understand it, it is also intended to implement Article 26 CPC.

i. 203. I do not consider it necessary to go into further detail, because I did not understand counsel for Lilly to contend that, if Lilly failed to establish indirect infringement applying UK law, Lilly could nevertheless succeed applying any of the foreign laws. I therefore conclude that Actavis will not infringe the French, Italian or Spanish designations either.

<u>Law applicable to the DNI claims</u>

i. 204. As I stated in my judgment of 27 November 2012 at [31], it is common ground that, by virtue of Article 8(1) of European Parliament and Council Regulation 864/2007/EC of 31 July 2007 on the law applicable to non-contractual regulations ("the Rome II Regulation"), the law applicable to the question of whether Actavis' proposed acts would infringe each non-UK designation of the Patent is the *lex loci protectionis*, that is, the substantive patent law of the relevant country. As indicated above, however, an important dispute has arisen between the parties to the law which is applicable to the other conditions which must be satisfied by Actavis in order to obtain DNIs: is this the *lex fori* (as Actavis contend) or is it the *lex loci protectionis* (as Lilly contends)? It is

common ground that this issue depends on the proper interpretation of the Rome II Regulation.

ii. 205. Before I proceed further, I should explain for the benefit of foreign readers that the *lex loci protectionis* with regard to the UK designation of the Patent is UK law, since it is governed by the UK Patents Act 1977, and there is no difference between the law of England and Wales and the laws of Scotland and Northern Ireland in this respect. The *lex fori*, however, is the law of England and Wales (or English law for short) since this Court is a court of England and Wales. There are differences between the rules of evidence and procedure of England and Wales, Scotland and Northern Ireland respectively.

The relevant provisions of the Rome II Regulation

i. 206. Recital (6) states:

> "The proper functioning of the internal market creates a need, in order to improve the predictability of the outcome of litigation, certainty as to the law applicable and the free movement of judgments, for the conflict-of-law rules in the Member States to designate the same national law irrespective of the country of the court in which an action is brought."

i. 207. Article 1 provides:

> "**Scope**
>
> 1. This Regulation shall apply, in situations involving a conflict of laws, to non-contractual obligations in civil and commercial matters. …
>
> 3. This Regulation shall not apply to evidence and procedure, without prejudice to Articles 21 and 22."

i. 208. Article 15 provides:

> "**Scope of the law applicable**
>
> The Law applicable to non-contractual obligations under this Regulation shall govern in particular:
>
> (a) the basis and extent of liability, including the determination of persons who may be held liable for acts performed by them;
>
> (b) the grounds for exemption from liability, any limitation of liability and any division of liability;
>
> (c) the existence, the nature and the assessment of damage or the remedy claimed;
>
> (d) within the limits of powers conferred on the court by its procedural law, the measures which a court may take to prevent or terminate injury or damage or to ensure the

provision of compensation;

(e) the question whether a right to claim damages or a remedy may be transferred, including by inheritance;

(f) persons entitled to compensation for damage sustained personally;

(g) liability for the acts of another person;

(h) the manner in which an obligation may be extinguished and rules of prescription and limitation, including rules relating to the commencement, interruption and suspension of a period of prescription or limitation."

i. 209. Article 22 provides:

"**Burden of Proof**

1. The law governing a non-contractual obligation under this Regulation shall apply to the extent that, in matters of non-contractual obligations, it contains rules which raise presumptions of law or determine the burden of proof.

2. Acts intended to"

Brief summary of the rival contentions

i. 210. Actavis contend that the rules for obtaining negative declaratory relief are matters of procedure within Article 1(3) and hence fall outside the scope of the Regulation. Lilly contends that the rules for obtaining negative declaratory relief are not questions of procedure, but fall within the scope of the *lex causae* as determined by Article 15. Lilly particularly relies upon Article 15(c), but it also relies on Article 15(h) and Article 22 by way of analogy. It is common ground that, if Actavis are right that the matter falls outside the scope of the Regulation, the question of the applicable law is to be determined by English private international law and that, under English private international law, the applicable law is the *lex fori*, because English law regards the rules for obtaining negative declaratory relief as being procedural: see *Plastus Kreativ AB v Minnesota Mining and Manufacturing Co* [1995] RPC 438 and *Messier-Dowty Ltd v Sabena SA* [2000] 1 WLR 2040 at [8], [27], [33], [34], [42], [43], [46] (Lord Woolf MR).

Characterisation of the rules

i. 211.Before considering the proper interpretation of the Rome II Regulation, it is necessary to characterise the relevant rules.

ii. 212. Each of the national legal systems in issue in this case has its own rules which specify the conditions which must be satisfied by a claimant in order to obtain a DNI in addition to establishing that the product or process in question does not infringe the patent in question.

iii. 213. Counsel for Actavis submitted, and I agree, that, while these rules all have their own specific modes of operation, broadly speaking two different kinds of mode of operation can be identified:

i. i) First, there are rules based on a fact-sensitive concept of interest or purpose. The notion of "real commercial interest" or "useful purpose" under the English inherent jurisdiction is an instance of this. So too are the rules in Article L 615-9 IPC under French law, Article 100 CCP under Italian law and Article 127.1 SPA under Spanish law considered below. The relevant interest or purpose required differs from legal system to legal system, but the nature of the issue is essentially the same.

ii. ii) Secondly, there are rules based on pre-action notification requirements. Section 71 of the Patents Act 1977 is an example of this. So too is Article L615-9 IPC under French law and Article 127.2 SPA under Spanish law.

i. 214. Counsel for Actavis submitted, and I agree, that, despite the differences in mode of operation, all of these rules are dealing with the same kind of issue. Accordingly, they must be characterised in the same way. As I understand it, it is common ground that they must be given an autonomous characterisation for the purpose of the Rome II Regulation. How they are characterised under the various national laws is not determinative.

ii. 215. Lilly describes these rules as rules of "title to sue" or "*locus standi*", while Actavis describe them as "procedural rules", but both of these descriptions tend to pre-empt the question to be decided.

iii. 216. In seeking to characterise these rules, it seems to me that it is useful to start by considering the purpose of a claim for a DNI. Normally, courts determine claims by claimants seeking to establish that defendants are liable and that a particular remedy should be granted. A claim for a DNI is an unusual kind of proceeding, because the claimant seeks a declaration by the court that there is no liability. Other than that declaration, the claimant seeks no relief. Why should the claimant want to obtain a DNI? Leaving aside considerations of forum shopping, the usual reason why the claimant wants a DNI is to provide legal certainty. In particular, he wants to know whether it is safe to commercialise a particular product or process before he exposes himself to the possibility of a claim for infringement, and hence the possibility of being subject to an injunction and/or of paying substantial damages (or accounting for his profits). If the patentee were to acknowledge that his product or process did not infringe, the claimant would not need to bring a claim for a DNI, because the acknowledgement would provide him with sufficient legal certainty. If the patentee were to sue him and do so quickly, the claimant would not need to bring a claim for a DNI either, because he could obtain legal certainty by defeating the patentee's claim. The claimant only needs to seek a DNI where the patentee declines either to give him an acknowledgement of non-infringement or to sue for infringement within a commercially acceptable time frame. This is particularly important where the patentee has a weak case and would prefer to rely on the uncertainty created by the absence of a decision than to obtain a determination by the court.

iv. 217. Against this background, it can be seen the rules identified in paragraph 213 above serve two main purposes. The first kind of rule serves to ensure that the claimant for a DNI has a sufficient justification for seeking an adjudication by the court.

Justification, that is, not in terms of the substantive merits of his case, but in terms of needing the court to make a declaration rather than requiring the claimant to wait until the patentee decides whether or not to sue. Suppose, for example, that the claimant has devised a clearly non-infringing product, but has no intention to commercialise that product. In those circumstances, he has no need of the court's assistance despite having an unanswerable case on the merits. The question whether he would infringe the patent is an academic question.

v. 218. The second kind of rule serves two objectives. First, it aims to avoid unnecessary litigation. If the patentee will give an acknowledgement of non-infringement, the prospective claimant for a DNI need not bring his claim. Counsel for Lilly submitted that the objective went further, and included giving the patentee the opportunity to bring a claim. Whatever may have been the thinking of the national legislatures in question, I do not consider that this is the true rationale. A patentee who wishes to sue will do so. He does not require a *locus poenitentiae* for that purpose. Again, therefore, the second kind of rule serves to ensure that the claimant for a DNI has a sufficient justification for seeking an adjudication by the court.

vi. 219. Secondly, the second kind of rule seeks to ensure that the dispute is sufficiently well defined for the court to adjudicate upon it. In the normal infringement scenario, one can determine the issue of infringement by reference to an actual product or process. By contrast, the claimant for a DNI frequently wants to obtain a DNI before he has a commercial product or process ready, because he wants to know whether it is safe to make the necessary investment. It follows that it may well be necessary to determine the issue of infringement by reference to what the claimant is proposing to do. For this purpose, it is necessary for the claimant to particularise what he is going to do.

vii. 220. Thus I would characterise the relevant rules in the following manner. They are rules which are designed to ensure that the machinery of the court is only invoked to determine disputes which genuinely require adjudication by the court and to ensure that the dispute is sufficiently well defined for the court to adjudicate upon it. They are not rules concerned with the substantive rights and obligations of the parties with regard to infringement of the patent in suit. In particular, the rules are not rules about who has title to sue in the sense of having a substantive right to bring a claim (as for example, is the requirement under English law that the claimant in a patent infringement claim be either the proprietor of, or an exclusive licensee under, the patent). Thus the evidence shows that decisions made under these rules that claims for DNIs are inadmissible do not give rise to any *res judicata* with regard to the substantive rights and obligations of the parties. Furthermore, the court can adjudicate upon the substantive rights and obligations of the parties with regard to the infringement of the patent in suit without these rules being engaged at all, namely if the patentee brings a claim for infringement.

Interpretation of the Regulation

i. 221. Both sides relied upon the recent decision of the Court of Appeal in *Wall v Mutuelle de Poitiers Assurances* [2014] EWCA Civ 138, [2014] CP Rep 23. In that case Mr Wall was severely injured while riding a motorcycle in France as a result of a collision with a motor car driven by a driver insured by MPA. MPA admitted that the driver was negligent, that it was liable and that Mr Wall could bring proceedings against it in England. The only remaining issue was as to quantum. Mr Wall wanted to adduce evidence from a number of independent experts in different disciplines in the usual English way. MPA contended that expert evidence should be placed before the court in

the same manner in which it would be in France, namely by a single agreed or court-appointed expert or pair of experts. The trial of a preliminary issue was ordered as to whether the issue of what expert evidence the court should order fell to be determined by English law or French law. Tugendhat J held that it was English law by virtue of Article 1(3) of the Rome II Regulation. The Court of Appeal dismissed MPA's appeal. On the appeal, however, a further issue emerged, which was whether the applicable law under Article 15 included guidelines for the assessment of damages. The Court of Appeal held that it did.

ii. 222. On the first point, the Court of Appeal held that the expression "procedure and evidence" was to be given its normal meaning and rejected MPA's submission that it should be narrowly construed: see Longmore LJ at [11]-[12], Jackson LJ at [40]-[41] and Christopher Clarke LJ at [47]. In this context, Longmore LJ specifically rejected MPA's argument that "the aim of Rome II was to promote certainty and uniformity and discourage forum-shopping and that it therefore followed that an English court applying foreign law should ensure (or at any rate do its best to ensure) uniformity of outcome, irrespective of which country tries the … claim". He went on to conclude that, given the exclusion of "evidence and procedure", it was inevitable that trial of the same dispute in different countries might result in different outcomes (see [15]).

iii. 223. So far as the second point was concerned, it was common ground that, pursuant to Article 15(c), the quantum of damages was to be governed by French law. There was a debate, however, as to whether the French law on the quantum of damages included judicial guidelines as to the assessment of damages, which a French court would take account of, but which were "soft law" rather than "hard law". The Court of Appeal concluded that such guidelines were law, and so fell within the scope of the law applicable to non-contractual obligations.

iv. 224. I accept the submission made by counsel for Actavis that, in so far as Lilly's argument relies upon the propositions that Article 1(3) should be narrowly construed and/or that the objective of the Regulation is to ensure uniformity of outcomes, then *Wall* is authority to the contrary. Apart from that, however, the decision sheds relatively little light on what kinds of rule fall within the scope of "procedure".

v. 225. As is common ground, the purpose of Article 15 of the Regulation is to determine the scope of the law applicable to the non-contractual obligation and thus to harmonise the differing national approaches to that question. It can be seen that some of the matters specified in the various paragraphs are matters that some national laws (such as English law) would have regarded as subject to the *lex fori*. As noted above, Lilly relies in particular on Article 15(c), and in particular the reference to "the remedy claimed". This prompted Actavis to rely upon the other language versions of Article 15(c). I was provided in Annex H to Actavis' Closing Submissions with a comparison table of the other language versions and literal English translations of the other language versions obtained by the parties. Many of the English translations are agreed, while a number are not. The disagreements do not affect the broad picture, however. The majority of the other language versions do not use a term equivalent to "remedy". Instead, they use a term equivalent to "compensation", "indemnity" or "reparation". By way of example, I would instance the French "*la réparation demandée*" and the Italian "*l'indennizzo chiesto*". Actavis contend that this shows that Article 15(c) is concerned with damage and compensation for damage.

vi. 226. In response to this, Lilly sought to rely upon some materials indicating that the

revision to the English wording was suggested by the United Kingdom as a consequence of the decision of the Court of Appeal in *Harding v Wealands* [2004] EWCA Civ 1725, [2005] 1 WLR 1539 (subsequently reversed by the House of Lords [2006] UKHL 32, [2007] 2 AC 1). As counsel for Actavis submitted, however, these materials are neither an admissible aid to construction of the Regulation nor very illuminating.

vii. 227. Nevertheless, it seems to me that Actavis' approach to Article 15(c) is unduly narrow. It must be interpreted in a manner which gives effect to the objectives of the Regulation. While the Regulation does not aim for uniformity of outcomes, it does aim to ensure a consistent application of the law applicable to the non-contractual obligation. I consider that it is well arguable that, as suggested by a minority of language versions, Article 15(c) extends beyond the assessment of damages and embraces the financial remedy claimed. On this basis, it would extend to the question of whether a proprietary remedy, such as tracing, is available. Coming closer to the present context, this interpretation of Article 15(c) would mean that the question of whether a successful patentee in an infringement claim can elect between an award of damages and an account of profits is governed by the *lex causae* rather than the *lex fori* (subject to the impact of Article 13 of the European Parliament and Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights).

viii. 228. On the other hand, it also seems to me that Lilly's approach to Article 15(c) is too broad. "Remedy" in Article 15(c) cannot extend to any remedy. The question whether an injunction may be granted to restrain future infringement is clearly governed by the *lex causae*, as Sir Andrew Morritt C held in *OJSC TNK-BP v Lazurenko* [2012] EWHC 2781 (Ch) at [20], but that is because this is provided for by Article 15(d). In that regard, I consider that it is telling that Article 15(d) contains the qualification "within the limits of powers conferred on the court by its procedural law". In my judgment this makes it clear that there is a distinction between the question of principle as to whether an injunction should be granted, which will be a matter for the *lex causae*, and the procedural conditions which must be observed, which will be a matter for the *lex fori*. Thus the rule under English law that three clear days' notice must be given of an application for an interim injunction, save where circumstances of urgency justify giving less notice or where it is justified to take the defendant by surprise by giving no notice at all, is a procedural condition which is a matter for the *lex fori*.

ix. 229. I have considerable doubts as to whether a DNI is a remedy in this sense at all. Under English law, it is little more than a formal record of the court's decision on the substantive issue. I can conceive that, under some systems of law, one would not need or obtain even that much, but merely a judgment of the court. Even if a DNI is a remedy, and even if it is a remedy within Article 15(c), it seems to me that Article 15(c) should be interpreted as only having the effect that the question of principle as to whether a DNI is available at all is a matter for the law applicable to the non-contractual obligation. It does not follow that rules of the kind presently under consideration, which are essentially concerned with whether it is necessary or possible for the court to consider the substantive issue at all, fall within Article 15(c).

x. 230. In this regard, it is worth emphasising that I have already decided that dealings by Actavis in their proposed products will not infringe the French, Italian and Spanish designations of the Patent. Thus I have already decided the substantive issue between the parties on the merits. Even on that basis, if a DNI was simply not available at all under, say, Spanish law, then there would be some logic in this Court declining to make a declaration that no Spanish court could make. It does not follow that it makes sense for

this Court to try to apply the rules which a Spanish court would apply in order to decide whether it was necessary and possible to adjudicate upon the dispute *before* it made a determination on the merits.

xi. 231. In my view Lilly's reliance upon Article 15(h) is misplaced. There is obviously room for a divergence of view as to whether rules as to limitation and prescription are substantive or procedural (as used to be the case under English law before the Foreign Limitation Periods Act 1984). Article 15(h) makes it clear that they are to be governed by the *lex causae*. I see no analogy between a rule of limitation or prescription and the rules presently under consideration, however. The same goes for Article 22, and the burden of proof.

xii. 232. Both sides relied upon the *travaux préparatoires* for the Regulation. These show that what became Article 1(3) was introduced by the European Parliament. As the Juri Committee explained:

> "This amendment takes account of the universal principle of *lex fori* within private international law that the law applicable to procedural questions, including questions of evidence, is not the law governing the substantive legal relationship (*lex causae*), but, rather, the law of the forum."

It does not seem to me, however, that the *travaux* shed much light on the correct answer to the present question.

i. 233. I was also referred to a number of academic articles. Interesting as these are, I have not found many of them particularly helpful so far as the present issue is concerned. A number of commentators have suggested that "evidence and procedure" should be narrowly construed, but this is inconsistent with the decision of the Court of Appeal in *Wall*. In any event, it is not clear that they were addressing their minds to the kind of rules in issue here. The commentary I have found most helpful, perhaps only because it fits most closely with my own thinking, is that of Professor Maria Pertegas on the draft Regulation in "Intellectual Property and Choice of Law Rules" in Alberto Malatesta (ed), *The Unification of Choice of Law Rules on Torts and other Non-Contractual Obligations in Europe: the "Rome II" Proposal* (CEDAM, 2006) at 221-248, in particular the following passage at 240-241:

> "A distinction should be made between the availability of a given remedy – generally, injunctive relief and/or damages – and the procedure(s) available to the plaintiff to request those remedies. It is submitted that only the latter is governed by the law of the forum.
>
> If this distinction is applied to the thorny question of the applicable law to an action for interim injunctive relief, a distinction must be made between two legal issues. First, the court must investigate whether the claimed remedy is available under the *lex loci protectionis*. Provided this is so, it is up to the national procedural rules to determine whether shortened and/or accelerated proceedings are available to the plaintiff."

i. 234. Counsel for Actavis pointed out that Article 1(3) of European Parliament and Council Regulation 593/2008/EC of 17 June 2008 on the law applicable to contractual obligations ("the Rome I Regulation"), and the Rome Convention before that, contain a

parallel exclusion for "evidence and procedure". There have been many claims for negative declarations in relation to contractual liability under the Rome Convention and the Rome I Regulation. Counsel for Actavis asserted that such claims have always proceeded on the basis that the conditions for obtaining a negative declaration were matters for the *lex fori* rather than the law governing the contract. On the other hand, it does not appear from anything I have been shown that the question has ever been argued.

ii. 235. Finally, counsel for Actavis relied upon the consequences of deciding that the rules in question were governed by the *lex causae*, as shown by the issues and evidence in the present case. As he submitted, these demonstrate that one ineluctably gets drawn deep into the procedures of the foreign legal system. This is particularly graphically illustrated by the debates with regard to the requirements under French and Spanish law. By way of example only, I would instance the issues as to whether it is possible to rely upon letters requesting the patentee to take a position sent during the pendency of the proceedings. One also gets entangled in questions of what evidence would be acceptable to the foreign court. By way of example, I would instance the issue under Spanish law with regard to the requirement for the taking position letter to be sent "through notarial channels".

iii. 236. Having taken all of these matters into account, I conclude that the rules presently in issue are matters of procedure within Article 1(3) and are not governed by the law applicable to the non-contractual obligation in accordance with Article 15. It follows that they are governed by English law.

Procedural timetable

i. 237. Due to the objections raised by Lilly to Actavis' claims for DNIs in respect of the French, Italian and Spanish designations of the Patent, it is necessary for me to set out a detailed procedural timetable.

ii. 238. On 12 July 2012 Actavis' solicitors, Bird & Bird wrote to Lilly "C/O Ivan J. Burnside, Lilly Research Centre, Erl Wood Manor, Windlesham, Surrey GU20 6PH". This letter is quoted in my judgment dated 27 November 2012 at [7]. This letter sought a written acknowledgement from Lilly that Actavis' importation, keeping, offering to dispose of and disposing in the UK and in Spain, France, Italy and Germany of a medicament containing pemetrexed dipotassium for use in combination therapy for inhibiting tumour growth in mammals would not infringe the UK and the foreign designations of the Patent in the respective countries.

iii. 239. On 26 July 2012 Lilly's solicitors, Hogan Lovells, wrote to Bird & Bird, not giving the acknowledgment sought, but instead seeking further information about the proposed acts, in particular asking about the details of the pharmaceutical form, including qualitative and quantitative composition and a list of excipients (see [PP/3]).

iv. 240. On 26 July 2012 Bird & Bird replied saying that the claims of the Patent do not claim particular forms, posology or excipients.

v. 241. On 27 July 2012 Actavis Group ehf (the Second Claimant) issued the Claim Form in action HC12E02962 ("the First Action"), seeking (1) a declaration pursuant to

section 71 of the Patents Act 1977 that dealings in pemetrexed dipotassium in the UK as proposed in Bird & Bird's letter dated 12 July 2012 would not infringe any claim of the UK designation of the Patent and (2) a declaration pursuant to the Court's inherent jurisdiction that dealings in pemetrexed dipotassium in France, Germany, Italy and Spain as proposed in Bird & Bird's letter dated 12 July 2012 would not infringe the relevant designations of the Patent.

vi. 242. On 31 July 2012 Hogan Lovells replied to Bird & Bird confirming that they were instructed to accept service on behalf of Lilly.

vii. 243. On 1 August 2012 Bird & Bird wrote to Hogan Lovells enclosing by way of service the Claim Form, Particulars of Claim and Response Pack in the First Action.

viii. 244. On 15 August 2012 Hogan Lovells filed an acknowledgement of service on behalf of Lilly contesting jurisdiction.

ix. 245. On 23 August 2012 Hogan Lovells wrote to Bird & Bird disputing that Bird & Bird's letter of 1 August 2012 constituted valid service of the Claim Form in the First Action.

x. 246. On 29 August 2012 Lilly filed an application contesting the Court's jurisdiction to hear the First Action in respect of the non-UK designations.

xi. 247. Also on 29 August 2012 Medis ehf (the Fourth Claimant) issued the Claim Form in action HC12 A03340 ("the Second Action"), seeking the same relief as that sought in the First Action. On the same day Bird & Bird wrote to both Hogan Lovells and Dr Burnside enclosing the Claim Form, Particulars of Claim and the Response Pack in the Second Action by way of service.

xii. 248. On 4 September 2012 Hogan Lovells wrote to Bird & Bird disputing service of the Claim Form in the Second Action insofar as it related to the non-UK designations of the Patent.

xiii. 249. On 26 September 2012 Lilly filed an application contesting the Court's jurisdiction to hear the Second Action in respect of the non-UK designations.

xiv. 250. On 11 October 2012 Bird & Bird wrote to Lilly at the Windlesham address enclosing the Claim Form, Particulars of Claim etc. in the First Claim without prejudice to the contention that these documents had already been served.

xv. 251. On 27 November 2012 I handed down my judgment dismissing Lilly's applications contesting jurisdiction. Lilly appealed against this decision.

xvi. 252. On 17 April 2013 Actavis (i.e. all of the Claimants) issued and served the Claim Form in the action HC13 A01487 ("the Third Action") seeking DNIs in relation to the use of pemetrexed ditromethamine and pemetrexed diacid, as well as in relation to pemetrexed dipotassium.

xvii. 253. On 1 May 2013 Lily filed an acknowledgement of service in respect of the Third Action contesting jurisdiction.

xviii. 254. On 15 May 2013 Lilly filed an application contesting the Court's jurisdiction to hear the Third Action in respect of the non-UK designations.

xix. 255. On 21 May 2013 the Court of Appeal dismissed Lilly's appeal contesting jurisdiction. In its judgment the Court of Appeal concluded that the Second Action was unnecessary, and for that reason only dismissed it.

xx. 256. On 26 June 2013 Lilly filed an acknowledgement of service in the First and Third Actions defending the claim.

xxi. 257. By a consent order dated 27 June 2013 the parties agreed that Lilly's application challenging jurisdiction of the non-UK designations in the Third Action be dismissed and that the First and Third Actions be case managed together, with Actavis serving a combined Particulars of Claim.

xxii. 258. On 3 July 2013 Actavis served their Combined Particulars of Claim.

xxiii. 259. On 18 July 2013 Lilly served its Combined Defence in the First and Third Actions. Lilly contended in its Defence, contrary to its previous position, that the applicable law for determining the conditions of negative declaratory relief was that of the *lex loci protectionis*, and claimed that Actavis had not complied with various requirements for obtaining DNIs under the relevant laws of France, Italy, Germany and Spain. The Defence also stated that Actavis was required to prove that the use of sodium hydroxide as an excipient did not result in literal infringement. Lilly also brought a counterclaim for infringement of the UK designation of the Patent.

xxiv. 260. On 16 September 2013, as a response to Lilly's claim in the Defence that Actavis had not complied with certain requirements under French and Spanish law, Actavis sent a further taking position letter to Lilly. This letter was sent through an English notary.

xxv. 261. On 18 September 2013 Actavis issued and served the Claim Form in action HP13 E04212 ("the Fourth Action"). The Fourth Action included for the first time claims in relation to pemetrexed dipotassium by Claimants other than Actavis Group ehf. Actavis also applied to amend its Claim Form in the First and Third Actions to add the other Actavis companies as Claimants and to include the other products as well as the dipotassium product.

xxvi. 262. On 30 September 2013 Actavis served its Combined Reply in the First and Third Actions, which explained Actavis' position that the applicable law relating to the conditions for seeking negative declaratory relief was the *lex fori*, but that in any event Actavis had complied with the relevant requirements under foreign law.

xxvii. 263. On 7 October 2013 Lilly filed an acknowledgement of service in the Fourth Action, defending the claim.

xxviii. 264. On 17 October 2013 I gave directions for the trial of the First and Third Actions at a case management conference. Among other things I granted Actavis permission to amend the Claim Forms in the First and Third Actions. The effect of those amendments was to introduce claims by all the Claimants in respect of pemetrexed diacid and ditromethamine in the First Action and by all the Claimants in respect of pemetrexed dipotassium in the Third Action. The amended Claim Forms were issued and served on 22 October 2013.

xxix. 265. Also on 17 October 2013 Actavis issued and served the Claim Form in action HP13 E4604 ("the Fifth Action"), which was brought by Actavis to overcome Lilly's reliance on an alleged one month's notice requirement under Spanish law (as the claim was started one month after the 16 September 2013 letter), but without prejudice to Actavis' primary case that it did not need to send the 16 September 2013 letter.

xxx. 266. On 1 November 2013 Lilly acknowledged service of the Fifth Action, defending the claim.

xxxi. 267. On 11 November 2013 Lilly applied to stay the Fourth and Fifth Actions until 28 days after judgment on the First and Third Actions on the ground that the Fourth and Fifth Actions were an abuse of process.

xxxii. 268. On 12 November 2013 Actavis issued an application for the Fourth and Fifth Actions to be heard together with the First and Third Actions.

xxxiii. 269. On 27 November 2013 I dismissed Lilly's application to stay the Fourth and Fifth Actions and gave directions for the trial of the Fourth and Fifth Actions with the First and Third Actions.

xxxiv. 270. On 3 December 2013 Actavis served their amended Combined Particulars of Claim in the First, Third, Fourth and Fifth Actions.

xxxv. 271. On 10 December 2013 Bird & Bird wrote to Hogan Lovells providing some confidential information about the formulations of the products which Actavis had been working on and explaining that Actavis had no intention to use sodium hydroxide or any other sodium salt as an excipient.

xxxvi. 272. On 11 December 2013: Lilly served its amended Combined Defence and Counterclaim in the First, Third, Fourth and Fifth Actions. The amended Combined Defence alleged that the Fourth and Fifth Actions were an abuse of process.

xxxvii. 273. On 20 December 2013 Actavis served on Lilly a draft re-amended Combined Reply, which referred to and relied upon the information set out in Actavis' letter of 10 December 2013.

xxxviii. 274. Also on 20 December 2013 Actavis issued and served the Claim Form in action HP13 B05505 ("the Sixth Action") and served Further Particulars in the First, Third, Fourth and Fifth Actions re-iterating Actavis' claims, both of which were intended to overcome Lilly's reliance on an alleged three months' notice requirement under

French law (as the claim was started three months after the 16 September 2013 letter).

xxxix. 275. Lilly did not file an acknowledgement of service in respect of the Sixth Action, and thus did not dispute jurisdiction in respect of it.

xl. 276. On 7 January 2014 it was ordered by consent that the Sixth Action should be tried with the First, Third, Fourth and Fifth Actions.

xli. 277. On 13 January 2014 Actavis sent Lilly a further "taking position" letter referring to, relying on and enclosing copies of the letters dated 16 September 2013 and 10 December 2013, although again without prejudice to their primary case that they did not need to send this further taking position letter. This letter was again sent through an English notary. On the same date Actavis served Dr Stefánsson's first witness statement explaining Actavis' preparations for launch of the pemetrexed diacid, dipotassium and ditromethamine products.

xlii. 278. On 7 February 2014 there was a case management conference at which Lilly objected to Actavis' amendments to the Reply relating to and relying upon the 10 December 2013 letter. Actavis were given permission to make some of the amendments to the Reply on condition that they amended the prayer for relief in the Combined Particulars of Claim to clarify that they were not seeking a declaration in relation to the use of the products with sodium hydroxide or any other sodium salt as an excipient.

xliii. 279. On 14 February 2014 Actavis served a re-amended Combined Particulars of Claim with the clarification regarding the scope of the declaration pursuant to the order of 7 February 2014 and an amended Combined Reply.

xliv. 280. On 18 February 2014 Actavis issued and served the Claim Form in action HP14 D00753 ("the Seventh Action"). This action was issued in order to overcome Lilly's reliance on the alleged one month's notice requirement under Spanish law (as the claim was started one month after Actavis' 13 January 2014 taking position letter).

xlv. 281. On 26 February 2014 Lilly served a re-amended Combined Defence, which alleged that the Sixth Action was also an abuse of process.

xlvi. 282. Lilly did not file an acknowledgement of service in respect of the Seventh Action, and thus did not dispute jurisdiction in respect of it.

xlvii. 283. On 17 March 2014 it was ordered by consent that the Seventh Action be tried with the First, Third, Fourth, Fifth and Sixth Actions.

xlviii. 284. Also on 17 March 2014 Actavis served a re-re-amended Combined Particulars of Claim which incorporated the Seventh Action.

xlix. 285. On 19 March 2014 Lilly served a re-re-amended Combined Defence which alleged that the Seventh Action is an abuse of process. Lilly also alleged for the first time that the letters of 16 September 2013 and 13 January 2014 were not sent through proper

notarial channels, although it did not explain why.

l. 286. On 20 March 2014 Actavis re-sent the letter of 13 January 2014 through a Spanish notary (without prejudice to its case that this is not necessary). Lilly has acknowledged that it received this at its premises in Indianapolis, Indiana, USA on 31 March 2014. The Spanish notary has produced a certificate of transmission and by the date this judgment is handed down will have produced a certificate of receipt.

li. 287. On 21 March 2014 Lilly served a response to a Request for Further Information alleging that the letter of 13 January 2014 had not been properly notarised as it did not comply with certain features of Spanish notarial practice which it alleged was required.

lii. 288. On 24 March 2014 Actavis served a re-amended Combined Reply which incorporated the Seventh Action.

liii. 289. On 26 March 2014 Actavis served Mr Stefánsson's second witness statement, updating Actavis' preparations for launch.

liv. 290. On 4 April 2014 Actavis sent a new taking position letter with regard to the French and Spanish designations of the Patent, referring to, relying on and enclosing copies of the letters dated 16 September 2013, 10 December 2013 and 13 January 2014 and Dr Stefánsson's second statement. Again, this letter was sent without prejudice to Actavis' case that it is not necessary, and as a precaution. This was notarised by a Spanish notary and hand delivered by a US notary to Lilly at its premises in Indianapolis on 4 April 2014.

lv. 291. On 14 April 2014 Actavis issued and served the Claim Form in action HP14 A01611 ("the Eighth Action"), and I made an order that it be tried with the earlier actions.

lvi. 292. On 6 May 2014 Actavis issued and served the Claim Form in action HP14 F01792 ("the Ninth Action").

<u>Actavis' preparations for launch of a pemetrexed product</u>

i. 293. Again due to Lilly's objections under French, Italian and Spanish law, I must describe Actavis' preparations for launch of a pemetrexed product and how they have developed over time. Since Actavis regards the details of its preparations as confidential, I shall be circumspect in what I say.

ii. 294. It was Dr Stefánsson's idea to develop an alternative salt to pemetrexed disodium in order to avoid infringing the Patent. This was discussed internally at Actavis at a meeting in [REDACTED]. Dr Stefánsson suggested three alternatives and another person suggested a fourth. [REDACTED].

iii. 295. On [REDACTED] a business case was finalised and expenditure on the

project was approved by Actavis' Pipeline Committee. In [REDACTED], solubility tests were carried out on the calcium salt which showed that it was insufficiently soluble. The results of those tests are in evidence. [REDACTED] As a result, Actavis' Research & Development department came up with some alternative suggestions, which led to the selection of pemetrexed diacid and ditromethamine as additional candidates some time before 17 April 2013.

iv. 296. [REDACTED] Actavis' manufacturing site in Nerviano, Italy is owned and operated by Actavis Italy SPA a Socio Unico ("Actavis Italy"), the Tenth Claimant. Actavis Italy has been chosen to perform the industrial scaling up necessary for the commercial manufacture of whichever of the pemetrexed formulations gets legal clearance and goes through the regulatory process. In due course, the manufacture of commercial batches of Actavis' pemetrexed product will also be done at Nerviano.

v. 297. Actavis' Confidential PPD dated 28 November 2013 sets out test data obtained by Actavis by that date in respect of the (a) solubility, (b) stability, (c) shelf-life and (d) toxicity of pemetrexed disodium, dipotassium, diacid and ditromethamine. [REDACTED]

vi. 298. Exhibit SES3 to Dr Stefánsson's first witness statement shows the status of the project as at 17 December 2013. [REDACTED]

vii. 299. Exhibit SES6 to Dr Stefánsson's second witness statement shows the status of the project as at 19 March 2014. [REDACTED]

viii. 300. Actavis' Confidential Supplementary PPD dated 21 March 2014 sets out additional test data obtained by Actavis since the date of the original PPD. [REDACTED]

ix. 301. In addition to the test data which they have generated themselves, it appears that Actavis have obtained some data from the manufacturer of the API, although the evidence does not establish precisely what data they have obtained from this source.

x. 302. As stated above, Actavis' preferred candidate at present is pemetrexed diacid. [REDACTED]

xi. 303. Dr Stefánsson explains in his witness statements that the launch companies in each country are planned to be chosen from among the remaining Claimants in these actions near to the launch date. If necessary, Actavis will launch through Actavis Italy in France, Germany and Spain as well as in Italy.

<u>DNI in respect of the UK designation applying English law</u>

i. 304. Under its inherent jurisdiction, this Court has a broad discretionary power to grant a negative declaration if it is in the interests of justice to do so: see *Messier-Dowty* at [41]-[42] (Lord Woolf MR). The old restrictive approach under which a negative declaration would not be granted unless there was a claim of right (*Re Clay* [1919] 1 Ch 66) has been abandoned. The modern law is that a negative declaration will be granted if

it is right in all the circumstances to do so, and in particular if it will serve a "useful purpose": *Messier-Dowty* at [41]-[42]. It will do so if the claimant has a "real commercial interest" in the negative declaratory relief sought or a "real commercial reason" for it to be granted: *Nokia Corp v InterDigital Technology Corp* [2006] EWCA Civ 1618, [2007] FSR 23 at [19]-[20] (Jacob LJ).

ii. 305. Lilly does not seriously dispute that, if Actavis establish that dealings in their products would not amount to an infringement of the UK designation of the Patent, then Actavis should be granted a DNI in respect of that designation pursuant to the inherent jurisdiction of the Court. It follows that it is unnecessary for me to consider whether Actavis have satisfied the requirements of section 71 of the Patents Act 1977.

iii. 306. I would emphasise that, although I have found it convenient in writing this judgment to address this issue after determining the substantive issue between the parties on the merits, which is the same order adopted by the parties in their submissions, it would make no difference if I had considered the issues the other way round. I would add that Lilly did not seek the trial of this issue as a preliminary issue, as it could have done if there had been any real doubt about Actavis' entitlement to a DNI even if Actavis were right on the substantive issue.

DNI in respect of the French, Italian and Spanish designations applying English law

i. 307. If, as I have concluded, the law applicable to the question of whether Actavis are entitled to a DNI in respect of the French, Italian and Spanish designations of the Patent is English law, then I consider that Actavis should be granted DNIs in respect of those designations pursuant to the inherent jurisdiction of the Court because Actavis have clearly demonstrated that they have a real commercial interest in obtaining such declarations and such declarations would serve a useful purpose. Nevertheless, in case I am wrong about the applicable law, in the remainder of this judgment, I shall consider the position on the assumption that the relevant law is the law applicable to the non-contractual obligation.

DNI in respect of the French designation applying French law

French law

i. 308. Article L 615-9 IPC provides as follows:

> "Any person who proves exploiting industrially on the territory of a Member State of the European Economic Community, or serious and effective preparations to that effect, may invite the owner of a patent to take position on the opposability of his title against such industrial exploitation, the description of which shall be communicated to him.
>
> If such person disputes the reply that is given to him or if the owner of the patent has not taken a position within a period of three months, he may bring the owner of the patent before the Court for a decision on whether the patent constitutes an obstacle to the industrial exploitation in question, without prejudice to any proceedings for the nullity of the

patent or subsequent infringement proceedings if the working is not carried out in accordance with the conditions specified in the description referred to in the above paragraph"

i. 309. Article 31 of the Civil Procedure Code ("FCPC") provides as follows:

> "The right of action is available to all those who have a legitimate interest in the success or dismissal of a claim, without prejudice to those cases where the law confers the right of action solely upon persons who it authorises to raise or oppose a claim, or to defence a particular interest."

i. 310. There are a number of issues between the parties concerning these provisions. The first concerns the relationship between Article L 615-9 IPC and Article 31 FCPC. Prof Azéma considers that Art L 615-9 IPC is a special derogation from Article 31 FCPC and that this provision was necessary because a DNI was not previously allowed under Art 31 FCPC. Prof Galloux considers that Article L 615-9 IPC is not a derogation from Art 31 FCPC and that a DNI can be obtained under Article 31 FCPC even if the conditions laid down by Article L 615-9 are not satisfied.

ii. 311.On this question I prefer the opinion of Prof Azéma, which is supported by three main points:

i. i) Before Article L 615-9 IPC was introduced in 1984, no action for a DNI was in fact admitted by a French court.

ii. ii) The weight of scholarly comment on Article L 615-9 IPC accords with Prof Azéma's view.

iii. iii)The maxim *specialia generalibus derogant* (the specific overrides the general) applies. This is supported by the decision of the President of the First Instance Court of Lyon in *Eurodif v Gravisse* dated 17 January 1995.

i. 312. The second issue is whether it is always necessary for the party seeking a DNI pursuant to Article L 615-9 IPC to show that it has invited the patent owner to take a position three months before bringing the action. Lilly admits in paragraph 25 of its Combined Defence that it is possible for the party seeking the declaration to avoid this procedure "if the patentee has expressed his position irrevocably and unambiguously in a patent infringement action brought against the party seeking the declaration". The existence of this qualification is supported by the decisions of the Court of First Instance of Paris in *Yamanouchi Pharmaceutical Co Ltd v Biogen NV* of 16 March 1999 and *Alcon v Corneal* of 16 November 2007 cited by Prof Galloux.

ii. 313. Prof Galloux considers, however, that it is not necessary for the patentee to have expressed its position irrevocably or in a patent infringement action provided that the patentee has unambiguously expressed its position on the opposability of its French patent to the other party's product. In support of his opinion Prof Galloux cited the decision of the Court of Appeal of Bordeaux in *Hembert v Composites Aquitaine SA* of 9 April 2002, in which a claim by Composites Aquitaine under Article L 615-9 IPC was held admissible where the patentee had sent letters alleging infringement to another

defendant, to the Ministry of Industry and to the Maritime Prefect of Toulon, and the allegation of infringement had been widely disseminated amongst potential customers. (Prof Galloux also cited the decision of Court of First Instance of Paris in *SEB SA v Euromenage SARL* of 22 April 2003, but in that case Compania Menaje Domestico SL ("CMD") had sent a request for an acknowledgement of non-infringement in respect of a modified product a few days after Euromenage had applied to join CMD as a third party to infringement proceedings brought by SEB against Euromenage in respect of a product supplied by CMD, and SEB subsequently alleged that the modified product also infringed.)

iii. 314. I accept Prof Galloux's opinion on this point. Although Prof Azéma states in paragraph 13 of his second report that the "amicable phase" set out in the first paragraph of Article L 615-9 IPC is a pre-requisite to obtaining a DNI, he does not explicitly contradict what Prof Galloux says in his first report on this issue, nor does he comment on the case law cited by Prof Galloux.

iv. 315. The third issue is whether it is also possible for the party seeking a DNI to avoid the requirement to show that it has made serious and effective preparations for industrial exploitation if the patentee has unambiguously expressed its position on the opposability of its French patent to the other party's product. Prof Galloux considers that this is possible, but as I understand it, on the basis that a DNI could still be obtained under Article 31 FCPC. I have already concluded that it is not possible to obtain a declaration under Article 31 FCPC if it is not available under Article L 615-9. Furthermore, I note that in the *Hembert* case the Court of Appeal went on to consider whether Composites Aquitaine had made serious and effective preparations, holding that the Court of First Instance had been entitled to conclude that it had. One can understand why the Court of Appeal was willing to dispense with strict compliance with the requirement for a "taking position" letter to be sent when the patentee had unambiguously alleged infringement in letters to other parties, but nevertheless required Composites Aquitaine to show that it had a sufficient interest in obtaining a DNI.

v. 316. The fourth issue is whether it is possible for the party seeking a DNI to rely upon a taking position letter, and the failure of the patentee to give an acknowledgement of non-infringement within the following three months, sent during the pendency of the proceedings. Prof Galloux considers that this is possible in accordance with Articles 122 and 126 FCPC, and his opinion is supported by the decisions of the Court of First Instance of Paris in *Biberian v Commissariat a l'Energie Atomique* of 22 November 1996 and *Justamente v Hopital Broussais* of 28 June 2000 he cited. It appears to me that it is also supported by the judgment in the *SEB* case. Prof Azéma considers that this is not possible, and that it is necessary for the claimant to start a new action, but he does not address Articles 122 and 126 FCPC or the case law cited by Prof Galloux. I therefore prefer Prof Galloux's opinion.

vi. 317. The fifth issue is what is meant by "industrial exploitation". Prof Azéma considers that this means manufacture, whereas Prof Galloux considers that it includes marketing the product. Prof Azéma's opinion is supported by three first instance decisions: *Boston Scientific SA v Palmaz* (28 October 1998), *Boston Scientific SA v Cordis Corp* (23 June 1999) and *Abbott Ireland v Evysio Medical Devices ULC* (14 January 2009). Prof Galloux's opinion receives some support from the *Yamanouchi* judgment. In my judgment the superior French courts will conclude that marketing the product is enough for this purpose. Marketing an infringing product is a form of industrial exploitation and it is an act of direct infringement. Furthermore, there is no

rational reason for restricting the availability of DNIs to manufacturers.

vii. 318. The sixth issue is what is meant by "serious and effective preparations". The experts agreed that this "supposes that investments have already been launched, or at least, means have been put in place to enable an exploitation to be implemented". Lilly contends that the seriousness and effectiveness of the preparations must be assessed at the date the action is commenced, whereas Actavis contend that it is possible to rely upon further preparations during the pendency of the proceedings. Prof Galloux's evidence supports Actavis' position, as do the decisions in *SEB*, *Dijkstra* and *Yamanouchi* cited by him. Prof Azéma does not contradict Prof Galloux, and so I accept Prof Galloux's opinion.

Assessment

i. 319. Actavis rely upon no less than six alternative "routes to admissibility" of their claim for a DNI in respect of the French designation. Lilly contends that all six routes fail for one or more of four reasons: (i) Article L 615-9 IPC must always be complied with; (ii) Actavis have not given Lilly three months' notice; (iii) Actavis have not carried out the necessary serious and effective preparations; and (iv) it is not possible for Actavis to cure defects within an existing action, but only by starting again and commencing a new action. For reasons that will appear, I consider that it is sufficient for me to deal with Actavis' first three routes.

ii. 320. *Route 1*. Actavis contend that, by the date of the Sixth Action (20 December 2013), Lilly had unambiguously taken a position on the opposability of the French designation of the Patent to each of pemetrexed diacid, dipotassium and ditromethamine. In support of this contention, Actavis rely in particular on (i) Lilly's counsel's confirmation at the case management conference on 17 October 2013, which was formally recited in the order made on that date, that "it is Lilly's positive case in these proceedings that Actavis' proposed products fall within the scope of the claims of the foreign designations of [the Patent], whether literally or by equivalence", (ii) Lilly's pleading with regard to the scope of the claims of the French designation of the Patent in its Statement of Case served pursuant to that order on 8 November 2013 and (iii) Lilly's statement in a letter from Hogan Lovells to Bird & Bird dated 10 December 2013 that "It necessarily follows [from Lilly's positive case on the construction of the claims] that Lilly considers that the products do fall within the scope of those claims …". Lilly relies on the facts that (i) counsel for Lilly also made it clear that, as the recital to the order continued, "Lilly raises no positive case of infringement in respect of the foreign designations" and (ii) no allegation of infringement was made in the Statement of Case or in the letter dated 10 December 2013.

iii. 321. In my judgment Lilly did unambiguously take a position on the opposability of the French designation of the Patent to each of Actavis' proposed products at the case management conference on 17 October 2013 and in its Statement of Case. It is immaterial that Lilly did not positively allege infringement (or threatened infringement) by Actavis. Furthermore, the reality of Lilly's position was perfectly clear by that date from the fact that Lilly had (i) brought a counterclaim for threatened infringement of the UK designation and (ii) brought proceedings in Düsseldorf for threatened infringement of the German designation. The only reason why Lilly had not positively alleged infringement of the French designation was that it wanted, so far as possible, to preserve its position that Actavis should have brought the claim in France in accordance with French procedure rather than in England in accordance with English procedure, and

thereby make it more difficult for Actavis to obtain a DNI even if they were right on the merits.

iv. 322. Accordingly, I agree with Actavis that it does not matter whether they had properly complied with the requirement to send a taking position letter three months before the Sixth Action. I do not agree that this relieves Actavis from the obligation to demonstrate that they have made serious and effective preparations, however.

v. 323. In my judgment the evidence demonstrates that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013 and certainly by the time of the trial. By 20 December 2013 Actavis had concrete and well-developed plans to manufacture and market each of the products, had taken a number of steps towards implementing those plans and had invested a certain amount of time, effort and money in doing so. By the trial Actavis had taken further steps and invested a lot more money. By 20 December 2013, and still more so by the trial, Actavis had a developed formulation of each product which they could be reasonably confident would receive regulatory approval and which they could manufacture on an industrial scale, although further work remained to be done. This was particularly true of the diacid. Accordingly, I conclude that Actavis are entitled to a DNI pursuant to Article L 615-9 IPC. Even if only the intended manufacturer can obtain a DNI, Actavis Italy is the intended manufacturer and will, if necessary, import the product into France.

vi. 324. *Route 2*. For the purpose of considering route 2, I shall assume that Lilly is correct that Actavis cannot circumvent the requirement of Article L 615-9 IPC for a taking position letter by relying upon Lilly's statements in these proceedings because Lilly has not positively asserted infringement by Actavis. Actavis contend that, by the date of the Sixth Action, more than three months had elapsed since Actavis' taking position letter dated 16 September 2013, and accordingly Actavis had fully complied with the requirements of Article L 615-9.

vii. 325. Lilly does not concede that the letter dated 16 September 2013 satisfied the requirements of Article L 615-9 IPC, but in my judgment it did. In closing submissions counsel for Lilly raised a new argument that Actavis could not rely upon this letter since it was sent during the currency of earlier actions, in particular the First and Third Actions, but this point is unpleaded and unsupported by the expert evidence. More than three months elapsed between the date of the letter and the date the Sixth Action was commenced. I have already held that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013, and certainly by the date of the trial. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article L 615-9 IPC on this basis.

viii. 326. *Route 3*. Although my conclusion in relation to routes 1 and 2 makes it strictly unnecessary to consider route 3, I shall do so because it is relied upon by Actavis as one of their answers to Lilly's abuse of process argument (as to which, see below). Route 3 is essentially the same as route 2, except it relies upon the First and Third Actions and the contention that Actavis can rely upon a taking position letter sent during the pendency of those proceedings. I have concluded that Actavis are right about that. I have already held that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013, and certainly by the date of the trial. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article L 615-9 IPC on this basis.

DNI in respect of the Italian designation applying Italian law

Italian law

i. 327. Article 100 of the Code of Civil Procedure ("CCP") provides:

> "In order to state a claim or to oppose the same, the claimant and the opponent must have a legitimate interest."

i. 328. It is common ground that this applies to claims for DNIs. It is also common ground that the test for a legitimate interest in relation to a claim for a DNI is that there is an objective uncertainty giving rise to a present, concrete prejudice to the claimant which the judgment of the court is capable of curing. It is also common ground that there is no need for a cease-and-desist letter to have been sent.

ii. 329. Prof Gugliemetti considers that there must be some form of actual, articulated objection ("*contestazione*") from the patentee in order for the required uncertainty to exist. Prof Franzosi does not agree with this, although he does agree that the uncertainty must not be academic or hypothetical. Both experts have referred to a number of cases as supporting their respective positions.

iii. 330. Prof Franzosi's position is supported by some decisions of the Supreme Court in non-patent cases, and in particular Case 17026 *VS v TA* of 26 July 2006, in which the Court stated:

> "The most recent case law of the Supreme Court has in fact broadened the scope of enforceability of declaratory actions or of actions of mere declaratory assessment, observing that the interest in bringing forth a lawsuit for a mere declaratory judgment does not necessarily imply the actual occurrence of an infringement on a right or a dispute (*contestazione*) as a state of objective uncertainty is sufficient with regards to the exact scope of rights and mutual obligations arising from any legal transaction as in the present case."

i. 331. Prof Franzosi's position is also supported by some recent decisions of the lower courts in patent cases, in particular three decisions of the Ordinary Court of Milan (Case 77566/2011 *Medexpo International Srl v Medel Group SpA* (1 February 2012), Case 89281/2012 *Ranbaxy UK Ltd v AstraZeneca AB* (12 February 2013) and Case 11770/2011 *Mylan SpA v AstraZeneca* AB (2 April 2013)) and one of the Court of Appeal of Milan (Case 4074/2009 *M.E.P. Maccine Elettroniche Piegatrici SpA v Titanfer Srl* (19 May 2011)). Of these cases, I find the analysis in *Ranbaxy v AstraZeneca* the most comprehensive, helpful and persuasive. In this judgment the Court is explicit that it is not necessary for an objection already to have been made. Thus Italian law on this question appears to be evolving in the same direction as English law has evolved. Accordingly, I accept Prof Franzosi's opinion on this issue.

ii. 332. It does not appear to be disputed that, as stated by Prof Franzosi, legitimate interest is to be assessed at the date of the court's decision and therefore events after the issue of the claim can be taken into account. Prof Gugliemetti does say that a subordinate counterclaim under Italian procedure cannot give rise to a legitimate interest. Prof

Franzosi disagrees with this, but in my view it does not matter who is right, because these proceedings have not been conducted in accordance with Italian procedure and Lilly has not made a subordinate counterclaim.

Assessment

i. 333. Actavis contend that they have a legitimate interest in obtaining a DNI in respect of the Italian designation of the Patent because there is an objective uncertainty giving rise to a present, concrete prejudice to Actavis which the declaration of the court is capable of curing. I agree with this. Actavis are well advanced with plans to manufacture and market a generic pemetrexed product. They contend that none of pemetrexed diacid, dipotassium or ditromethamine fall within the scope of the claims of the Italian designation of the Patent. Lilly disputes this. This means that, objectively viewed, there is uncertainty. That gives rise to present, concrete prejudice to Actavis, because they need a determination of the issue in order to know whether they will be safe to launch their product. In short, the uncertainty affects their business. A declaration of the court will cure this uncertainty.

ii. 334. If, contrary to the conclusion I have reached above, an objection from Lilly is required, I consider that there has been an objection by Lilly for this purpose. Lilly has expressly alleged that pemetrexed diacid, dipotassium or ditromethamine fall within the scope of the claims of the Italian designation of the Patent and has adduced evidence and arguments in support of that allegation. Indeed, paragraph 88 of Lilly's Combined Defence alleges in relation to the Italian designation of the Patent that "There is infringement by equivalence ….". It is immaterial that Lilly has not expressly alleged that Actavis have committed or threaten to commit any infringing acts. Again, it is clear that the only reason why Lilly has not done so is because it would prefer Actavis to have to bring their claim in the Italian courts.

<u>DNI in respect of the Spanish designation applying Spanish law</u>

Spanish law

i. 335. Article 127 of the Spanish Patents Act 1986 ("SPA") provides as follows:

> "1. Any interested person may file an action against the owner of the patent so that the competent judge may declare that a particular act does not constitute infringement of the patent.
>
> 2. Before filing the action, the interested person shall, through notarial channels, demand that the patent owner make known his position on the opposability of the patent to the industrial exploitation carried out in Spain by the claimant or serious and effective preparations being made for that purpose. The person making the demand may file the action provided for in the preceding paragraph if the patent owner has not replied within one month of the date of the demand, or if he does not agree with the reply.
>
> 3. The action specified in paragraph 1 above may not be filed by any person against whom a claim for infringement of the said

patent has been brought.

4. Where the claimant proves that the act referred to in the claim does not constitute infringement of the patent, the judge shall grant the declaration that was demanded.

5. The claim shall be notified to all persons owning rights in the patent who are duly entered in the Register, so that they may appear and take part in the proceedings. Nevertheless, holders of contractual licenses may not appear in the proceedings where their license contracts so specify.

6. The action referred to in the present Article may be brought jointly with an action to declare the invalidity of the patent."

i. 336. There are a considerable number of issues between the parties with regard to this provision, and there is a great deal of expert evidence on those issues (and not merely because of Lilly's use of two experts to address some of them). I shall confine my attention to the issues which matter and deal with them as concisely as I can. In particular, I do not propose to enter into the debate between the experts as to whether Article 127 is procedural or substantive as a matter of Spanish law. Nor, to the extent that it is a separate question, do I propose to enter into the question of whether Article 127 is a provision as to standing as a matter of Spanish law. Nor, to the extent that it is a separate question, do I propose to enter into the debate as to the relationship between Article 127.1 and Article 127.2. In so far as these matters relate to the issue over the interpretation of Rome II, as I have already said, they are not determinative. While it is fair to say that the debates over these issues are linked with debates over the issues considered below, it does not appear to me that it is essential to resolve them in order to resolve the issues considered below.

ii. 337. The first issue is whether it is necessary for the claimant to comply with the requirement of Article 127.2 for a demand through notarial channels one month before filing the action if the patentee has already clearly taken a position on the opposability of its patent to the product. Prof Desantes considers that it is not, relying in particular on the decision of the Court of First Instance of Bilbao in Judgment 156/02 *Teodosio v Metro Bilbao SA* of 24 June 2012 concerning a dispute as to whether the domain name metrobilboa.com registered and used by the claimant infringed the defendant's trade mark METRO BILBAO. In that case the Court rejected the defendant's argument that the claimant had not complied with Article 127.2 (which the Spanish trade mark law applies to trade marks) because the purpose of the notarised request was to allow the trade mark owner to take a position with regard to the activity in question, but there was no need for this in the instant case because the trade mark owner had already filed a complaint against the claimant with the World Intellectual Property Organisation's Arbitration and Mediation Centre.

iii. 338. Prof Bercovitz accepts in paragraph 143 of his first report that this decision showed that "under exceptional circumstances, where the purpose of such requisites had been deemed to have been fulfilled", it was not necessary to send a notarial request and wait for a month as required by Article 127.2. In paragraph 118 of his second report he states that Article 127.2 has not been dispensed with in any other case and the decision "cannot be extrapolated to any *de facto* circumstance imaginable in which there has been no notarial request". In paragraph 30 of his third report, he points out that there was no appeal, and so one does not know what the position of the higher courts would have

been. He does not go so far as to say that the decision is wrong, however. Similarly, Prof Arenas states in paragraph 57 of his second report that in that case "the purpose sought by the notarial request had been achieved by an equivalent channel: (i) the trademark holder was aware of the claimant's activity; (ii) the trademark holder had 'sufficient time' to assess the infringement …; (iii) the trademark holder had an opportunity to file an infringement complaint".

iv. 339. Accordingly, the experts are agreed that there can be circumstances in which it is not necessary for the party seeking a DNI to comply with the requirement in Article 127.2 for a prior demand through notarial channels. The dispute is as to what circumstances suffice for this purpose. In my judgment, the evidence demonstrates that compliance with this requirement in Article 127.2 can be dispensed with, but only if the purposes which it serves have already been achieved before commencement of the claim for DNI. This will be the case if the patentee has been made aware of the product in question, has had at least a month to consider its position and has clearly taken a position on the opposability of its patent to the product.

v. 340. I do not consider that this conclusion is contradicted by the decision of the Court of Appeal of Navarre in Judgment 130/2011 *Laboratorios Cinfa SA v Novartis AG* of 27 May 2011 which was relied on by counsel for Lilly. In that case Cinfa had sent a letter dated 16 April 2008 to Novartis stating that it had made serious and effective preparations to market generic valsartan in Spain and asserting that its product did not infringe Novartis' patent. It does not appear that this letter identified the manufacturer of the active ingredient. Novartis replied asserting that the patent covered the marketing of such a product and formally requesting Cinfa not to market the product. On 3 June 2008 Cinfa commenced a claim under Article 127 requesting a declaration that valsartan manufactured by Química Sintética SA did not infringe the patent. Novartis objected that Cinfa had not complied with the requirements of Article 127. Prior to the trial, Cinfa sought to amend its claim to seek a declaration in respect of its own marketing of valsartan made by Química Sintética, but this application was refused and there was no appeal. The first instance court agreed with Novartis, holding that Cinfa only had *locus standi* to request a DNI in respect of its own activities and not in respect of manufacture by a different company. Cinfa's appeal was dismissed. Among Cinfa's arguments on appeal was that Novartis had given it *locus standi* by its subsequent actions and statements, namely, bringing infringement proceedings against Cinfa. The Court of Appeal rejected this argument on the ground that "The requirements for *locus standi* as claimant must exist on the date the complaint is filed, and this cannot be remedied subsequently ….". It does not follow that a prior taking of position cannot be relied upon.

vi. 341. The second issue is whether, if the patentee has stated its position clearly, this also removes the need for the claimant to show that it has made serious and effective preparations. Prof Desantes considers that this is the case, while Prof Bercovitz and Prof Arenas do not. In my judgment the logic which I have identified in the decision in *Teodosio v Metro Bilbao* for dispensing with the requirement for a notarial request one month before the claim where the purposes of that requirement have already been achieved does not justify dispensing with the requirement for serious and effective preparations. This conclusion receives some slight support from the judgment in *Cinfa v Novartis*, in which the Court of Appeal held that, if Cinfa had wanted to obtain a DNI in respect of its marketing of the product "it should have been expressly requested in the petition section of the complaint, specifying the 'serious and effective preparations' in its complaint and accrediting the reality of the same at the evidentiary stage".

vii. 342. The third issue concerns the requirement for a demand through notarial channels ("*requerirá notarialmente*"), assuming that it is not sufficient for the patentee to have clearly stated his position on the opposability of the patent. Prof Bercovitz considers that this means that there must be a notarial summons ("*acta de requiriminto*") in accordance with Article 202 of the Notary Rules and Regulations, although he accepts that a foreign notary, rather than a Spanish notary, can be employed for this purpose where the patentee is based outside Spain. Prof Desantes disagrees, and considers that Article 127.2 merely requires a notarial notification ("*acta de notificación*"). On this point I find Prof Desantes' reasoning in paragraphs 21-24 of his fourth report convincing.

viii. 343. Even if a notarial summons is required, Prof Desantes considers that proof of transmission of the demand through notarial channels is not required where the patentee has acknowledged receipt of the demand. Prof Bercovitz and Prof Arenas disagree with this. Again, I find Prof Desantes' reasoning convincing. It seems clear that the purpose of requiring the demand to be sent through notarial channels is to ensure that the claimant can prove transmission and receipt. If the patentee has acknowledged receipt, proof by notarial means is not required. As the decision in *Teodosio v Metro Bilbao* shows, the Spanish courts will not insist upon compliance with pointless formalities.

ix. 344. The fourth issue is what constitutes "serious and effective preparations". It is not disputed that "industrial exploitation" includes marketing a product. Prof Bercovitz considers that "serious and effective preparations" requires the preparations to have reached the point that the claimant has the capacity to proceed imminently with the exploitation. In support of his opinion, Prof Bercovitz argues that "serious and effective preparations" in Article 127 should be interpreted in the same way as those words have been interpreted in the context of a prior use defence to infringement under Article 54 SPA (similar to section 64 of the UK Patents Act 1977). This argument receives some support from the decision of the Court of Appeal of Barcelona in Judgment 375/06 *Rolabo SL v Medichem SA* of 20 July 2006. That was a case concerning the interpretation of Article 54. In the course of its judgment, the court referred to a number of other provisions of the SPA, including Article 127. On the other hand, Article 127 was not itself in issue in that case. More significantly, in *Cinfa v Novartis* the Court of Appeal of Navarre adopted the judgment in *Rolabo v Medichem* to the extent it held that "experimental acts" were not sufficient to constitute "serious and effective preparations". On the other hand, that passage was what an English court would regard as *obiter*, although I appreciate that Spanish courts do not make the same distinction between *ratio* and *obiter*.

x. 345. Against this, Prof Desantes argues that, while it is justified to interpret the words narrowly in the context of the Article 54 defence to infringement, the purpose of Article 127 is different and so it does not follow that they should be interpreted in the same way in that context. Prof Desantes points out that Article 127 is based on section 162 of the BIRPI (the predecessor to WIPO) Model Law for Developing Countries on Inventions. The commentary to section 162 states:

> "The purpose of this Section is to avoid future infringement proceedings in borderline cases. It is possible that a person's present or future activity may perhaps be an infringement, but that the person is not certain. In order to clarify the matter, he may avail himself of the procedure provided for in this Section. If the outcome is favourable to him, in other words, if the court's finding is that the performance of the act in question does not infringe the patent, the person may engage in (or continue) his

> activity without risk, whereas he will discontinue (or forgo) the activity if the court's finding is unfavourable to him."

Furthermore, Prof Bercovitz, who was the draftsman of the bill which introduced Article 127, himself stated in an article introducing the new law:

> "When starting or continuing a particular industrial activity it is of extreme relevance to have the assurance that no other's patents are violated. Consider, in fact, that for any productive activity it is necessary to make investments that may be lost if later that activity cannot be developed because it infringes a patent. This unfortunate situation can be avoided if in cases of doubt the action for declaration of non-infringement is filed, avoiding therefore the invidious position of a defendant accused of having infringed the rights arising from a patent."

i. 346. Prof Desantes also points out that other commentators have interpreted "serious and effective preparations" in Article 127 more broadly. One suggests that merely experimental acts are not enough, but not a requirement of immediacy of exploitation. Another suggests that serious and effective preparations "may consist of tests following the trial period and technical and economical studies making this operation visible". Prof Desantes considers even these approaches are too restrictive, however.

ii. 347. Accordingly, Prof Desantes considers that "serious and effective preparations" is a broad concept which is for the overall factual assessment of the court, and that it could include (but would not necessarily require): (a) laboratory tests; (b) business plans to launch after a future marketing authorisation; (c) commencement of industrial scaling up; (d) preparation of a marketing authorisation dossier; or (e) starting preparations in order to be in a position to launch after expiry of SPCs.

iii. 348. In my judgment, the decision in *Cinfa v Novartis* and the weight of the commentary indicates that mere experimental acts will not suffice for "serious and effective preparations". I am not persuaded that it is necessary for the claimant to demonstrate that exploitation is imminent, which would be contrary to the purpose of Article 127 as explained by Prof Bercovitz in his article. Thus if there are concrete and well developed plans for industrial exploitation and preparations have been made to implement those plans extending beyond mere experimental acts, that will suffice.

iv. 349. The fifth issue is whether the serious and effective preparations must be in Spain. Prof Desantes considers that this is not necessary. As counsel for Actavis pointed out, Prof Bercovitz and Prof Arenas do not take issue with this, as opposed to emphasising that the serious and effective preparations must be for industrial exploitation in Spain. Prof Desantes accepts the latter point.

v. 350. It is common ground that the question whether the claimant has made serious and effective preparations is to be assessed as at the date the claim was commenced.

vi. 351. The sixth issue is whether it is possible for the claimant in a claim under Article 127 to remedy deficiencies in his claim, such as a failure to send a demand through notarial channels one month before the claim, during the course of the

proceedings. Prof Desantes considers that this is possible, relying upon various provisions of the Spanish Code of Civil Procedure. Prof Bercovitz and Prof Arenas disagree. For reasons that will appear, I do not consider it necessary to resolve this dispute.

vii. 352. The seventh issue is whether it is possible for the claimant in a claim under Article 127 to remedy deficiencies in his claim, such as a failure to send a demand through notarial channels one month before the claim, by starting a further action during the pendency of the first action. Again, Prof Desantes considers that this is possible, while Prof Bercovitz and Prof Arenas disagree. Again, I do not consider it necessary to resolve this dispute.

Assessment

i. 353. Actavis rely upon no less than seven alternative "routes to admissibility" of their claim for a DNI in respect of the Spanish designation. Lilly again contends that all seven routes fail for one or more of four reasons: (i) Article 127.2 SPA must always be complied with; (ii) Actavis have not given Lilly one month's notice through notarial channels; (iii) Actavis had not at the relevant dates, and still have not, carried out the necessary serious and effective preparations; and (iv) it is not possible for Actavis to cure defects within an existing action, but only by starting again and commencing a new action. I shall confine my attention to routes 1, 2, 3 and 5.

ii. 354. *Route 1*. Actavis contends that, by the time the Sixth Action was commenced, Lilly had clearly taken a position as to the opposability of the Spanish designation of the Patent to the products. As with France, Actavis rely in particular on the recital to the order dated 17 October 2013, Lilly's Statement of Case and the letter dated 10 December 2003. Lilly again relies on the same points as with France. Again, I conclude that Lilly had clearly taken a position on the opposability of the Spanish designation of the Patent to the products by 20 December 2013. Again, the only reason why Lilly had not positively alleged infringement of the Spanish designation was that it wanted, so far as possible, to preserve its position that Actavis should have brought the claim in Spain in accordance with Spanish procedure rather than in England in accordance with English procedure, and thereby make it more difficult for Actavis to obtain a DNI even if they were right on the merits.

iii. 355. Accordingly, I agree with Actavis that it does not matter whether they had properly complied with the requirement to send a taking position letter through notarial channels one month before the Sixth Action. I do not agree that this relieves Actavis from the obligation to demonstrate that they had made serious and effective preparations, however.

iv. 356. In my judgment the evidence demonstrates that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013 for similar reasons to those I have given in relation to the French designation. Accordingly, I conclude that Actavis are entitled to a DNI pursuant to Article 127 SPA.

v. 357. *Route 2*. For the purpose of considering route 2, I shall assume that Lilly is correct that Actavis cannot circumvent the requirement of Article 127.2 SPA for a letter

to be sent through notarial channels one month prior to the action by relying upon Lilly's statements in these proceedings. Actavis contend that, by the date of the Fifth Action, more than one month had elapsed since Actavis' taking position letter dated 16 September 2013, and accordingly Actavis had fully complied with the requirements of Article 127.2. The same goes for the later actions.

vi. 358. Lilly does not concede that the content of the letter dated 16 September 2013 satisfied the requirements of Article 127.2, but in my judgment it did. Lilly contends that the letter was not sent through notarial channels as required. As is common ground, however, Lilly acknowledged receipt of the letter. Thus there is no doubt that the letter was both sent and received. I therefore conclude that the sending of the letter did comply with Article 127.2. I have already found that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by the date of the Sixth Action. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article 127 SPA on this basis.

vii. 359. *Route 3*. Route 3 again relies upon the letter dated 16 September 2013. I shall nevertheless consider it because it is relied upon by Actavis as one of their answers to Lilly's abuse of process argument. The difference from route 2 is that, instead of relying on the starting of the Fifth Action more than one month after that letter, Actavis rely upon the amendments which Actavis made to the First and Third Actions on 22 October 2013 pursuant to the order dated 17 October 2013. The effect of the amendments was to introduce claims in relation to pemetrexed diacid and ditromethamine into the First Action and pemetrexed dipotassium into the Third Action more than one month after the letter dated 16 September 2013. This raises the question of whether Actavis had made serious and effective preparations by 22 October 2013. With slightly more hesitation than in the case of 20 December 2013, I consider that they had. Lilly also advances an argument in relation to route 3 of abuse of process under English law, which I shall consider below.

viii. 360. *Route 5*. For the purpose of considering route 5, I shall assume that Actavis fail on routes 1, 2 and 3 and that Actavis must prove transmission of a taking position letter through notarial channels. In my judgment Actavis has complied with all the notarial requirements relied on by Lilly with respect to the letter dated 4 April 2014. The Ninth Action was issued more than one month after that. Furthermore, even if Actavis had not made serious and effective preparations by the dates of the Sixth Action, I consider that they had done so by the date of the Ninth Action, having continued to progress their plans. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article 127 SPA on this basis.

<u>Lilly's abuse of process argument in relation to the French and Spanish designations</u>

i. 361. Lilly contends that, if (i) on the proper interpretation of the Rome II Regulation the law applicable to the non-contractual obligation includes the rules with regard to interest and pre-notification under French and Spanish law on which Lilly relies, (ii) the First and Third Actions were not well founded due to non-compliance by Actavis with those rules at the dates of those actions, but (iii) the Fourth or any of the subsequent Actions was well founded because by the date of those actions Actavis had complied with the relevant rules, the Fourth and subsequent Actions should be struck out as an abuse of the process in so far as they relate to the French and Spanish designations ("the Main Abuse Argument"). Lilly also contends that, if Actavis is correct that the First and Third Actions were well founded in relation to the Spanish designation as from the

date of the amendments on 22 October 2013 even if not originally, the making of those amendments was an abuse of process ("the Amendment Abuse Argument").

ii. 362. Given my earlier conclusions, I need to make clear the bases upon which I shall consider these arguments. So far as the French and Spanish designations are concerned, I have concluded that (i) Actavis will not infringe those designations applying the *lex loci protectionis*, (ii) on a proper interpretation of the Rome II Regulation the other conditions which must be satisfied for the making of a DNI are governed by the *lex fori* and (iii) applying English law Actavis are entitled to a DNI. It follows that Actavis succeed in the First and Third Actions, and the later actions were unnecessary. Even if I am wrong on point (ii), I have held that, applying French law, Actavis succeed on route 3. Again it follows that Actavis succeed in the First and Third Actions, and the later actions were unnecessary. If I am wrong about that, but right that Actavis succeed on routes 1 or 2, it follows that Actavis succeed in the Sixth Action, but not in the First and Third Actions. I shall therefore consider Lilly's contention that the Sixth Action is an abuse of process on that assumption. Applying Spanish law, I have held that (subject to the Amendment Abuse Argument) Actavis succeed on route 3. If I am wrong about that, but right that Actavis succeed on routes 1, 2 or 5, it follows that Actavis succeed in the Fifth, Sixth or Ninth Actions, but not in the First and Third Actions. I shall therefore consider Lilly's contention that the Fifth, Sixth and Ninth Actions are an abuse of process on that assumption.

iii. 363. It should be noted before proceeding further that Lilly advances these arguments in reliance upon the English law of abuse of process i.e. the *lex fori*. Lilly does not rely upon the laws of France or Spain for this purpose. It must therefore be assumed that the Fourth and subsequent Actions would not be struck out or dismissed as an abuse of process or on an equivalent ground applying French and Spanish law. As I understand it, the reason why Lilly contends that the relevant law is English law is because the court whose process Lilly claims is being abused is the English court. I am unable to understand why, if Lilly is correct that the relevant rules are substantive rules governed by the *lex loci protectionis*, the question whether it is legitimate for Actavis to try to ensure compliance with those rules by starting fresh actions during the pendency of earlier actions or by amending pending actions should be judged by reference to the *lex fori*. Be that as it may, I will consider the merits of Lilly's arguments on the assumption that it is correct as to the applicable law for this purpose.

iv. 364. It is convenient first to consider the Amendment Abuse Argument. This relates to route 3 in respect of the Spanish designation. As I have explained, route 3 relies upon the amendments to the First and Third Actions made on 22 October 2013. Counsel for Lilly submitted that route 3 failed because the amendments were an abuse of process. I do not consider that this argument is open to Lilly for the following reasons. First, the order giving Actavis permission to make those amendments provided that the amendments would be made "without prejudice to Lilly's or Actavis' ability to argue such points as they may have as to the effect of those amendments in respect of the Fourth Action". Lilly's purpose in seeking this qualification was, as counsel for Lilly made clear at the hearing on 17 October 2013, to ensure that it was not prevented by the amendments from arguing that the Fourth (or any later) Action was an abuse of process. Lilly did not resist the amendments on the ground that they were in and of themselves an abuse of process. Secondly, Lilly has not appealed or applied to set aside that part of the order of 17 October 2013. Thirdly, Lilly has not pleaded that the amendments were an abuse of process. Even if the argument is open to Lilly, I do not accept it. As I have pointed out, Actavis were given permission to make the amendments by an order of this Court. There is no dispute that this Court had power under the Civil Procedure Rules to

give Actavis permission to make the amendments. Furthermore, viewed from the perspective of English procedural law, there was nothing abusive about Actavis' application for permission to make the amendments, which is precisely why Lilly did not in the end resist it provided that permission was qualified in the way that I have described. Even if Lilly is right that no such amendment could be made under Spanish procedural law, and the claimant would have to start a new action, that is immaterial.

v. 365. I turn to consider the Main Abuse Argument. The applicable principles can be summarised as follows. In *Hunter v Chief Constable of the West Midlands* [1982] AC 529 at 536, Lord Diplock referred to:

> "… the inherent power which any court of justice must possess to prevent misuse of its procedure in a way which, although not inconsistent with the literal application of its procedural rules, would nevertheless be manifestly unfair to a party to litigation before it, or would otherwise bring the administration of justice into disrepute among right‑thinking people. The circumstances in which abuse of process can arise are very varied .... It would, in my view, be most unwise if this House were to use this occasion to say anything that might be taken as limiting to fixed categories the kinds of circumstances in which the court has a duty (I disavow the word discretion) to exercise this salutary power."

i. 366. As Lord Bingham of Cornhill explained in *Johnson v Gore Wood & Co* [2002] 2 AC 1 at 31, this involves:

> "... a broad, merits‑based judgment which takes account of the public and private interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court ..."

i. 367. In the context of the Civil Procedure Rules, assessment of whether there is an abuse of process is inseparably bound up with the question of what the overriding objective requires. Thus, as Lord Phillips of Worth Matravers MR said in *Jameel v Dow Jones & Co Inc* [2005] EWCA Civ 75, [2005] QB 946 at [54]:

> "An abuse of process is of concern not merely to the parties but to the court. It is no longer the role of the court simply to provide a level playing field and to referee whatever game the parties choose to play upon it. The court is concerned to ensure that judicial and court resources are appropriately and proportionately used in accordance with the requirements of justice."

i. 368. Furthermore, even where the claimant has been guilty of an abuse of process, it does not necessarily follow that his claim must be struck out if that would be a disproportionate sanction in the circumstances: see *Summers v Fairclough Homes Ltd* [2012] UKSC 26, [2012] 1 WLR 2004. As the decision of the Supreme Court in that case indicates, this is particularly true where there has been a fair trial of the merits of the claim and the claim has been upheld at least to some extent.

ii. 369. As was indicated in the *Hunter* case, the categories of abuse of process are not closed. There are a number of established situations in which abuse of process may be recognised. One is where the court's process is being used for an improper or collateral purpose: see in particular *Goldsmith v Sperrings Ltd* [1977] 1 WLR 478. Another is re-litigation of matters that could and should have been litigated previously: see in particular *Johnson v Gore Wood*. A third is where it is plain that the litigation is pointless and wasteful: see in particular *Jameel v Dow Jones*. A fourth is where the claimant advances a false case and/or relies upon false evidence: see in particular *Summers v Fairclough*.

iii. 370. The particular form of abuse which Lilly invokes is that which can arise where the claimant has framed its claim in such a manner as to attempt to circumvent a time restriction. Counsel for Lilly relied, in particular, upon the decision of Jackson J (as he then was) in *Carter Commercial Developments v Bedford Borough Council* [2001] EWHC 669 (Admin) applying the judgment of the Court of Appeal in *Clark v University of Lincolnshire and Humberside* [2000] 1 WLR 1988. In *Carter*, the gravamen of the complaint of abuse of process was concisely identified by the judge at [30] as follows:

> "The issues which the claimant seeks to raise are plainly public law issues and should properly be dealt with by judicial review proceedings under Part 54. The reason why the claimant has resorted to the Part 8 procedure is obvious. The claimant is seeking to circumvent the time limits contained in Part 54."

As will be clear from that quotation, the claimant was well out of time for an application for judicial review under Part 54 and was, therefore, seeking to bring private law proceedings under Part 8 instead. That was held to be an abuse of process because the claimant should have proceeded by way of judicial review. Thus the claimant was clearly using the procedures of the court in an improper way.

i. 371. As counsel for Actavis submitted, however, it is not an abuse of process to bring a further claim on the same cause of action during the pendency of an existing claim if there is a good reason for doing so and case management tools like consolidation are used to avoid unnecessary duplication of effort and cost: see *Rozenberg v Nazarov* [2008] EWHC 812 (Ch) at [71]-[77] (Thomas Ivory QC sitting as a Deputy High Court Judge). A common example of this in the intellectual property field is where the claimant is relying upon a cause of action, such as secondary infringement of copyright, which requires knowledge or reason for belief on the part of the defendant. Prior to the CPR, it was common for claimants, where there was doubt that the defendant had the requisite knowledge or reason for belief as at the date of the writ, but it was clear that the defendant did have it at a later date, to issue a second writ and apply to consolidate the two actions or to have them heard together. Under the CPR it is possible to take the simpler course of pleading facts arising after the date of the claim form. If there was doubt about that, however, it would not be an abuse of process for the claimant to issue a second claim form in order to ensure that it was able to rely upon the defendant's knowledge or reason for belief as at the date of the second claim form in the alternative to the date of the first claim form and then to apply for the two claims to be heard together on the same evidence.

ii. 372. In my judgment what Actavis have done in the present case is no different in principle to what I have just described. Lilly contends that it is different because the *lis pendens* effect of the First and Third Actions deprived it of the opportunity of responding

to Actavis' later taking position letters by bringing infringement proceedings in France and Spain. As to that, my view remains as stated in my judgment dated 27 November 2013 at [33]:

> "… the problem which Lilly says exists is one which exists, to the extent that it does, by virtue of the First and Third Actions and the consequences of the pendency of those actions. There is, and can be, no dispute that the First and Third Actions are properly constituted actions over which it has been decided that this court has jurisdiction. Those actions have whatever consequences in terms of *lis pendens* that they have. If Lilly is correct in saying that the *lis pendens* consequences of those actions is to prevent Lilly from bringing actions in France and Spain and thus of depriving Lilly of the procedural protections to which it claims to be entitled under French and Spanish law, as to which I express no view, then that is a natural consequence of the existence of the First and Third Actions. It is not a consequence of the bringing of the Fourth and Fifth Actions. In those circumstances, I cannot see that the Fourth and Fifth Actions are an abuse. Actavis are simply taking ordinary procedural steps to overcome procedural obstacles raised by Lilly."

i. 373. Lilly argues that this is wrong because Actavis should have discontinued the First and Third Actions before commencing the later Actions, and even before writing the letters upon which those Actions are founded. I see no reason, however, why Actavis should have been obliged to discontinue claims which were properly constituted, jurisdictionally well founded and had a perfectly good prospect of success. Even if Actavis should have discontinued the First and Third Actions because they were destined to fail, that would at best found an argument that maintaining the First and Third Actions was an abuse. It would not follow that bringing the Fourth and subsequent Actions was an abuse. So Lilly's argument has to be that, given that the First and Third Actions were maintained, it was an abuse to bring the later Actions. But that simply amounts to saying that it was an abuse for Actavis to pursue an alternative case while maintaining their primary case, which is commonplace in English litigation (and in litigation in many other legal systems).

ii. 374. I would add two points. The first is that Lilly's argument makes it clear that what Lilly is really complaining about is not the bringing of the Fourth and subsequent Actions during the pendency of the First and Third Actions, but the fact that Actavis have brought these proceedings before this Court. That complaint is not open to Lilly, however, because its jurisdictional challenge to the First and Second Actions failed and it has rightly accepted that this Court has jurisdiction over the Third and subsequent Actions. Furthermore, it is not an abuse of process for a claimant to bring a claim before a forum which he perceives to be more advantageous (e.g. because it is quicker) in order to forestall the defendant from bringing proceedings in a forum which the claimant perceives to be less advantageous (e.g. because it is slower) provided that the first forum is one which properly has jurisdiction in respect of the claim: see *Research In Motion UK Ltd v Visto Corp* [2008] EWCA Civ 153, [2008] FSR 499 at [12]-[17] (Jacob LJ) and *Pell Frischmann Consultants Ltd v Prabhu* [2013] EWHC 2203 (Ch), [2013] ICR 153.

iii. 375. The second point is that Lilly can only complain that it has been the victim of an abuse of process in this respect if it has been prevented by Actavis' conduct from bringing infringement actions against Actavis in France and Spain that it would otherwise have brought. Lilly has not adduced any evidence, nor even asserted through

counsel's submissions, that it would have brought such actions but for Actavis' conduct, however. By contrast, Lilly has brought and pursued a claim in Germany even though this Court was first seized. Lilly's stance with regard to France and Spain is simply obstructive.

Summary of conclusions

i. 376. For the reasons given above I conclude that:

i. i) neither pemetrexed diacid nor pemetrexed dipotassium nor pemetrexed ditromethamine falls within the scope of the claims 1 or 12 of the UK, French, Italian or Spanish designations of the Patent;

ii. ii) accordingly dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will not constitute direct infringement of the UK, French, Italian or Spanish designations of the Patent;

iii. iii)nor will dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will constitute indirect infringement of the UK, French, Italian or Spanish designations of the Patent;

iv. iv)the law applicable to the question of whether Actavis are entitled to a DNI is English law;

v. v) applying English law, Actavis are entitled to a DNI in respect of the UK, French, Italian and Spanish designations of the Patent;

vi. vi)even if French, Italian and Spanish law is the applicable law respectively, Actavis are entitled to a DNI in respect of the French, Italian and Spanish designations of the Patent; and

vii. vii) if French and Spanish law is applicable, if the First and Third Actions are not well founded, but one or more of Actavis' later Actions are well founded, those later Actions are not an abuse of process in so far as they relate to the French and Spanish designations.

Neutral Citation Number: [2015] EWCA Civ 555

Case No: A3 2014 2047

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT
MR JUSTICE ARNOLD
[2014] EWHC 1511 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: Thursday 25th June 2015

Before :

LORD JUSTICE LONGMORE
LORD JUSTICE KITCHIN and
LORD JUSTICE FLOYD

- -

Between:

	ACTAVIS UK LIMITED and others	**Claimants/ Respondents**
	- and -	
	ELI LILLY & COMPANY	**Defendant/ Appellant**

- -

(Transcript of the Handed Down Judgment of
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- -

Henry Carr QC, Thomas Mitcheson QC and **Stuart Baran** (instructed by **Hogan Lovells International LLP**) for the **Appellant**
Richard Meade QC, Thomas Raphael QC and **Isabel Jamal** (instructed by **Bird & Bird LLP**) for the **Respondents**

Hearing dates: 9-12 March 2015

- -

Judgment**Lord Justice Floyd :**

Introduction and issues

1. 1. This appeal is from the judgment of Arnold J dated 15 May 2014 and his consequent order in an action by companies in the Actavis group of companies (together "Actavis") for declarations of non-infringement ("DNIs") of European Patent (UK) No. 1 313 508 and the corresponding national designations in France, Italy and Spain. I will refer to European Patent 1 313 508 as "the 508 patent" or "the patent". The patentee of the 508 patent and the appellant is Eli Lilly & Company ("Lilly"). The appeal first raises issues of substantive patent law, which I shall call "the patent law issues". The first of the patent law issues concerns the correct approach under our law (and the law of certain

other designated states) to the construction of the 508 patent claims, in particular the requirement under the European Patent Convention 2000 ("EPC 2000") to take account of "equivalents" as well as the extent, if at all, to which it is permissible to make use of the prosecution history of the patent in reaching conclusions about construction. The second of the patent law issues concerns whether the application of our law of contributory infringement (as well as that of the other designated states) justifies a finding of infringement in this case.

2. 2. Depending on the outcome of the patent law issues, there are further issues about whether European Parliament and Council Regulation 864/2007/EC of 31 July 2007 ("the Rome II Regulation" or "Rome II") means that the English court must apply the corresponding foreign laws governing the conditions for applying for DNIs in each of the foreign jurisdictions, or whether English law, as the *lex fori*, applies. I will call this "the Rome II issue". Finally, if the foreign laws apply, there would be further issues about precisely what the foreign laws provide about the conditions for applying for DNIs in those countries and whether Actavis have complied with those conditions. I will call these "the DNI factual issues" notwithstanding that, as is well known, issues of foreign law are a rather special type of issue of fact.

3. 3. Pemetrexed disodium is a cancer treatment which Lilly has marketed under the brand name Alimta since 2004. Lilly had patent protection for pemetrexed disodium by way of European Patent No 0 432 677 ("the 677 patent"). Actavis sought the DNIs of the 508 patent in order to place themselves in a position to market a competing product to Alimta on the expiry of the 677 patent in December 2015. They did so in a single action in this jurisdiction. Actavis make no challenge to the validity of the 508 patent: to do so would have meant that this court did not have jurisdiction to deal with the DNIs in respect of the foreign designations, because there is exclusive jurisdiction in relation to issues of validity in the courts of the country where the patent is registered. In an earlier judgment Arnold J rejected Lilly's challenge to the English court's jurisdiction to hear and determine Actavis' action for DNIs in respect of the foreign designations and his judgment was upheld in this court: [2013] EWCA Civ 517; [2013] RPC 37. This court considered that there was jurisdiction on the ground that Lilly had accepted service of the proceedings. It did not find it necessary to decide an alternative issue concerning whether Arnold J had been right to refuse to stay the proceedings on the ground of *forum non-conveniens*.

4. 4. The 508 patent relates to the use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy with vitamin B12 and, optionally, folic acid. The active ingredient in Actavis' proposed product is one of (a) pemetrexed diacid, (b) pemetrexed ditromethamine or (c) pemetrexed dipotassium ("the Actavis AIs"). Actavis' case is a simple one. It is that, because they intend to use the Actavis AIs and not pemetrexed disodium, the 508 patent's claims to the use of pemetrexed disodium are not infringed. Lilly does not agree and contends that there will be either direct or indirect infringement of the 508 patent if Actavis launch any of the Actavis AIs in the UK or in any of the other states in relation to which DNIs are sought.

5. 5. Arnold J agreed with Actavis that their proposed uses of the Actavis AIs would not infringe any claim of the 508 patent as a matter of English law. Next, he had to consider whether the same result would follow under the laws of France, Italy and Spain. It was common ground that those foreign laws applied to the issue of whether the Actavis AIs would infringe in those countries. He concluded that applying the infringement laws of those countries would lead to the same result as the application of English law, and that,

therefore, there was no infringement in those countries either.

6. 6. This meant that the judge needed to go on and deal with the Rome II issue before he could decide whether it followed that his decisions thus far would lead to DNIs in respect of the French, Italian and Spanish designations of the 508 patent. He concluded that English law, as the *lex fori*, applied to the conditions for the admissibility of a DNI, rejecting Lilly's argument that it was the *lex loci protectionis* or *lex causae*, that is to say the patent law of the contracting state in respect of which the declaration was sought. Because there is no difference on the facts of this case between these two Latin descriptors, I will use the term *lex causae* in this judgment to describe the laws of the designated states in respect of which the DNI is requested.

7. 7. Those conclusions were sufficient to enable the judge to grant DNIs in respect of each of the designations sought by Actavis, but the judge went on to consider whether, if he was wrong as to the applicability of the *lex fori*, Actavis had in fact complied with the conditions for obtaining a DNI under the *lex causae*. He concluded that Actavis had so complied.

8. 8. Lilly appeals with the judge's permission. On the appeal Mr Henry Carr QC, Mr Thomas Mitcheson QC and Mr Stuart Baran presented the arguments for Lilly. Mr Richard Meade QC, Mr Thomas Raphael QC and Ms Isabel Jamal did the same for Actavis.

9. 9. In summary, therefore, the issues we have to decide on this appeal are:

i. i) whether the judge was wrong to decide that there was no direct or indirect infringement applying English law by use of the Actavis AIs as a matter of English law;

ii. ii) whether the judge was wrong to decide that the same result followed under the laws of France, Italy and Spain;

iii. iii)if the judge was wrong on issue (ii), whether the judge was also wrong on the Rome II issue;

iv. iv)if the judge was wrong on the Rome II issue, whether he was also wrong on the DNI factual issues.

v. 10. I turn first to deal with the patent law issues.

The 508 patent and its claims

i. 11. The 508 patent is entitled "*Combination containing an antifolate and methylmalonic acid lowering agent*". It has an earliest claimed priority date of 30 June 2000. Pemetrexed is a member of the class known by the name antifolates. Vitamin B12 is a methylmalonic acid lowering agent.

ii. 12. The specification begins at [0001] by stating that "*Potentially, life-threatening toxicity remains a major limitation to the optimal administration of antifolates*". It is explained at [0002] that antifolates work by inhibiting anti-folate-requiring enzymes by competing with reduced folates for binding sites on those enzymes. The specification identifies several antifolate drugs as being in development, including Lilly's Alimta.

iii. 13. The specification then explains at [0003] that a limitation to the development of these drugs is that they may be associated with substantial toxicity, including mortality, for some patients. These toxicity effects had led to the abandonment of the development of some antifolates. In [0004] the specification explains that previous work had been done on the use of folic acid as a treatment for toxicity in this area. It also records work on vitamin B12 as a predictor of cytotoxic events.

iv. 14. The specification then continues:

> "[0005] Surprisingly and unexpectedly, we have now discovered that certain toxic effects such as mortality and non-hematologic events, such as skin rashes and fatigue, caused by antifolates, as a class, can be significantly reduced by the presence of a methylmalonic acid lowering agent as vitamin B12, without adverse adversely affecting therapeutic efficacy. The present invention thus generally relates to a use in the manufacture of a medicament for improving the therapeutic utility of antifolate drugs by administering to the host undergoing treatment with a methylmalonic acid lowering agent as vitamin B12. We have discovered that increased levels of methylmalonic acid is a predictor of toxic events in patients that receive an antifolate drug and that treatment for the increased methylmalonic acid, such as treatment with vitamin B12, reduces mortality and nonhematologic events, such as skin rashes and fatigue events previously associated with the antifolate drugs. Thus, the present invention generally relates to a use in the manufacture of a medicament for reducing the toxicity associated with the administration of an antifolate to a mammal by administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent as vitamin B12.
>
> [0006] Additionally, we have discovered that the combination of a methylmalonic acid lowering agent as vitamin B12 and folic acid synergistically reduces the toxic events associated with the administration of antifolate drugs. Although, the treatment and prevention of cardiovascular disease with folic acid in combination with vitamin B12 is known, the use of the combination for the treatment of toxicity associated with the administration of antifolate drugs was unknown heretofore."

i. 15. These early, general statements are made in relation to antifolates as a class. However at [0010] the specification says, in what patent lawyers refer to as "a consistory clause", that the invention:

> "specifically provides the use of the antifolate pemetrexed disodium in the manufacture of a medicament for use in a

combination therapy for inhibiting tumour growth wherein said medicament is to be administered in combination with methylmalonic acid lowering agent selected from vitamin B12 and pharmaceutical derivatives thereof."

i. 16. This paragraph, in referring only to pemetrexed disodium, is highly specific. However at [0016] the specification reverts to greater generality when it states:

> "The current invention concerns the discovery that administration of a methylmalonic acid lowering agent such as vitamin B12 or a pharmaceutical derivative thereof, in combination with an antifolate drug such as pemetrexed disodium reduces the toxicity of the said antifolate drug." (emphasis supplied).

i. 17. Paragraph [0022] is in a section which contains a number of definitions:

> "[0022] The terms 'antifolate' and 'antifolate drug' generally refer to a chemical compound which inhibits at least one key folate-requiring enzyme of the thymidine or purine biosynthetic pathways, preferably thymidylate synthase ('TS'), dihydrofolate reductase ('DHFR'), or glycinamide ribonucleotide formyltransferase ('GARFT'), by competing with reduced folates for binding sites of these enzymes. The 'antifolate' or 'antifolate drug' for use in this invention is Pemetrexed Disodium (ALIMTA®), as manufactured by Eli Lilly & Co." (emphasis added)

i. 18. This passage, with its use of "the antifolate" rather than "an antifolate" in the emphasised sentence, is another indication that the invention is not the use of antifolates as a class. The invention is then illustrated by reference to a number of examples, which relate to animal and human tests in which the only antifolate used is pemetrexed disodium. At paragraph [0035] the specification states that animals were treated with "*pemetrexed disodium (ALIMTA®) (100 mg/kg or 150 mg/kg) once daily … by intraperitoneal injection alone or along with folic acid*". This is an indication that pemetrexed disodium is administered in a solution. In a similar fashion, the specification indicates at [0044] that, in a typical clinical evaluation using cancer patients, the antifolate is to be administered in four doses over a two week period by rapid intravenous injection. This again can only be the case if the antifolate, in this case pemetrexed disodium, is in solution.

ii. 19. Claims 1-11 of the Patent are use claims in the general form "use of A in the manufacture of a medicament for treatment of disease B" (so-called "Swiss" claims). Claims 12-14 are in the general form "product A for use in a treatment Y" (so-called "purpose-bound product" claims). It is only necessary to refer to claims 1 and 12, which are as follows:

> "1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-

chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.

12. A product containing pemetrexed disodium, vitamin B 12 or a pharmaceutical derivative thereof said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and, optionally, a folic binding protein binding agent selected from the group consisting of folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically available salt or ester thereof, as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumor growth."

i. 20. It is beyond argument, therefore, that the claims are limited by reference to the words “pemetrexed disodium”. The task for the court is to determine what the skilled reader would have understood that phrase to mean.

ii. 21. Lilly alleges that the use of the Actavis AIs will give rise to direct or indirect infringement of claim 1. It does not so allege in the case of claim 12 because of the limitation to a combined preparation. Before coming on to the questions of construction which arise, I will summarise the prosecution history of the 508 patent. This is necessary because the judge relied on it in support of his interpretation of the patent. I will discuss the relevance of the prosecution history to an exercise such as this at a later point in the judgment.

The prosecution history

i. 22. The 508 patent was applied for by an international application under the Patent Co-operation Treaty filed on 15 June 2001. The application contained claims directed to a method of treatment, claims in Swiss form and purpose-bound product claims.

ii. 23. Under cover of a letter dated 8 January 2003 Dr Ivan Burnside, Lilly's in-house European Patent Attorney, filed a revised set of claims which omitted the method of treatment claims. Claims 1 and 2 were as follows:

"1. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate.

2. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate and a FBP binding agent." Claim 10 was a dependent claim "wherein the antifolate is ALIMTA".

i. 24. These claims are of course the other way round from the claims ultimately granted (i.e. they start with the use of the methylmalonic lowering agent rather than pemetrexed

disodium), but that fact is of no significance here. The point to note is that these claims were entirely general as to the identity of the antifolate. On 9 March 2004 the EPO examiner issued an official communication which raised, amongst other things, objections under Article 83 EPC (disclosure) and Article 84 EPC (clarity). The clarity and lack of disclosure objections were that the claims related to too many possible combinations of compounds by using general expressions such as "antifolate", "methylmalonic acid lowering agent" and "FBP binding agent". Moreover the claims, by using those same terms covered all compounds having these characteristics or properties, whereas the application provided support and disclosure for only a very limited number of such compounds.

ii. 25. Dr Burnside replied to the official communication in a letter dated 23 December 2004, under cover of which he filed new claims 1 and 2, this time starting with the use of the antifolate, now limited to "pemetrexed" as follows:

> "1. Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.
>
> 2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid or a physiologically available salt or ester thereof."

i. 26. As the patent did not define what was meant by "pemetrexed" as a free-standing descriptor, it was perhaps inevitable that Dr Burnside was going to meet further official objection. Although the specification of the patent contains one mention of the term "pemetrexed" at [0004], it is followed by a Lilly reference number which, so we were told, shows it to be pemetrexed disodium. However, in support of the new claims, Dr Burnside said that, "*in order to expedite the application proceeding to grant*" Lilly had elected to amend the claims so as to reflect more closely the specific examples provided. The amendments were made without prejudice to Lilly's right to obtain protection for other patentable subject matter in one or more divisional applications.

ii. 27. Notwithstanding these amendments, on 17 May 2005 the EPO examiner issued a further official communication objecting to the admissibility of the new claims. He said that the amendments introduced subject matter beyond the content of the originally filed documents, contrary to Art. 123(2) EPC ("added matter"). Thus the inclusion in claim 1 of "use of pemetrexed..." and in claim 13 of "a product containing pemetrexed..." did not find basis in the application documents as filed. According to the EPO Examiner "pemetrexed" was a distinct compound from pemetrexed disodium in that it was accorded a different number in a Registry maintained by the Chemical Abstracts Service from that accorded to pemetrexed disodium. Although the prosecution history does not reveal this fact, examination of the Chemical Abstracts Service Registry reference for "pemetrexed" shows that it is the diacid. The specification of the patent does contain one mention of the term "pemetrexed" at [0004], but it is followed by a Lilly reference number which, so we were told, shows it to be pemetrexed disodium. It was therefore, at best, uncertain what the term "pemetrexed" on its own was intended to refer to.

iii. 28. Dr Burnside replied to the official communication in a letter dated 8 March 2006, under cover of which he again filed new claims. The new claims were limited to pemetrexed disodium. Dr Burnside said:

> "The Claims have been amended to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug. The Claims have also been amended to incorporate the list of vitamin B12 derivatives set out on page 7 lines 6-7 of the application as filed."

i. 29. The EPO examiner accepted the new claims, and the application proceeded to grant.

The skilled person or team

i. 30. A patent specification is to be taken to be addressed to those likely to have a practical interest in the subject matter of the invention, in other words to a person skilled in the art: see per Lord Diplock in *Catnic v Hill & Smith* [1982] RPC 242. It is well settled that the skilled addressee may be a notional team of people with different specialisations where more than one specialisation is involved in the invention: *General Tire v Firestone* [1972] RPC 457 at 485.

ii. 31. Lilly contends that the 508 patent is addressed to an oncologist, whereas Actavis contends that it is addressed to a team which, although it includes an oncologist, also includes a chemist. The judge preferred Actavis' argument on this point. Lilly's argument ran as follows:

iii. i) The judge should have addressed the identity of the skilled team by reference to the problem which the patent had solved, namely the reduction in side effects caused by the administration of pemetrexed whilst retaining efficacy. The role of a chemist was peripheral.

iv. ii) Claim 1 is only framed by reference to "manufacture" (i.e. in the Swiss form) because of the legal fiction required to circumvent the restriction on patenting of methods of treatment. The skilled reader would appreciate this and therefore take no account of the reference to manufacture.

v. iii)There are many peripheral roles which would be involved in implementing an invention such as the present: for example there might be questions as to the appropriate packaging for the finished product. Not every peripheral task involved in bringing an invention to market justified a representative on the skilled team.

vi. iv)The evidence showed that the oncologist was not concerned with the source of the pemetrexed anions, and the sodium ions present in the injectable solution of pemetrexed were not relevant to the efficacy of the invention.

vii. 32. Actavis, for its part pointed to claim 12, and submitted that it included within its scope a combined preparation of pemetrexed disodium and vitamin B12. Accordingly a

formulation chemist would be needed to carry out the invention of claim 12. If that was so then claim 1, being of broadly similar scope, was addressed to the same set of persons.

viii. 33. I have no doubt that the judge was right to find that the patent is addressed to a team which includes a chemist in addition to the oncologist. Firstly, the invention requires the use of the pemetrexed disodium, and the specification of the 508 patent expects the skilled person to be able to obtain it and make it into an injectable solution. It is no answer to say, as Lilly does, that the claim is only framed in relation to manufacture because of a legal fiction concerned with the restriction on patentability of second medical use inventions. However the claim is formulated, the skilled addressee needs to manufacture the medicament and the manufacturing step is an essential requirement of the claim, necessary to prevent the claim falling foul of the method of treatment exclusion from patentability. In the absence of evidence that pemetrexed disodium was generally available, manufacture of the medicament includes making the active ingredient. Secondly, as the judge found, the teams who deal with developing and making medicaments for use in treatment in the real world comprise specialists in a range of disciplines, and in this context would comprise both a medical oncologist and a chemist. Finally, there is a fundamental inconsistency as the judge pointed out, arising out of Lilly's case that the claim would be understood as extending to the use of active ingredients other than pemetrexed disodium. Assuming for a moment that Lilly is correct, the evidence showed that choice of an appropriate alternative salt would not be something that the medical oncologist could assist with.

ix. 34. I would prefer not to express any concluded view on whether any weight can be attached to Actavis' argument based on claim 12, which attracted the judge. If the only reason for engaging the discipline in question were the existence of a separate set of claims, or a subsidiary claim, I would be disinclined to hold that the same addressee was necessarily required for all claims. But as I am of the view that claim 1 requires a chemist in any event, I need not explore that question further.

Common general knowledge of the oncologist

i. 35. The judge found that the relevant common general knowledge of the oncologist in 2000/2001 included the following:

ii. i) Antifolates were a class of drugs which were used in cancer chemotherapy. Some drugs in this class, such as methotrexate, had been used for a considerable period of time, but others were under development. There was some understanding of the mechanism of action of antifolates. It was well known that the use of antifolates in chemotherapy caused toxic side effects which it would be desirable to avoid or reduce if possible.

iii. ii) The antifolate pemetrexed was the subject of clinical trials for use in chemotherapy. It operated by targeting multiple enzymes and was administered intravenously.

iv. iii)The only form of pemetrexed which had been shown to be effective and safe, to the extent that this had been shown, was pemetrexed disodium, which was manufactured by Lilly under the trade mark Alimta.

v. iv) Both vitamin B12 and folic acid had been well known for a considerable period of time, and their characteristics, structure and functions were well understood. It was well known that there were a number of different safe and effective forms of both vitamin B12 and folic acid available.

vi. 36. However the judge found that skilled oncologists did not think about drugs such as pemetrexed in their ionic form, nor did they consider issues regarding the choice of counter-ion or the effect, if any, of counter-ions on the efficacy, safety or other properties of the drug. Both parties' experts agreed that the choice of salt form was really the province of the chemist and that the oncologist would not be involved in this. Professor Ferry, Lilly's expert, agreed that the properties of salt forms and free acids were difficult to predict and that the chemist would need to address this problem by conducting experiments.

Common general knowledge of the chemist

i. 37. The judge also made detailed findings as to the common general knowledge of the chemist:

ii. i) Drugs frequently contain one or more acidic or basic groups. Where this is the case, it is generally possible to form different salts of the parent molecule by reacting it with a complementary base or acid. The salt will typically have different properties from the parent molecule. For example, a salt may be a solid at room temperature, whereas the parent molecule is a liquid; a salt may be soluble in water, whereas the parent molecule is not; and so on. Furthermore, different salts will typically have different properties from each other. For these reasons, salt screening is a routine, but important, part of the process of determining the most suitable form of a drug for formulation.

iii. ii) Formation of a salt involves the transfer of one or more protons (hydrogen ions) from the acid to the base, resulting in a negatively charged species (an anion) and a positively charged species (a cation). The ion which is not derived from the parent molecule is generally referred to as the "counter-ion". Where the parent molecule is an acid, it will form an anion when reacted with a base. The base will provide the counter-ion. Thus pemetrexed diacid reacts with sodium hydroxide to form pemetrexed disodium salt. In this case the counter-ion is sodium, which is a cation.

iv. iii) Solid salts consist of the anions and cations regularly arranged in a fixed lattice structure. In a salt consisting of a single cation and a single anion, there are equal numbers of alternating cations and anions in the lattice. Where there are different ratios of cations and anions, this gives rise to different lattice structures. The different lattice structures in turn give rise to different crystal structures. Although lattices contain infinite numbers of cations and anions, the fact that the cations and anions are present not only in fixed proportions, but also fixed relative positions, means that it is possible to speak meaningfully of the salt as being present in solid form.

v. iv) When a salt such as pemetrexed disodium is dissolved in a solvent such as water, the ions dissociate from each other and become surrounded by solvent

molecules. The result is free cations and anions in solution. It follows that the salt does not exist as such in the solution, but rather there is a solution containing the separate constituent cations and anions. Thus a solution of sodium chloride does not contain sodium chloride, it contains sodium cations and chloride anions. It is commonplace to refer to "a salt solution" or "a salt in solution", but this is a convenient shorthand which is not technically entirely accurate.

vi. v) The salt form can have a significant impact on the effectiveness of a drug in that it can modify the solubility, therapeutic use, pharmaceutical dosage forms, pharmacokinetic properties (e.g. absorption, distribution, metabolism and excretion of the parent molecule in the body) and the chemical and physical stability of the drug, and its suitability for industrial processing.

vii. vi) In particular, in relation to solubility, if a salt form has poor solubility and dissolution, this can result in poor bioavailability, as good solubility and/or dissolution are indicators of how likely it is that the drug will be absorbed in the gut. When considering a drug for intravenous chemotherapy, the solubility of the salt form is crucial.

viii. vii) By contrast, if a salt is too soluble, then it may not result in direct crystallization or precipitation of the desired salt, and therefore the salt cannot be made in solid form in the first place.

ix. viii) In general, there can be many dead-ends and false leads when attempting to prepare salts of a parent molecule for the first time.

x. ix) It was common ground between the experts that one could not predict in advance (a) whether one could make a particular salt form of a parent molecule, (b) what its properties would be once the salt form was made or (c) whether it would affect the efficacy of the drug.

xi. 38. *Sodium salts*. It was well known that sodium was the most preferred counter-ion. Thus sodium would be the chemist's first choice. It was known that sodium salts were generally not toxic. Sodium salts would generally be expected to be reasonably soluble, but they were not always easy to make.

xii. 39. *Potassium salts*. Potassium was known to be used in pharmaceutical compositions. Although it had a general tendency to be in the "more soluble" class of salt with sodium, there were exceptions to this tendency. It was known that there were some concerns about the potential toxicity of potassium salts in terms of cardiac side effects. This is something which would require particular consideration if large quantities of the drug (such as gram quantities) were to be administered.

xiii. 40. *Tromethamine salts*. Tromethamine salts were very much in the minority in 2000/2001 and there were only a small handful of examples of its use. It is still not particularly high on the list to be used as a counter-ion even now. It was known that tromethamine salts might well be too soluble, such that one would not be able to make and harvest the solid form.

xiv. 41. *Free acids*. In principle, an acidic parent molecule could be administered in the form of the free acid, and this is something that the chemist would consider. It was often the case, however, that there was a need or desire to change from the free acid to a salt form in order to improve kinetics, absorption or physicochemical properties. In particular, the free acid might not be adequately soluble, and a common way to try to address that was through salt formation.

The law on construction of claims

i. 42. The correct approach to the construction of a patent claim is that explained in the speech of Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel Limited* [2004] UKHL 46. The claims of a patent specification are not to be approached on the basis that the literal meaning of the claims is to prevail unless it is possible to detect some ambiguity in them. As Lord Hoffmann explained at [29] such an approach, if strictly applied, could result in the court construing the specification in a sense which a reasonable reader, aware of the context and background, would not have thought the author intended. The purpose of the specification (to identify and communicate a novel idea) and the identity of the audience (the addressee of the specification equipped with the common general knowledge in the art) are essential to determining the meaning which would be conveyed by the words chosen in the claims of the patent.

ii. 43. On the other hand, as Lord Hoffmann explained at [34], such a purposive construction does not justify going beyond the definition of the technical subject matter for which the patentee seeks protection in the claims:

> "Purposive construction" does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often."

i. 44. Lord Hoffmann also considered the approach which should be taken to the understandable concern, often expressed, that it should not be possible to avoid infringement by making an immaterial variant to that which is expressly claimed, when

the variant would have no material effect on the way the invention worked. In the United States, and in some European countries, the courts apply a doctrine of equivalence which extends the scope of protection outside the scope of the claims. Lord Hoffmann firmly rejected the adoption of such an approach into our patent law. On his analysis, such a doctrine was born out of the application of "unsparing logic" and literalism to the interpretation of claims, which were constraining courts to hold that the scope of protection was narrower than the person skilled in the art would reasonably have understood it to be. Although one answer to this problem was to apply a doctrine of equivalence, Lord Hoffmann preferred the abandonment of "literalism" and the adoption of a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming. That step had already been taken before the EPC came into effect in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, when the House of Lords had preferred a doctrine of purposive construction over one which allowed for infringement by "taking the pith and marrow of the invention". Lord Hoffmann said at [44]:

> "Since the *Catnic* case we have article 69 which, as it seems to me, firmly shuts the door on any doctrine which extends protection outside the claims. I cannot say that I am sorry because the *Festo* litigation suggests, with all respect to the courts of the United States, that American patent litigants pay dearly for results which are no more just or predictable than could be achieved by simply reading the claims."

i. 45. The fact that English courts do not apply a general doctrine of equivalence to the construction of patent claims does not mean that the existence of equivalents which have no material effect on the way the invention works has no bearing on the proper, purposive interpretation of a patent claim. To the contrary, it has long been the law that such equivalents form part of the background of facts known to the skilled reader which would affect what he understands the claim to mean (see *Kirin-Amgen* at [49]). It is in this way that English law complies not only with the Protocol to Article 69 of the EPC in its original form, but also with the new article 2 added to the Protocol by the EPC 2000:

> "For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

i. 46. English law recognises the impact of equivalents in what became known as the *Improver* and subsequently the *Protocol* questions, after their exposition by Hoffmann J (as he then was) in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181. In that case he said, at page 189:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim ("a variant") was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
>
> (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader

skilled in the art? If no, the variant is outside the claim. If yes?

(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

i. 47. As Lord Hoffmann stressed in *Kirin*-Amgen at [52], the *Protocol* questions are not legal rules, but guides more useful in some cases than in others which in appropriate cases help to decide what the skilled person would have understood the patentee to mean. On the other hand, the basic principles of purposive construction, what Lord Hoffmann called "the bedrock of patent construction", are applicable in every case. There was a tendency before the decision of the House of Lords in *Kirin-Amgen* for the *Protocol* questions to be deployed in every case, regardless of whether a sensible answer could be arrived at without reference to them: so that the tail had, in a sense, started to wag the dog.

ii. 48. In cases where it is useful to ask it, the second *Protocol* question involves asking whether it would be obvious to the skilled reader that the variant has no material effect on "*the way the invention works*". At [75] in *Kirin Amgen* Lord Hoffmann suggested that in future it might be better to ask, as the German courts apparently do, whether it "*solves the problem underlying the invention by means which have the same technical effect"*. The advantage of posing the question in that way is that it avoids any assumption that the variant works at all. In both cases, however, it is axiomatic that one is concerned with what would be obvious, in the sense of immediately apparent, to the skilled reader from a reading of the specification informed by common general knowledge.

iii. 49. Thus, for the purposes of the assessment involved in the second *Improver* question, I would take it as clear that the notional addressee is not presented with information which he cannot derive from the patent or his common general knowledge about whether the variant will in fact have no material effect on the way the invention works. Quite apart from the inference to be drawn from Lord Hoffmann's observation which I have referred to in the previous paragraph, the *Improver* questions are no more than an aid to construction in suitable cases. In arriving at the skilled person's understanding of the language of the claim, it cannot possibly be right to provide him with information which he could not derive either from the specification or his common general knowledge.

iv. 50. Mr Carr submitted that there may be situations, of which the present case is an example, where the missing information is so easy for the skilled person to obtain that it should be taken to have been reasonably available to him when he reads the patent. It may be that the law allows for some flexibility in this respect by analogy with the material which, in the context of construing contracts, is taken to be reasonably available to the parties. However it is not clear to me that this is how the case was advanced

before the judge, and as it is a matter on which some evidence might have been of assistance, I do not think it right to explore that way of putting the case any further on this appeal.

v. 51. Mr Carr also reminded us of two cases, one before and one after the EPC and its transposition into domestic law by the Patents Act 1977. These, he said, illustrated the generous approach to construction which the courts had been inclined to adopt when what the defendant was doing or proposing to do was making use of the underlying invention, albeit that, in the defendant's hands, the invention was "temporarily masked". The first of these cases was *Beecham Group Limited v Bristol Laboratories Limited and others* [1978] RPC 153. In that case the defendant imported the acetone derivative of the patented drug, the well known antibiotic ampicillin. The acetone derivative reverted, in the presence of water, to ampicillin itself, which was exclusively responsible for the clinical effectiveness of the defendant's product. The House of Lords, applying what was then called the "doctrine of infringement by taking the pith and marrow of the invention" held that the defendant's drug was an infringement. Although it was literally true that the defendant's drug did not conform to the formula in the claim at the time of importation, that fact ceased to be true as soon as the drug was put to the only use for which it was intended.

vi. 52. The second case was *Pharmacia Corp v Merck & Co. Inc.* [2001] EWCA Civ 1610; [2002] RPC 41. The patent in suit claimed a chemical species, I will call it X, which was an "enol". In the presence of water X existed in equilibrium with the keto form of X, the keto form being by far the major form. The allegedly infringing product was the solid keto form. Direct and indirect infringement were both alleged. Even though the words used in the claim had a precise chemical meaning, i.e. the enol form, the Court of Appeal held that there was direct infringement. The court did not therefore need to (and did not) express a view on indirect infringement. Aldous LJ held (at [46] – [47]) that, in order to arrive at a scope of claim which gave fair protection to the patentee it was necessary to take account of what occurred to the substance in the body. There the enol would be in an inseparable equilibrium with the keto form, and it was the composite which would have the therapeutic effect. This would not prevent a reasonable degree of certainty for third parties, as third parties "*would therefore not be surprised if manufacture and sale of the other tautomers which would form the enol in solution, would infringe*". Arden LJ held that there was infringement because (paragraph [175]) the skilled person would know that the keto form exists in equilibrium with the enol form in solution and that "*it cannot be divided up from the enol in that form*". The words of the claim were capable of being read as the enol form and the keto form into which the enol form is "*constantly and ineluctably interconverting when in solution.*"

vii. 53. It is true that both of these cases are examples of situations in which the courts eschewed literalism in favour of a purposive construction of chemical claims. It is, however, dangerous to draw factual analogies between those cases and the present case. The skilled reader of the patent in the present case would not, in the normal run of things, expect any of the Actavis AIs to convert into pemetrexed disodium when dissolved in aqueous solution, or *vice versa*. In so saying I put to one side the special factors which are relied upon in support of the allegation of indirect infringement. I therefore do not think that Mr Carr can derive any assistance on his direct infringement case from these two authorities.

Prosecution history as a guide to construction

i. 54. It was common ground between the parties that the prosecution history was not inadmissible as a guide to construction.

ii. 55. That common approach was said to be consistent with what Lord Hoffmann had said on the topic in *Kirin-Amgen* at [35]:

> "The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide."

i. 56. In *Rohm & Haas v Collag* [2002] FSR 28 at [42] Walker LJ (as he then was) held, *obiter*, that it was permissible to refer to "objective information about and commentary on experiments which were conducted in response to official observations" in resolving an issue of construction. I note, however, that the material in question was referred to in a note in the specification itself, which means that it is matter which was expressly drawn to the attention of the reader. Beyond that, and beyond the useful summary of the problems associated with taking it into account in the judgment of Jacob J in *Bristol-Myers Squibb Co v Baker Norton Inc.* [1999] RPC 253 at 274-275, there is no direct English authority on the point. I have to say that a rule which merely discourages reference to material, as opposed to treating it as inadmissible, has obvious practical disadvantages, as in the absence of an exclusionary rule the cost and expense associated with its deployment will almost invariably be incurred. However, as we are not asked to decide that the material is altogether inadmissible, I will, somewhat reluctantly, leave it at that.

ii. 57. The essence of the judge's reasoning as to the relevance of the file history was given at [111] of his judgment:

> "… I accept that, for the reasons explained by Jacob J in *Bristol-Myers Squibb* and Lord Hoffmann in *Kirin-Amgen*, courts should be cautious before relying upon prosecution history as an aid to construction. In the real world, however, anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection) and will consider it to see if it sheds light on the matter. In some cases, perhaps not very many, the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in some broader manner. In such a situation, there is no good reason why the court should shut its eyes to the story told by the prosecution file. On the contrary, consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement. For the reasons discussed below, I consider that the present case provides a good illustration of this."

i. 58. The difficulty I feel with endorsing this reasoning is as follows. Firstly it assumes that the skilled reader will always read the prosecution history. I do not see why this

should be so, given the limited value which, at least before the judgment in this case, it was generally recognised to have. Secondly, and more importantly, it suggests that the story told by the prosecution history of how the claims came to be drafted as they were will assist the court in preventing abuse of the system. To my mind this will be a very rare case indeed. Unless the acceptance of a restriction in a claim is to operate as some kind of estoppel against the patentee arguing for wider claims (a proposition for which neither side contended and which Jacob J rejected, at least on the basis of domestic estoppel, in *Bristol Myers)*, there will always remain an issue as to whether the applicant *needed* to accept the restriction notwithstanding that he did so. In those circumstances, the light which the prosecution history sheds on the ultimate question of construction is likely to be extremely limited.

ii. 59. I therefore do not regard it as useful to go to the prosecution history in order to discover that the patentee accepted a restriction to his claim against an objection of lack of support in the specification. It is always open to a party attacking the patent to argue that the claims as sought to be construed by the patentee lack support in the specification: see for example *American Home Products v Novartis* [2001] RPC 8 at [31]. What purpose does it serve to illustrate this point by showing that the patentee was faced with an official objection to that effect and amended his claims in the light of it? It is still open to the patentee to say that he need not have done so, and the apparent concession he made in prosecution was wrongly made. If it is not open to the patentee so to contend, then the prosecution history is indeed creating a form of estoppel.

iii. 60. In any event, patent offices are usually concerned with patentability, not scope of protection. If an applicant were to conclude every letter by saying that he did not accept that by accepting this or that limitation he was necessarily restricting the scope of protection, no inference could be drawn from his conduct in accepting it. I would be reluctant to put the patent attorneys' profession to this unnecessary trouble.

Construction of the UK designation of the 508 patent

i. 61. There are two issues of construction which I must address. The first, which relates to direct infringement, is whether the claim is limited to use of pemetrexed disodium as Actavis contends, or whether it extends to cover the use of the Actavis AIs as Lilly contends. The second is whether the claim is limited to the use of pemetrexed disodium in solid form, as Actavis contends, or whether it extends to a solution which contains pemetrexed ions and sodium ions, as Lilly contends. This second issue is of relevance to the argument about contributory infringement.

Pemetrexed disodium

i. 62. I can take this point relatively shortly, as I agree with the judge. The parties have approached the trial and this appeal on the basis that it is a case where the answer is provided by asking the three *Protocol* questions.

ii. 63. It is common ground that the variants represented by the various Actavis AIs have no material effect on the way the invention works. The judge explained that this was for two reasons. Firstly, from the oncologist's perspective, the active anti-cancer principle in an aqueous solution of pemetrexed disodium for intravenous administration is the pemetrexed anion. From the oncologist's perspective the source of that anion is

immaterial, since it will not affect the efficacy or safety of the medicine for the treatment of cancer. Secondly, from the chemist's perspective, it did not lie in Actavis' mouth to contend that the Actavis AIs were not all bioequivalent to Alimta, as this was the basis on which they would be granted marketing approval. Thus the first *protocol* question must be answered favourably to Lilly.

iii. 64. In order to succeed on the appeal Lilly must additionally persuade me that, it is right on the second and third *Protocol* questions. Thus I must first consider whether the judge was wrong to hold that it would not be obvious to the skilled team that the variants represented by the Actavis AIs would have no material effect on the way the invention worked.

iv. 65. The judge had the benefit of expert technical evidence on this subject. He concluded that the crucial member of the team for this purpose would be the chemist, as the oncologist would have no idea as to the effect of the substitutions in question. The view of the chemist would be that he would not be able to predict the effect of the substitution without testing at least the solubility of the AI in question. Although the chemist would be reasonably confident that he would come up with a substitute for the sodium counter-ion, predicting in advance whether any particular counter-ion would work was not possible. In those circumstances, given that getting an effective amount of pemetrexed anion into solution was essential, it could not be said that the variant had no material effect on the way the invention worked. The same answer was arrived at if one asked whether the variant solved the problem underlying the invention by means which had the same technical effect.

v. 66. Mr Carr attacks the judge's conclusion with three main arguments. The first argument was that the skilled team did not include a chemist, and that the only response of relevance was that of the oncologist. This argument turns on the composition of the skilled team. I have already concluded that the judge was right to say that the skilled team included a chemist.

vi. 67. Mr Carr's second argument is that when asking the second *Protocol* question about the Actavis AIs it is permissible to assume that the skilled chemist knows that the AIs are soluble. In support of this first argument he further submits that Actavis have committed large sums of money already to its project (including large sums in litigation costs) on the basis of its assumption that its AIs will be satisfactory substitutes for pemetrexed disodium.

vii. 68. I cannot accept this argument. The skilled reader of the patent simply does not know, and cannot predict whether variants such as the Actavis AIs will be sufficiently soluble to work. It is not a legitimate exercise to feed information about the Actavis AIs to the skilled team to help them to deal with their technical concerns about the workability of variants. The answer to such concerns must, as I have explained above, be found in the specification or from the team's common general knowledge.

viii. 69. Mr Carr's third argument is that the judge focused on the wrong problem when considering whether it was obvious that the variant had a material effect on the way the invention worked. The problem underlying the invention was not a manufacturing one, but a therapeutic one. The oncologist would know that the source of pemetrexed anions would have no effect at all in this context.

ix. 70. The judge recognised the force of this argument but, at [128], rejected it in the following terms:

> "This is a powerful argument. In the end, however, and not without considerable hesitation, I do not feel able to accept it. My reasons are similar to those I have given in relation to the question of the identity of the addressee. Although it is true to say that the underlying invention is an improved method of treatment, that invention was not and is not patentable as such. The only patentable invention is the use of the drug for the manufacture of a medicament for use in the combination therapy (claim 1) or a product containing the drug in combination with the other ingredient(s) for use in therapy (claim 12), depending on whether one is looking at it from the perspective of EPC 1973 or EPC 2000. Either way, the patentable invention involves the making of the medicament or the product. If the proposed source of pemetrexed anions is not sufficiently soluble or is not pharmaceutically acceptable for some other reason, then as a practical matter the skilled team cannot make that medicament or product and therefore cannot obtain the benefit of the patented invention. To that extent, therefore, it would not be obvious to the skilled team that pemetrexed diacid would have no material effect on the way the invention works. The same goes for pemetrexed dipotassium and ditromethamine."

i. 71. I agree with the judge's reasoning. Once the claim includes the step of manufacturing a medicament for treating a disease, it necessarily includes a requirement that the manufactured medicament is to some extent effective for treating the disease. If the skilled chemist is unable to predict that a variant will be sufficiently soluble to deliver an effective amount of pemetrexed anions in solution, then he is unable to say that the variant would have no material effect on the way the invention works.

ii. 72. I also think that the judge was right to hold, in answering the third *Protocol* question, that the skilled team would understand that the patent was clearly limited to the disodium salt, and did not extend to the diacid, or the dipotassium or ditromethamine salts. I would give the following reasons, many of which were relied on by the judge:

iii. i) As I have pointed out when summarising the disclosure of the patent, the specification contains certain passages where the invention is described in very general "class" terms and others where the invention is clearly limited to pemetrexed disodium. When the reader comes to the claims, therefore, he or she will appreciate readily that the patentee has chosen to claim narrowly and by reference to a single chemical, and not broadly by reference to any class.

iv. ii) Pemetrexed disodium is a highly specific chemical compound. Putting aside for present purposes the precise form in which the compound is present, there is no obvious leeway as a matter of language for giving it a broad as opposed to a narrow construction.

v. iii)The only escape from the above would be to say that pemetrexed disodium would be understood by the skilled person to be used in a figurative sense, so as to denote the best known member of a class. It is true that sodium is a well

known and perhaps the best known counter ion for use in circumstances such as these. But if the claim is not limited to the sodium salt, there are great difficulties in ascertaining what that class might be. Anti-folates were a known class, but the claim cannot be to all anti-folates, because that term is used in the specification, but not chosen in the claims. As to pemetrexed, the disodium salt was the only salt known to be efficacious and safe.

vi. iv) The only data contained in the specification are for pemetrexed disodium, and broader claims therefore lack support and might have been unacceptable to the EPO.

vii. v) Importantly, there is a striking contrast between this very specific language and the general terms used in the claim for the methyl malonic acid lowering agent (any "pharmaceutical derivative") and the folic acid components (any "physiologically available salt or ester thereof") which the skilled reader could not fail to notice.

viii. vi) The skilled reader would have understood that there are plausible reasons why the patentee might have wished to limit to the disodium salt: for example he might have been content with a claim limited to his commercial embodiment ALIMTA.

ix. 73. For the reasons I have given I would not have found it necessary to go to the prosecution history to arrive at this conclusion when one can get there, straightforwardly, by reading the claims in the light of the specification.

Is the claim limited to the solid form?

i. 74. It will be recalled that the judge held, when dealing with the common general knowledge, that it is not strictly technically accurate to say that a salt can exist in solution. Once a salt is dissolved, it dissociates into its constituent ions and any organised lattice structure which exists in the solid form disappears as the ions are dispersed in the solvent medium. The judge nevertheless recognised that it was commonplace to refer, for example, to a solution containing sodium ions and chloride ions as being sodium chloride in solution.

ii. 75. Subject to an irrelevant dispute about whether pemetrexed disodium is ever in a lattice structure in the solid form (as opposed to being amorphous) Mr Carr accepts, indeed embraces, these propositions. He goes on to submit that there are places in the specification of the 508 patent where it uses the term "pemetrexed disodium" not in its strict, technically accurate sense, but in the looser sense to which the judge refers. In particular the term is also used to refer to a solution in which there are sodium ions and pemetrexed ions in at least the same proportions as in pemetrexed disodium. This is made plain, amongst other places, at [35] in the specification, where the patentee refers to treating patients with an intraperitoneal injection of pemetrexed disodium. This can only refer to an injection of a solution containing pemetrexed ions and sodium ions in dissociated form, as the solid disodium salt will necessarily have dissociated. This is something which the skilled team would immediately have recognised.

iii. 76. Thus far I think Mr Carr is obviously right. His construction is supported by a consideration of what the term "medicament" in the claims of the patent would be understood to include. Although one form of the medicament covered by the claims of the 508 patent would be a solid dosage form, it is obvious that another form is an injectable solution, arrived at by dissolving pemetrexed disodium in water. The skilled person reading claim 1 of the patent would consider that pemetrexed disodium was present in the medicament, even though, as a matter of strict (one might even say literal) chemical nomenclature that is not a technically correct way of putting it. To put it another way, if one asks what, for the patentee's purposes, constitutes the presence of pemetrexed disodium, the skilled reader would understand that it included a solution containing pemetrexed ions and sodium ions.

iv. 77. I recognise of course that the solution of pemetrexed ions and sodium ions that the skilled person would have in mind as one version of pemetrexed disodium covered by the claim could be said to arise in particular and limited circumstances. Thus, firstly, the solution contemplated by the examples of the specification will presumably (although this is not spelled out) have been made by taking solid pemetrexed disodium and dissolving it. One question is therefore whether an identical solution containing pemetrexed and sodium ions, but arrived at in a different way, would also be thought by the skilled reader to fall within the ambit of the language. I consider that it would be. I can see no reason why the skilled reader who understands from the specification that a solution containing pemetrexed ions and sodium ions is regarded as pemetrexed disodium should assume that the method by which that solution is prepared was of concern to the patentee. That is a matter of history, and has no bearing on the essential characteristics of what is called for by the term.

v. 78. A second question is whether the skilled person would understand that the ratio of sodium ions to pemetrexed ions in the solid state (i.e. 2:1) should be maintained in the solution. I am fully prepared to accept that the ratio must reach the threshold of 2:1: anything less would not meet the description "disodium". However I cannot see why the presence of more sodium ions, i.e. in excess of the 2:1 ratio should be regarded as material. Pemetrexed disodium in the sense called for by the claim would still be present, despite the presence of more sodium ions.

vi. 79. A final question is whether the presence of ions other than sodium could take the solution out of the claim. Again, I do not see why this should be so. A patent claim is normally to be construed as setting a set of requirements which must be present in the alleged infringement. Infringement is not generally avoided if the alleged infringement has all those features and adds something more. As Bowen LJ colourfully put it in *Wenham Gas Co Ltd v Champion Gas Lamp Co* (1892) 9 RPC 49 at 56 "the super adding of ingenuity to robbery does not make the operation justifiable".

Direct infringement in English law

i. 80. It follows from what I have said about the proper construction of the claim that it does not extend to pemetrexed diacid or any other pemetrexed salts other than disodium. On this basis there can be no direct infringement by Actavis by dealing in the Actavis AIs.

Indirect infringement in English law

i. 81. Section 60(2) of the Patents Act 1977 provides, so far as relevant, as follows:

> "(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom."

i. 82. The section therefore has potential application where the invention is not put into effect by the defendant himself, but, for example, by someone who is supplied with means relating to an essential element of the invention ("essential means"). Lilly's case is that by supplying the Actavis AIs, Actavis are supplying an essential means for the doctor or pharmacist who makes up the solution to put the invention into effect.

ii. 83. If all that the doctor or pharmacist were doing was making an aqueous solution of one of the Actavis AIs, Actavis' case of indirect infringement would add nothing to its case of direct infringement. A solution made by dissolving pemetrexed dipotassium in plain water results in a solution which contains only potassium ions and pemetrexed ions, and is therefore not within the claims because sodium ions are missing. However in the present case the facts may give rise to indirect infringement because, in the ordinary course, each of Actavis' AIs will be dissolved and/or diluted in saline, which is of course a source of abundant sodium ions.

iii. 84. The judge summarised the relevant facts in the following way at [194] to [198] of his judgment, starting with the instructions for reconstituting Lilly's product Alimta (for reasons which appear):

> "Section 6.6 of the Summary of Product Characteristics for Alimta states as follows:
>
> > "3. Reconstitute 500mg vials with 20 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed. Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely affecting product quality. The pH of the reconstituted solution is between 6.6 and 7.8. Further dilution is required.
> >
> > 4. The appropriate volume of reconstituted pemetrexed solution must be further diluted to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes."
>
> The effect of this reconstitution and dilution is that there will be present in a solution of Alimta used for the infusion both pemetrexed ions and sodium ions which emanate both from the

> pemetrexed disodium and from the saline solution. Thus there will be an excess of sodium ions. The solution will also contain chloride ions from the saline.
>
> Actavis admit that their product will be reconstituted and diluted in the same way, save that in the case of the diacid it will simply be diluted. The result will be a solution containing pemetrexed ions, sodium ions and chloride ions. Again, there will be an excess of sodium ions present, albeit that they are all derived from the saline. If the product is pemetrexed dipotassium, there will also be potassium ions present. If it is pemetrexed ditromethamine, ditromethamine ions will be present.
>
> Actavis also admit that it would be obvious to the skilled team that this will occur.
>
> Finally, Actavis also admit that the product will be administered in combination with vitamin B12 and folic acid, and that they know this."

i. 85. On the basis of these facts Lilly submits that Actavis would be indirectly infringing the patent. First, Lilly claims that each of the AIs is an essential means. Then, to take the example of pemetrexed dipotassium, they contend that when the solid is reconstituted in saline there will be present pemetrexed ions and sodium ions just as there are pemetrexed ions and sodium ions present when pemetrexed disodium is reconstituted. The fact that there will be potassium ions and chloride ions in addition is of no relevance, as is the fact that the sodium and pemetrexed ions have a different history. In the course of the procedure outlined in the statement of product characteristics pemetrexed disodium (in the loose, non-technical sense that that expression is used in the 508 patent) is formed. Moreover it will be used in the final stages of manufacture of the medicament.

ii. 86. The judge dealt with this issue in the following way:

> "200. … Actavis point out that the issue only arises if the expression "pemetrexed disodium" in claim 1 of the Patent means pemetrexed disodium and not any form of pemetrexed that is pharmaceutically acceptable and sufficiently soluble. Accordingly, Actavis contend that they cannot be liable for indirect infringement because at no point is pemetrexed disodium used in the manufacture of a medicament by anyone. The fact that, when Actavis supply their product to third parties who reconstitute (or in the case of diacid, dilute) the Products with saline, there will be sodium ions and pemetrexed ions floating around, does not mean that those third parties are implementing the invention; they have not used pemetrexed disodium in the manufacture of a medicament as required under claim 1. It is no answer to this to say that pemetrexed ions on their own constitute an essential element of the invention, as this is just another way of saying that the claim does not require pemetrexed disodium, but merely requires any form of pemetrexed which makes pemetrexed ions available.
>
> 201. I agree with Actavis' analysis. Accordingly, I conclude that

> there will be no indirect infringement by Actavis of the UK designation of the Patent."

i. 87. I cannot agree with the argument advanced by Actavis which the judge accepted. The construction of pemetrexed disodium which that argument advances appears to assume that it is a solid. I say this because it proceeds from the finding that pemetrexed disodium "means pemetrexed disodium and not any form of pemetrexed that is pharmaceutically acceptable and sufficiently soluble". It is thus relatively easy for the judge to accept the submission that "at no point is pemetrexed disodium used in the manufacture of a medicament by anyone". It is undoubtedly the case that solid pemetrexed disodium is not used. However, as I have explained, the skilled team, particularly the chemist, would understand from the 508 patent that pemetrexed disodium is also used to refer to solutions which contain pemetrexed ions and sodium ions in solution.

ii. 88. The judge plainly regarded the fact that no solid pemetrexed disodium was used as conclusive of the indirect infringement argument. The judge then accepted Actavis' characterisation of Lilly's case as being that pemetrexed ions on their own constituted an essential element of the invention, and dismissed this on the basis that it was just another way of saying that the claim does not require pemetrexed disodium, but merely requires any form of pemetrexed which makes pemetrexed ions available. I do not think that this analysis does justice to Lilly's argument. Lilly's argument does not involve saying that the claim does not require pemetrexed disodium. It asserts that it does require it, and that pemetrexed disodium is used in the process of making up the medicament.

iii. 89. It is possible, although I doubt, that the judge thought that pemetrexed dipotassium and the other Actavis AIs could not be a "means relating to an essential element of the invention" because they did not themselves represent a free standing feature or element of the claim. If this was the judge's reasoning I cannot accept it. The language of section 60(2) does not require the supply of an element of the claim, but a means *relating* to an essential element. A means for releasing pemetrexed ions into solution relates to an essential element of the invention where the invention calls for pemetrexed ions and sodium ions in solution, particularly as it is the presence of the pemetrexed ions in the manufactured medicament which is essential for its efficacy as a medicament. The invention is then put into effect when the pharmacist makes up the solution using pemetrexed dipotassium (or the other Actavis AIs), because there comes a stage in the course of that activity when pemetrexed disodium is present and is used.

iv. 90. In *Grimme Maschinenfabrik v Scott* [2010] EWCA Civ 1110 this court recognised that the essential means of section 60(2) did not have to be something which could be used without alteration by the buyer. In that case the defendant was selling whole machines with steel rollers which the buyer could adapt by incorporation of rubber rollers. The argument that this could not be an essential means was rejected. As Jacob LJ put it at [103]:

> "…we can see no rational basis for the "whole machine" point. Why should a device to which a part can be readily added to make it fall within the claim be a "means essential", but a device from which a part can readily be removed or replaced to make it fall within the claim not be such a means?"

i. 91. Applying this reasoning, pemetrexed dipotassium is a means relating to an essential

element of the invention, notwithstanding that potassium is dissociated and sodium caused to be present in order to put the invention into effect.

ii. 92. I would therefore disagree with the judge on the issue of contributory infringement. I would refuse Actavis their DNIs as a matter of English law on these grounds.

Infringement under the laws of France, Italy and Spain

i. 93. It was common ground both before the judge and before us that there was no detectable difference in the laws of France, Italy and Spain on the approach to contributory infringement. It follows that the declarations should also be refused in respect of those countries.

ii. 94. It is thus unnecessary for me to decide whether the courts of France, Italy and Spain would arrive at the same result as me on the issue of direct infringement, applying their respective laws. I would nevertheless record my conclusion, having heard Lilly's arguments, that the judge was right to hold that there would be no direct infringement applying the laws of those countries either.

The Düsseldorf judgments

i. 95. Actavis had originally included the German designation of the 508 patent within its action for DNIs. Despite the fact that the court first seised was England, Lilly brought proceedings against Actavis for threatened infringement of the German designation in the Landgericht Düsseldorf. However, in its judgment of 3 April 2014 delivered a few days before the start of the trial before Arnold J, the Landgericht Düsseldorf rejected Actavis' jurisdictional challenge and proceeded to give judgment on the merits in favour of Lilly. Actavis launched an appeal in Germany against the Landgericht Düsseldorf's judgment, but decided to discontinue the part of its claim in this jurisdiction which related to the German designation. At the trial, Lilly pressed Arnold J with the reasoning of the Düsseldorf court, but at paragraphs [150] to [158] of his judgment, the judge explained why he was not convinced by it.

ii. 96. In its written skeleton argument for this appeal Lilly renewed its reliance on the judgment of the Landgericht Düsseldorf. However, shortly before this appeal was heard, the appeal court, the Oberlandesgericht Düsseldorf, allowed Actavis' appeal.

iii. 97. On the issue of direct infringement, therefore, the Oberlandesgricht and I are in agreement. No purpose would be served by a comparison of the routes by which we have arrived at this result.

iv. 98. By comparison with its reasoning on direct infringement, the issue of indirect infringement is covered shortly in the judgment of the Oberlandesgericht. The issue is dealt with at pages 35 to 36 of the translation. The court holds, firstly, that the "essential means" must be configured in such a way that a direct use of the invention is possible. However that was not the case in the present circumstances. Although the court recognised that a solution formed from pemetrexed dipotassium results in dissociated ions of potassium and pemetrexed, and that normal saline will include sodium ions in addition, it concluded that pemetrexed disodium was at no time used by either Actavis or

its buyers for preparing a medicament. Arnold J's similar conclusion was mentioned by the court in this context.

v. 99. Whilst the decision of the Oberlandesgricht is entitled to great respect, including as it does distinguished patent judges, I am not persuaded by its reasoning to change the view which I have formed on the issue of contributory infringement. Firstly, if by its requirement that "the means must be configured in such a way that a direct use of the invention is possible" it is indicating that pemetrexed dipotassium cannot be an essential means, then that result is inconsistent with *Grimme* and it is not open to us to follow it. Secondly, it seems to me that the Oberlandesgericht has failed to give sufficient recognition to the fact that, applying the teaching of the patent, it is sufficient if one finds in the medicament in question sodium ions and pemetrexed ions in solution in a ratio of at least 2:1. Rather, as I read the judgment, the court appears to understand "pemetrexed disodium" as describing only that substance in solid form. I have explained why I do not agree with that construction.

The Rome II issue

i. 100. As I have concluded that the proposed use of the Actavis AIs would amount to contributory infringement of the 508 patent, Actavis are not entitled to the DNIs sought and it is not necessary for us to decide the Rome II issue. However, as we have heard full argument on what is potentially a point of some importance, I will deal with it.

ii. 101. A party who applies for a DNI of a UK national patent or a European patent (UK) may do so by following the statutory procedure prescribed in section 71 of the Patents Act 1977. That section requires it to be shown that the party seeking the DNI has applied in writing to the proprietor for a written acknowledgement to the effect of the declaration claimed, provided full particulars in writing of the act in question, and that the proprietor has refused or failed to give any such acknowledgement.

iii. 102. Section 71 is expressly without prejudice to the court's power to make a declaration apart from that section. As this court made clear in *Messier-Dowty Ltd v Sabena SA* [2000] 1 WLR 2040 at [41] the court has a general jurisdiction to make declarations of non-liability where such a declaration would serve a useful purpose. Actavis sought its DNIs under this more general jurisdiction, as the jurisdiction under the Patents Act does not appear to extend to foreign patents.

iv. 103. It is common ground that Actavis is entitled to bring its proceedings for a DNI in respect of the UK designation of the 508 patent under the court's general jurisdiction as it has a sufficient commercial interest in knowing whether the use of the Actavis AIs would infringe, and the declarations would therefore serve a useful purpose. The Rome II issue is whether Actavis, by satisfying the *lex fori* (i.e. English law) test for the availability of a declaration, can obtain DNIs in respect of the French, Italian and Spanish designations of the 508 patent as well. Actavis contend that they can, and that this is the result of a correct application of Rome II. Lilly contends that Actavis must satisfy the requirements of the foreign law in the designated states, *the lex causae*.

v. 104. The starting point is the Rome II regulation itself, so I set out the material provisions below. Recital (6) states:

"The proper functioning of the internal market creates a need, in order to improve the predictability of the outcome of litigation, certainty as to the law applicable and the free movement of judgments, for the conflict-of-law rules in the Member States to designate the same national law irrespective of the country of the court in which an action is brought."

i. 105. Article 1 provides:

"Scope

1. This Regulation shall apply, in situations involving a conflict of laws, to non-contractual obligations in civil and commercial matters. …

3. This Regulation shall not apply to evidence and procedure, without prejudice to Articles 21 and 22."

i. 106. Articles 21 and 22, which are referred to in Article 1(3), make specific provision for formal validity of unilateral acts intended to have legal effect, and burden of proof. Article 8 provides:

"Infringement of intellectual property rights

1. The law applicable to a non-contractual obligation arising from an infringement of an intellectual property right shall be the law of the country for which protection is claimed."

i. 107. Article 15 provides:

"Scope of the law applicable

The Law applicable to non-contractual obligations under this Regulation shall govern in particular:

(a) the basis and extent of liability, including the determination of persons who may be held liable for acts performed by them;

(b) the grounds for exemption from liability, any limitation of liability and any division of liability;

(c) the existence, the nature and the assessment of damage or the remedy claimed;

(d) within the limits of powers conferred on the court by its procedural law, the measures which a court may take to prevent or terminate injury or damage or to ensure the provision of compensation;

(e) the question whether a right to claim damages or a remedy may be transferred, including by inheritance;

(f) persons entitled to compensation for damage sustained personally;

(g) liability for the acts of another person;

(h) the manner in which an obligation may be extinguished and rules of prescription and limitation, including rules relating to the commencement, interruption and suspension of a period of prescription or limitation."

i. 108. Actavis contend that the rules for obtaining DNIs are matters of procedure within Article 1(3) and hence fall outside the scope of the Regulation. Lilly contends that those rules are not procedural. The rules are either within Article 15, or are closely analogous to the matters specified in Article 15. In either case the rules are those found in the law applicable to non-contractual obligations which, under Rome II, is the *lex causae*.

ii. 109. If Actavis are right that the matter falls outside the scope of the Rome II Regulation, the applicable law will be determined by the English common law rules of private international law. In that event it is common ground that the applicable law is the *lex fori*, because English law regards the rules for obtaining negative declaratory relief as being procedural: see *Messier-Dowty Ltd v Sabena SA* [2000] 1 WLR 2040.

iii. 110.It would appear from the materials before us that English law takes the most relaxed attitude amongst the relevant designated states of what must be shown before a party can apply to the court for a DNI. The laws of Spain, France and Italy lay down more specific requirements as follows.

iv. 111.In Spain, Article 127 of the Spanish Patents Act 1986 provides as follows:

"1. Any interested person may file an action against the owner of the patent so that the competent judge may declare that a particular act does not constitute infringement of the patent.

2. Before filing the action, the interested person shall, through notarial channels, demand that the patent owner make known his position on the opposability of the patent to the industrial exploitation carried out in Spain by the claimant or serious and effective preparations being made for that purpose. The person making the demand may file the action provided for in the preceding paragraph if the patent owner has not replied within one month of the date of the demand, or if he does not agree with the reply.

3. The action specified in paragraph 1 above may not be filed by any person against whom a claim for infringement of the said patent has been brought.

4. Where the claimant proves that the act referred to in the claim does not constitute infringement of the patent, the judge shall grant the declaration that was demanded.

5. The claim shall be notified to all persons owning rights in the patent who are duly entered in the Register, so that they may appear and take part in the proceedings. Nevertheless, holders of contractual licenses may not appear in the proceedings where

their license contracts so specify.

6. The action referred to in the present Article may be brought jointly with an action to declare the invalidity of the patent."

i. 112. In France, Article L 615-9 of the Intellectual Property Code provides as follows:

"Any person who proves exploiting industrially on the territory of a Member State of the European Economic Community, or serious and effective preparations to that effect, may invite the owner of a patent to take position on the opposability of his title against such industrial exploitation, the description of which shall be communicated to him.

i. 113. In Italy, Article 100 of the Code of Civil Procedure provides:

"In order to state a claim or to oppose the same, the claimant and the opponent must have a legitimate interest."

i. 114. It is common ground that this general provision of the Code of Civil Procedure applies to claims for DNIs of patents. It is also common ground that the test for a legitimate interest in relation to a claim for a DNI is that there is "an objective uncertainty giving rise to a present, concrete prejudice to the claimant which the judgment of the court is capable of curing". It is also common ground that there is no need for a cease-and-desist letter to have been sent.

ii. 115. The judge dealt with the Rome II issue at [204] to [236] of his judgment. He concluded, in accordance with Actavis' submissions, that the national rules which specify the conditions which must be satisfied by a claimant in order to obtain a DNI fell into two categories. Firstly there were those rules which provided for a fact sensitive requirement of interest or purpose, as did the requirement under the general jurisdiction in English law. Secondly there were rules which required pre-action notification together with details of the proposed acts of the claimant, as in section 71 of the Patents Act 1977. The first type of rule was concerned with ensuring that the claimant had sufficient practical justification for seeking the adjudication of the court, and thus with avoiding the time of the court being taken up with academic questions. The second type of rule had two purposes. The first was to allow the patentee to give an acknowledgment of non-infringement, and thus avoid unnecessary litigation. The second was to ensure that the dispute, if it is to go forward, is sufficiently well defined for the court to adjudicate on it.

iii. 116.

At [220] the judge said:

> "Thus I would characterise the relevant rules in the following manner. They are rules which are designed to ensure that the machinery of the court is only invoked to determine disputes which genuinely require adjudication by the court and to ensure that the dispute is sufficiently well defined for the court to adjudicate upon it. They are not rules concerned with the substantive rights and obligations of the parties with regard to infringement of the patent in suit. In particular, the rules are not rules about who has title to sue in the sense of having a substantive right to bring a claim (as for example, is the requirement under English law that the claimant in a patent infringement claim be either the proprietor of, or an exclusive licensee under, the patent). Thus the evidence shows that decisions made under these rules that claims for DNIs are inadmissible do not give rise to any res judicata with regard to the substantive rights and obligations of the parties. Furthermore, the court can adjudicate upon the substantive rights and obligations of the parties with regard to the infringement of the patent in suit without these rules being engaged at all, namely if the patentee brings a claim for infringement."

i. 117.The judge next focused on Article 15 of Rome II, and in particular on Lilly's argument that the DNI was a remedy within Article 15(c). He rejected Actavis' submission that "remedy" in that article was limited to damages, holding that it extended to all financial remedies. He also rejected Lilly's argument that "remedy" extended to anything which might be described as a remedy, thus including DNIs. In this connection he doubted whether a DNI was a remedy in the relevant sense at all. He concluded, in any event, that there was a distinction to be drawn between the availability in principle of a remedy and the steps which must be taken in order to obtain that remedy. It was only the former which was caught by Article 15 and made subject to the *lex causae*.

ii. 118.The judge thus concluded that the rules in issue here were matters of procedure and thus not subject to the *lex causae*.

iii. 119.Mr Mitcheson QC, who argued this part of the case on behalf of Lilly, submitted, firstly, that it was no longer appropriate to give weight to the convenience involved in applying the *lex fori* as opposed to the *lex causae*. Even if that were appropriate under English common law conflict rules, it had been all but swept away under Rome II. Rather the approach should be that the court should apply the *lex causae* unless it was inconvenient or inefficient to do so. The *lex causae* should apply except in limited matters concerned with the constitution of the courts and the method of trial which were deeply embedded in the procedural system of the domestic court, in the sense that they were integral and indispensable features of that country's legal system such that they cannot be replaced by corresponding features of the *lex causae*.

iv. 120.

Mr Mitcheson went on to submit that a number of paragraphs of Article 15 either covered or were closely analogous to the rules in issue here:

v. i) There was an "echo" of the DNI in paragraph (a), when it refers to "the basis and extent of liability, including the determination of persons who may be held liable for acts performed by them". By a DNI a party sought to be determined to be a person who could not be held liable for acts performed by it.

vi. ii) The rules in paragraph (c) are about "the existence .. of a remedy". A DNI was a remedy, but even if that is wrong and paragraph (c) is limited to monetary compensation, the rules were still concerned with the existence of a remedy for Lilly, because if a declaration is granted any monetary relief which would otherwise be available to Lilly is ruled out.

vii. iii)Paragraph (d) was also relevant because what Actavis were seeking to do was to insulate themselves against a remedy in damages, or alternatively to terminate the prejudice caused by the uncertainty of not knowing whether or not they infringed.

viii. iv)Finally, there was an analogy with limitation rules under paragraph (h).

ix. 121. Next, Mr Mitcheson submitted that a helpful test is "is the rule concerned with a decision on the merits?" All the matters here are "concerned with" a decision on the merits, as the foreign law questions were concerned with determining issues of scope of claim and infringement. If the court is applying foreign law to those issues, it is sensible and convenient to apply foreign law to the question of whether Actavis would have a cause of action at all for the DNI which it seeks. Actions for infringement by the patentee and actions for DNIs are, for the purposes of Article 21 of the Brussels Convention, recognised as actions between the same parties in respect of similar or identical subject matter. Viewed in that light the law which governed them should be the same. Mr Mitcheson's submission that an issue is governed by the *lex causae* if it is "concerned with the decision on the merits" is derived from an article by Dr Martin Illmer in Civil Justice Quarterly Volume 28 Issue 2 pages 237-260. Dr Illmer proposes a criterion of "neutrality" as the autonomous criterion for allocating rules to the *lex fori*. Applying this criterion, rules which are regarded by national law as procedural, but which are nonetheless so closely intertwined with the rules governing the material dispute that their non-application would frustrate the rights and remedies under the applicable law, may be governed by the *lex causae*. Dr Illmer recognises that it is not every rule which might affect the outcome of the case which is to be made subject to the *lex causae*, only those which are "directed at" the decision on the merits. Dr Illmer suggests that:

> "Applying the criterion of neutrality, the *only* matters of procedure to be governed by the *lex fori* … are those concerned with the commencement of the proceedings, the manner in which proceedings are conducted and the machinery of the administration of justice by the national courts. These aspects cover in particular the formalities of bringing a claim, summons, service, types of proceedings (such as summary proceedings or a procedure based on documentary evidence only), case management and the conduct of the proceedings, a stay of the proceedings, consolidation of claims, admissibility of

counterclaims, functions of judge and jury, costs and appeals."

i. 122. Viewed in this way, one would ask whether the rules concerning the availability of a DNI are directed at the decision on the merits, and so intertwined with the merits as to affect the outcome as to require the application of the *lex causae*, or whether they are concerned on the other hand with the commencement of proceedings and the formalities of bringing a claim, so as to fall under the *lex fori*.

ii. 123. Mr Mitcheson also relied on what the authors of *Dicey, Morris & Collins* The Conflict of Laws, 15th Edn ("*Dicey*") say at 34-036. They suggest that the Article 1(3) exclusion of evidence and procedure should be construed narrowly as covering only matters such as the constitution and powers of courts and the mode of trial, that are an integral and indispensable feature of the forum's legal framework for resolving disputes, such that they cannot satisfactorily be replaced by corresponding rules of the *lex causae*.

iii. 124. Further, Mr Mitcheson submitted that the judge had been wrong in his characterisation of the rules. The rules in issue on the appeal were about whether the party had done sufficient acts to raise the issue of infringement at all, and were at the heart of the substantive rights given by the patent. Without formally conceding that the rules of the second type identified by the judge (written acknowledgments, full particulars in writing etc) were procedural, he submitted that the rules of the first type, which required a fact sensitive inquiry into the state of the claimant's actual preparedness to exploit the invention, were not. Such rules went to the availability of the remedy and not to procedural steps necessary to obtain it. Thus Mr Mitcheson submitted that, even if the judge was right to distinguish between the availability of a remedy in principle and the steps necessary to obtain it, the rules in question fell into the former category.

iv. 125. Mr Raphael QC, who argued this part of the case for Actavis, drew our attention to the relevant parts of the legislative history of Rome II. The Commission's original proposal for Rome II did not include the exclusion now contained in Article 1(3) for evidence and procedure, which it regarded as implicit in the original draft of Article 15 (then Article 11). The commentary in the proposal for what was then Article 11 explains that the approach taken in Member States to the listed questions was not entirely uniform, and so the step was therefore taken, as was done in Rome I, of listing the questions to be settled by the law actually designated.

v. 126. The Commission's commentary on the various paragraphs of Article 11 (now 15) is informative. Thus Article 11(a) was said to be particularly concerned with "intrinsic factors of liability", i.e. nature of liability (strict or fault-based); the definition of fault; causation; persons potentially liable, and division of liability between joint perpetrators.

vi. 127. It is also worth noting that, in relation to what is now Article 15(c) (then 11(c)) the language of the proposal was simply "the existence and kinds of injury or damage for which compensation may be due". There was no use of the more general term "remedy" until later. The word "redress" was first used (and said to be a "technical, grammatical and terminological correction and distinction"), and then substituted by "remedy" without further explanation.

vii. 128. A report on the proceedings in the Parliament on the Commission Proposal

records the proposal for the inclusion of Article 1(3), as it now is, in the following terms:

> "This amendment takes account of the universal principle of '*lex fori*' within private international law that the law applicable to procedural questions, including questions of evidence, is not the law governing the substantive legal relationship ('*lex causae'*), but, rather, the procedural law of the forum."

i. 129. Mr Raphael submitted that the position had been correctly stated by Professor Halfmeier of the Frankfurt School of Finance & Management, Department of Law and Ethics in his contribution to *Calliess* Rome Regulations – Commentary on the European Rules on the Conflict of Laws (Kluwer 2011) when he said at page 391:

> "Traditionally the question of whether and under what conditions a purely declaratory action can be brought has also been treated as a procedural issue which is to be answered according to the *lex fori*. There is no indication that the Rome II Regulation intended to change this principle. The only argument against it could be drawn from Article 15(c) which subjects the 'remedy claimed' under the *lex causae* as determined under the Regulation. However, the legislative materials do not show this provision was drafted in respect of declaratory actions. Therefore the traditional rule pointing to the *lex fori* can be upheld. In particular, it does not interfere with the goal of harmony in results, since it only relates to the admissibility of the declaratory action and not to the substance of the declaration which certainly must be assessed according to the *lex causae*."

Discussion and disposition

i. 130. Article 1(3) of Rome II is a rule about what is sometimes called the "vertical scope" of the Regulation. Evidence and procedure are excluded from the scope of the Regulation. Although it does not automatically follow that these issues will be subject to the *lex fori*, the private international law principle that such matters are for the law of the forum is well recognised. It is enough to quote *Dicey* at paragraph 7.002:

> "The principle that procedure is governed by the *lex fori* is universally admitted."

i. 131. Article 15 of Rome II is not itself directly concerned with clarifying the distinction between substance on the one hand and evidence and procedure on the other. It simply contains a list of matters which are "in particular" to fall under the designated law. Included in the list are matters, such as limitation periods, which were traditionally the subject of some debate as to whether they were substance or procedure. Article 15 does not answer that question, but merely declares that they will be subject to the law which governs non-contractual obligations under Rome II. I therefore do not regard Article 15 as a safe guide to whether matters which do not fall within its scope are procedural or substantive.

ii. 132. The distinction between substance and procedure is a fundamental one. The principle underlying it is said to be that a litigant resorting to a domestic court cannot expect to occupy a different procedural position from that of a domestic litigant. Thus,

that litigant cannot expect to take advantage of some procedural rule of his own country to enjoy greater advantage than other litigants here. Equally he should not be deprived of some procedural advantage enjoyed by domestic litigants merely because such an advantage is not available to him at home. Thus, at common law, every remedy was regarded as procedure: see for example *Don v Lippmann* (1837) 2 Sh. & MacL. 682 at 724-5.

iii. 133. Whether a rule is to be classified as one of substance or one of procedure or evidence under Rome II is a matter of EU law: the fact that a rule is classified as one or the other under domestic law is of no relevance. There is therefore a need for an autonomous EU criterion for allocating rules into one or the other category.

iv. 134. In *Wall v Mutelle de Poitiers Assurances* [2014] EWCA Civ 138; [2014] 1 WLR 4263, the claimant motorcyclist was injured in a motor accident in France. He claimed damages against the other driver's insurers in England. Liability, which was governed by French law, was admitted. The question arose as to whether the claimant should be permitted to adduce expert evidence in accordance with English practice, or whether a single joint expert should be instructed, as would be the practice in France. This court held that the issue of which expert evidence the court should order was one of "evidence and procedure" within Article 1(3) and not an issue relating to "the existence, the nature and the assessment of damage" within Article 15(c) of Rome II. It was argued that the objective of the Regulation was to ensure uniformity of outcome, and that the English court should do its best to ensure that uniformity by adopting all the rules of the foreign court which might affect outcome. The court rejected that argument (see Longmore LJ at [11] to [14] and Jackson LJ at [40] to [43]), holding that it was inevitable that the same facts tried in different countries might achieve different outcomes. The words "evidence and procedure" were thus given what Jackson LJ called their "natural meaning".

v. 135. In my judgment, subject to any impact on the question which Rome II may have had, the rules with which we are concerned are conditions of admissibility of actions, rather than rules concerned with the substance or content of parties' rights. They are all concerned with whether the court should hear a dispute about substance. They are not concerned directly with the substance itself. Thus:

vi. i) a rule about the need to seek an acknowledgement from the patentee will avoid the dispute coming to court if the acknowledgment is given;

vii. ii) a rule requiring the giving of particulars will ensure that the proposed act is sufficiently formulated for the court to be able to adjudicate on whether it infringes;

viii. iii)a rule requiring some form of interest, or degree of preparation, will avoid cases coming to court if the party seeking the DNI has not reached a stage where it has sufficiently formulated its plans;

ix. iv)a rule requiring that the party seeking the DNI can show that it would serve a useful purpose avoids the court adjudicating on pointless disputes.

x. 136. Such rules would traditionally, for private international law purposes, be classified as procedural and not substantive. In my judgment, therefore, they should continue to be so treated unless Rome II requires a different outcome.

xi. 137. I do not think Mr Mitcheson's argument based on Dr Illmer's illuminating article displaces this view. As Dr Illmer himself recognises, "matters of procedure concerned with the commencement of the proceedings" will continue to be governed by the *lex fori*. I consider that the rules with which we are concerned fall within that description. They are not so intertwined with matters of substance as to require them to be dealt with under the *lex causae*. Whilst the passage from *Dicey* on which Mr Mitcheson relies suggests a very narrow interpretation of "evidence and procedure", the authors nevertheless say at 7-072:

> "It is clear that rules on the conduct of the parties prior to the instigation of proceedings, for example on providing notice before action, or on the need for a meeting between parties before starting proceedings, are procedural."

i. 138. Whilst rules which require an interest, or effective preparations, are different, I can see no reason in principle why they should not be categorised in the same way. As the judge observed, they have the same broad purpose as the more formalistic rules to which Dicey expressly refers, and are quite distinct from the rules which govern the parties' substantive rights.

ii. 139. I do not accept that Article 15 should be given a wider effect than its language suggests, treating the listed matters as no more than examples of a class of analogous matters regarded as procedural in private international law, but now to be brought within the designated law. Mr Raphael is right that the legislative history shows that the Regulation was intended to respect the private international law principle that the '*lex fori*' is applicable to procedural questions.

iii. 140. Although Article 15 applies the *lex causae* to a number of matters which at least the English common law would have treated as procedural, none of them, as it seems to me, is apt to encompass the rules for admissibility of a DNI. I take these in turn.

iv. 141. Paragraph (a) is concerned with the basic conditions and extent of liability under a non-contractual obligation, and the persons who may potentially be held liable. Whilst Mr Mitcheson's attempt to fit the negative declaration into the wording of the paragraph is ingenious, it does not seem to me that, even if correct, it gets him home. That is because the conditions of admissibility of a a positive claim are not caught by the section. If that is so, then I fail to see how the conditions of admissibility of a DNI can be caught either.

v. 142. The problem with reading paragraph (c) as widely as Mr Mitcheson contends is that it covers any remedy, when the legislative history shows it was concerned with financial remedies alone. Moreover, as the judge pointed out, other language versions of paragraph (c) use words which translate as "compensation", "indemnity" or "reparation". Reading it more broadly, the domestic court could find itself having to apply remedies of a nature unknown to its law. This would be in stark contrast to paragraph (d) which covers specific remedies aimed at preventing or terminating injury

or damage, but which are limited by the opening words "within the limits of the powers conferred on the court by its procedural law." To my mind, the negative declaration, whilst no doubt a remedy, is not a remedy which falls within (c).

vi. 143. The negative declaration is also not within (d), because it is not a measure which the court takes to prevent or terminate injury or damage, or provide compensation. Unlike an injunction to prevent infringement, it cannot be said that a characteristic of a DNI is that it prevents injury or damage. Moreover paragraph (d) is again concerned with the availability of such remedies, not the conditions which must be satisfied for their admissibility.

vii. 144. Finally, the mention of limitation periods in paragraph (h) is not a basis for suggesting that the conditions of applying for a DNI should be brought within the *lex causae*.

viii. 145. It follows that, had we needed to decide the point, I would have agreed with the judge that Rome II does not result in the conclusion that the *lex causae* applies to the conditions for applying for a DNI. Those conditions are procedural, and subject to the *lex fori.*

The Rome II factual issues

i. 146. It is therefore, as it was for the judge, unnecessary for us to decide the factual issues which arose in relation to the application of the *lex causae* conditions for admissibility of the DNIs. Nevertheless, I should record that I was not persuaded that the judge had made any error in his assessment of the evidence of foreign law or its application to the facts.

Overall conclusion

i. 147. For the reasons I have given relating to contributory infringement, I would allow Lilly's appeal and set aside the declarations of non-infringement of the 508 patent by the Actavis AIs.

Post-script

i. 148. After this judgment was circulated to the parties for suggested editorial corrections, and very shortly before it was due to be formally handed down, counsel for Actavis wrote to the court with a request that we amend or qualify the draft judgment before it was handed down. The letter said:

> "The draft judgment finds that there is no direct infringement under UK law but that there may be or is indirect infringement if (and, we would submit, only if) the Actavis AIs are intended to be diluted with saline sufficient to achieve a molar ratio of sodium to pemetrexed of 2:1 or greater… .
>
> Actavis accepts that, subject to a further appeal to the Supreme Court, this finding means that the form of declaration of non-

infringement sought in the claim form cannot be made without modification."

i. 149. The letter went on to say that the court "ought to" make a modified declaration which reflects the court's finding "so that it is clear that it would be lawful for Actavis to sell its AIs to the extent that they are not intended for reconstitution with any source of sodium ions", and in particular if they are for reconstitution with dextrose instead of saline. The letter also ventilated other possible scenarios, including one in which the AI was for reconstitution with saline in a ratio of less than 2:1.

ii. 150. Actavis went on to submit that, given the supposed need for alternative declarations, the court should consider revising its judgment so as formally to decide not only the Rome II issue but also the issue of whether there is direct infringement of any of the other foreign designations in issue (as opposed to expressing *obiter* opinions). This was on the ground that if the court were to make a declaration that there was no direct infringement in respect of the UK designation, it could also do so in respect of the foreign designations as well.

iii. 151. In the light of these suggestions for significant changes to the draft judgment it was no longer possible to hand the judgment down on the originally intended date of 28 May 2015. On 3 June 2015 Actavis filed voluminous "Post Appeal Submissions". In its draft order Actavis proposed a declaration for the UK in two parts. The first part declares that acts done in relation to the Actavis AIs would not be an infringement of the 508 patent under s. 60(1) of the Patents Act 1977. The second part of the declaration contains a positive declaration that supplying or offering to supply the Actavis AIs would be an infringement of the 508 Patent under section 60(2) of the Act "*if and only if Actavis knows, or it is obvious to a reasonable person in the circumstances, that such Actavis AI is suitable and intended for dilution or reconstitution in the United Kingdom so as to achieve a molar ratio of sodium to pemetrexed ions of 2:1 or more*".

iv. 152. Actavis also propose additional separate declarations for each of the foreign designations, referring in each case to the relevant national designation and the relevant national statutory provisions, again split into two parts, namely (a) a negative declaration for direct infringement and (b) a positive declaration for indirect infringement, "if and only if" Actavis have the relevant knowledge.

v. 153. In its Post Appeal Submissions, however, Actavis have slightly amended all the proposed declarations for indirect infringement by changing "if and only if" to "if".

vi. 154. Lilly opposes the making of these or any modified declarations. I will call this issue "the declaration issue".

vii. 155. Actavis also ask the court to remit for trial in the Patents Court an issue concerned with their proposed new product for reconstitution with dextrose. The issue is (a) under what circumstances and with what frequency, if any, persons administering Actavis AIs to patients would dilute or reconstitute them with saline if directed to do so with dextrose and not with saline, (b) to what extent the same would be known or foreseeable to Actavis, and (c) any appropriate relief as a result of its findings on (a) and (b).

viii. 156. Lilly opposes this order for remission. I will call this issue the "dextrose remission issue".

ix. 157. I would not make any of the alternative declarations proposed by Actavis. So far as the declaration on direct infringement is concerned I do not think this would serve any useful purpose. Actavis sought DNIs in order to clear the way as against Lilly's 508 patent for the launch of specific products. They sought declarations in order to have protection from an action for infringement brought by Lilly if they launched those products. The direct infringement declaration sought does not serve that purpose, but merely recites one of the court's conclusions. It provides Actavis with no protection for their products. In addition the proposed declaration presents the result of the litigation in a way which could be misleading to readers who have not read the judgment, and who are not alerted to the limited nature of the conclusion. That is undesirable.

x. 158. No doubt in order to meet the second of these reasons, and to provide a more balanced view of the outcome, Actavis proffer the indirect infringement declaration. In its original form (including the words "if and only if") this was plainly objectionable, as it could have been used to give the impression that, provided that Actavis did not have the particular state of knowledge identified, this court had decided positively that there was no indirect infringement either. Whilst the alternative wording meets that objection to some extent, I do not believe it is appropriate either. By continuing to make the declaration conditional on Actavis' state of mind, it fails to record what the court has actually decided, namely that the supply of Actavis' product for reconstitution in saline in their admitted state of knowledge will be an infringement of the patent.

xi. 159. That is sufficient to deal with the declaration issue. I would add that Actavis ought to have come forward with the wording of its proposed declaration at a much earlier stage. I accept that it is often not possible for a litigant to predict all the possible outcomes. In this case however the possibility that the court might find indirect but not direct infringement has been ventilated from an early stage: see for example the transcript of the hearing before Arnold J on 7 February 2014 at page 23. Indeed in the 15th witness statement of Mark Hilton dated 3 June 2015 he says that Actavis had been aware of the potential issue of indirect infringement for some time and had been looking at alternative ways to reconstitute or dilute its products "for some time". There would be no point in looking at these alternatives except in the context of a finding of no direct infringement. In his 16th witness statement Mr Hilton explains that "for some time" means since November 2013. There has been ample time to formulate satisfactory declarations for the eventuality in question.

xii. 160. I am more sympathetic to Actavis' position on the dextrose remission issue. At the hearing before Arnold J which I have just referred to, Actavis applied for an amendment to raise an issue concerned with reconstitution in dextrose. In the end Actavis did not press the amendment, making it clear that they wanted simply to avoid any finding in these proceedings that the Actavis AIs could only be reconstituted in saline. On the other hand counsel for Lilly, Mr Thorley QC, made it clear that Lilly reserved its right to contend in the future that to raise a claim at that stage for a declaration based on non-infringement with a dextrose product would be an abuse of process. We are not in a position to determine ourselves whether Lilly is right in its contention.

xiii. 161. The court has power under CPR 52.10(2)(b) to refer claims or issues for determination by the lower court. Given that the parties disagree over whether acts done

in relation to a product recommended for reconstitution in dextrose infringe the 508 patent, there are obvious procedural advantages in that issue being decided in the presently constituted proceedings, if it can be, with the minimum of additional formality and expense. At the same time the fact that this court has taken the step of remitting this issue should be entirely without prejudice to Lilly's right to contend that to raise the issue at this stage, either within this action or by way of a separate action, is an abuse of process. I would therefore be prepared to exercise the power under CPR 52.10(2)(b) to remit an issue for determination in the Patents Court.

xiv. 162. I am not however content with Actavis' formulation of the issue. I would remit the issue in the broadest possible terms, namely whether the supply or offer to supply of the Actavis AIs when recommended for reconstitution in dextrose would infringe the 508 patent. The patents judge will then be in a position to give the necessary procedural directions for the proper identification of the issue and its trial.

Kitchin LJ

i. 163. I agree.

Longmore LJ

i. 164. I agree also.

Trinity Term
[2017] UKSC 48
On appeals from: [2015] EWCA Civ 555 and 556

JUDGMENT

Actavis UK Limited and others (Appellants) *v* Eli Lilly and Company (Respondent)
Eli Lilly and Company (Appellant) *v* Actavis UK Limited and others (Respondents)
Eli Lilly and Company (Appellant) *v* Actavis UK Limited and others (Respondents)

before

Lord Neuberger, President
Lord Mance
Lord Clarke
Lord Sumption
Lord Hodge

JUDGMENT GIVEN ON

12 July 2017

Heard on 4, 5 and 6 April 2017

Actavis and others
Daniel Alexander QC
Thomas Raphael QC
Isabel Jamal
(Instructed by Bird & Bird LLP)

Eli Lilly and Company
Thomas Mitcheson QC
Andrew Waugh QC
Stuart Baran
(Instructed by Hogan Lovells International LLP)

LORD NEUBERGER: (with whom Lord Mance, Lord Clarke, Lord Sumption and Lord Hodge agree)

1. The issue raised on this appeal and cross-appeal is whether three products manufactured by the Actavis group of companies ("Actavis") would infringe a patent whose proprietor is Eli Lilly & Company ("Lilly"), namely European Patent (UK) No 1 313 508 ("the Patent"), and its corresponding designations in France, Italy and Spain.

2. This judgment was circulated in draft to the parties' legal representatives in the normal way on 5 July 2017, on the basis that it would be handed down a week later. On the following day, just after midday, Actavis's solicitors emailed the Court expressing concern about the potential prejudice which their clients could suffer if they did not know of the outcome of this appeal until 12 July. Not least because publication of our decision could have an effect on the share prices of Actavis or Lilly or both of them, the Court proposed to the parties' respective solicitors that we should announce our decision at once, while maintaining the intention, in accordance with this Court's usual practice, to hand down the judgment a week after circulation of the draft. This was agreed by both solicitors, and accordingly on 7 July at 11.30 am, the following announcement appeared on the Court's website:

> "The Supreme Court allows Eli Lilly's appeal and holds that Actavis's products directly infringe Eli Lilly's patent in the United Kingdom, France, Italy and Spain. The Court dismisses Actavis's cross-appeal on the basis that if its products did not directly infringe, they would indirectly infringe to the extent held by the Court of Appeal."

Accordingly, these are technically the reasons for those conclusions.

The factual and technical background

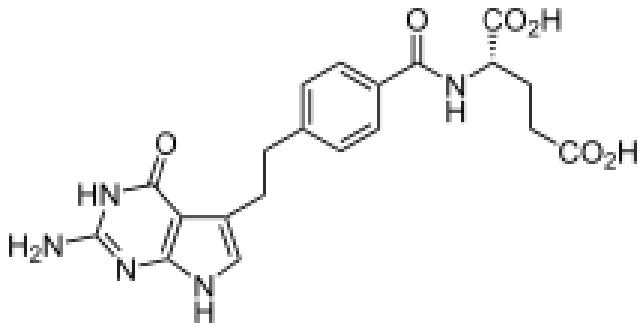
The factual background

3. Pemetrexed is a chemical which has been known for some time to have therapeutic effects on cancerous tumours. However, when used for that purpose on its own, pemetrexed can often have seriously damaging, sometimes even fatal, side-effects. Accordingly, its use as an anti-cancer drug was effectively precluded in

practice. The essential disclosure of the Patent was that the damaging side-effects could largely be avoided if a compound called pemetrexed disodium was administered together with vitamin B12. This has enabled pemetrexed disodium to be used for treatment in the form of a medicament which includes the vitamin. Such a medicament has been successfully marketed, under the brand name Alimta, by Lilly since 2004.

4. The Patent primarily claims the use of pemetrexed disodium in the manufacture of a medicament for use in combination with vitamin B12 (and, optionally, folic acid) for the treatment of cancer.

5. Pemetrexed itself is a member of a class of chemicals known as antifolates, and its molecular structure is shown below, with C, N, O and H being respectively the chemical symbols for carbon, nitrogen, oxygen and hydrogen; and the unallocated points on the chains and the rings being carbon.



6. The presence of the two -CO_2H units results in pemetrexed being an acid (hence it is also known as pemetrexed diacid), or as it is sometimes called, a free acid. When pemetrexed is dissolved in water, the hydrogens in those two units separate from the rest of the molecule as positively charged entities, protons, and the rest of the molecule becomes a negatively charged entity called an anion. The structure of pemetrexed disodium is similar except that, instead of the two -CO_2H units, it has two -CO_2Na units (Na being the symbol for sodium). Pemetrexed disodium dissolves in water, where the two sodiums separate from the rest of the molecule as positively charged entities called cations, and the rest of the molecule becomes an anion. Because it is the pemetrexed anion which is of interest, the sodium cation is often referred to as a counter-ion. A substance such as pemetrexed disodium, where the acidic hydrogens have been replaced, is known chemically as a salt.

7. Although one might have thought that the actual invention should have been characterised as a disclosure that pemetrexed could be administered safely if it was combined in a medicament with vitamin B12, the claimed invention in the Patent is,

as mentioned in para 4 above, the manufacture of such a medicament. This formulation was required by the then-prevailing law contained in article 52(4) of the European Patent Convention 1973 ("EPC 1973"), which prohibited from patentability any method of treatment of humans or animals. This led to inventions which otherwise might have been expected to be expressed as being new therapeutic treatments being cast as manufacturing claims. Such claims are known as Swiss form claims, and they were illuminatingly discussed by Kitchin J in *Ranbaxy (UK) Ltd v Astrazeneca AB* [2011] FSR 45, paras 42 to 60. As he explained, the prohibition was substantially modified in article 53 in the European Patent Convention 2000 ("EPC 2000"), but that modification had not come into force when Lilly applied for the Patent.

8. Actavis's proposed products involve pemetrexed compounds being used together with vitamin B12 for cancer treatment. However, rather than pemetrexed disodium, the active ingredient in those products ("the Actavis products") is (a) pemetrexed diacid, (b) pemetrexed ditromethamine, or (c) pemetrexed dipotassium. In other words, rather than including the disodium salt referred to in claim 1 of the Patent, the Actavis products include as the active ingredient (a) pemetrexed itself (ie the free acid), or pemetrexed with the hydrogens on the two $-CO_2H$ units replaced by (b) tromethamine, or (c) potassium. Actavis contend that, because they intend to use the Actavis products which do not include pemetrexed disodium, the claims of the Patent, which are expressed as involving the use of pemetrexed disodium, would not be infringed. By contrast, Lilly contends that there would be either direct or indirect infringement of the Patent if Actavis launch any of the Actavis products on the market in the UK or in France, Italy, or Spain. The allegation of direct infringement is based simply on the proposition that marketing or use of the Actavis products would infringe the Patent; indirect infringement is said to arise because pemetrexed disodium is claimed to be involved in the preparation of the Actavis products before they are administered.

9. After a four-day trial, Arnold J decided that none of the Actavis products would directly or indirectly infringe the Patent in the UK or in France, Italy or Spain - [2015] Bus LR 154; [2015] RPC 6. The Court of Appeal allowed Lilly's appeal to the limited extent of holding that there would be indirect infringement in the four jurisdictions, but they agreed with the Judge that there would be no direct infringement - [2015] Bus LR 1068. Lilly appeals against the rejection of its case that there would be direct infringement, and Actavis cross-appeal against the rejection of their case that there would be no indirect infringement.

10. As Floyd LJ explained in the Court of Appeal, the appeal raises the issue of the correct approach under UK law (and the law of the three other states) to the interpretation of patent claims, and in particular the requirement of EPC 2000 to take account of "equivalents", and also the extent to which it is permissible to make use of the prosecution history of a patent when determining its scope. The issue on the

cross-appeal is rather more fact-specific, namely whether the application of the law of contributory infringement justifies a finding of indirect infringement in this case.

11. It is appropriate to start by setting out the relevant provisions of the Patent and the knowledge of its assumed addressee, topics on which my account is largely taken from the clear judgment of Floyd LJ in the Court of Appeal. I will then turn to the issue of direct infringement, which involves considering the proper approach to that issue generally, and also the relevance of the prosecution history. I will then consider the position in the three other states and finally I will address the issue of indirect infringement.

The specification and claims in the Patent

12. The Patent is entitled "Combination containing an antifolate and methylmalonic acid lowering agent", and it has a claimed priority date of 30 June 2000.

13. The specification begins at para [0001] by stating that "[p]otentially, life-threatening toxicity remains a major limitation to the optimal administration of antifolates". It then explains at para [0002] that antifolates work by inhibiting anti-folate-requiring enzymes by competing with reduced folates for binding sites on those enzymes. The specification identifies several antifolate drugs as being in development, including Lilly's branded product Alimta.

14. The specification then explains at para [0003] that a limitation to the development of these drugs is that they may be associated with substantial toxicity, including mortality, for some patients. These toxicity effects had led to the abandonment of the development of some antifolates. In para [0004] the specification explains that previous work had been done on the use of folic acid as a treatment for toxicity in this area. It also records work on vitamin B12 as a predictor of cytotoxic events.

15. The specification then states in para [0005]:

> "Surprisingly and unexpectedly, we have now discovered that certain toxic effects such as mortality and non-hematologic events, such as skin rashes and fatigue, caused by antifolates, as a class, can be significantly reduced by the presence of a methylmalonic acid lowering agent as vitamin B12, without adverse adversely affecting therapeutic efficacy. The present invention thus generally relates to a use in the manufacture of

> a medicament for improving the therapeutic utility of antifolate drugs by administering to the host undergoing treatment with a methylmalonic acid lowering agent as vitamin B12."

16. Para [0006] of the specification continues:

> "Additionally, we have discovered that the combination of a methylmalonic acid lowering agent as vitamin B12 and folic acid synergistically reduces the toxic events associated with the administration of antifolate drugs. Although, the treatment and prevention of cardiovascular disease with folic acid in combination with vitamin B12 is known, the use of the combination for the treatment of toxicity associated with the administration of antifolate drugs was unknown heretofore."

17. These early, general statements are made in relation to antifolates as a class. However, at para [0010] the specification says, in what is known as a consistory clause, that the invention:

> "specifically provides the use of the antifolate pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with a methylmalonic acid lowering agent selected from vitamin B12 and pharmaceutical derivatives thereof."

18. Having referred specifically to pemetrexed disodium, the specification reverts to generality at para [0016], where it states:

> "The current invention concerns the discovery that administration of a methylmalonic acid lowering agent such as vitamin B12 or a pharmaceutical derivative thereof, in combination with an antifolate drug such as pemetrexed disodium reduces the toxicity of the said antifolate drug."

19. Para [0022] contains a definition:

> "The terms 'antifolate' and 'antifolate drug' generally refer to a chemical compound which inhibits at least one key folate-requiring enzyme of the thymidine or purine biosynthetic

> pathways ... by competing with reduced folates for binding sites of these enzymes. The 'antifolate' or 'antifolate drug' for use in this invention is Pemetrexed Disodium (ALIMTA®), as manufactured by Eli Lilly & Co."

20. The invention is then illustrated by reference to a number of examples relating to animal and human tests, in which the only antifolate used is pemetrexed disodium. At para [0035] the specification states that animals were treated with "pemetrexed disodium (ALIMTA®) (100 mg/kg or 150 mg/kg) once daily … by intraperitoneal injection alone or along with folic acid". The specification also indicates at para [0044] that, in a typical clinical evaluation using cancer patients, the antifolate is to be administered in four doses over a two-week period by rapid intravenous injection.

21. Turning to the claims, it is only necessary for present purposes to refer to claims 1 and 12, which are in these terms:

> "1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof [which it then specifies]."

> "12. A product containing pemetrexed disodium, vitamin B12 or a pharmaceutical derivative thereof said pharmaceutical derivative [which it again specifies], and, optionally, a folic binding protein binding agent selected from [a specified group of chemicals including folic acid], as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumour growth."

The notional addressee of the Patent

22. A patent is interpreted on the basis that it is addressed to a person or group of persons who is or are likely to have a practical interest in the claimed invention, ie through the eyes of a person or persons skilled in the art. There is now no challenge to the Judge's conclusion that the notional addressee of the Patent would be a group consisting of an oncologist and a chemist, a conclusion upheld by the Court of Appeal.

23. The Judge found that the common general knowledge of an oncologist as at the relevant time, 2001/2002, included the following:

i) Antifolates were used in cancer chemotherapy, but their use caused toxic side effects which it would be desirable to avoid or reduce.

ii) Pemetrexed was the subject of clinical trials for use in chemotherapy, and it targeted multiple enzymes and was administered intravenously.

iii) The only form of pemetrexed which had been shown to be effective and safe to any extent was pemetrexed disodium, which was manufactured by Lilly under the trade mark Alimta.

iv) The characteristics of both vitamin B12 and folic acid were well understood, and it was well known that there were many different safe and effective forms of both available.

24. The Judge also concluded that oncologists did not think about drugs such as pemetrexed in their ionic form, nor did they consider issues regarding the choice of counter-ion or the effect, if any, of counter-ions on the efficacy, safety or other properties of the drug. This was the province of the chemist and, because the properties of different salt forms and free acids were difficult to predict, a chemist would need to address any such issue by conducting experiments.

25. The Judge made the following findings as to the common general knowledge of a chemist as at 2001/2002:

i) Where a drug is or is based on an acid, different salts of the parent acid can be formed by reacting it with a complementary base or acid. The salt will often have different properties from the parent acid, and different salts will often have different properties from each other. So, salt screening is a routine but important exercise in determining the most suitable form of a drug.

ii) The facts set out in paras 5 and 6 above.

iii) Solid salts consist of the anions and cations regularly arranged in a fixed lattice structure. Because the cations and anions are present in fixed proportions and in fixed relative positions it is possible to speak meaningfully of the salt as being present in solid form.

iv) When a salt is dissolved in water, the ions dissociate, forming free cations and anions in solution. Although the salt ceases to exist, it is common to refer to "a salt solution" or "a salt in solution".

v) The salt form can have a significant impact on the effectiveness of a drug in that it can modify many aspects of the drug.

vi) When considering a drug for intravenous chemotherapy, the solubility of the salt form is crucial, as good solubility is an indicator of how likely it is that the drug will be absorbed in the gut.

vii) But if a salt is too soluble, it cannot be made in solid form.

viii) In general, there can be many dead-ends and false leads when attempting to prepare salts of a parent molecule for the first time.

ix) One cannot predict (a) whether one could make a particular salt form of a parent molecule, (b) what its properties would be once it was made or (c) whether it would affect the efficacy of the drug.

26. The Judge made specific findings about a chemist's state of knowledge about three types of salts and about free acids:

i) Sodium was generally the preferred counter-ion, and so would be first choice. Sodium salts generally were not toxic, and would be expected to be reasonably soluble, but they were not always easy to make.

ii) Potassium salts were also generally soluble, but there were exceptions. There were concerns about the potential toxicity of such salts, which was particularly significant if large quantities of the drug were involved.

iii) There were only a small handful of examples of tromethamine salts being used in 2001. It was known that tromethamine salts might well be too soluble, so one would not be able to make and harvest the solid form.

iv) In principle, the acidic parent molecule could be administered in the form of the free acid. But it was often necessary to change from the free acid to a salt form for various reasons including solubility.

Direct infringement

27. In a nutshell, the rival contentions are these. Lilly argues that the Actavis products infringe the Patent because they are medicaments to be used as a treatment for cancer consisting of pemetrexed diacid, or a pemetrexed salt, with vitamin B12, which represents the essence of the teaching and claim of the Patent. By contrast, Actavis argues that their products do not infringe because the claims of the Patent are limited to a specific pemetrexed salt, namely pemetrexed disodium, and the Actavis products contain either pemetrexed diacid or different pemetrexed salts.

The legislative context

28. The domestic provision governing direct patent infringement is section 60(1) of the Patents Act 1977. However, section 130(7) declares that certain provisions of that Act, including section 60, are "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention … have in the territories to which [that Convention applies]". Accordingly, it is common ground that it is appropriate to consider the present case by reference to the EPC 2000.

29. Article 69(1) EPC 2000 provides that "[t]he extent of the protection conferred by a European patent … shall be determined by the claims", although it is followed by another sentence, namely "[n]evertheless, the description and drawings shall be used to interpret the claims".

30. As a matter of ordinary language, it is quite clear that the only type of pemetrexed compound to which the Patent's claims expressly extend is pemetrexed disodium. One only needs to read claim 1 and claim 12 to justify that: as a matter of ordinary language, "pemetrexed disodium" means that particular salt, and no other salt, let alone the free acid. If the first few words of each claim were not enough to make this good, the contrast between the specific reference to pemetrexed disodium and the wider reference to "vitamin B12 or a pharmaceutical derivative thereof" underlines the point. As Floyd LJ said, this conclusion is also supported by what is said in the specification - eg in paras [0010] and [0022] quoted above. It is fair to say that para [0016] could be said to point the other way, but it is far too weak a basis for even arguing that the Patent's claims extend, as a matter of language, to pemetrexed compounds other than pemetrexed sodium.

31. In these circumstances, The Protocol on the Interpretation of article 69 as amended in 2000 ("the Protocol") is crucial to Lilly's contention that the scope of

protection afforded by the Patent extends to the Actavis products. The Protocol provides:

> "*Article 1*
>
> General principles
>
> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.
>
> *Article 2*
>
> Equivalents
>
> For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

The original Protocol was agreed in 1973; the amendments made in 2000 effected very slight modifications to what is now article 1, and introduced article 2 for the first time.

32. The drafting of the Protocol bears all the hallmarks of the product of a compromise agreement. This is unsurprising. There is an inevitable conflict between the desirability of giving an inventor an appropriate degree of protection in a particular case and the need for clarity of principle as to the extent of such protection generally; and, of course, there is an unavoidable tension between the appropriateness of giving an inventor a monopoly and the public interest in

maximising competition. In addition, the EPC 2000 and the Protocol apply in many different states which have different traditions and approaches in relation to the law of patents. In that connection, as the Supreme Court observed in *Schütz (UK) Ltd v Werit (UK) Ltd (Nos 1 to 3)* [2013] Bus LR 565; [2013] RPC 16, para 40, "complete consistency of approach" between different national courts of the EPC states "is not a feasible or realistic possibility at the moment", but nonetheless "it is sensible for national courts at least to learn from each other and to seek to move towards, rather than away from, each other's approaches".

33. More specifically, two points appear to be clear from the Protocol. The first, which can be deduced from article 1, is that the scope of protection afforded to a patentee is not to be limited by the literal meaning of the claims. However, it is not at all clear how far a court is permitted to move away from the literal meaning. I do not consider that the last part of the first sentence of article 1 only enables the description (ie the specification) and the drawings to be taken into account when interpreting the claims, in cases where the claims would otherwise be ambiguous. Any doubt about this must be put to rest by the second and third sentences, which make it clear to my mind that that would be too narrow a reading. However, it is very hard to be confident how far they were intended to permit a court to go beyond the actual language of a claim when interpreting a claim. Secondly, it is apparent from article 2 that there is at least potentially a difference between interpreting a claim and the extent of the protection afforded by a claim, and, when considering the extent of such protection, equivalents must be taken into account, but no guidance is given as to precisely what constitutes an equivalent or how equivalents are to be taken into account.

34. The question of how far one can go outside the wording of a claim to enable the patentee to enjoy protection against products or processes which are not within the ambit of the actual language, construed in accordance with ordinary principles of interpretation, has been considered in three significant UK cases and in a number of significant cases decided in the courts of other Convention states.

The domestic case law

35. The UK case of *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 was decided under the previous, purely domestic, legislation, the Patents Act 1949. At pp 242 to 243, Lord Diplock deprecated the notion that there were two types of infringement, "textual infringement" and "infringement of the 'pith and marrow' of the invention", and said that there was "a single cause of action", which involved asking the question:

> "whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked."

He continued:

> "The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked."

36. In that case, the patent was for a novel type of galvanised steel lintel, which the relevant claim described as including a rear support back plate "extending vertically" from a horizontal plate. The allegedly infringing article included a rear support member which was inclined between 6 degrees and 8 degrees from the vertical. Overruling the Court of Appeal's decision that this meant that there was no infringement, Lord Diplock said at p 244, that it would have been:

> "obvious to a builder familiar with ordinary building operations that the description of a lintel in the form of a weight-bearing box girder of which the back plate was referred to as 'extending vertically' from one of the two horizontal plates to join the other, could not have been intended to exclude lintels in which the back plate although not positioned at precisely 90 degree to

> both horizontal plates was close enough to 90 degree to make no material difference to the way the lintel worked when used in building operations."

He then added this:

> "No plausible reason has been advanced why any rational patentee should want to place so narrow a limitation on his invention. On the contrary, to do so would render his monopoly for practical purposes worthless, since any imitator could avoid it and take all the benefit of the invention by the simple expedient of positioning the back plate a degree or two from the exact vertical."

37. A few years later, Hoffmann J (as he then was) gave judgment in *Improver Corpn v Remington Consumer Products Ltd* [1990] FSR 181. The case concerned a patent for a depilator, known as the "Epilady", which worked by trapping hairs in a rotating "coiled helical spring", and the alleged infringement worked in very much the same way save that, instead of a spring, it used a slotted rubber rod. The case had already gone on an interlocutory issue to the Court of Appeal, where it was held that Lord Diplock's approach in *Catnic* [1982] RPC 183 was consistent with the 1977 Act, the EPC 1973 and the Protocol as it then was - see [1989] RPC 69.

38. At [1990] FSR 181, 189, Hoffmann J suggested the following approach, largely based on his reading of the reasoning in *Catnic* [1982] RPC 183, 242 to 243:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or a contextual meaning of a descriptive word or phrase in the claim ('a variant') was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> > (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
> >
> > (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -

> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.
>
> On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal, but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which included the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

39. Hoffmann J then proceeded to apply those three questions to the facts of the case before him. He held that the first two questions were to be answered in the patentee's favour and then turned to the third question. On that question, he held that the patentee failed for the reasons he gave at p 197, namely that "[t]he rubber rod is not an approximation to a helical spring", that "the spring [cannot] be regarded as an 'inessential' or the change from metal spring to rubber rod as a minor variant", and that it could be appreciated that the patentee would wish to restrict his claim to helical springs as "[i]t would be obvious that the rubber had problems of hysteresis which might be very difficult to overcome".

40. Thereafter, for the next 15 years or so, this three-stage approach was almost routinely applied by judges in UK patent infringement cases, where the three "*Improver* questions" were subsequently renamed the three "Protocol questions" - see *Wheatley v Drillsafe Ltd* [2001] RPC 7, para 23.

41. Lord Hoffmann (as he had by then become) addressed the issue again in his speech in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9, where one of the issues was whether a protein manufactured by gene-activation infringed a patent relating to production of the same protein by recombinant DNA technology. At paras 27 to 35, Lord Hoffmann discussed "the English rules of construction". At paras 30 to 32 he effectively equated Lord Diplock's approach to patents in *Catnic* [1982] RPC 183, 243 with "purposive construction" of commercial contracts. At para 34, he said that "[t]he question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance".

42. Lord Hoffmann then turned to the doctrine of equivalents, which he explained in para 37 had been developed in the United States courts and "allow[ed]

the patentee to extend his monopoly beyond his claims", so as to prevent "the unscrupulous copyist [from making] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law", quoting Jackson J in *Graver Tank & Manufacturing Co Inc v Linde Air Products Co* 339 US 605, 607 (1950). Lord Hoffmann expressed concern that "once the monopoly had been allowed to escape from the terms of the claims, it is not easy to know where its limits should be drawn", and concluded that, rather than adhering to literalism and adopting the doctrine, the solution was "to adopt a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming", as Lord Diplock had done in *Catnic* [1982] RPC 183. He also said that article 69 EPC 2000 "firmly shuts the door on any doctrine which extends protection outside the claims" (see at paras 39 and 42 to 44).

43. Having considered the issue in the three preceding paragraphs of his speech, at para 48 Lord Hoffmann stated that the approach adopted by Lord Diplock was "precisely in accordance with the Protocol", as it was "intended to give the patentee the full extent, but no more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim". He concluded his discussion by quoting with approval the passages quoted above from *Catnic* [1983] RPC 183, 243 and *Improver* [1990] FSR 181, 189, and saying in para 52 that the principle of purposive construction as Lord Diplock and he had explained it, gave "effect to the requirements of the Protocol" and was "the bedrock of patent construction, universally applicable", whereas the Protocol or *Improver* questions were simply "guidelines for applying that principle to equivalents … , more useful in some cases than in others".

The approach in the courts of other EPC states

44. In Germany, the Bundesgerichtshof has stated that a variant will infringe if (i) "it solves the problem underlying the invention with modified but objectively equivalent means", (ii) this would be recognised by the person skilled in the relevant art, and (iii) that person "focus[sing] on the essential meaning of the technical teaching protected in the patent" would regard the variant "as being equivalent to the solution" offered by the invention - see Case No X ZR 168/00, 2002 GRUR 519 (*Schneidmesser I*), para 30. (It is worth noting that in paras 36 to 38 of its judgment in that case, the Bundesgerichtshof expressly considered the approach which had been adopted in *Catnic* [1982] RPC 183 and *Improver* [1990] FSR 181.) Judge Meier-Beck of the Bundesgerichtshof, writing extra-judicially (*The Scope of Patent Protection - The Test for Determining Equivalence* (2005) 36 IIC 339, 342 to 343) has suggested that the second step involves asking whether "the person skilled in the art, using his specialist knowledge, [would be] able to find the modified means at the priority date as having the same effect", which he then says has the "meaning that no inventive step is needed". That seems to be supported by what was said by

the Bundesgerichtshof in Case No X ZR 156/97, 1999 GRUR 977, (*Räumschild*), paras II.2(c)(aa) and III.1.

45. Further guidance as to the German approach to equivalents was very recently given by the Munich Oberlandesgericht, upholding the decision of the Landgericht, in Case No 6 U 3039/16 (*Eli Lilly & Co v ratiopharm GmbH*), when considering whether pemetrexed ditromethamine infringed the German equivalent of the Patent in this case. At para II.B.3(a), the Oberlandesgericht said that in order for "an embodiment that deviates from the literal meaning of the claim" to be within the scope of protection, "generally three requirements must be met". The first was that "the embodiment must solve the problem underlying the invention with means that are indeed modified, but are objectively equivalent". The second requirement was that "the expertise of the person skilled in the art must enable him to discover the modified embodiment with its divergent means to be equivalent". Thirdly, "the thought processes that the person skilled in the art has to perform in order to do so must be oriented on the meaning of the teaching protected in the claim". In para II.B.3(b)(aa), the Oberlandesgericht suggested that "the decisive factor" was "what individual effects the features according to the patent … provide in order to attain the object underlying the claims and whether these effects are achieved through other means by the [allegedly infringing] embodiment". The court added that the doctrine of equivalence would apply to an embodiment "if it not only essentially achieves the entire effect of the invention, but specifically also achieves the effect that the feature, which has not been literally implemented, is supposed to achieve".

46. French law, according to the expert witnesses in this case, applies the doctrine of equivalents where the variant is "different in form but perform[s] the same function" as the invention, but only where "the function [claimed in the patent] is a new one". This seems to be supported by *Azéma and Galloux, Droit de la propriété industrielle*, 7th ed (2012), which distinguishes at p 442 between two categories of patents. The first category is those which "in general terms claim the means that provide for a particular function" (*moyens généraux*), or as Arnold J put it in para 160 of his judgment, claims which cover "general means". The second category is patents "which indicate the particular means which infer such function" (*moyens particuliers*), or claims which are "narrowly worded to cover specific means" as Arnold J expressed it. The doctrine is only normally applicable to the first category of claims. Arnold J added in para 160 that the categorisation of a patent for this purpose may depend in part on what was known at the priority date - see the decisions of the Cour de Cassation in Appeal S 09-15668 *Institut Pasteur v Chiron Healthcare*, 23 November 2010 and of the Paris Tribunal de Grande Instance in Case 09/01863 *Mundipharma Laboratories GmbH v Sandoz SAS*, 2 July 2010.

47. As Arnold J also explained in para 159 of his judgment, "there is no need for the claim to be unclear or for it to be widely worded" for the doctrine of equivalents to be invoked in the French court. Thus, in the decision of the Cour de Cassation in

Appeal No 06-17915 *B2M Industries v Acome*, 20 November 2007, "the function of the particular integer that was said to be infringed pursuant to an equivalent was held to be novel, and therefore because the means that was said to be equivalent to that integer performed the same function and produced the result sought by the invention the means was equivalent to that integer", to quote from para 161 of Arnold J's judgment.

48. In the Italian courts, the expert witnesses in this case agreed that a variant would be held to infringe if (i) it reproduced the "inventive core" of the patent and (ii) it was an obvious variation, although (iii) the fact that the variant included some modifications which were not obvious and/or the fact that the variant does not include some of the elements of the patent claim does not necessarily prevent the variant infringing - see per Arnold J at para 171 of his judgment. This analysis is supported by the Corte di Cassazione decisions in Case No 257, *Forel SpA v Lisec* (13 January 2004), Case No 30234, *Barilla GER Fratelli SpA v Pastifico Fazion SpA* (30 December 2012) and Case No 622, *Entsorga Italia Srl v Ecodeco Srl* (11 January 2013).

49. At any rate at local appellate level, Spanish courts appear to have effectively adopted the approach embodied in the three questions suggested by Hoffmann J in *Improver* [1990] FSR 181 - see for instance *Laboratorios Cinfa SA v Eli Lilly & Co Ltd ("Olanzapine")* Court of Appeal of Barcelona judgment no 8/2008, 17 January 2008.

50. Following circulation of this judgment in draft, Actavis referred us to a decision of the Spanish Tribunal Supremo *Lundbeck v Cinfa*, no 223/2015, 29 April 2015. In the closely reasoned section ELEVEN of its judgment, the Tribunal Supremo (i) recorded the fact that none of the parties challenged the approach of the Court below which applied the three *Improver* questions (para 5), (ii) stated that the real issue in the case centred on the second question (para 6), (iii) cast some doubt on the applicability of the *Improver* questions in Spanish law (para 10), (iv) disapproved the notion that the test for obviousness in patentability is necessarily applicable to the second *Improver* question (paras 10 and 14), (v) disapproved the notion that, for the second *Improver* question to be answered yes, "the skilled person must be absolutely certain that the variant … would work successfully in resolving the technical problem faced by the patented invention" (paras 11 and 12), (vi) preferred instead, a test of "easy to see or comprehend" and "a degree of predictability" (paras 11 and 18), which involves "a high probability", rather than a "reasonable expectation" that the variant would work (paras 15 and 18), and (vii) concluded on this basis that the Court of Appeal was right to rule that the allegedly infringing products in that case did not infringe (paras 18 and 19).

51. As for the Netherlands, helpful guidance may be found in a lecture given in 2016 by Judge Kalden, the head of the IP division in the Court of Appeal in The Hague - *Article 69 EPC - the Scylla and Charybdis of the European Patent Convention - Which route did the Dutch courts take?* (2016 Symposium German Bundespatentgericht). She said that, although there have been subtle changes of emphasis in its decisions, the Supreme Court tends to focus on "the inventive concept in order to prevent a too literal interpretation of the claims, which could do injustice to fair protection for the patentee (or lead to an unnecessary broad interpretation)". She also explained that the doctrine of equivalents applies if (i) the variant is "foreseeable at the priority date", (ii) "the inventive concept is sufficiently broad to … cover [the] variant", (iii) "the variant makes use of - and thus benefits from - the inventive concept", and (iv) "reasonable legal certainty [is not thereby] unduly compromised". She added that, despite the first condition:

> "Variants that are not foreseeable at the priority date may well, due to later developments, become an obvious variant at a later date. This may happen in case of a pioneer invention, where at the priority date the full breadth of the possible applications could or has not been fully recognised and therefore was not sufficiently taken into account when drafting a claim. Another possibility is that a new technique becomes available after the patent was granted, which makes available an obvious variant. It would be harsh and contrary to fair protection for the patentee to deny him the right to attack those, again provided such variant falls within the inventive concept and reasonable legal certainty is taken into account. So infringement by equivalence is not limited to foreseeable variants only."

52. It may be of some significance that the product which Hoffmann J concluded in *Improver* [1990] FSR 181 was non-infringing was held by the German, Italian and Dutch courts to infringe. Of course, the fact that courts of two states reach different conclusions on the same issue does not of itself mean that there is a difference in the law of those states, let alone that one court is wrong and the other right: the evidence may be different, and there may be issues of judgment on which reasonable judges could differ. However, consideration of the judgments in those three other courts does suggest a difference of approach. Thus, in Germany, the Düsseldorf Oberlandesgericht based its conclusion on the propositions that "a person skilled in the art will not interpret the coil spring as a spring, but as an elastic body with gaps ... as it is obvious that the helical spring is not used as a spring per se", and that its only essential function, which was shared by the allegedly infringing product's slitted rubber rod, was that it could "enter between adjacent areas of the body (walls), and that the walls must approach it up to clamping it" - see Epilady Germany II (1993) 24 IIC 838. In Italy, the Milan District Court held that there was infringement because the slitted rubber rod had structural characteristics which

enabled it to perform the same function in the same way as the coiled spring referred to in the patent in suit - see Epilady Italy (1992) Giur Ann Dir Ind, Case No 2823. In the Netherlands, the Gerechtshof upheld the first instance decision that the allegedly infringing "device embodies an application of the patented invention, on the grounds that the hair-engaging component [ie the slitted rubber rod] of the device is a mechanical equivalent of the helical spring specified in the patent claims", and the rod was "not state of the art in the field of depilatory devices" - Epilady Netherlands III (1993) 24 IIC 832, paras 9 and 11.

The proper approach to infringement claims

53. Any patent system must strike a balance between the two competing factors referred to at the end of article 1 of the Protocol, namely "a fair protection for the patent proprietor [and] a reasonable degree of legal certainty for third parties". The balance cannot be struck on an *ad hoc* case-by-case basis without any guiding principles, as that would mean that there was no legal certainty. On the other hand, striking the balance by adopting a normal approach to interpretation would risk depriving patentees of a proper measure of protection; as explained in paras 37 to 39 and 52 above, that is clear from the approach of all the courts which considered the "Epilady" patent, where it could not seriously have been suggested that, as a matter of language, a slotted rubber rod falls within the expression "helical metal spring", even if one was construing those words in the context of the claim in the patent in suit. But, if one departs from ordinary language, it is necessary to have some guidance or to draw some lines, as Lord Hoffmann implied in *Kirin-Amgen* [2005] RPC 9, para 37. That is why he promulgated his three questions in *Improver* [1990] FSR 181, 189. By means of an extended version of the ordinary concept of "construction" or "interpretation", Hoffmann J explained how our domestic law, as laid down in *Catnic* [1982] RPC 183, implements article 2 of the Protocol and thus, as I see it, how it gives effect to the doctrine of equivalents. That approach was (perhaps unsurprisingly) then adopted in *Kirin-Amgen* [2005] RPC 9.

54. In my view, notwithstanding what Lord Diplock said in *Catnic* [1982] RPC 183, 242, a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? If the answer to either issue is "yes", there is an infringement; otherwise, there is not. Such an approach complies with article 2 of the Protocol, as issue (ii) squarely raises the principle of equivalents, but limits its ambit to those variants which contain immaterial variations from the invention. It is also apparent that the two issues comply with article 1 of the Protocol in that they involve balancing the competing interests of the patentee and of clarity, just as much as they seek to balance the encouragement of inventions and their disclosure

with the need for a competitive market. In my view, issue (i) self-evidently raises a question of interpretation, whereas issue (ii) raises a question which would normally have to be answered by reference to the facts and expert evidence.

55. In *Kirin-Amgen* [2005] RPC 9, Lord Hoffmann, following his approach in *Improver* [1990] FSR 181 (which itself had followed Lord Diplock's analysis in *Catnic* [1982] RPC 183) effectively conflated the two issues, and indicated that the conflated issue involved a question of interpretation. I have considerable difficulties with the notion that there is a single conflated, or compound, issue, and, even if that notion is correct, that that issue raises a question of interpretation. Indeed, in my view, to characterise the issue as a single question of interpretation is wrong in principle, and unsurprisingly, therefore, can lead to error. While normal principles of interpretation could, I think, accommodate the notion that "vertically" extended to an item which was not at precisely 90° to another item, I do not see how such principles could possibly lead to the conclusion that a slotted rubber rod was within the expression "helical metal spring". As Hoffmann J said in *Improver* [1990] FSR 181, 197, "the angle of the support member [in the allegedly infringing product in *Catnic* [1982] RPC 183] can be regarded as an approximation to the vertical", but "[t]he rubber rod is not an approximation to a helical spring". The problem with treating the issue as one of normal interpretation is thus that that point alone may be thought to have been sufficient to put an end to the patentee's infringement argument on facts such as those in *Improver* [1990] FSR 181, and there would seem to have been little purpose in going through the three questions in that case.

56. I had wondered whether the question whether issue (ii) truly involves a question of interpretation raised what was merely an arid issue of categorisation. However, I have concluded that that nettle needs to be grasped, because, so long as the issue is treated as one of interpretation, it will lead to a risk of wrong results in patent infringement cases and it will also lead to a risk of confusing the law relating to the interpretation of documents. In my opinion, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning. As Sir Hugh Laddie wrote in his instructive article *Kirin-Amgen - The End of Equivalents in England?* (2009) 40 IIC 3, para 68, "[t]he Protocol is not concerned with the rules of construction of claims" but with "determining the scope of protection".

57. I might add that the notion of a product or process which infringes despite an immaterial variation from the invention as claimed is by no means new to domestic patent law. That point is convincingly demonstrated by Sir Hugh in his article at paras 33 to 39. Thus, in *Walton v Potter & Horsfall* (1843) 1 WPC 585, Tindal CJ told the jury that they had to decide whether the defendant's product was "perfectly distinct" from the patented product, or whether it varied "only in certain circumstances, which are not material to the principle and substance of the

invention". And Lord Cairns LC in *Clark v Adie* (1877) 2 App Cas 315, 320, referred to the alleged infringer having "really taken and adopted the substance of the instrument patented", and having "taken in substance the pith and marrow of the invention". The patents in these cases included relatively primitive forms of claim, but that does not undermine the fact that our domestic law has long recognised that an immaterial variation does not get an infringer off the hook. Particularly in the light of what he said in *Catnic* [1983] RPC 183, 242, it is worth mentioning that Lord Diplock himself in *Beecham Group Ltd v Bristol Laboratories Ltd* [1978] RPC 153, 200 rejected a submission that "[t]he increasing particularity with which claims are drafted … has made the doctrine [of pith and marrow] obsolete", and said that the doctrine "still remains a part of patent law".

58. Turning to the two issues identified in para 54 above, issue (i), as already mentioned, involves solving a problem of interpretation, which is familiar to all lawyers concerned with construing documents. While the answer in a particular case is by no means always easy to work out, the applicable principles are tolerably clear, and were recently affirmed by Lord Hodge in *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095, paras 8 to 15. In the present case, there is no doubt that, according to normal principles of interpreting documents, the Actavis products do not infringe the Patent, as in no sensible way can pemetrexed free acid, pemetrexed ditromethamine, or pemetrexed dipotassium mean, ie be said to fall within the expression, "pemetrexed disodium" in claim 1 of the Patent, any more than a slotted rubber rod can be said to be within the expression "a helical metal spring" in the claim in the *Improver* patent. According to normal principles of interpreting documents, then, this would be the end of the matter.

59. However, the second issue poses more difficulties of principle: what is it that makes a variation "immaterial"? In that connection, I consider that Hoffmann J's three questions in *Improver* [1990] FSR 181 provide helpful assistance, a view supported by the fact explained in paras 44 to 52 above that similar but not identical tests have been adopted in other EPC jurisdictions. However, each of the three questions requires some exegesis, and, particularly the second question, some reformulation.

60. The first *Improver* question, which asks whether the variant has a material effect on the way in which the invention works, seems generally satisfactory. It is a question which was framed in the context of a mechanical patent, and is not wholly aptly expressed for every type of case. However, in practice, the question as framed by Hoffmann J, with its emphasis on how "the invention" works, should correctly involve the court focussing on the "the problem underlying the invention", "the inventive core", or "the inventive concept" as it has been variously termed in other jurisdictions. In effect, the question is whether the variant achieves the same result in substantially the same way as the invention. If the answer to that question is no, then it would plainly be inappropriate to conclude that it could infringe. If, by

contrast, the answer is yes, then it provides a sound initial basis for concluding that the variant may infringe, but the answer should not be the end of the matter.

61. The second *Improver* question is more problematic. In my view, it imposes too high a burden on the patentee to ask whether it would have been obvious to the notional addressee that the variant would have no material effect on the way in which the invention works, given that it requires the addressee to figure out for himself whether the variant would work. The facts of the present case serve to make that proposition good. As Floyd LJ explained in para 65 of his judgment below, because a chemist "would not be able to predict the effect of [a] substitution [for the sodium counter-ion] without testing at least the solubility of the [active ingredient in the Actavis products]", it followed that "predicting in advance whether any particular counter-ion would work was not possible", and therefore that the second *Improver* test could not be answered yes. However, as mentioned in para 25(i) above, salt screening is a routine exercise in determining suitability, and as Floyd LJ said, "the chemist would be reasonably confident that he would come up with a substitute for the sodium counter-ion". In those circumstances, given that the inventive concept of the patent is the manufacture of a medicament which enables the pemetrexed anion to be administered with vitamin B12, it appears to me that application of the second *Improver* question fails to accord "a fair protection for the patent proprietor" as required by article 1 of the Protocol.

62. In my opinion, the second question is better expressed as asking whether, on being told what the variant does, the notional addressee would consider it obvious that it achieved substantially the same result in substantially the same way as the invention. In other words, it seems to me that the second *Improver* question should be asked on the assumption that the notional addressee knows that the variant works to the extent that it actually does work. That, I think, would be a fair basis on which to proceed in terms of balancing the factors identified in article 1 of the Protocol, and it is, I think, consistent with the approach of the German, Italian and Dutch courts. It is also consistent with the fact that the notional addressee is told (in the patent itself) what the invention does.

63. This reformulated second question should also apply to variants which rely on, or are based on, developments which have occurred since the priority date, even though the notional addressee is treated as considering the second question as at the priority date. Such an approach is supported by the desirability of both consistency of approach and pragmatic justice. It seems right in principle to have the same question, including the same assumption (ie that the variant works) for all cases. As to pragmatism, the point is touched on by Judge Kalden in the passage quoted at the end of para 51 above: while the notional addressee may answer the reformulated second question affirmatively even where the variant was unforeseeable at the priority date, he is less likely to do so than in relation to a variant which was unforeseeable as at that date.

64. The second test applied by the German courts, as I understand it, at least sometimes appears to require the variation not to be inventive, but I am not sure that that is an appropriate requirement, although it is unnecessary to decide that point on this appeal. If the variation represents an inventive step, while it may render it less likely that the patentee will succeed on the second reformulated question, I find it hard to see why that alone should prevent the resultant variant from infringing the original invention. It may entitle the infringer to a new patent, in the same way as the invention of a novel use for a patented invention can itself be patented, but like such a novel use I see no reason why the variant should not infringe the original patent. Having said that, it should be added that the German version of the second test will, I suspect, usually produce the same result as the reformulated second question.

65. The third *Improver* question as expressed by Hoffmann J is whether the notional addressee would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. That is in my view an acceptable test, provided that it is properly applied. In that connection, I would make four points. First, although "the language of the claim" is important, consideration of the third question certainly does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have. Secondly, the fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question. Hence, the fact that the rubber rod in *Improver* [1990] FSR 181 could not possibly be said to be "an approximation to a helical spring" (to quote from p 197) was not the end of the infringement issue even in Hoffmann J's view: indeed, as I have already pointed out, it was because the rubber rod could not possibly be said to be a helical spring that the allegedly infringing product was a variant and the patentee needed to invoke the three *Improver* questions. Thirdly, when considering the third question, it is appropriate to ask whether the component at issue is an "essential" part of the invention, but that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. So, in *Improver* [1990] FSR 181, 197, Hoffmann J may have been (and I mean "may have been") wrong to reject the notion that "the spring could be regarded as an 'inessential'": while it was undoubtedly essential to the functioning of the "Epilady", the correct question was whether the spring would have been regarded by the addressee as essential to the inventive concept, or inventive core, of the patent in suit. Fourthly, when one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is, as explained in para 63 above, necessary to imbue the notional addressee with rather more information than he might have had at the priority date.

66. In these circumstances, given the weight that has been given by courts in this jurisdiction (and indeed in some other jurisdictions) to the three "*Improver*

questions", I think it must be right for this court to express in our own words our reformulated version of those questions. In doing so, it is right to emphasise, as Lord Hoffmann did in *Kirin-Amgen* [2005] RPC 9, para 52, that these questions are guidelines, not strict rules (as indeed the Oberlandesgericht indicated in Case No 6 U 3039/16, when saying that it was "generally" true that "three requirements must be met"). While the language of some or all of the questions may sometimes have to be adapted to apply more aptly to the specific facts of a particular case, the three reformulated questions are as follows:

> i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?
>
> ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
>
> iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

Provisional conclusion on direct infringement in the UK

67. Given that the Actavis products do not infringe on the basis of a normal interpretation of claim 1 of the Patent, it is necessary to consider whether they represent an immaterial variation on that claim. I propose to address that issue initially disregarding the prosecution history, and having reached a provisional conclusion, I will then address that history and its effect on the provisional conclusion.

68. In my view, application in the present case of the three questions just identified results in the conclusion that the Actavis products infringe. So far as the first question is concerned, there can be no doubt but that those products work in the same way as the invention: they all ultimately involve a medicament containing the pemetrexed anion and vitamin B12. Thus, they achieve substantially the same result

in substantially the same way as the invention. Indeed, as in the Court of Appeal, Actavis realistically accept that the first question is to be answered yes.

69. As to the second question, it seems to me clear that the notional addressee of the Patent would appreciate (and would have appreciated as at the priority date) that each of the Actavis products would work in precisely the same way as pemetrexed disodium when included in a medicament with vitamin B12. When it comes to different versions of pemetrexed medicaments, it is clear that the use of a free acid, and of ditromethamine and dipotassium salts was in each case well established as at the priority date - see para 26(ii) to (iv) above. Furthermore, the notional addressee of the Patent would regard investigating whether pemetrexed free acid, pemetrexed ditromethamine or pemetrexed dipotassium worked as a purely routine exercise - see para 25(i) above. The reason why I differ from the Court of Appeal and Arnold J on this second question is that, in accordance with the second question as formulated in *Improver* [1990] FSR 181, 189, they considered that the notional addressee should not be treated as knowing that the Actavis products did in fact work at all, whereas, as explained above, that seems to me to involve too strict a test.

70. Turning to the third question, the Court of Appeal considered that the notional addressee "would understand that the patent was clearly limited to the disodium salt, and did not extend to the diacid, or the dipotassium or ditromethamine salts". They based this conclusion on the fact that the specification of the Patent contains a number of passages (eg in Para [0022] of the specification, quoted in para 19 above) which refer to "anti-folates" and the like and other passages which refer to pemetrexed disodium, which is "a highly specific chemical compound", and the fact that the claim is limited to pemetrexed disodium would therefore lead the notional addressee to conclude that the claim is indeed intended to be so limited (see paras 71 and 72 of Floyd LJ's judgment).

71. In my opinion, the Court of Appeal adopted an approach which places too much weight on the words of the claim and not enough weight on article 2 of the Protocol (and it is only right to add that, in doing so, they were, like Arnold J at first instance, following Lord Hoffmann's guidance in *Kirin-Amgen* [2005] RPC 9). Thus, when considering the third test, Floyd LJ made the point at para 72(ii) of his judgment that "there is no obvious leeway as a matter of language for giving it a broad as opposed to a narrow construction". That seems to me to demonstrate the risk of treating the issue raised by the third question as being one of normal interpretation. (Another way of looking at the point is, in the language of Sir Hugh Laddie, that it involves wrongly conflating the issue of interpretation with the issue of scope of protection.) As already explained, if it was a decisive point it would make a nonsense of asking the three questions: if one cannot depart from the language of the claim when considering those questions, what is the point of the questions in the first place?

72. More specifically, I do not agree with the Court of Appeal's view that, because the specification referred to "anti-folates" and "anti-folate drugs", the fact that the claims were limited to pemetrexed disodium means that the drafter of the Patent would have been understood to intend that the other pemetrexed compounds would not infringe. As Mr Mitcheson QC contended in his well argued case, the point is neutral because there is no reference to pemetrexed salts as a class in the specification, and the contrast therefore does not help on the question whether pemetrexed salts other than pemetrexed disodium were intended to be excluded.

73. Further, contrary to the Court of Appeal's reasoning, I would have thought that if the specification had not referred to anti-folates but had only referred to pemetrexed disodium, that would have been a more powerful indication that the patentee was intending to limit himself to pemetrexed disodium. The very fact that the specification teaches that there are other anti-folate drugs which have a similar effect to pemetrexed disodium (coupled with the fact that it was generally known that cations other than sodium could be successfully used with anti-folates) highlights a point similar to that made by Lord Diplock in *Catnic* [1982] RPC 183, 244, namely "No plausible reason has been advanced why any rational patentee should want to place so narrow a limitation on his invention" as to limit the scope of protection afforded by the Patent to pemetrexed disodium - a telling but not always conclusive point. Additionally, there is no teaching in the specification which relates to the relevance or importance of the sodium cation.

74. Looking at matters more broadly, the addressee of the Patent would, as I see it, understand that the reason why the claims were limited to the disodium salt was because that was the only pemetrexed salt on which the experiments described in the specification had been carried out. However, it does not follow that the patentee did not intend any other pemetrexed salts to infringe: the suggestion confuses the disclosure of the specification of a patent with the scope of protection afforded by its claims. Particularly given the facts set out in para 25 above, it seems to me very unlikely that the notional addressee would have concluded that the patentee could have intended to exclude any pemetrexed salts other than pemetrexed disodium, or indeed pemetrexed free acid, from the scope of protection.

75. Accordingly, I would conclude that, subject to considering the prosecution history, the Actavis products infringe claim 1 of the Patent.

The effect of the prosecution history

76. The application for the patent was filed at the EPO in June 2001, and it contained claims directed to a method of treatment, claims in Swiss form, and purpose-related product claims. In January 2003, Dr Burnside, Lilly's patent

attorney, filed a revised set of claims which omitted the method of treatment claims. Claims 1 and 2 were as follows:

> "1. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate.
>
> 2. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate and a FBP binding agent."

Claim 10 was a dependent claim "wherein the antifolate is ALIMTA".

77. As Floyd LJ said, these claims are in the reverse order from the claims ultimately granted (as they start with the use of the methylmalonic lowering agent rather than pemetrexed disodium), but nothing hangs on that. The essential point is that these claims were entirely general as to the identity of the antifolate. In March 2004, the EPO examiner wrote raising various objections including some under articles 83 and 84 EPC 2000 (disclosure and clarity). The clarity and lack of disclosure objections were that the claims related to too many possible combinations of compounds by using general expressions such as "antifolate", "methylmalonic acid lowering agent" and "FBP binding agent". Moreover, the examiner was concerned that the claims covered all compounds having these characteristics or properties, whereas the application provided support and disclosure for only a very limited number of such compounds.

78. Dr Burnside replied in a letter of December 2004, under cover of which he filed new claims 1 and 2, this time starting with the use of the antifolate, now limited to "pemetrexed" in these terms:

> "1. Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.
>
> 2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a

> pharmaceutical derivative thereof and a folic binding protein binding agent [which was then defined].”

In support of these new claims, Dr Burnside said that, “in order to expedite the application proceeding to grant”, Lilly had elected to amend the claims so as to reflect more closely the specific examples provided. However, he added, the amendments were made without prejudice to Lilly’s right to obtain protection for other patentable subject matter in one or more divisional applications.

79. Notwithstanding these amendments, in May 2005 the EPO examiner formally objected to the admissibility of the new claims. He contended that the amendments introduced subject matter beyond the content of the originally filed documents, contrary to article 123(2) EPC 2000. Thus, he said, the inclusion in claim 1 of “use of pemetrexed ...” and similar provisions in other claims did not find any basis in the application documents as filed. According to the examiner, “pemetrexed” was a distinct compound from pemetrexed disodium. (This is supported by the Chemical Abstracts Service Registry, where the “pemetrexed” is recorded as being the free diacid.) The patent does contain one mention of the term “pemetrexed” at para [0004] of the specification, followed by a Lilly reference number which shows it to be pemetrexed disodium. It was therefore, at best, uncertain as to what the term “pemetrexed” on its own was intended to refer.

80. Dr Burnside replied in March 2006 by a letter under cover of which he filed new claims, which this time were limited to pemetrexed disodium, and are now embodied in the claims of the Patent as set out in para 21 above. Dr Burnside said:

> “The Claims have been amended to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug. The Claims have also been amended to incorporate the list of vitamin B12 derivatives set out on p 7 lines 6-7 of the application as filed.”

The EPO examiner accepted the claims in this form, and the application proceeded to grant.

81. Actavis contends that the prosecution history, as summarised in paras 76 to 80 above, makes it clear that the claims of the Patent should be interpreted as being limited to pemetrexed disodium not only as a matter of language, but in the sense that the use of any other pemetrexed compound, including other pemetrexed salts and the free acid, could not infringe. This contention gives rise to two issues. The

first is one of relatively general application, namely whether and if so when it is permissible to have recourse to the prosecution history of a patent when considering whether a variant infringes that patent. The second issue is whether the prosecution history of the Patent in this case alters the provisional conclusion reached in para 75 above.

82. So far as the first issue is concerned, Lord Hoffmann said in *Kirin-Amgen* [2005] RPC 9, para 35:

> "The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed."

83. In the absence of good reason to the contrary, it would be wrong to depart from what was said by the House of Lords. It is said by Actavis that there is good reason to depart from what Lord Hoffmann said on the ground that he was wrong in his description of the German and Dutch approaches to this issue, and that anyway he failed to have regard to the jurisprudence of other European courts.

84. In my view, Lord Hoffmann was right about the approach of the German and Dutch courts to this issue. Thus, the Bundesgerichtshof, in a decision involving the German equivalent of the instant Patent, Case No X ZR 29/15 (*Eli Lilly v Actavis Group PTC*), paras 39-40, stated that "it is permissible … to use statements made by the applicant [and the examiner] during the grant procedure as an indication of how the person skilled in the art understands the subject matter of the patent" but "such indications cannot be readily used as the sole basis for construction". And in *Ciba-Geigy AG v Oté Optics BV* (1995) 28 IIC 748, the Dutch Supreme Court said that "a court will only be justified in using clarifying information from the public part of the granting file, when it holds that even after the average person skilled in the art has considered the description and the drawings, it is still open to question how the contents of the claims must be interpreted".

85. It is argued by Actavis that this limited approach to the circumstances in which reference can be made to the prosecution file may be more restrictive than the

approach adopted in France, Italy, and Spain, as analysed by Arnold J. Thus, he said in para 162 of his judgment, that the Cour d'Appel observed in Case No 08/00882, *Hewlett Packard GmbH v Agilent Technologies Deutschland GmbH* (27 January 2010) that "the patentee who amended its clauses to give them a limited scope may not, without putting the safety of third parties at risk, claim that the amendments were not necessary, nor that the limited claims have the same scope as the broader claims". However, the court in that case had already decided on the natural meaning of the patent, and the contents of the file were merely being invoked to confirm the decision. The position in Italy, according to Arnold J in para 174 of his judgment, is that "there is no doctrine of prosecution history estoppel" and "there is no clear rule as to the relevance, if any, of the prosecution history as an aid to the interpretation of claims". In Spain there is a doctrine of *actos propios*, which as Arnold J explained in para 184, is "the doctrine of one's own acts", but it only justifies relying on the prosecution file in relation to statements which are "unequivocal, clear, precise, conclusive, undoubted and [do] not reflect any kind of ambiguity".

86. While the French courts appear to be more ready to refer to the prosecution file on issues of interpretation or scope than the German or Dutch courts, it is unclear how much, if any, difference there is in outcome. The position in relation to the Italian courts is more unclear, and it may well be that the effect of the approach of the Spanish courts is the same in outcome as that of the German and Dutch courts. In those circumstances, particularly as it may be inevitable that there is a degree of difference in the approach of different national courts on such an issue, there is nothing in the French, Italian, or Spanish jurisprudence which causes me to depart from the conclusion expressed by Lord Hoffmann.

87. In my judgment, it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement, along substantially the same lines as the German and Dutch courts. It is tempting to exclude the file on the basis that anyone concerned about, or affected by, a patent should be entitled to rely on its contents without searching other records such as the prosecution file, as a matter of both principle and practicality. However, given that the contents of the file are publicly available (by virtue of article 128 EPC 2000) and (at least according to what we were told) are unlikely to be extensive, there will be occasions when justice may fairly be said to require reference to be made to the contents of the file. However, not least in the light of the wording of article 69 EPC 2000, which is discussed above, the circumstances in which a court can rely on the prosecution history to determine the extent of protection or scope of a patent must be limited.

88. While it would be arrogant to exclude the existence of any other circumstances, my current view is that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the

specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.

89. Turning to the second issue, I do not consider that the contents of the prosecution file in this case justify departing from the provisional conclusion expressed in para 75 above. It seems to me clear that the reason why the examiner considered that the claims in the patent should be limited to pemetrexed disodium was because the teaching in the specification did not expressly extend to any other anti-folates. It is unnecessary to decide the issue, but, at least as at present advised, I am inclined to think that the examiner was wrong in taking that view. Indeed, in the course of his well-presented argument for Actavis, Mr Alexander QC seemed to accept that Lilly could have expressed its claims more widely than it did (albeit that this was not a point which was carefully explored). However, even if the examiner was right or at least justified in taking the stance that he did, I do not consider that that consideration can have any bearing on the question whether any pemetrexed salts other than pemetrexed disodium should be within the scope of the patent pursuant to the doctrine of equivalents. The whole point of the doctrine is that it entitles a patentee to contend that the scope of protection afforded by the patent extends beyond the ambit of its claims as construed according to normal principles of interpretation.

90. This point was well made by the Dutch Court of Appeals in *Boston Scientific Ireland Ltd v Cordis Europa NV* 01/639 (unreported) 3 July 2003, when they held that the contents of the prosecution file were of no assistance, as they related to a concern which the examiner had expressed about added matter which went to disclosure, whereas that had no relevance to the point at issue which was the scope of the claim - which properly included equivalents.

91. I draw comfort from the fact that neither party was able to refer to a case where a French or Spanish Court had relied upon the patentee's response to a disclosure or added matter objection by the examining officer as being relevant to the scope of claim. It is true that the Madrid Appeal Court in *Inmobiliaria Masife SL v Vale y Tino SA* (decision 268/2013) (unreported) 27 September 2013 held that a patentee was bound by an exclusion which he had agreed during prosecution but that was "to overcome an objection of the examiner based on the prior art", a very different point. I draw even greater comfort from the fact that the Bundesgerichtshof reached the same conclusion on this very issue in relation to the German equivalent of the Patent in this case in Case No X ZR 29/15 (*Eli Lilly v Actavis Group PTC*), para 72.

Direct infringement in France, Italy and Spain

92. Having concluded that the Actavis products directly infringe the Patent as a matter of UK law, it is necessary to consider whether the same result obtains under French, Italian and Spanish law. In my judgment, direct infringement is established in those jurisdictions as well.

93. Turning first to French law, it appears to me that the answer to the question of direct infringement ultimately turns on whether the Patent in this case falls into the *moyens généraux* category or the *moyens particuliers* category, because, as discussed in para 46 above, the doctrine of equivalents is apparently only applicable to patent claims in the former category. With some diffidence, I have reached a different conclusion from Arnold J on this issue and have concluded that the Patent in this case falls into the former category. It is of course true that an appellate court should be very slow indeed to differ from the trial judge on a question of fact. However, the notion that the resolution of a dispute as to foreign law involves a factual finding rather than a legal conclusion is somewhat artificial, and in any event, the Judge did not hear any oral evidence from the expert foreign law witnesses. We are therefore in as good a position as he was to analyse the effect of the evidence as to foreign law.

94. The Judge considered that the Patent in this case represents a *moyen particulier*, because pemetrexed disodium was the relevant means and the Patent did not reveal it having a novel function: it merely revealed a new and better way in which its function could be achieved. To my mind the better analysis is that the Patent discloses that pemetrexed disodium could be used for a function for which it could not previously have been satisfactorily or safely used in practice; specifically, that pemetrexed disodium could be used with vitamin B12 to achieve an end which could not have been achieved by either chemical on its own, pemetrexed disodium because of its harmful side-effects and vitamin B12 because it would not have worked. The essential point, as I see it, is that the Patent revealed for the first time the existence of a combined means which functioned in a certain way, namely to alleviate certain cancers without serious side-effects. It would be different if the overall function of the combination of the two chemicals had not been new.

95. Support for this conclusion appears in the book referred to in para 46 above, *Droit de la propriété industrielle*, whose two authors were the expert witnesses on French law in this case. At para 719, p 443, they wrote "when the claim is over a combination of means for which global function is novel, any combination of means with a different structure but achieving the same global function is a priori equivalent and thus infringing". That passage was effectively applied by the Cour de Cassation in Appeal P08-14741, *Diffusion Equipements Loisirs v Helge*, 15 September 2009.

96. As to Italian law, Arnold J said at paras 178 and 179 of his judgment that he had concluded that the Actavis products did not infringe the Italian designation of the Patent on two grounds. The first (which he only accepted with "some hesitation") was "because on its face the patent clearly demonstrated a conscious intention of the patentee to limit the claims to pemetrexed disodium". The second ground was "because if there was any doubt about that, it was amply confirmed by the prosecution history". It is clear that (as one would expect) the Italian courts accept the doctrine of equivalents, and accordingly for the reasons given in paras 70 to 74 above, I would reject the first ground; and, for the reasons given in paras 91 to 93 above, I would reject the second ground also.

97. So far as Spanish law is concerned, it is common ground that the Spanish courts have followed the United Kingdom approach, which leads to the difficult question whether one should assume that they would follow this decision in modifying the *Improver* questions and in particular the second question. I incline to the view that judicial comity would tend to suggest that the Spanish courts would follow this court in modifying the *Improver* questions, not least because this appears to render the UK courts and therefore the Spanish courts more consistent with the German and Dutch courts, and no more inconsistent with the French and Italian courts.

98. In a written note dated 10 July 2017, Actavis applied for what would amount to a reconsideration of the conclusion expressed in para 97 above, on the ground that the reasoning of the Spanish Tribunal Supremo in the *Lundbeck* decision, discussed in para 50 above, should lead to the opposite conclusion, namely that marketing Actavis's products in Spain would not infringe the Patent.

99. In my view, it is too late for Actavis to raise such an argument. Lilly had sought to rely on the *Lundbeck* decision in its written case in this appeal, and Actavis had objected on the ground that the decision had been given after the Court of Appeal decision in these proceedings. It seems to me that in these circumstances it would be wrong to permit Actavis to raise the *Lundbeck* decision to support their case, especially as they are seeking to do so after knowing the result of this appeal and the reasons for that result. I am unimpressed by Actavis's argument that their application is nonetheless justified because the reasoning in para 97 above was not raised on this appeal. Actavis's written case stated that "Spanish law has been directly modelled on *Catnic* and *Improver*", and in paras 182 and 187 of his judgment on this case Arnold J effectively treated the *Improver* questions as part of Spanish law. It appears to me that the conclusion that, if the UK Supreme Court modifies the *Improver* questions, the Spanish courts would adopt any such modification, was therefore within the scope of the argument raised in this Court.

100. Furthermore, I consider that it would be wrong for Actavis to be permitted to raise a new ground in support of their contention that their products would not infringe in Spain, after publication of our decision, which was done with their consent and at their instigation following receipt of our draft judgment which concluded that their products would infringe in Spain. It is not as if Actavis had come across new information since they had agreed to that publication. It is true that, as explained in para 2 above, Actavis's solicitors wrote to the Court very shortly after they received the draft judgment, but thereafter they had nearly a full 24 hours within which they could have withdrawn their agreement to publication of our decision. In any event, there is obvious force in the simple point that, having agreed to publication of the decision in advance of the handing down of the judgment, they have to take the consequences. I do not suggest that, in every case where the decision is published with the consent of the parties after they have seen the draft judgment, it would be impossible for either party to invite the court to change the decision, or any aspect of it. However, it seems to me that, in the absence of a good reason, the interests of finality and certainty should prevail, and I do not consider that Actavis have come up with a good enough reason in this case.

101. It is right to add that I am by no means convinced that, even if we had permitted Actavis to re-argue their case in relation to Spain, on the basis of the *Lundbeck* decision, I would have reached a different conclusion from that expressed in para 97 above. Quite what constitutes "a degree of predictability" or "a high probability" when it comes to assessing whether the notional addressee would expect the variant to work must be fact-sensitive. Further, if, as seems likely but not, I accept, certain, the German, Dutch, French and Italian courts would all hold that Actavis's products infringed, there would have been much to be said for the view, which I have already expressed, that the Spanish courts would follow suit.

102. Accordingly, I would hold that the French, Italian and Spanish designations of the Patent are also directly infringed by the Actavis products.

Indirect infringement

103. In these circumstances, Actavis's cross-appeal, which seeks to challenge the Court of Appeal's conclusion that its products indirectly infringed does not, I think, arise in the sense that it has no practical effect on the parties (other, perhaps, than on the issue of costs). However, as the point was fully argued, gave rise to a disagreement between the Court of Appeal and the trial judge, and can be dealt with shortly, it is appropriate to consider it.

104. Indirect infringement is provided for in section 60(2) of the 1977 Act, and it states that a person infringes a patent if, without the patentee's consent, he supplies

or offers to supply in the United Kingdom to someone not authorised by the patentee with "any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect".

105. The reason why Lilly contends that, even if they did not directly infringe, the Actavis products would indirectly infringe is because, when they are supplied to a doctor or a pharmacist, they are, as Actavis would know, dissolved in a saline solution in order to enable them to be administered to patients. Saline is a solution of common salt, ie sodium chloride, in water, and when common salt is dissolved in water, it separates into sodium cations and chloride anions. Accordingly, when one of Actavis's products, say that containing pemetrexed dipotassium, is dissolved in saline, the solution contains pemetrexed anions and potassium cations plus sodium cations and chloride anions. In those circumstances, argues Lilly, even if pemetrexed dipotassium would not of itself infringe if it was administered with vitamin B12, at least provided that the ratio of sodium ions to pemetrexed ions was at least 2:1, there will be infringement when it is administered in saline solution, because the solution which is administered will contain pemetrexed disodium.

106. The Court of Appeal, disagreeing with the Judge, acceded to Lilly's argument on this point.

107. Actavis argue that a solution consisting of, or including, pemetrexed ions and sodium ions is not within the expression "pemetrexed disodium" in the Patent, because it is limited to the solid, or crystalline, chemical. I agree with Floyd LJ in rejecting that argument. There is no reason to think that the patentee intended to limit the expression in that way; quite the contrary. It is clear that solubility was an important issue, and indeed that was one of the two main reasons on which Actavis rested their contention that their products did not infringe, as discussed in paras 24 to 25, 59, and 66 above. Further, and even more in point, as Floyd LJ said, in the passages quoted in para 19 above the specification made it clear that references to pemetrexed disodium extended to that chemical in solution.

108. Actavis also argue that there is an inconsistency between the Court of Appeal holding, when considering direct infringement, that the notional addressee could not be assumed to know that pemetrexed dipotassium would dissolve, and holding, when considering indirect infringement, that pemetrexed dipotassium did in fact dissolve. Even if I had not concluded that the notional addressee should be treated as knowing that pemetrexed dipotassium could dissolve, I would have rejected that argument which seems to me to involve a non-sequitur. By the time that they were ready to market their products, Actavis knew perfectly well that they were all soluble.

109. Actavis further argue that a solution of pemetrexed dipotassium dissolved in saline does not in any event contain "pemetrexed disodium" within the meaning of that term in the Patent; it is simply pemetrexed dipotassium dissolved in saline. In my view that is a bad point. If dissolving pemetrexed disodium in an aqueous solution of potassium chloride can be said to result in a solution containing pemetrexed disodium (as Actavis's argument impliedly accepts), then it must follow as a matter of elementary chemical logic that dissolving pemetrexed dipotassium in saline also result in a solution which contains pemetrexed disodium: the two solutions are chemically identical, as each would consist of potassium and sodium cations and chloride and pemetrexed anions in water.

110. Actavis additionally argue that it is irrational to hold that there could be indirect infringement because it would all depend on the solvent in which the Actavis product is dissolved, and, even if that solvent was saline, it would depend on the proportion of sodium ions and pemetrexed ions in the solution which would vary by reference to the weight of the patient. The fact that infringement may depend on the nature of solvent and the relative amounts of ions in the solution does not seem to me to be irrational. It is simply a result of the extent of the scope of protection afforded by the patent given that (as determined by the Court of Appeal) its claims are limited to pemetrexed disodium, which, when dissolved in water produces two sodium cations to every one pemetrexed anion.

111. Finally, Actavis argue that, rather than being used in the manufacture of a medicament as described in claim 1 of the Patent, pemetrexed disodium is part of the medicament. Like the Court of Appeal, I do not agree. The pemetrexed disodium comes into the manufacturing process rather later than it would if the original medicament included pemetrexed disodium rather than pemetrexed dipotassium, but that cannot alter the fact that, before it is administered to the patient, the medicament includes pemetrexed disodium and vitamin B12.

112. Accordingly, I would uphold the Court of Appeal's determination that Actavis are liable to Lilly for indirect infringement in the United Kingdom with respect to their products if Actavis know, or it is obvious in the circumstances, that ultimate users will dilute in saline - or at least Actavis would be liable for indirect infringement if they were not liable for direct infringement. The Court of Appeal said that this conclusion would apply equally to France, Italy, and Spain, and there is no challenge to that from Actavis.

Conclusion

113. For these reasons, I would (i) allow Lilly's appeal in direct infringement and hold that the Actavis products infringe the Patent in the United Kingdom, and also

in France, Italy and Spain, (ii) dismiss Actavis's cross-appeal on the basis that if its products did not directly infringe, they would indirectly infringe to the extent held by the Court of Appeal.

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NOTIFICACIÓN

04 JUL 2011

TRIBUNAL SUPREMO
Sala de lo Civil
PLENO

Presidente Excmo. Sr. D. Juan Antonio Xiol Ríos

SENTENCIA

Sentencia Nº: 309/2011
Fecha Sentencia: 10/05/2011
CASACIÓN
Recurso Nº: 575/2008
Fallo/Acuerdo: Sentencia Desestimando
Votación y Fallo: 11/04/2011
Ponente Excmo. Sr. D.: Jesús Corbal Fernández
Procedencia: AUD. PROVINCIAL BARCELONA, SECC. 15ª
Secretaría de Sala: Ilma. Sra. Dña. María Angeles Bartolomé Pardo
Escrito por: RSJ

PROPIEDAD INDUSTRIAL. PATENTES. Patente europea farmacéutica. Extensión de la patente: reivindicaciones: doctrina de los equivalentes. Aplicabilidad del Acuerdo sobre los ADPIC. Incompatibilidad entre el art. 167.5 CPE, de aplicación en virtud de la Reserva de España al CPE, y los arts. 27.1 y 70.2 del Acuerdo-ADPIC.

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CASACIÓN Num.: **575/2008**
Ponente Excmo. Sr. D.: **Jesús Corbal Fernández**
Votación y Fallo: **11/04/2011**
Secretaría de Sala: **Ilma. Sra. Dña. María Angeles Bartolomé Pardo**

TRIBUNAL SUPREMO
Sala de lo Civil
PLENO

SENTENCIA Nº: **309/2011**

Excmos. Sres.:

D. Juan Antonio Xiol Ríos
D. Xavier O'Callaghan Muñoz
D. Jesús Corbal Fernández
D. Francisco Marín Castán
D. José Antonio Seijas Quintana
D. Antonio Salas Carceller
Dª. Encarnación Roca Trías
D. Román García Varela

En la Villa de Madrid, a diez de Mayo de dos mil once. Visto por la Sala Primera del Tribunal Supremo, integrada por los Magistrados al margen indicados, el recurso de casación interpuesto respecto la Sentencia dictada en grado de apelación por la Audiencia Provincial de Barcelona, Sección Decimoquinta, como consecuencia de autos de Juicio Ordinario seguidos ante el Juzgado de lo Mercantil Número Tres de Barcelona, sobre nulidad parcial de patente de invención; cuyo recurso fue interpuesto por las entidades LABORATORIOS CINFA, S.A., LABORATORIOS ALTER, S.A. y KERN PHARMA, S.L., representadas por el Procurador D. Anibal Bordallo Huidobro; siendo parte recurrida, la entidad ELI LILLY AND COMPANY LIMITED, representada por la Procurador Dª. María Dolores Girón Arjonilla.

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ANTECEDENTES DE HECHO

PRIMERO.- 1.- El Procurador D. Ignacio López Chocarro, en nombre y representación de las entidades Laboratorios Cinfa, S.A., Kern Pharma, S.L. y Laboratorios Alter, S.A., interpuso demanda de juicio ordinario ante el Juzgado de lo Mercantil Número 3 de Barcelona, siendo parte demandada la entidad "Eli Lilly and Company Limited", sobre declaración de no-violación y de nulidad parcial de patente de invención; alegando los hechos y fundamentos de derecho que estimó aplicables para terminar suplicando al Juzgado dictase en su día Sentencia "por la que: 1.- Se declare que la explotación por CINFA, KERN y ALTER de olanzapina obtenida por el "procedimiento DRL" no constituye una violación de las reivindicaciones 1 a 4 de la patente EP 454.436 - ES 2.078.440 de LILLY. 2.- Se declare la nulidad de la reivindicación 5 de dicha patente y, en consecuencia, se ordene su cancelación en la Oficina Española de Patentes y Marcas. 2.1.- Subsidiariamente, sólo para el caso de que se desestimara el anterior pedimento número 2, se declare que la explotación por CINFA, KERN y ALTER de medicamentos de olanzapina no constituye una violación de la reivindicación 5 de la patente de LILLY, toda vez que dicha reivindicación no surte efectos. 3.- Se condene a LILLY al pago de las costas del juicio.".

2.- El Procurador D. Angel Quemada Cuatrecasas, en nombre y representación de la entidad Eli Lilly and Company Limited, contestó a la demanda alegando los hechos y fundamentos de derecho que estimó aplicables para terminar suplicando al Juzgado dictase en su día Sentencia "por la que se desestime íntegramente la demanda presentada por las entidades Laboratorios Cinfa, S.A., Laboratorios Alter, S.A. y Kern Pharma, S.A., con imposición a las entidades actoras de las costas causadas.".

3.- Recibido el pleito a prueba, se practicó la que propuesta por las partes fue declarada pertinente. Unidas a los autos las partes evacuaron el trámite de resumen de prueba en sus respectivos escritos. El Juez de lo

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Mercantil Número Tres de Barcelona, dictó Sentencia con fecha 16 de octubre de 2.006, cuya parte dispositiva es como sigue: "FALLO: Desestimando la demanda interpuesta por la representación en autos de las entidades mercantiles KERN PHARMA, S.L. LABORATORIOS ALTER, S.A. y LABORATORIOS CINFA, S.A. se absuelve a la entidad mercantil ELI LILLY & CO LTD de lo pretendido de contrario. Cada parte asumirá sus costas y las comunes por mitad.".

SEGUNDO.- Interpuesto recurso de apelación contra la anterior resolución por la representación de las entidades actoras, la Audiencia Provincial de Barcelona, Sección Decimoquinta, dictó Sentencia con fecha 17 de enero de 2.008, cuya parte dispositiva es como sigue: "FALLAMOS: Que desestimando el recurso de apelación interpuesto por la representación de LABORATORIOS CINFA, S.A., LABORATORIOS ALTER, S.A. y KERN PHARMA, S.L. contra la sentencia dictada con fecha 16 de octubre de 2006 por el Juzgado de lo Mercantil nº 3 de Barcelona, cuya parte dispositiva obra transcrita en los antecedentes de la presente resolución. CONFIRMAMOS íntegramente dicha resolución, sin efectuar condena por las costas de la alzada.".

TERCERO.- El Procurador D. Ignacio López Chocarro, en nombre y representación de las entidades Laboratorios Cinfa, S.A., Laboratorios Alter, S.A. y Kern Pharma, S.A., interpuso recurso de casación ante la Audiencia Provincial de Barcelona, Sección Decimoquinta, respecto la Sentencia dictada en grado de apelación de fecha 17 de enero de 2.008, con apoyo en los siguientes motivos, **MOTIVOS DEL RECURSO:** PRIMERO.- Se alega infracción del art. 26 y 60.1 de la Ley de Patentes, los arts. 84 y 69 del Convenio sobre concesión de Patentes Europeas (CPE) y el Protocolo interpretativo de este último y el art. 9.3 CE. SEGUNDO.- Se alega infracción de la Reserva española al CPE ex art. 167.2.a) del mismo, el art. 167.5 CPE, la Disposición Transitoria 1ª LP, el art. 70.1 del Acuerdo ADPIC, los arts. 28 y 30.2 de la Convención de Viena de 1969 sobre el Derecho de los Tratados, el art. 9.3 CE y el art. 2.3 del Código Civil, al aplicar retroactivamente los arts. 27 y 70.2 del Acuerdo ADPIC. TERCERO.- Se denuncia infracción del art. 3.1 del Código Civil.

CUARTO.- Por Providencia de fecha 11 de marzo de 2.008, se tuvo por interpuesto el recurso de casación anterior, y se acordó remitir las actuaciones

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a la Sala Primera del Tribunal Supremo, con emplazamiento de las partes ante la misma.

QUINTO.- Recibidas las actuaciones en esta Sala, comparecen, como parte recurrente, las entidades LABORATORIOS CINFA, S.A., LABORATORIOS ALTER, S.A. y KERN PHARMA, S.L., representadas por el Procurador D. Anibal Bordallo Huidobro; y como parte recurrida, la entidad ELI LILLY AND COMPANY LIMITED, representada por la Procurador Dª. María Dolores Girón Arjonilla.

SEXTO.- Por esta Sala se dictó Auto de fecha 7 de julio de 2.009, cuya parte dispositiva es como sigue: "ADMITIR EL RECURSO DE CASACIÓN interpuesto por la representación procesal de LABORATORIOS CINFA S.A, KERN PHARMA S.L Y LABORATORIOS ALTER S.A, contra la Sentencia dictada, en fecha 17 de enero de 2008, por la Audiencia Provincial de Barcelona (Sección 15ª), en el rollo de apelación nº 368/2007 dimanante de los autos de juicio ordinario nº 601/2005, del Juzgado de Primera Instancia nº 3 de Barcelona.".

SEPTIMO.- Dado traslado, la Procurador Dª. María Dolores Girón Arjonilla, en nombre y representación de la entidad Eli Lilly and Company Limited, presentó escrito de impugnación al recurso formulado de contrario.

OCTAVO.- No habiéndose solicitado por todas las partes la celebración de vista pública, se acordó por Providencia de la fecha 24 de marzo de 2.011 someter el recurso al conocimiento del Pleno de la Sala, acto para el que se señaló el día 11 de abril de 2.011, en el que efectivamente se celebró.

Ha sido ponente el Excmo. Sr. D. **JESÚS CORBAL FERNÁNDEZ**,

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FUNDAMENTOS DE DERECHO

PRIMERO.- El objeto del proceso versa sobre Propiedad Industrial, y en concreto sobre protección de patente europea. Se plantean, como cuestiones más importantes, la aplicación de la doctrina de los equivalentes en orden a la extensión de la protección de una patente farmacéutica de selección que reivindica la Olanzapina, que es un medicamento de singular utilidad en el tratamiento de trastornos del sistema nervioso central, y la incidencia del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) -Anexo 1C del Acuerdo por el que se estableció la Organización Mundial de Comercio (OMC), BOE núm. 20, de 24 de enero de 1995- en los efectos de la Reserva de España al Convenio Europeo de Patentes (CPE) en relación con las patentes de productos farmacéuticos.

Por las entidades mercantiles LABORATORIOS CINFA, S.A., KERN PHARMA, S.L. y LABORATORIOS ALTER, S.A. se dedujo demanda sobre declaración de no violación y de nulidad parcial de patente de invención contra la compañía británica ELI LILLY AND COMPANY LIMITED en la que solicita: 1. Se declare que la explotación por CINFA, KERN y ALTER de la Olanzapina obtenida por el "Procedimiento DRL" no constituye una violación de las reivindicaciones 1 a 4 de la patente EP 454.436 - ES 2.708.440 de LILLY; 2. Se declare la nulidad de la reivindicación 5 de dicha patente y, en consecuencia, se ordene su cancelación en la Oficina Española de Patentes y Marcas; y 2.1. subsidiariamente solo para el caso de que se desestimara el anterior pedimento número 2, se declare que la explotación por CINFA, KERN y ALTER de medicamentos de Olanzapina no constituye una violación de la reivindicación 5 de la patente de LILLY, toda vez que dicha reivindicación no surte efectos. La demanda está relacionada con la fabricación y comercialización de medicamentos antipsicóticos a base de Olanzapina para el tratamiento de desórdenes del sistema nervioso central, esquizofrenia, estados de ansiedad, etc. La patente europea fue solicitada el 24 de abril de 1991 con fecha de prioridad 1990, publicada en la Oficina Europea de Patentes -OEP- (EPO) el 30 de octubre de 1991; concedida el 3 de agosto de 1995 y validada en España (publicación en el BOPI) el 16 de diciembre de 1995. La patente fue transferida en el año 1998 por LILLY INDUSTRIES LIMITED a la entidad (aquí demandada) ELI LILLY AND COMPANY LIMITED.

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La Sentencia dictada por el Juzgado de lo Mercantil número 3 de Barcelona el 16 de octubre de 2006, en los autos de juicio ordinario número 601 de 2005, desestima la demanda y absuelve a la entidad demandada.

La Sentencia dictada por la Sección 15ª de la Audiencia Provincial de Barcelona el 17 de enero de 2008, en el Rollo número 368 de 2007, desestima el recurso de apelación de las actoras y confirma la resolución del Juzgado de lo Mercantil, sin efectuar condena en las costas de la alzada.

Contra esta última Sentencia se interpuso por Laboratorios Cinfa S.A., Kern Pharma S.L. y Laboratorios Alter S.A. recurso de casación articulado en tres motivos, que fue admitido por Auto de esta Sala del 7 de julio de 2009, aclarado por Auto de 13 de octubre de 2009.

SEGUNDO.- En el motivo primero del recurso se alega infracción de los artículos 26 y 60.1 de la Ley de Patentes y 84 y 69 del Convenio sobre concesión de patentes europeas y del Protocolo Interpretativo de este último y del artículo 9.3 CE (seguridad jurídica), al aplicar los referidos preceptos de la LP y del CPE en contradicción con la jurisprudencia del Tribunal Supremo que tiene declarado que la extensión de la protección conferida por una patente se determina por el contenido de las reivindicaciones, y ello por elementales razones de seguridad jurídica.

El planteamiento del motivo parte de la base de que son las reivindicaciones de la patente las que determinan la extensión o alcance de la protección conferida, y que la descripción o memoria descriptiva tiene solo una función interpretativa. Y fundamenta la alegación en los arts. 26 y 60 de la LP, 84 y 69 del CPE y 1 del Protocolo Interpretativo del art. 69 CPE, y en la doctrina jurisprudencial de esta Sala (SS. de 22 y 28 de abril y 1 de diciembre de 2005). A continuación se hace referencia a que el procedimiento que se pretende utilizar para fabricar la olanzapina (el IDRL) es el de alquilación -adición en dos pasos-, el cual no está recogido en la patente de LILLY que solo describe y reivindica el de adición en un solo paso, por lo que aquél queda fuera del alcance de las reivindicaciones de procedimiento 1 a 4 de la EP 454.436 - ES 2.708.440. A lo dicho añade que no cabe la aplicación de la "doctrina de los equivalentes" porque (i) la LP y el CPE establecen, expresa y claramente, por elementales razones de seguridad jurídica, que el alcance de la protección que confiere una patente viene determinada por el contenido de las reivindicaciones interpretadas a la vista de la descripción; (ii) que tanto el Juzgado como la Audiencia han considerado probado que la patente de LILLY no describe ni reivindica en absoluto un procedimiento de

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alquilación para la obtención de olanzapina, sino únicamente un procedimiento de adición en un solo paso; (iii) la sentencia de la Audiencia considera probado que en la patente de LILLY hay una "exclusión explícita" del procedimiento de alquilación; y, (iv) que no se está hablando de un solo elemento diferente, ni de una variante del mismo procedimiento, sino de dos procedimientos diferentes. Y finalmente insiste en que el principio de seguridad jurídica constituye un límite a la aplicación de la doctrina de los equivalentes y que la protección de la patente comprende el contenido de lo reivindicado, y no lo que el titular ha pretendido proteger.

La patente de LILLY de 1991 -EP 454.436 (Es 2078440)- es una invención de selección que registra el compuesto "olanzapina" incluyendo un procedimiento con dos variantes: la ciclación (que aquí no interesa) y la adición de un solo paso. Las entidades demandantes se proponen comercializar un genérico de olanzapina para lo que pretenden importar un compuesto, fabricado por la entidad de la India (que identificaremos como DRL) cuyo procedimiento de obtención es el de alquilación o adición en dos pasos, que no aparece en la reivindicación de LILLY expresada pero sí lo estaba en una patente anterior de esta sociedad. La diferencia entre los dos procedimientos consiste en que para obtener la olanzapina se hace reaccionar un compuesto de partida con piperacina y metilo, y en tanto en el procedimiento de "un paso" la reacción tiene lugar con piperacina metilada, en el de "dos pasos" se añade al compuesto de partida la piperacina y posteriormente se alquila el grupo metilo. Para los demandantes se trata de dos procedimientos distintos, aparte de que los productos de partida son diferentes, en tanto para la demandada el procedimiento de LILLY es único y también lo es el producto de partida.

La Sentencia de primera instancia estima que el procedimiento de DRL es equivalente al que se recoge en las cuatro primeras reivindicaciones de la patente EP 454.436. La Sentencia de la Audiencia efectúa un amplio estudio de los test relativos a la aplicación de la doctrina de los equivalentes: de la doble identidad -función y resultado-; de la triple identidad -función, resultado y "modus operandi"- y de la alternativa obvia para el experto, y entiende aplicable al caso la doctrina denominada de las tres preguntas, la cual considera adecuada a las circunstancias del caso, compartiendo el criterio de la resolución de primera instancia aunque con un importante matiz argumentativo. Estima la Sentencia de la Audiencia que la sentencia apelada analiza la respuesta a las dos primeras preguntas del test: que el método de alquilación (a+b+c= olanzapina) no altera el funcionamiento del procedimiento

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patentado de adición (a+bc= olanzapina), ni supone actividad inventiva (obviedad de la solución técnica para el experto), pero no a la tercera, que, sin embargo, se desprende sin duda del contexto (de la resolución del Juzgado), que es negativa, y que hace referencia a que, aunque la alquilación no aparezca en la 2ª patente de LILLY, ello no obedece a una renuncia expresa o inequívoca de la solicitante, sino estrictamente a su obviedad y a su incorporación por referencia. Y concluye, que los compuestos de partida son los mismos, el funcionamiento del procedimiento de reacción es el mismo y el producto final, claro, es idéntico. Por consiguiente, no puede considerarse acreditado que el procedimiento DRL al que acuden las demandantes no vulnere la patente en vigor de la demandada, algo que les correspondía probar (art. 217 LEC).

Las alegaciones expuestas en el motivo no desvirtúan la fundamentación de la resolución recurrida.

El art. 69 del CPE, interpretado por el Protocolo Interpretativo de 1973, se inclinó por un sistema intermedio, entre los sistemas del Derecho Inglés (y norteamericano) -que delimita el ámbito del derecho de exclusiva con sujeción al texto de las reivindicaciones, las cuales se han de interpretar de modo estricto de conformidad con su tenor literal- y el de la concepción tripartita (seguida en Alemania, Holanda y Suiza) -que extendía la protección a la "idea general de la invención" que consiste "en la aportación global del inventor al estado de la técnica y que es el resultado de un proceso de generalización del objeto de la invención"-. El art. 84 CPE dispone que las reivindicaciones definen el objeto para que se solicita la protección. Deben ser claras y concisas y han de fundarse en la descripción; y el art. 69.1 CPE establece que "el alcance de la protección que otorga la patente europea está determinado por las reivindicaciones; no obstante, la descripción y los dibujos servirán para interpretar las reivindicaciones". El Protocolo Interpretativo, del año 1973, del art. 69 (y que pasó a constituir el artículo 1 del Protodolo interpretativo redactado en la Conferencia de revisión, del año 2000) señala que «el art. 69 no deberá interpretarse en el sentido de que el alcance de la protección que otorga la patente europea haya de entenderse según el sentido estricto y literal del texto de las reivindicaciones y que la descripción y los dibujos sirvan únicamente para disipar las ambigüedades que pudieran contener las reivindicaciones. Tampoco debe interpretarse en el sentido de que las reivindicaciones sirvan únicamente de línea directriz y que la protección se extienda también a lo que, en opinión de una persona experta que haya examinado la descripción y los dibujos, el titular de la patente haya querido

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proteger. El art. 69 deberá, en cambio, interpretarse en el sentido de que define entre esos extremos una posición que garantiza a la vez una protección equitativa para el solicitante y un grado razonable de certidumbre a terceros».

Como consecuencia de la normativa expuesta no rige en el CPE (que es el régimen jurídico aplicable al asunto) el sistema del tenor literal (a pesar de que la versión castellana del precepto recoge la expresión "tenor", igual que las versiones francesa e inglesa, y sin que nada signifique que el artículo correspondiente de la LP 11/1986, recoja el término "contenido" como la ley alemana). Pero es que, además, la protección de la patente se extiende al "uso equivalente" de la invención, que tiene lugar "cuando se ejecuta la invención patentada con medios no reivindicados expresamente, pero que contienen características esenciales de la invención patentada". La conferencia de Revisión (Acta de Munich de 29 noviembre 2000) añadió al Protocolo interpretativo del art. 69 el artículo 2, en el que se establece que «para determinar la extensión de la protección otorgada por la patente europea, deberá tenerse debidamente en cuenta todo elemento equivalente a un elemento indicado en las reivindicaciones», aunque no recogió el concepto que figuraba en la Propuesta de base, que consideraba equivalente un elemento «cuando sea evidente para un experto en la materia que su utilización permite obtener esencialmente el mismo resultado que el obtenido por el elemento indicado en las reivindicaciones». La aplicación de la doctrina de los equivalentes por la sentencia recurrida es cabalmente adecuada, máxime dada la obligatoria observancia del Protocolo, sin que obste que el artículo 2 esté en vigor desde el 13 de diciembre de 2007, dado que, además de su carácter interpretativo, la doctrina de los equivalentes ya se reconocía y aplicaba con anterioridad [en cuanto a las patentes nacionales mediante el test jurídico del "criterio de la insustancialidad de las diferencias": SS, entre otras, de 19 oct. 1993, 22 oct. 2005, 1 mar. 2007]. Y, por otro lado, el criterio seguido por la resolución recurrida para el reconocimiento de la equivalencia no se ha desvirtuado en el motivo que se estudia (ni tratado de desvirtuar salvo los concretos aspectos que examinaremos a continuación), y en absoluto es contrario a la seguridad jurídica -grado razonable de certeza por terceros-.

La alegación de la parte recurrente (ii) de que la patente LILLY no describe ni reivindica en absoluto un procedimiento de alquilación para la obtención de olanzapina, sino únicamente un procedimiento de adición de un solo paso, resulta contradicha por la doctrina de los equivalentes y su adecuada aplicación por la resolución recurrida, y la afirmación (iv) de que hay "dos procedimientos diferentes" no se considera aceptable porque como

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razona el juzgador "a quo" «la adición del grupo metilo, en uno o en los dos pasos, no dejan de ser dos variantes equivalentes del mismo procedimiento patentado».

Y, finalmente, la alegación (iii) relativa a que la Audiencia considera probado que en la patente de LILLY hay una "exclusión explícita" del procedimiento de alquilación carece de consistencia, porque la referencia a la "exclusión" es sacada de contexto. Efectivamente, a propósito de examinar el juzgador "a quo" la respuesta a la "tercera pregunta" se plantea que no puede ser equivalente (aun cuando la variación no altere el funcionamiento de la invención y haya obviedad para el experto en la materia) lo que haya sido objeto de una renuncia o limitación aceptada por parte del solicitante -"prosecution history stoppel"; doctrina de los actos propios-, entendiendo que no es necesario que se mencione la palabra renuncia o un sinónimo, si bien, en el caso, estima que la exclusión (es decir, que la alquilación no aparezca en la 2ª patente) no obedece a una renuncia expresa e inequívoca, la cual debe ser interpretada [resalta] en términos restrictivos. Así claramente resulta de los dos últimos párrafos del fundamento tercero y penúltimo párrafo del fundamento cuarto.

Por todo ello, el motivo decae.

TERCERO.- En el motivo segundo se alega infracción de la Reserva española al CPE ex art. 167.2.a) del mismo, el art. 167.5 CPE, la Disposición Transitoria 1ª LP, el art. 70.1 del Acuerdo ADPIC, los arts. 28 y 30.2 de la convención de Viena sobre el Derecho de los Tratados, el art. 9.3 CE y el art. 2.3 del Código Civil, al aplicar retroactivamente los arts. 27 y 70.2 del Acuerdo ADPIC en contradicción con la jurisprudencia del Tribunal Supremo que tiene declarado que los principios de seguridad jurídica e irretroactividad de las normas son principios básicos y de orden público del ordenamiento jurídico que deben ser respetados escrupulosamente, determinando la interpretación restrictiva de la retroactividad y de las normas de derecho transitorio.

El supuesto histórico del litigio se refiere a una patente de producto farmacéutico la cual fue solicitada y concedida por la Oficina Europea de Patentes (EPO) y no se hallaba caducada con anterioridad al 7 de octubre de 1992, y que en virtud de la normativa jurídica relativa a la Reserva formulada por España en su día al CPE los efectos de la Reserva continuaban subsistentes con posterioridad a dicha fecha.

La parte demandante pretende que se declare la nulidad de la reivindicación 5 de la patente EP 454.436 - ES 2.078.440 de LILLY y, en

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consecuencia, se ordene su cancelación en la Oficina Española de Patentes y Marcas, y señala que dicha patente (reivindicación 5), aunque accedió al Registro español "disfrazada" de patente de procedimiento, lo es de producto farmacéutico por lo que le son de aplicación los efectos de la Reserva de España al CPE (art. 167.5 CPE).

La Sentencia de la Audiencia Provincial, aquí recurrida, desestima la pretensión de nulidad, resolviendo numerosas cuestiones, con base fundamentalmente en la aplicabilidad al caso de los arts. 27.1 y 70.2 del Acuerdo sobre las ADPIC, que deroga los efectos de la Reserva dando lugar a una "patentabilidad sobrevenida" -en realidad eficacia sobrevenida para los efectos futuros- de la patente europea en España.

La parte recurrente impugna la sentencia de la Audiencia con base fundamentalmente en que incurre en una aplicación retroactiva del Acuerdo ADPIC con lo que conculca los arts. 2.3 del Código Civil y 9.3 de la Constitución Española, que vedan la retroactividad, y la doctrina jurisprudencial que cita, cuya infracción constituye el presupuesto de recurribilidad.

Para dar respuesta casacional al motivo y facilitar su exposición procede, con carácter prioritario, hacer referencia a las normas jurídicas que inciden en el litigio.

Con anterioridad a la entrada de España en la Comunidad Europea (actualmente Unión Europea) regía en nuestro país en materia de patentes el Estatuto de la Propiedad Industrial (aprobado por Real Decreto-Ley de 26 de julio de 1929, texto refundido aprobado por Real Orden de 30 de abril de 1930, ratificado con fuerza de Ley el 16 de septiembre de 1931), el cual no admitía la patentabilidad de los productos farmacéuticos, ni de los productos en general (arts. 46 y 48.2 EPI). Una de las obligaciones asumidas por España para el ingreso en las Comunidades Europeas fue la de aceptar el Convenio Europeo de Patentes (CPE) o Convenio de Munich, de 5 de octubre de 1973, en el cual, para facilitar el acceso de algunos países, se estableció la posibilidad (facultad) de que estos se reservasen, con carácter temporal o transitorio, la no aplicabilidad del convenio a patentes de productos farmacéuticos (además de químicos y alimentarios). Al efecto se estableció en el art. 167.2 que "cualquier Estado contratante podrá reservarse la facultad de prever: a) Que la patentes europeas, en la medida que confieran protección a productos químicos, farmacéuticos o alimenticios como tales, no surtirán efecto o podrán ser anuladas conforme a las disposiciones en vigor para las patentes nacionales; esta reserva no afectará a la protección conferida por la patente en

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la medida que se refiera a un procedimiento de fabricación o de utilización de un producto químico o a un procedimiento de fabricación de un producto farmacéutico o alimentario". En el art. 167.3 se previó el carácter transitorio de la reserva: por diez años como máximo desde la entrada en vigor del Convenio, ampliables por otros cinco años como máximo, a condición de que el Estado ejercitante de la facultad presentase un año antes de la expiración del periodo decenal una petición razonada que permitiera al Consejo de Administración de la Organización de la Patente Europea decidir que ese Estado no está en condiciones de renunciar a dichas reservas al expirar el periodo de diez años. España se comprometió en el Tratado de Adhesión a las Comunidades Europeas (Protocolo 8 del Tratado de 12 de junio de 1985) a adherirse al CPE con las reservas del art. 167, y lo hizo mediante Instrumento de 10 de julio de 1986 (BOE 30 septiembre 1986) con el siguiente texto: "conforme a lo previsto en el art. 167.2,a), las Patentes Europeas, en la medida que confieran protección a los productos químicos y farmacéuticos como tales, no surtirán efecto en España". Y en los mismos términos se manifiesta el Real Decreto 2424/1986, de 10 de octubre, de aplicación a las solicitudes de patente europea y a las patentes europeas que produzcan efecto en España, en cuya Disposición Transitoria se dispone que "En virtud de la reserva temporal hecha en el momento del depósito del instrumento de Adhesión de España al Convenio de Munich, y de acuerdo con lo previsto en el art. 167, apartado 2, del Convenio las patentes europeas que designen a España no producirán ningún efecto en España en la medida que confieran protección a productos químicos y farmacéuticos y mientras dicha reserva esté en vigor". España solicitó y obtuvo la prórroga de cinco años prevista en el art. 167.3 del CPE, por lo que, dado que la entrada en vigor general del CPE se había producido el 7 de octubre de 1977, se extendió la vigencia de la Reserva hasta el 7 de octubre de 1992 (diez años iniciales más los cinco de prórroga).

Al llegar a este punto procede observar que en la reserva no se incluyen las patentes de productos alimenticios -solo se mencionan los productos químicos y farmacéuticos- y que la fórmula del Convenio, de posible aceptación mediante la reserva, de "no surtirán efecto o podrán ser anuladas conforme a las disposiciones en vigor para las patentes nacionales" se recoge con la expresión "no surtirán [o no producirán] ningún efecto en España". En la Ley de Patentes española 11/1986, de 20 de marzo, disposición transitoria primera, se dispone: "1. No serán patentables las invenciones de productos químicos y farmacéuticos antes del 7 de octubre de 1992. 2. Hasta esa fecha

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no tendrá vigencia ninguno de los artículos contenidos en la presente Ley en los que se disponga la patentabilidad de invenciones de productos químicos y farmacéuticos ni aquellos otros preceptos que se relacionen indisolublemente con la patentabilidad de los mismos. 3. Lo dispuesto en los apartados anteriores no afecta a las invenciones de procedimiento o aparatos para la obtención de productos químicos o farmacéuticos ni a los procedimientos de utilización de productos químicos, todos los cuales podrán ser patentados conforme a las normas de la presente Ley desde la entrada en vigor de la misma. 4. Las invenciones de los productos obtenidos por los procedimientos microbiológicos, a que se refiere el art. 5.2 de la presente Ley, no serán patentables hasta el 7 de octubre de 1992".

Aun cuando la fecha límite de la reserva fue tanto para las patentes europeas, como para las nacionales, el 7 de octubre de 1992, sin embargo los efectos de la reserva se extendía a la vigencia de las patentes "solicitadas" en la OEP (EPO). Así lo disponía el art. 167.5 del CPE: "cualquier reserva se extenderá a las patentes europeas concedidas en base a solicitudes de patentes europeas presentadas durante el periodo en el transcurso del cual la reserva produce efectos. Los efectos de esta reserva subsistirán durante toda la duración de esas patentes".

De conformidad con el régimen expuesto es claro que la patente controvertida no podía surtir efecto en España. Sin embargo, el problema surge una vez ratificado por España el Acuerdo sobre los ADPIC.

El 15 de abril de 1994 se firmó en Marraquech el Tratado por el que se crea la Organización Mundial de Comercio (OMC), en el cual se recoge como Anexo 1 C el Acuerdo sobre los Aspectos de Derecho de Propiedad Intelectual relacionados con el Comercio (Acuerdo ADPIC, TRIPS en la versión en lengua inglesa), el cual fue ratificado por España el 30 de diciembre de 1994, y publicado en el BOE del 24 de enero de 1.995, si bien, aunque el tema es polémico, se viene entendiendo (y en tal sentido la sentencia recurrida) que la fecha de aplicación práctica es la de 1 de enero de 1.996 (en interpretación para España del art. 65.2 del Acuerdo). De la normativa del Acuerdo son de interés respecto del asunto los preceptos de los arts. 27.1, y 70.1, 2 y 7. El art. 27, rubricado "Materia patentable", dispone en el apartado 1 que "sin perjuicio de lo dispuesto en los párrafos 2 y 3, las patentes podrán obtenerse por todas las invenciones, sean de productos o de procedimientos, en todos los campos de la tecnología, siempre que sean nuevas, entrañen una actividad inventiva y sean susceptibles de aplicación industrial. Sin perjuicio de lo dispuesto en el párrafo 4 del artículo 65, en el párrafo 8 del art. 70 y en el párrafo 3 del

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presente artículo, las patentes se podrán obtener y los derechos de patente se podrán gozar sin discriminación por el lugar de la invención, el campo de la tecnología o el hecho de que los productos sean importados o producidos en el país". El precepto recoge el principio de "no discriminación de invenciones patentables". El art. 70, con la rúbrica "protección de la materia existente", recoge la normativa de derecho transitorio o intertemporal. El apartado 1 establece la regla general de la irretroactividad al disponer que "El presente Acuerdo no genera obligaciones relativas a actos realizados antes de la fecha de aplicación del Acuerdo para el Miembro de que se trate"; y los apartados 2 y 7 contienen dos reglas especiales. El ap. 2 declara que "salvo disposición en contrario, el presente Acuerdo genera obligaciones relativas a toda la materia existente en la fecha de aplicación del presente Acuerdo para el Miembro de que se trate y que esté protegida en ese Miembro en dicha fecha, o que cumpla entonces o posteriormente los criterios de protección establecidos en el presente Acuerdo [...]"; y el apartado 7 señala que "en el caso de los derechos de propiedad intelectual cuya protección esté condicionada al registro, se permitirá que se modifiquen solicitudes de protección que estén pendientes en la fecha de aplicación del presente Acuerdo para el Miembro de que se trate para reivindicar la protección mayor que se prevea en las disposiciones del presente Acuerdo. Tales modificaciones no incluirán materia nueva".

Si no hubiera el precepto del art. 70.2 ADPIC, en el supuesto histórico enjuiciado no se habría planteado controversia alguna porque, de conformidad con los arts. 167.5 del CPE y 70.1 del Acuerdo, subsistirían los efectos de la reserva y carecería de interés práctico para el presente proceso el régimen jurídico establecido en el Acuerdo ADPIC. Sin embargo, como el apartado 2 del art. 70 del Acuerdo contiene una regla que restringe la regla general de irretroactividad del apartado 1, la incompatibilidad del principio de no discriminación de patentes que establece el art. 27.1 del mismo con la subsistencia del efecto discriminatorio para las patentes de productos farmacéuticos no caducadas a fecha 7 de octubre de 1.992, por aplicación del art. 167.5 CPE, plantea como tema básico qué normativa debe prevalecer.

Por consiguiente, aunque la Reserva española al CPE terminó el 7 de octubre de 1.992, como sus efectos siguieron operando, respecto de las patentes europeas de productos farmacéuticos concedidas con anterioridad, durante toda su vigencia -es decir, hasta su caducidad y entrada en el dominio público-, conforme al art. 167.5 CPE, hay que decidir si la aplicación del Acuerdo sobre los ADPIC (arts. 27.1 y 70.2), deja sin efecto la prolongación de

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la ineficacia de las patentes de que se trata, de modo que éstas adquieren plena vigencia, sin que sea necesario precisar por el momento si cabe hablar de "renacer", "convalidación", "sanatio in radice", "patentabilidad sobrevenida", etc, que son varias de las expresiones utilizadas en la doctrina para designar la desaparición de la subsistencia de efectos de la Reserva.

CUARTO.- Si una normativa jurídica establece una prolongación de ineficacia de un derecho patrimonial y otra normativa distinta le atribuye eficacia desde su fecha de aplicación, es claro que existe una incompatibilidad, la cual, en el caso, se produce no entre el CPE y el A-ADPIC, sino entre las consecuencias de la Reserva formulada por España al CPE (cuya única incidencia es permitir la reserva de forma limitada y temporal) y el Acuerdo ADPIC firmado por España sin reserva alguna (art. 72).

Con carácter previo a la decisión debemos hacer referencia a ciertas cuestiones de atención prioritaria.

La primera cuestión se refiere a que la parte demandante -aquí recurrente- pide la declaración de nulidad de la patente europea, en cuanto a la reivindicación número cinco, de la demandada, y sucede que la Reserva española al CPE no ejercitó la facultad con toda la amplitud que permitía el art. 167.2.a) del CPE, pues, aparte de no incluir los productos alimenticios (solo comprendió los productos químicos y farmacéuticos), no recogió el texto de dicho precepto en lo que se refiere a la nulidad, sino solo en la parte de "no producción de efectos". Si el tenor del CPE aludía a "no surtirán efecto o podrán ser anuladas", el de la Reserva habla solo de "no surtirán ningún efecto en España". Y aunque por algunos autores se entiende que se cobija una causa de nulidad en tanto que prohibición legal, no cabe desconocer (i) la literalidad de la fórmula de la Reserva que, además, debe ser interpretada restrictivamente por su carácter excepcional, (ii) que la doctrina de esta Sala distingue los diferentes efectos de la nulidad y de la ineficacia (en tanto que no producción de efectos temporal o definitiva) en numerosas resoluciones, y (iii) que dada la naturaleza de la Reserva (obedeció a consideraciones proteccionistas y de oportunidad, y no de orden técnico-jurídico) no tiene sentido suponer una nulidad radical, pues no concurren razones estructurales, de ilicitud o de orden público. Esta apreciación, que rechaza la nulidad, debería conllevar la desestimación de plano del motivo dado que, como se dijo, la pretensión ejercitada fue la de declaración de nulidad de la reivindicación. Sin embargo procede examinar la pretensión porque el efecto de ineficacia -"no producción de efectos jurídicos"- puede considerarse

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una petición implícita dentro de la ejercitada, que, por el carácter de "efecto menor" dentro del mismo ámbito jurídico de lo reclamado, no quebranta el principio de la congruencia, ni genera indefensión para la otra parte, sin perjuicio de que, de prosperar el recurso, habría de ajustarse el fallo a dicho efecto de ineficacia de la reivindicación, y no el de nulidad. Abunda además en dicha solución la polémica doctrinal existente sobre el alcance de la fórmula de la Reserva española, siendo de interés apuntar que otros países optaron por otra diferente. Por otra parte debe también señalarse que no obsta al examen de la pretensión que el planteamiento del tema aludido no se haya fundamentado adecuadamente en la perspectiva del presupuesto de recurribilidad del interés casacional, porque, dado el relevante interés general y trascendencia jurídica del mismo, requiere un pronunciamiento jurisprudencial.

Una segunda cuestión previa es la relativa a que realmente el objeto del recurso de casación, pese a sus múltiples alegaciones, se circunscribe esencialmente a si la aplicación al caso del art. 27.1 A-ADPIC -que recoge el principio de no discriminación de patentes en el campo tecnológico-, con carácter enervador de la congelación de efectos de las patentes concedidas antes del 7 de octubre de 1992 producida por mor del art. 167.5 CPE, infringe el principio de irretroactividad de las leyes de los arts. 9.3 CE y 2.3 CC. El problema preliminar radica en que solo en cuanto a tal aspecto se ha fundamentado adecuadamente el interés casacional, lo que implica la exclusión de las restantes consideraciones efectuadas por la parte recurrente en discrepancia con la resolución recurrida. Sin embargo, habida cuenta que algunas de las apreciaciones constituyen presupuestos de inexcusable tratamiento previo respecto del tema de la retroactividad, además del interés general anteriormente apuntado, resulta preciso analizar las alegaciones básicas que están íntimamente relacionadas con el "thema decidendi".

Y una tercera cuestión previa es la relativa a que la reivindicación impugnada, aunque es de producto (lo que no se discute en el proceso, ni es discutible), accedió al Registro como de procedimiento. El tema carece de trascendencia porque, aparte de no plantearse una situación de existencia de procedimiento alternativo, no cabe apreciar la concurrencia de fraude, máxime si se tiene en cuenta que no había un criterio seguro acerca de la constancia formal en el Registro español de las patentes europeas que contuvieran reivindicaciones de productos farmacéuticos, como lo revela que se hacía constar en el mismo (como sucedió en el supuesto de autos) nota informativa de la OEPM de no surtir efectos en España, a lo que debe añadirse que, de

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aceptarse la aplicación del Acuerdo, nada habría impedido la adición a la patente de procedimiento de la de producto, pues no se trata de "materia nueva".

Examinadas las precedentes cuestiones previas se plantea seguidamente, como presupuesto insoslayable de la retroactividad o irretroactividad, la cuestión relativa a la aplicabilidad del Acuerdo sobre los ADPIC. La respuesta afirmativa no ofrece duda ni en el aspecto del ordenamiento jurídico interno, ni en el del internacional público. En el primer aspecto se debe señalar que el Acuerdo -como Anexo 1C- forma parte del Tratado de Marraquech ratificado por España y que fue publicado en el BOE. Por lo tanto, se dan los requisitos para que se convierta en norma del ordenamiento interno, con valor superior incluso a las normas de legalidad ordinaria, por aplicación de los artículos 96.1 CE y 1.5 CC, y según reconocen reiterada doctrina del Tribunal Constitucional y jurisprudencial de esta Sala 1ª del Tribunal Supremo. Por otra parte, y en lo que atañe a los preceptos que aquí interesan -arts. 27.1 y 70.2 del Acuerdo- son normas claras, precisas e incondicionales, que no precisan de mecanismo complementario, como desarrollo legal o reglamentario, y que tienen carácter sustantivo civil generando derechos y obligaciones para los particulares (en cuanto que las patentes constituyen derechos de carácter patrimonial). Por lo tanto, nos hallamos ante normas del ordenamiento jurídico interno, auto-ejecutivas ("self-executing") y de aplicación directa por los órganos jurisdiccionales -en este caso, Tribunales civiles-.

Tampoco hay objeción a la aplicación del Acuerdo en la perspectiva del Derecho de la Unión Europea -ni de Derecho derivado, ni de jurisprudencia del TJUE-, porque, dada la naturaleza de la materia, no hay contradicción alguna. Y asimismo, no hay obstáculo de Derecho internacional público. De conformidad con la Convención de Viena sobre el Derecho de los Tratados de 23 de mayo de 1969 (Instrumento de Adhesión de 2 de mayo de 1.972, BOE 17 de junio de 1.980), los Tratados deben ser cumplidos y observados (art. 27), el posterior deroga el anterior en lo que no sea compatible (art. 30.3), la regla de la irretroactividad no rige para las situaciones posteriores (art. 28) y deberán ser interpretados de buena fe conforme al sentido corriente que haya de atribuirse a los términos del tratado en el contexto de éstos y teniendo en cuenta el objeto y fin (art. 31.1). No hay conflicto con el CPE porque, con independencia de que las partes son prácticamente las mismas (aparte de que en su caso habría que reducir la operatividad de la Reserva al Estado no parte que la invocase), debe tenerse en cuenta que España no "blindó" en el art. 2.2

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del Acuerdo-ADPIC el CPE, ni tampoco formuló reserva alguna al art. 27.1 A-ADPIC (art. 72), y, en cualquier caso, la Reserva al CPE no es un acuerdo sino una declaración unilateral de España, que no le supone obligación alguna respecto de la Organización Europea de Patentes, constituyendo únicamente una facultad, de modo que podría retirar la reserva sin contradecir el CPE, el cual incluso la alienta (art. 167.4). Por ello, una afectación de la Reserva por el A-ADPIC en nada menoscaba el CPE; más bien, al contrario, contribuye a la unificación del Derecho europeo en la materia, que es uno de los anhelos (junto a la transparecencia y seguridad jurídica) que impregnan la regulación unitaria.

Siendo clara la aplicación directa en España del A-ADPIC (en cuanto a las normas susceptibles de tal efecto) se plantea seguidamente el tema de la retroactividad. La tesis contraria a dejar sin efecto la congelación ex art. 167.5 CPE, o dicho de otro modo, de oposición a la aplicación plena del art. 27.1 A-ADPIC, aparte de otros argumentos menores e inconsistentes, como la idea de separar con un distinto nivel de protección las patentes de procedimiento y de producto, que no tiene base y contradice el principio de no discriminación, entiende que en el tema que se debate rige el principio de irretroactividad que consagra el art. 70.1 del Acuerdo, de modo que dicha irretroactividad comprende los actos realizados y se extiende a todos sus efectos. Sin embargo, dicha tesis no tiene en cuenta que el art. 70.2 recoge una manifestación de la denominada retroactividad media o limitada, que distingue las situaciones consumadas o agotadas de las situaciones realizadas con posterioridad a la entrada en vigor de la segunda norma (la retroactiva), y que está admitida por reiterada doctrina del Tribunal Constitucional y jurisprudencial del Tribunal Supremo. La afirmación de que el art. 70.2 recoge un supuesto de retroactividad media se deduce (i) del tenor literal de la norma de dicho apartado 2, (ii) de la regla de interpretación lógica de que, de no entenderlo así, dicho precepto (70.2) quedaría vacío de contenido, (iii) de la interpretación resultante de relacionar el apartado 2, con los otros apartados del art. 70, singularmente los números 3, 4, 6 y 7, y (iv), finalmente, coincide con la conclusión sentada por el Órgano de Apelación de la Organización Mundial del Comercio en la Decisión de 18 de septiembre de 2.000 que resolvió una disputa sobre aplicación del art. 33 del A-ADPIC (aunque la decisión contiene doctrina general) entre Canadá y Estados Unidos (WT/DS 170/AB/R); y cuyas principales apreciaciones se pueden resumir en que los apartados 1 y 2 del art. 70 son disposiciones independientes y mutuamente excluyentes; la expresión "actos realizados" del art. 70.2 (principio de

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irretroactividad, y respecto de los que el Acuerdo no genera obligaciones) se refiere a "las cosas hechas", "a lo que ha sido hecho" y "está actualmente completo y acabado"; y "materia existente" a la que se refiere el art. 70.2, alude a las invenciones protegidas mediante patente, comprendiendo las situaciones que no han dejado de existir, respecto de las que el Acuerdo genera derechos y obligaciones.

Por todo lo expuesto, el art. 167.5 CPE no puede seguir aplicándose a patentes concedidas y vigentes al 7 de octubre de 1.992, debiendo prevalecer el principio de no discriminación del art. 27.1 del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio, Anexo 1 C del Acuerdo por el que se estableció la OMC (BOE 24 de enero de 1.995).

Por consiguiente, el motivo decae.

QUINTO.- En el tercero y último motivo del recurso se acusa infracción del art. 3.1 del Código Civil, al aplicar dicho precepto en contradicción con la jurisprudencia del Tribunal Supremo que tiene declarado que no cabe dejar de aplicar una norma jurídica bajo el pretexto de que no se adecua a la realidad social, y que el elemento sociológico de interpretación debe ser utilizado con prudencia y en modo alguno permite tergiversar o cambiar el sentido de la ley.

En el cuerpo del motivo se argumenta, en síntesis, por un lado, que la Audiencia no ha realizado una interpretación sociológica -pese a la cita del art. 3.1 CC- de las normas sobre prohibición de patentar productos farmacéuticos antes del 7 de octubre de 1.992 (art. 167 CPE, disposición transitoria 1ª LP, etc.) sino que directamente ha inaplicado dichas normas en atención a que, presuntamente, ya no se adecuarían a la realidad social española, lo que contradice la doctrina jurisprudencial (SS. 20 de diciembre de 2.006 y 31 de julio de 2.007) que tiene declarado que no cabe dejar de aplicar una norma con tal pretexto, tal y como se expone en el enunciado del motivo, y, por otro lado, que el razonamiento de la Audiencia es erróneo en cuanto al fondo, en el sentido de que no es cierto que la realidad social española imponga un cambio interpretativo.

El motivo se desestima porque como resulta de la propia argumentación de la Sentencia recurrida (ap. 5 del fto. de derecho quinto) la referencia a la realidad social en la aplicación de la norma, con cita del art. 3.1 del Código Civil, no constituye un argumento "ratio decidendi" sino de los denominados de refuerzo, o a mayor abundamiento, contra los que, como reiteradamente viene declarando esta Sala, no cabe el recurso de casación, entre otras consideraciones porque cualquier eventual estimación devendría

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estéril, y, consecuentemente, contraria al efecto útil que exige el planteamiento del recurso extraordinario.

A lo dicho cabe añadir que, en cualquier caso, la alusión de la sentencia recurrida a que la Reserva española ex art. 167.2.a) del CPE no obedeció a razones endógenas del propio derecho de patentes, sino exógenas y de raíz económica, y a que la realidad social y económica española del año 1.995 no es la misma que la del tiempo en que se ejercitó la reserva, no es en absoluto irrazonable, y su invocación se acomoda al valor interpretativo que cabe atribuir a la realidad social del tiempo en que han de ser aplicadas las normas (en este caso los artículos 27.1 y 70.2 del Acuerdo ADPIC) sin contradecir el sentido propio de sus palabras, tal y como previene el art. 3.1 del Código Civil.

SEXTO.- La desestimación de los motivos conlleva la del recurso de casación, sin que en el presente caso proceda la imposición de las costas por hacer uso este Tribunal de la facultad que le confiere al respecto el art. 394.1 LEC, al que se remite el art. 398.1 del mismo Cuerpo Legal, motivándose esta decisión con la apreciación de que el conflicto jurídico examinado -incidencia del Acuerdo ADPIC en la Reserva española al CPE, y concretamente en los efectos del art. 167.5 de este Convenio- es polémico en la doctrina y de solución compleja, al presentar las disposiciones legales que inciden en el asunto serias dificultades interpretativas, siendo, por lo demás, el primer asunto sobre la materia que llega a esta Sala 1ª del Tribunal Supremo.

Por lo expuesto, en nombre del Rey y por la autoridad conferida por el pueblo español.

F A L L A M O S

Que desestimamos el recurso de casación interpuesto por la representación procesal de las entidades mercantiles LABORATORIOS CINFA, S.A., KERN PHARMA S.L. y LABORATORIOS ALTER, S.A. contra la

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Sentencia dictada por la Sección Décimoquinta de la Audiencia Provincial de Barcelona el 17 de enero de 2.008, en el Rollo número 368 de 2.007, sin hacer especial imposición de las costas causadas en el presente recurso. Publíquese eta resolución con arreglo a derecho, y devuélvanse a la Audiencia los autos originales y rollo de apelación remitidos con testimonio de esta resolución a los efectos procedentes.

Así por esta nuestra sentencia, que se insertará en la COLECCIÓN LEGISLATIVA pasándose al efecto las copias necesarias, lo pronunciamos, mandamos y firmamos.- Juan Antonio Xiol Ríos.- Xavier O'Callaghan Muñoz.- Jesús Corbal Fernández.- Francisco Marín Castán.- José Antonio Seijas Quintana.- Antonio Salas Carceller.- Encarnación Roca Trías.- Román García Varela.- Firmado y Rubricado.

PUBLICACIÓN.- Leída y publicada fue la anterior sentencia por el EXCMO. SR. D. **Jesús Corbal Fernández**, ponente que ha sido en el trámite de los presentes autos, estando celebrando Audiencia Pública la Sala Primera del Tribunal Supremo, en el día de hoy; de lo que como secretario de la misma, certifico.

ADMINISTRACION
DE JUSTICIA

TRIBUNAL SUPREMO
Sala de lo Civil

Presidente Excmo. Sr. D. Francisco Marín Castán

SENTENCIA

Sentencia Nº: 598/2014
Fecha Sentencia: 07/11/2014
CASACIÓN E INFRACCIÓN PROCESAL
Recurso Nº: 647/2013
Fallo/Acuerdo: Sentencia Desestimando
Votación y Fallo: 15/10/2014
Ponente Excmo. Sr. D.: Ignacio Sancho Gargallo
Procedencia: AUD. PROV. DE MADRID
Secretaría de Sala: Ilma. Sra. Dña. María Angeles Bartolomé Pardo
Escrito por: RSJ
Nota:

Infracción de patente. Interpretación del ámbito de protección de la patente. Infracción por equivalente. Alcance de la revisión del juicio de infracción en casación.

ADMINISTRACION DE JUSTICIA

CASACIÓN E INFRACCIÓN PROCESAL Num.: **647/2013**
Ponente Excmo. Sr. D.: **Ignacio Sancho Gargallo**
Votación y Fallo: **15/10/2014**
Secretaría de Sala: **Ilma. Sra. Dña. María Angeles Bartolomé Pardo**

TRIBUNAL SUPREMO
Sala de lo Civil

SENTENCIA Nº: **598/2014**

Excmos. Sres.:

D. Francisco Marín Castán
D. José Ramón Ferrándiz Gabriel
D. Ignacio Sancho Gargallo
D. Francisco Javier Orduña Moreno
D. Sebastián Sastre Papiol

En la Villa de Madrid, a siete de Noviembre de dos mil catorce.

La Sala Primera del Tribunal Supremo, integrada por los Magistrados al margen indicados, ha visto el recurso extraordinario por infracción procesal y recurso de casación interpuestos respecto la Sentencia dictada en grado de apelación por la sección 28ª de la Audiencia Provincial de Madrid, como consecuencia de autos de juicio ordinario seguidos ante el Juzgado de lo Mercantil núm. 2 de Madrid.

Los recursos fueron interpuestos por la entidad Wyeth, LLC, representada por la procuradora María Dolores Girón Arjonilla.

Es parte recurrida la entidad Germed Farmacéutica, S.L.U. (en su condición de sociedad absorbente de la entidad Uso Racional, S.L.U.) representada por el procurador Javier Zabala Falco.

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ANTECEDENTES DE HECHO

Tramitación en primera instancia

1. La procuradora María Dolores Girón Arjonilla, en nombre y representación de la entidad Wyeth, interpuso demanda de juicio ordinario ante el Juzgado de lo Mercantil núm. 2 de Madrid, contra la entidad Uso Racional S.L., para que se dictase sentencia:

> *"por la que, dando lugar a los pedimentos de mi principal, se declare que:*
>
> *1. WYETH es titular de las patentes ES 2.210.454 y ES 2.174.864.*
>
> *2. USO RACIONAL, S.L. ha realizado actos de infracción de las patentes ES 2.210.454 y ES 2.174.864 de WYETH.*
>
> *3. USO RACIONAL, S.L. ha causado a WYETH unos daños y perjuicios ciertos y efectivos, cuya determinación deberá realizarse a lo largo del procedimiento tomando en consideración las siguientes bases:*
>
> *- Todos los gastos incurridos por WYETH con relación a los actos de infracción de la patente ES 2.210.454 llevados a cabo por USO RACIONAL, S.L. entre los que enunciamos, a título de ejemplo, los gastos derivados del asesoramiento de profesionales especializados, de la remisión de requerimientos, de la realización de pruebas analíticas, del coste de oportunidad por las horas dedicadas por el personal de WYETH a preparar y atender el litigio, viajes realizados con dicho fin y cualquier otro concepto que resulte acreditado en autos;*
>
> *- Los beneficios que WYETH habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la infracción de USO RACIONAL, S.L.; y*

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- *Los beneficios que USO RACIONAL, S.L. haya obtenido de la explotación de la invención patentada.*

Y SE CONDENE A USO RACIONAL, S.L. a:

1. Estar y pasar por las anteriores declaraciones.

2. Cesar en la importación y abstenerse de importar a España, mientras las patentes ES 2.210.454 y ES 2.174.864 estén en vigor de (i) una formulación de esferoides de liberación sostenida y prolongada de VENLAFAXINA; y (ii) una formulación de VENLAFAXINA indicada para el tratamiento del trastorno de ansiedad generalizado.

3. Cesar en el ofrecimiento e introducción en el comercio y abstenerse de ofrecer a terceros e introducir en el comercio español, mientras las patentes ES 2.210.454 y ES 2.174.864 estén en vigor de (i) una formulación de esferoides de liberación sostenida y prolongada de VENLAFAXINA; y (ii) una formulación de VENLAFAXINA indicada para el tratamiento del trastorno de ansiedad generalizado; y en cualquier caso, se le ordene colocar en un lugar visible de todas las cajas o prospectos de cualquier EFG de liberación prolongada de VENLAFAXINA un aviso que informe de que "la presente especialidad farmacéutica no puede prescribirse por el médico o suministrarse por el farmacéutico para el tratamiento del trastorno de ansiedad generalizado al no haber sido autorizada dicha indicación por estar protegida por la patente ES 2.174.864 de WYETH".

4. Retirar del tráfico económico y de sus locales todas las unidades de venta que consistan en (i) una formulación de esferoides de liberación sostenida y prolongada de VENLAFAXINA; y (ii) una formulación de VENLAFAXINA indicada para el tratamiento del trastorno de ansiedad generalizado.

5. Al embargo de los objetos importados con violación de los derechos de patente de WYETH y de los medios principalmente destinados a tal producción o a la realización de la infracción y, en

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particular, al embargo de las unidades de venta de (i) toda formulación de esferoides de liberación sostenida y prolongada de VENLAFAXINA; y (ii) toda formulación de VENLAFAXINA indicada para el tratamiento del trastorno de ansiedad generalizado.

6. A la destrucción de las unidades de venta de las especialidades farmacéuticas genéricas de VENLAFAXINA que consistan en (i) una formulación de esferoides de liberación sostenida y prolongada de VENLAFAXINA; y (ii) una formulación de VENLAFAXINA indicada para el tratamiento del trastorno de ansiedad generalizado que sean retiradas del tráfico económico y de los locales de USO RACIONAL, S.L. y hayan sido embargadas conforme a lo solicitado en el apartado 5 anterior.

7 Resarcir a WYETH por los daños y perjuicios causados por USO RACIONAL, S.L., en la cuantía que se determine en periodo de prueba.

Para el cálculo de la indemnización de daños y perjuicios habrán de tomarse las siguientes bases:

- *Todos los gastos incurridos por WYETH con relación a los actos de infracción de la patente ES 2.210.454 llevados a cabo por USO RACIONAL, S.L. entre los que enunciamos, a título de ejemplo, los gastos derivados de (i) los análisis realizados para comprobar la realidad de dichos actos; (ii) el asesoramiento de profesionales especializados; (iii) la remisión de requerimentos; (iv) el coste de oportunidad por las horas dedicadas por el personal de WYETH a preparar y atender el litigio; (v) viajes realizados con dicho fin; y (vi) cualquier otro concepto que resulte acreditado en autos.*

- *Las unidades de las especialidades farmacéuticas genéricas "VENLAFAXINA UR 75 MG" y "VENLAFAXINA UR 150 MG" vendidas por USO RACIONAL, S.L..*

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- Los beneficios que WYETH habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la infracción de USO RACIONAL, S.L.; y

- Los beneficios que USO RACIONAL, S.L. haya obtenido de la explotación de la invención patentada.

8. A notificar la sentencia condenatoria, a costa de la demandada, a la Agencia Española del Medicamento, con domicilio en la calle Huertas, número 75, 28014 Madrid, al objeto de que proceda a anotar la sentencia en el Registro de Especialidades Farmacéuticas.

9. Se notifique la sentencia condenatoria a los distintos Colegios Farmacéuticos y Colegios de Médicos de España a los efectos que informen a sus colegiados de la misma y en particular de la imposibilidad de prescribir o dispensar una EFG de la VENLAFAXINA diferente del "VANDRAL RETARD" y del "DOBUPAL RETARD" y en concreto "VENLAFAXINA UR 75 MG" y "VENLAFAXINA UR 15 MG", para el tratamiento del trastorno de la ansiedad generalizado.

10. A la publicación íntegra de la sentencia condenatoria, a costa de la demandada, en los periódicos de tirada nacional EXPANSIÓN y EL PAÍS, de conformidad con lo previsto en el artículo 63 (f) de la Ley de Patentes.

Y todo ello, con imposición de costas a USO RACIONAL, S.L.".

2. El procurador Antonio Sorribes Calle, en representación de la entidad Uso Racional S.L., contestó a la demanda y suplicó al Juzgado dictase sentencia:

"desestimando la demanda, con expresa imposición de costas a la parte actora.".

3. El procurador Antonio Sorribes Calle, en representación de la entidad Uso Racional S.L., formuló demanda reconvencional y pidió al Juzgado dictase sentencia:

"DECLARE: (1) Que WYETH ha cometido actos de competencia desleal contrarios al artículo 5 de la Ley de Competencia Desleal.

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(2) A estar y pasar por la anterior declaración.

(3) A la cesación y prohibición para el futuro de los actos consistentes en realizar una interpretación de su derecho de patente europea EP 797 991 validada en España con el nº ES 2.210.454 contraria a lo que le ha sido concedido por la Oficina Europea de Patentes.

(4) A indemnizar a USO RACIONAL, S.L. en la cuantía del enriquecimiento injusto derivada de los beneficios obtenidos como consecuencia de la no introducción en el comercio de las especialidades farmacéuticas "Venlafaxina UR 150 mg cápsulas de liberación prolongada, 30 cápsulas" y "Venlafaxina UR 75 mg cápsulas de liberación prolongada, 30 cápsulas", por el periodo de tiempo en el que estén vigentes las medidas cautelares estimadas en el incidente de Medidas Cautelares dependientes del presente procedimiento.

(5) A la publicación de la sentencia condenatoria, a costa de la demandada, en los periódicos de tirada nacional EXPANSIÓN y EL PAÍS.

(6) A la condena en costas a la demandada reconvenida en las presentes actuaciones.".

4. La procuradora María Dolores Girón Arjonilla, en representación de la entidad Wyeth, contestó a la demanda reconvencional y suplicó al Juzgado dictase sentencia:

"por la que se desestime la totalidad de las pretensiones deducidas en la demanda reconvencional, con condena en costas a la actora reconvencional y expresa declaración de temeridad de Uso Racional en la interposición de la demanda reconvencional.".

5. El Juez de lo Mercantil núm. 2 de Madrid, dictó Sentencia de fecha 31 de mayo de 2010, con la siguiente parte dispositiva:

"FALLO: Que, desestimando íntegramente tanto la demanda formulada por Wyeth contra Uso Racional S.L. como la

reconvención deducida por esta última contra aquella, absuelvo a ambas partes de los pedimentos respectivamente deducidos en su contra. Se imponen a la actora las costas ocasionadas por la demanda inicial y a la demandada reconviniente las originadas por su demanda reconvencional.".

Tramitación en segunda instancia

6. La sentencia de primera instancia fue recurrida en apelación por la representación de la entidad Wyeth.

La resolución de este recurso correspondió a la sección 28ª de la Audiencia Provincial de Madrid, mediante Sentencia de 27 de diciembre de 2012, cuya parte dispositiva es como sigue:

"FALLAMOS: 1.- Desestimar el recurso de apelación interpuesto por WYETH, LLC contra la sentencia dictada el 31 de mayo de 2010 por el Juzgado de lo Mercantil número 2 de Madrid en el procedimiento núm. 251/07 del que este rollo dimana.

2.- Imponer las costas ocasionadas por el recurso a la parte apelante.".

Interposición y tramitación del recurso extraordinario por infracción procesal y recurso de casación

7. La procurador María Dolores Girón Arjonilla, en nombre y representación Wyeth LLC, interpuso recurso extraordinario por infracción procesal y recurso de casación ante la Audiencia Provincial de Madrid, sección 28ª.

El motivo del recurso extraordinario por infracción procesal fue:

"1º) Infracción del art. 24 de la Constitución Española.".

Los motivos del recurso de casación fueron:

"1º) Infracción de la doctrina jurisprudencial que determina que una patente que reivindica un producto confiere una protección absoluta sobre dicho producto.

2º) Infracción del art. 60, párrafo primero, de la Ley 11/1986, de 20 de marzo, de Patentes, del art. 69 del Convenio sobre Concesión de

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Patentes Europeas de 5 de octubre de 1973 y arts. 1 y 2 de su Protocolo Interpretativo.".

8. Por diligencia de ordenación de 11 de marzo de 2013, la Audiencia Provincial de Madrid, sección 28ª, tuvo por interpuestos los recursos extraordinario por infracción procesal y recurso de casación mencionados, y acordó remitir las actuaciones a la Sala Primera del Tribunal Supremo con emplazamiento de las partes para comparecer por término de treinta días.

9. Recibidas las actuaciones en esta Sala, comparecen, como parte recurrente, la entidad Wyeth, representada por la procuradora María Dolores Girón Arjonilla; y como parte recurrida la entidad Germed Farmacéutica, S.L.U. (en su condición de sociedad absorbente de la entidad Uso Racional, S.L.U.) representada por el procurador Javier Zabala Falco.

10. Esta Sala dictó Auto de fecha 29 de octubre de 2013, cuya parte dispositiva es como sigue:

" ADMITIR EL RECURSO EXTRAORDINARIO POR INFRACCION PROCESAL Y DE CASACIÓN interpuestos por la representación procesal de la entidad mercantil WYETH contra la sentencia dictada con fecha de 27 de diciembre de 2012 por la Audiencia Provincial de Madrid, Sección 28ª, en el rollo de apelación nº 547/2010, dimanante de los autos de juicio ordinario nº 251/2007 del Juzgado de lo Mercantil nº 2 de Madrid.".

11. Con fecha 10 de diciembre de 2013, esta Sala dictó Auto de Aclaración de la anterior resolución, con la siguiente parte dispositiva:

"HA LUGAR a la aclaración del Auto de fecha de 29 de octubre de 2013 solicitada por la Procuradora Doña María Dolores Girón Arjonilla, en nombre y representación de la entidad mercantil WYETH LLC, y en consecuencia el Fundamento Jurídico Primero de la citada resolución cuando dice «Procede admitir el recurso extraordinario por infracción procesal y de casación interpuesto por la representación procesal de la entidad mercantil WYETH al concurrir los presupuestos y requisitos legalmente exigidos en el ordinal 2º del art. 477.2 de la LEC.», debe decir: «Procede admitir el

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recurso extraordinario por infracción procesal y de casación interpuesto por la representación procesal de la entidad mercantil WYETH al concurrir los presupuestos y requisitos legalmente exigidos en el ordinal 3º del art. 477.2 de la LEC.».

12. Dado traslado, la representación procesal de la entidad Germed Farmacéutica S.L.U. (antes Uso Racional, S.L.U.), presentó escrito de oposición a los recursos formulados de contrario.

13. Al no solicitarse por todas las partes la celebración de vista pública, se señaló para votación y fallo el día 15 de octubre de 2014, en que ha tenido lugar.

Ha sido ponente el Excmo. Sr. D. **IGNACIO SANCHO GARGALLO**,

FUNDAMENTOS DE DERECHO

Resumen de antecedentes

1. Para la resolución del presente recurso debemos partir de la relación de hechos relevantes acreditados en la instancia.

Wyeth, LLC (en adelante, Wyeth) es titular de la patente ES 2.210.454 (en adelante, ES 454), que es la validación en España de la patente europea EP 797.991, y de la patente ES 2.174.864 (en adelante, ES 864), que es la validación en España de la patente europea EP 639.374.

La patente ES 454 lleva por título "formulación que contiene venlafaxina de liberación prolongada". Las reivindicaciones 1 y 11 de la patente son principales. El contenido de estas reivindicaciones es el siguiente:

> "*1. Formulación de liberación prolongada, encapsulada, de clorhidrato de venlafaxina* ***que comprende*** *una cápsula de gelatina dura que contiene una cantidad terapéuticamente eficaz de esferoides que constan de clorhidrato de venlafaxina, celulosa microcristalina e hidroxipropilmetilcelulosa, recubiertos con etilcellulosa e hidroxipropilmetilcelulosa*".

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"*11. Esferoide recubierto,* ***en el que*** *el esferoide comprende clorhidrato de venlafaxina, celulosa microcristalina e hidroxipropilmetilcelulosa, y está recubierto con etilcelulosa e hidroxipropilmetilcelulosa*".

La patente ES 864 lleva por título "*nuevos tratamientos que utilizan derivados del fenetilo*" y reivindica la utilización de derivados del fenetilo, entre los que se encuentra la venlafaxina, para la preparación de medicamentos indicados para el tratamiento del trastorno de ansiedad generalizado.

En el momento de presentarse la demanda por Wyeth, la demandada Uso Racional, S.L. (en la actualidad, absorbida por Germed Farmacéutica, S.L.U.), iba a lanzar al mercado las especialidades farmacéuticas genéricas "Venlafaxina UR 75 mg cápsulas de liberación prolongada EFG" y "Venlafaxina UR 150 mg cápsulas de liberación prolongada EFG". En su demanda, la demandante entendía que la demandada con estas especialidades farmacéuticas genéricas infringía por equivalencia la invención protegida con la patente ES 454. También sostenía que, aunque los prospectos de las especialidades genéricas farmacéuticas controvertidas no incluían su indicación para el tratamiento del trastorno de ansiedad generalizado, su introducción en el mercado entrañaba un riesgo cierto de vulneración de la patente ES 864.

2. La sentencia del juzgado mercantil, al resolver la controversia sobre la infracción por equivalencia, advierte que ya se había pronunciado sobre esta cuestión la audiencia provincial al conocer de la apelación del auto que acordó las medidas cautelares. En aquella resolución (Auto de la sección 28ª de la Audiencia Provincial de Madrid de 22 de enero de 2010), sobre la base de la prueba practicada, que incluía los informes periciales aportados en los iniciales escritos de alegaciones, la audiencia concluyó, dentro del marco de enjuiciamiento del *fumus boni iuris*, que las realizaciones cuestionadas no incorporaban ni literalmente ni por equivalencia la invención protegida por la patente ES 454 y, por ello, dejó sin efecto las medidas.

3. En la sentencia sobre el fondo del asunto, el juzgado mercantil reprodujo la argumentación vertida por la audiencia en aquel auto de medidas cautelares, "en la medida que los planteamientos contenidos en dicha resolución (...)

representan la respuesta jurídica adecuada a la cuestión planteada en función del desarrollo de la prueba que se había alcanzado hasta el momento en que se dictó". Y, a continuación, analizó si las posteriores pruebas periciales presentadas por la demandante, así como el informe del perito judicial, aportaban "nuevos puntos de vista susceptibles de alterar los planteamientos contenidos" en aquel auto de la sección 28ª de la Audiencia Provincial de Madrid de 22 de enero de 2010.

En atención a que las partes reconocían un mayor alcance de protección a la reivindicación 11, el tribunal de instancia compara su contenido, elemento por elemento, con el de la realización cuestionada.

Los elementos de la reivindicación 11 serían:

a) un esferoide recubierto,

b) el esferoide ha de comprender clorhidrato de venlafaxina, celulosa microcristalina e hidroxipropilmetilcelulosa,

c) el esferoide ha de estar recubierto con etilcelulosa y hidroxipropilmetilcelulosa (HPMC).

Por su parte los elementos de las realizaciones cuestionadas serían:

a) una esfera inerte de azúcar,

b) recubierta con una capa de venlafaxina, hidroxipropilcelulosa (HPC) y otros,

c) otro recubrimiento de sellado de HPMC

d) un último recubrimiento de liberación sostenida de HPM y etilcelulosa.

Advertida con claridad que no existe una infracción literal, pues no se incorporan todos los elementos de la invención, el tribunal analiza, en los términos en que se planteó la cuestión en sede cautelar, si pudo existir infracción por equivalentes.

Para ello, rechaza el planteamiento inicial de la titular de la patente, que pretende extender su ámbito de protección a "toda formulación que consista en un esferoide, sea este matricial o compuesto por un núcleo inerte sobre el que

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se ha pulverizado el principio activo o en el que éste forma una capa sobre tal núcleo, sean cuales sean los excipientes utilizados, si están recubiertos por una capa que comprende etilcelulosa e hidroxipilmetilcelulosa, y si tiene como efecto la liberación sostenida del principio activo". El tribunal rechaza este planteamiento porque utiliza como elemento definidor del ámbito de protección de la patente la "esencia de la invención", que consistiría en el resultado perseguido, en su sentido más amplio, en este caso la liberación prolongada del principio activo venlafaxina. El tribunal entiende que "lo que no puede considerarse como 'elemento esencial' es el resultado perseguido por la patente, porque la protección de la patente no se extiende al resultado perseguido por la invención (la liberación prolongada del principio activo venlafaxina), sino al modo de obtenerlo. Y añade que la demandante, al esquematizar excesivamente la invención y reducirla a su esencia, determina su ámbito de protección no por el contenido de sus reivindicaciones interpretadas con la ayuda de la descripción y de los dibujos, sino por ese esquema esencial y el resultado que produce, de tal forma que bajo este planteamiento todas las realizaciones que reproduzcan dicho esquema esencial y consigan aquel resultado quedarían incluidas en el ámbito de protección y, por lo tanto, infringirían la patente.

El tribunal razona que las realizaciones cuestionadas difieren de la invención, en primer lugar, por la estructura, pues no utilizan un esferoide que contenga el principio activo junto con determinados excipientes y un recubrimiento compuesto de otros excipientes determinados, sino una esfera inerte compuesta por otras sustancias (azúcar y almidón, o sólo azúcar), que se recubre con una capa del principio activo junto con otro excipiente, y antes de añadir el recubrimiento retardante como el de la invención patentada, se interpone otro recubrimiento de sellado. También difiere porque las realizaciones cuestionadas no incluyen como excipiente la celulosa microcristalina. Y, además, el otro excipiente en el que existe coincidencia (el HPMC), cumple en las realizaciones cuestionadas una función distinta a la que desempeña en la invención patentada: en la invención se encuentra mezclado con el principio activo y con la celulosa microcristalina para permitir la extrusión de la masa y formar el esferoide que luego irá recubierto, y en las

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realizaciones cuestionadas se encuentra únicamente en el recubrimiento, sin estar mezclado con el principio activo.

El tribunal razona también que no existe prueba, siquiera indiciaria, de que el modo en que actúan unas y otras formulaciones sea el mismo debido a la supuesta equivalencia entre las características técnicas reivindicadas en la patente y las que presentan las realizaciones cuestionadas.

El tribunal no comparte la tesis de la demandante de que el problema técnico al que la patente pretende dar solución sea el de la liberación sostenida de la venlafaxina. Tras una análisis detallado de la descripción, concluye que la liberación sostenida de la venlafaxina es un primer problema general en el que se enmarca la invención, pero no constituye el problema técnico concreto al que se pretende dar solución de un modo más próximo. El problema técnico que se pretendía solucionar con la patente era, según se desprende de la descripción detallada de la invención, solventar los obstáculos que se presentaban al realizar una concreta formulación de la liberación prolongada de la venlafaxina. En concreto, se pretendía encontrar una formulación que pudiera proporcionar una mezcla de granulación adecuada para ser extraída de modo apropiado, solucionando el problema que suponía que durante el proceso de extrusión se produjera una acumulación de calor que secara de tal modo el material de extrusión que se dificultara la conversión de los cilindros extruidos en esferoides.

A la vista de lo anterior, la sentencia razona que no consta justificado que, desde el punto de vista jurídico, a la vista de los términos en que está redactada la patente, la celulosa microcristalina y los núcleos de azúcar y almidón puedan considerarse equivalentes. En la patente, la celulosa microcristalina sirve, junto con otro excipiente (HPMC) y el principio activo (venlafaxina), para conformar el esferoide por una técnica de extrusión-esferonización, superando los problemas de calentamiento de la masa que surgían en ese proceso, mientras que en las realizaciones cuestionadas los núcleos inertes no sirven para superar esos problemas del proceso de extrusión-esferonización.

Lo argumentado hasta ahora es lo que la sentencia de primera instancia reproduce del auto de la audiencia que resolvió sobre la apelación de las

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medidas cautelares. A lo anterior, el juzgado mercantil añadió a continuación el examen de los informes adicionales presentados por la demandante y del informe pericial, para comprobar si aportaban un nuevo punto de vista que contradijera lo ya razonado.

En la sentencia se advierte que la lectura de estos informes mostraba que persistían, en cierto modo, en la visión esencialista, al identificar la esencia de la invención (el problema que soluciona) con el resultado perseguido que era la liberación prolongada, por espacio de 24 horas, del principio activo. Aunque se introduce alguna ligera diferencia, para huir del esencialismo inicial, al presentar o identificar como el problema técnico a solucionar el propio mecanismo de liberación prolongada. Sobre la base de lo anterior, estos nuevos informes hacían hincapié en que el único componente que desempeña esa misión era la capa de etilcelulosa y HPMC, y que ningún protagonismo ejercían en el desarrollo de tal función la celulosa microcristalina y los demás componentes especificados en la reivindicación.

Frente a ello, la sentencia pone de relieve como el problema que resuelve la patente no puede ser el de la liberación prolongada del fármaco mediante una capa de etilcelulosa y HPMC, por un argumento de reducción al absurdo, ya que de otro modo no habría verdadera invención, pues la solución a ese problema ya se conocía en el estado de la técnica, y sí el de la acumulación de calor y consiguiente secado de los elementos, tal y como se expone en la descripción de la patente, en el apartado que da cumplimiento a lo prescrito en el art. 5.2.d) del Reglamento para la aplicación de la Ley de Patentes ("*una explicación de la invención, tal y como es caracterizada en las reivindicaciones que permita la comprensión del problema técnico planteado, así como la solución del mismo, indicándose, en su caso, las ventajas de la invención en relación con el estado de la técnica anterior...*"). Para la solución de este problema, en la invención cumple un especial protagonismo, según la descripción de la patente, la adición de HPMC a la celulosa microcristalina, que es un compuesto ausente en la realización cuestionada, sin que los peritos hayan llegado a afirmar que los excipientes de la realización cuestionada que consideran "equivalentes obvios" desempeñen, unida a la

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HPMC, y además de su genuina función diluyente o aglutinante, esa función de contención del calor y de su indeseable efecto de secado de los elementos.

Tras todo lo cual, la sentencia dictada en primera instancia niega que la realización cuestionada infrinja por equivalentes la patente ES 454.

Y en relación con la patente ES 864, también se niega la infracción, porque "si la simple comercialización de un medicamento que contiene un principio activo que está ya en el dominio público, autorizada para una indicación que no está protegida por una patente de nuevo tratamiento terapéutico, como es el caso de las EFGs de la recurrente, se considera como vulneradora (real o potencialmente) de la patente de nuevo tratamiento terapéutico, se está extendiendo el ámbito protegido por la citada patente hasta convertirla en una prolongación o una reactivación de la patente del principio activo ya caducada".

4. La audiencia provincial, que desestima el recurso de apelación formulado por la demandante titular de la patente frente a la sentencia de primera instancia, ratifica la interpretación realizada por el juez mercantil sobre el ámbito de protección de la invención contenida en la reivindicación 11 de la patente ES 454.

A la vista de la explicación que se hace en la descripción detallada de la invención sobre el problema técnico (se pretendía encontrar una formulación que pudiera proporcionar una mezcla de granulación adecuada para ser extruida de modo apropiado, solucionando el problema que suponía que durante el proceso de extrusión se produjera una acumulación de calor que secara de tal modo el material de extrusión que se dificultara la conversión de los cilindros extruidos en esferoides) y la solución alcanzada [la celulosa microcristalina sirve, junto con otro excipiente (HPMC) y el principio activo (venlafaxina) para conformar el esferoide por una técnica de extrusión-esferonización], la audiencia entiende que existe un elemento definidor de la invención identificado en la descripción que habría de integrarse en la reivindicación, quedando de esta forma delimitado el ámbito de protección conferido por la patente en términos más reducidos que los que resultan del estricto literal de aquella. Y en la medida en que la realización controvertida no participa de tal característica técnica, no cabría apreciar infracción.

La audiencia también rechaza que exista una infracción de la patente ES 684 con argumentos similares a los empleados por la sentencia de primera instancia.

5. Frente a la sentencia de apelación, Wyeth interpone recurso extraordinario por infracción procesal y recurso de casación. Ambos recursos afectan tan sólo al pronunciamiento por el cual se ha confirmado la desestimación de las acciones basadas en la infracción de la patente ES 454.

Recurso extraordinario por infracción procesal

6. *Formulación del único motivo*. En el encabezamiento del motivo se denuncia que la sentencia recurrida "infringe el derecho a la tutela judicial efectiva del art. 24 de la Constitución, al valorar la prueba practicada de forma manifiestamente ilógica y errónea".

En el desarrollo del motivo se alega que la sentencia de primera instancia llevó a cabo una valoración errónea y arbitraria de los dictámenes ampliatorios y del dictamen del perito judicial, que no aparecían en la pieza de medidas cautelares, lo que condicionó el fallo de aquella sentencia. Y, a continuación, se denuncia que la sentencia de apelación no se pronunciara sobre esta errónea y arbitraria valoración de la prueba pericial, a pesar de haberse aducido en el recurso de apelación. El error en la valoración de la prueba se habría producido al reducir el problema que soluciona la patente a una concreta técnica de obtención de esferoides que ya era conocida en la fecha de prioridad de la patente. Según el recurso, el tribunal de apelación, como ya hiciera el de primera instancia, equipara un problema rutinario derivado de un procedimiento de obtención de esferoides que ya era conocido en el estado de la técnica (como era el procedimiento de extrusión), con el problema que soluciona la patente.

Después, de forma muy pormenorizada, el recurso muestra, a la luz de los documentos que forman parte del estado de la técnica y de las consideraciones efectuadas en los dictámenes ampliatorios, la valoración incorrecta del problema que soluciona la patente llevada a cabo por la sentencia recurrida.

En otro apartado del motivo, se advierte que las conclusiones erróneas alcanzadas por la sentencia recurrida sobre el ámbito de protección de la patente han impedido que se pronunciara sobre la infracción por equivalencia, cuando la prueba practicada acreditaba de forma indubitada la existencia de tal infracción.

Procede desestimar el motivo por las razones que exponemos a continuación.

7. *Desestimación del único motivo del recurso extraordinario por infracción procesal.* Con este motivo, la recurrente pretende que la Sala vuelva a revisar el enjuiciamiento sobre la infracción de la patente, que presupone en primer lugar la determinación del alcance de la protección de la invención protegida por la patente de Wyeth.

La desestimación del motivo obedece a que lo que se impugna es la valoración realizada por el tribunal de instancia del ámbito de protección de la patente ES 454, al interpretar sus reivindicaciones 1 y 11, en relación con la descripción y los dibujos. Aunque para esta interpretación se tenga en cuenta el parecer de los peritos, la valoración de la prueba no lo es tanto para declarar unos hechos probados como para interpretar la patente, y, en concreto, determinar el alcance de la protección de la invención que se reivindica, que constituye el titulo jurídico.

Ya hemos advertido en otras ocasiones, como por ejemplo en la sentencia 533/2014, de 14 de octubre, en que por este mismo cauce del recurso de infracción procesal se pretendía impugnar la valoración que el tribunal de instancia hacía de un contrato, por considerarla arbitraria o porque incurría en un error notorio, que "no debe confundirse la revisión de la valoración de la prueba que, al amparo del ordinal 4º del art. 469.1 LEC, excepcionalmente puede llegar a realizarse en caso de error patente o arbitrariedad en la valoración realizada por la sentencia recurrida que comporte una infracción del derecho a la tutela judicial efectiva (Sentencias 432/2009, de 17 de junio; 196/2010, de 13 de abril; 495/2009, de 8 de julio y 211/2010, de 30 de marzo; 326/2012, de 30 de mayo), con la revisión de la valoración jurídica mediante la cual el tribunal califica la obligación asumida por los demandados de fianza". Lo mismo ocurre en este caso en que la valoración que se impugna versa sobre el alcance de la protección de la patente y, consiguientemente, sobre si

la realización cuestionada la infringe, pues se refiere a la interpretación del titulo jurídico, la patente, aunque se haga teniendo en cuenta el estado de la técnica existente en el momento de la solicitud y el análisis de la propia realización cuestionada.

De este modo, resulta de aplicación la conclusión alcanzada en aquellos otros casos, según la cual "una valoración como esta, al margen de que sea o no acertada, es jurídica y debería ser impugnada, en su caso, en el recurso de casación, si con esta valoración se infringe la normativa legal reguladora de la materia y su interpretación jurisprudencial" (Sentencia 533/2014, de 14 de octubre, con cita de la anterior Sentencia 77/2014, de 3 de marzo).

Recurso de casación

8. *Formulación de los dos motivos de casación.* El *motivo primero* se basa en la infracción de la doctrina jurisprudencial que determina que una patente que reivindica un producto confiere una protección absoluta sobre ese producto. Después de un excurso irrelevante en el presente caso sobre el efecto que provocó la entrada en vigor en España de los acuerdos ADPIC respecto de las invenciones afectadas por la prohibición de patentes de producto farmacéuticas y químicas, el recurso argumenta que la sentencia recurrida incurre en el error de interpretar las reivindicaciones 1 y 11 de la patente ES 454 como si fueran reivindicaciones de procedimiento en las que quedaría protegido el producto pero siempre condicionado a su procedimiento de fabricación.

El *motivo segundo* se basa en la infracción del art. 60.1 LP (Ley 11/1986, de 20 de marzo, de Patentes), en relación con el art. 69 CPE (Convenio sobre concesión de Patentes Europeas, hecho en Munich el 5 de octubre de 1973) y de la jurisprudencia que los interpreta, en que habría incurrido la sentencia recurrida, al restringir el ámbito de protección de las reivindicaciones de la patente, que son claras y concisas, a partir de la descripción. En el desarrollo del motivo, se insiste en que el tenor de las reivindicaciones 1 y 11 es perfectamente claro y no se presentan ambigüedades que justifiquen el recurso a la descripción de la patente en la forma que lo hace la sentencia recurrida, sobre todo si con ello se restringe el ámbito de protección de la invención. También argumenta que la sentencia recurrida confunde el modo de

realización expuesto en la descripción detallada de la invención con el ámbito de protección de la patente.

Finalmente, el recurso razona por qué, conforme al art. 2 del Protocolo Interpretativo del art. 69 CPE, la infracción de la patente también alcanza los productos que tengan características técnicas "equivalentes" a los de la invención patentada, de tal forma que la infracción de una reivindicación no queda excluida por el mero hecho de que alguna característica o elemento técnico de la misma se sustituya por otra característica o elemento técnico que sea "equivalente". E imputa a la interpretación sentencia recurrida que no tome en consideración en la determinación del ámbito de protección de la patente "todo elemento equivalente a un elemento indicado en las reivindicaciones", y que no entre a analizar la infracción por equivalencia llevada a cabo por Uso Racional al sustituir la celulosa microcristalina (único excipiente que no se encuentra en su formulación) por la esfera de azúcar, lo que entra en contradicción con la doctrina expuesta por la Sentencia de esta Sala 309/2011, de 10 de mayo.

Procede desestimar ambos motivos, que analizaremos conjuntamente, por las razones que exponemos a continuación.

9. *Alcance de la revisión en casación del juicio de infracción.* Con carácter previo al concreto análisis de los motivos aducidos, y en relación con la oposición formulada por la parte recurrida a la admisión del recurso, conviene hacer una breve reflexión sobre lo que puede ser objeto de revisión en casación, en un supuesto como el presente en que se impugna el enjuiciamiento sobre si la realización cuestionada incorpora la invención, en este caso, por equivalentes.

Aunque este juicio se apoye en unos hechos, que no pueden ser cuestionados en casación y sobre los que debe partirse, constituye una valoración de la relevancia jurídica de estos hechos. Esta relevancia jurídica viene configurada no sólo por la normativa de patentes, sobre la que no hay duda que debe existir una jurisprudencia clara, sino también por la propia patente, que constituye un título jurídico, de tal forma que el alcance de la protección jurídica que otorga la patente viene dado por la interpretación que se haga de sus reivindicaciones, a la vista de la descripción y de los dibujos.

El punto de equilibrio entre conocer en casación algunos de estos asuntos, que permita pueda aflorar una jurisprudencia sobre patentes, sin convertir el Tribunal Supremo en una tercera instancia, viene determinado por que, como en el caso de la interpretación de los contratos, reconozcamos con carácter general que la interpretación de la patente (en concreto de sus reivindicaciones, teniendo en cuenta la descripción y los dibujos) es una función que corresponde a los tribunales de instancia, y que sólo excepcionalmente puede ser revisada en casación cuando se aparta de las reglas legales y jurisprudenciales, y cuando sea arbitraria o incurra en un error notorio.

10. *Interpretación del alcance de protección de la patente*. Bajo el marco jurídico que regula la patente nacional y la europea, las reivindicaciones cumplen una doble función: de una parte, definen el objeto para el que se solicita la protección, conforme a los arts. 84 CPE y 26 LP, indicando para ello las características técnicas de la invención necesarias para ejecutar el procedimiento o definir el producto en que consiste la invención, y que permiten resolver el problema técnico anunciado en la memoria descriptiva; y de otra, determinan la extensión de la protección conferida por la patente o por la solicitud de patente, de acuerdo con los arts. 69.1 CPE y 60.1 LP, tomando en consideración la descripción y los dibujos.

Esta segunda función, de delimitar el ámbito de exclusiva de la patente, es esencial para juzgar sobre la violación de la patente. Si partimos de la consideración de que una patente protege tantas invenciones como reivindicaciones tiene, para determinar si se ha producido invasión de la exclusiva será preciso interpretar la reivindicación o reivindicaciones afectadas, a fin de conocer su sentido técnico y jurídico relevante, y así poder determinar el alcance de la protección que otorga la patente; y, ello sentado, una comparación entre lo que la patente reivindica tal como fue concedida, según su correcto alcance, y la realización cuestionada.

Como hemos advertido en otras ocasiones, por ejemplo en la Sentencia 466/2013, de 12 de julio, de acuerdo con la norma legal (el art. 69.1 CPE y el art. 60.1 LP), el alcance de la protección que otorga la patente estará determinado por el contenido de las reivindicaciones. No obstante, la

descripción y los dibujos servirán para interpretar éstas y conocer su contenido.

Con el fin de aclarar las dudas surgidas sobre el alcance de esta interpretación, el art. 1 del Protocolo Interpretativo del art. 69 CPE proporciona un poco más de precisión a la interpretación del alcance que debe reconocerse a las reivindicaciones.

Como tuvimos oportunidad de exponer en la Sentencia 309/2011, de 10 de mayo, «El art. 69 del CPE, interpretado por el Protocolo Interpretativo de 1973, se inclinó por un sistema intermedio, entre los sistemas del Derecho Inglés (y norteamericano) -que delimita el ámbito del derecho de exclusiva con sujeción al texto de las reivindicaciones, las cuales se han de interpretar de modo estricto de conformidad con su tenor literal- y el de la concepción tripartita (seguida en Alemania, Holanda y Suiza) -que extendía la protección a la "*idea general de la invención" que consiste "en la aportación global del inventor al estado de la técnica y que es el resultado de un proceso de generalización del objeto de la invención"*-.

»El art. 84 CPE dispone que las reivindicaciones definen el objeto para que se solicita la protección. Deben ser claras y concisas y han de fundarse en la descripción; y el art. 69.1 CPE establece que "*el alcance de la protección que otorga la patente europea está determinado por las reivindicaciones; no obstante, la descripción y los dibujos servirán para interpretar las reivindicaciones*".

»El Protocolo Interpretativo, del año 1973, del art. 69 (y que pasó a constituir el artículo 1 del Protocolo interpretativo redactado en la Conferencia de revisión, del año 2000) señala que "*el art. 69 no deberá interpretarse en el sentido de que el alcance de la protección que otorga la patente europea haya de entenderse según el sentido estricto y literal del texto de las reivindicaciones y que la descripción y los dibujos sirvan únicamente para disipar las ambigüedades que pudieran contener las reivindicaciones. Tampoco debe interpretarse en el sentido de que las reivindicaciones sirvan únicamente de línea directriz y que la protección se extienda también a lo que, en opinión de una persona experta que haya examinado la descripción y los dibujos, el titular de la patente haya querido proteger. El art. 69 deberá, en cambio, interpretarse*

en el sentido de que define entre esos extremos una posición que garantiza a la vez una protección equitativa para el solicitante y un grado razonable de certidumbre a terceros".

»Como consecuencia de la normativa expuesta, no rige en el CPE (...) el sistema del tenor literal (a pesar de que la versión castellana del precepto recoge la expresión "tenor", igual que las versiones francesa e inglesa, y sin que nada signifique que el artículo correspondiente de la LP 11/1986 , recoja el término "contenido" como la ley alemana)».

De este modo, el objeto de la interpretación es el *contenido* de las reivindicaciones (arts. 26 y 60.1 LP) o, lo que viene a ser lo mismo, el *tenor* de las mismas (art. 69.1 CPE), porque éstas definen el objeto de la invención y la extensión de la protección. Sin embargo, la descripción y los dibujos *deben* tenerse en cuenta en la labor interpretativa, para determinar su contenido. Esto equivale a decir que la interpretación es necesaria en todo caso.

No se trata de una interpretación meramente literal, o estrictamente literalista (como indica el primer inciso del Protocolo, que descarta una opción extrema), sino que se acepta un criterio espiritualista, en la búsqueda del verdadero significado del contenido de la reivindicación, más allá de las palabras empleadas; lo que no ha de impedir que se alcance un resultado más estricto que el que resulta de éstas.

Lo anterior no implica asumir un criterio voluntarista o subjetivo, pues a la hora de extraer el sentido técnico y jurídicamente relevante de las reivindicaciones, debe evitarse la concepción de éstas como una mera pauta o línea directriz de tal manera que lo relevante sea lo que el titular de la patente haya querido proteger.

La interpretación debe ser básicamente objetiva, pues se trata de identificar y situar una invención en el estado de la técnica, y ello ha de hacerse a partir de la declaración de ciencia que constituyen las reivindicaciones.

Pero es que, además, como añadía la citada Sentencia 309/2011, de 10 de mayo, «la protección de la patente se extiende al "uso equivalente" de la invención, que tiene lugar "*cuando se ejecuta la invención patentada con*

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medios no reivindicados expresamente, pero que contienen características esenciales de la invención patentada".

»La conferencia de Revisión (Acta de Munich de 29 noviembre 2000) añadió al Protocolo interpretativo del art. 69 el artículo 2, en el que se establece que "para determinar la extensión de la protección otorgada por la patente europea, deberá tenerse debidamente en cuenta todo elemento equivalente a un elemento indicado en las reivindicaciones", aunque no recogió el concepto que figuraba en la Propuesta de base, que consideraba equivalente un elemento "cuando sea evidente para un experto en la materia que su utilización permite obtener esencialmente el mismo resultado que el obtenido por el elemento indicado en las reivindicaciones"».

11. El tribunal de instancia, con mayor precisión el juzgado mercantil que la audiencia, que en última instancia ratifica el enjuiciamiento realizado en primera instancia, ha llevado a cabo una interpretación de la patente, en concreto de su ámbito de protección, para valorar después si la realización cuestionada incorpora la invención contenida en las dos reivindicaciones principales invocadas (1ª y 11ª), conforme a la doctrina antes expuesta.

El tribunal analiza la reivindicación 11, que es a la que se le reconoce mayor alcance en su protección, y para ello identifica sus elementos, conforme al tenor de las palabras empleadas:

a) un esferoide recubierto,

b) el esferoide ha de comprender clorhidrato de venlafaxina, celulosa microcristalina e hidroxipropilmetilcelulosa,

c) el esferoide ha de estar recubierto con etilcelulosa y HPMC (hidroxipropilmetilcelulosa).

Y la interpreta teniendo en cuenta la descripción detallada de la invención que, como se prevé en el art. 5.2.d) del Reglamento para la aplicación de la Ley de Patentes, debe contener "*una explicación de la invención, tal y como es caracterizada en las reivindicaciones que permita la comprensión del problema técnico planteado, así como la solución del mismo, indicándose, en su caso, las ventajas de la invención en relación con el estado de la técnica anterior...*").

El tribunal de instancia opera conforme a los criterios legales antes expuestos,

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cuando se apoya en la descripción para advertir que, en realidad, el problema técnico concreto al que pretende dar solución la invención, aunque se enmarca dentro de la obtención de un resultando consistente en la liberación sostenida de la venlafaxina, no se circunscribe a este resultado, sino a solventar los obstáculos que se presentan al realizar una concreta formulación de la liberación prolongada de la venlafaxina. Lo que se pretendía era encontrar una formulación que pudiera proporcionar una mezcla de granulación adecuada para ser extraída de modo apropiado, solucionando el problema que suponía que durante el proceso de extrusión se produjera una acumulación de calor que secara de tal modo el material de extrusión que se dificultara la conversión de los cilindros extruidos en esferoides.

Cuando el tribunal de instancia rechaza que la protección de la invención se extienda al resultado perseguido de liberación prologada del principio activo del principio activo de venlafaxina, que ya era conocido en el estado de la técnica antes de que solicitara la patente, y lo ciñe a un modo de obtenerlo que solventa el problema técnico expuesto, no está negando a la patente ES 454 la protección propia de una patente de producto, confundiéndola con una de procedimiento, sino que esta precisando que la invención de producto reivindicada es una concreta formulación y no el resultado perseguido con esta formulación, que se podía alcanzar con otras formulaciones distintas, como las realizaciones cuestionadas, sin que unas y otras pierdan la consideración de producto y sean consideradas como procedimientos. Por esta razón debía ser desestimado el primer motivo de casación.

Del mismo modo, y a la vista de la doctrina expuesta sobre la determinación del alcance de la protección de la patente, la sentencia recurrida, cuando interpreta el contenido de la reivindicación 11 teniendo en cuenta lo manifestado en la descripción detallada sobre el problema técnico que se pretendía solucionar, y alcanza un resulta más estricto que el que resultaría del tenor literal de las palabras empleadas, no sólo no infringe los arts. 60.1 LP y 69 CPE, sino que se acomoda a ellos, según los criterios emanados del protocolo interpretativo del art. 69 CPE, antes expuesto. Lo que además está en consonancia con el art. 84 CPE, según el cual el objeto de cada una de las reivindicaciones debe de tener una base en la descripción y el ámbito de

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protección de las reivindicaciones no se puede extender mas allá del ámbito justificado por la descripción y por los dibujos.

12. La sentencia recurrida, en la medida que ratifica el enjuiciamiento llevado a cabo por la sentencia de primera instancia, no obvia el juicio de equivalencia.

Descompone los elementos de la realización cuestionada:

a) una esfera inerte de azúcar,

b) recubierta con una capa de venlafaxina, hidroxipropilcelulosa (HPC) y otros,

c) otro recubrimiento de sellado de HPMC

d) un último recubrimiento de liberación sostenida de HPM y etilcelulosa.

Y expresamente argumenta por qué, contrariamente a lo sostenido por la demandante, la celulosa microcristalina empleada en la invención y los núcleos de azúcar y almidón de la realización cuestionada, no pueden considerarse equivalentes. En la invención, la celulosa microcristalina sirve, junto con otro excipiente (HPMC) y el principio activo (venlafaxina), para conformar el esferoide por una técnica de extrusión-esferonización, superando los problemas de calentamiento de la masa que surgían en ese proceso; mientras que en las realizaciones cuestionadas los núcleos inertes (azúcar y almidón, o sólo azúcar) no sirven para superar esos problemas del proceso de extrusión-esferonización.

A la vista del concreto problema técnico que se pretende solucionar con la invención, según la descripción de la patente, cumple un papel especial la adición de HPMC a la celulosa microcristalina, que es un compuesto ausente en la realización cuestionada, sin que los excipientes empleados en la realización cuestionada desempeñen, unidos a la HPMC, además de su genuina función diluyente o aglutinante, esa función de contención de calor y de su efecto de secado de los elementos.

Lo anterior puede bastar para concluir que la realización cuestionada no incorpora elementos equivalentes que constituyeran una alternativa obvia a los elementos reivindicados, para obtener un resultado sustancialmente igual al

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mismo problema técnico, pues, como hemos expuesto, los elementos empleados por la realización cuestionada que se denunciaban equivalentes a los de la invención, no responden a la solución del concreto problema técnico que pretendía solventar la invención.

De este modo, la sentencia recurrida, contrariamente a lo aducido en el segundo motivo de casación, se adecua al art. 2 del Protocolo Interpretativo del art. 69 CPE, y no obvia que en la determinación del ámbito de protección de la patente de la demandante deba tenerse en consideración "todo elemento equivalente a un elemento indicado en las reivindicaciones", sin perjuicio de en este caso concluya que no se da, después de haber analizado que no tiene esta consideración de elemento equivalente el empleo por las realizaciones cuestionadas de una esfera de azúcar, en relación con la celulosa microcristalina, excipiente empleado por la invención.

No puede negarse que la sentencia recurrida haya seguido los criterios legales y jurisprudenciales sobre el ámbito de protección de la invención y su posible infracción por la realización cuestionada mediante el empleo de elementos equivalentes, sin que la revisión en casación nos permita sustituir el enjuiciamiento realizado por el tribunal de instancia, una vez advertido que respeta las reglas legales y jurisprudenciales para realizarlo, y al hacerlo no incurre en error notorio ni en arbitrariedad.

Costas

13. Desestimados el recurso extraordinario por infracción procesal y el de casación, se imponen a la parte recurrente las costas generadas por ambos recursos (art. 398.1 LEC).

Por lo expuesto, en nombre del Rey y por la autoridad conferida por el pueblo español.

F A L L A M O S

Desestimamos el recurso extraordinario por infracción procesal interpuesto por la representación de Wyeth, LLC contra la Sentencia de la Audiencia Provincial

de Madrid (sección 28ª) de 27 de diciembre de 2012, que resolvió el recurso de apelación (rollo núm. 547/2010) interpuesto contra la Sentencia del Juzgado Mercantil núm. 2 de Madrid de 31 de mayo de 2010 (juicio ordinario núm. 251/2007), con imposición de las costas generadas por su recurso a la parte recurrente.

Desestimamos el recurso de casación interpuesto por la representación de Wyeth, LLC contra la referida Sentencia de la Audiencia Provincial de Madrid (sección 28ª) de 27 de diciembre de 2012, con imposición de las costas generadas por su recurso a la parte recurrente.

Publíquese esta resolución conforme a derecho y devuélvanse a la Audiencia los autos originales y rollo de apelación remitidos con testimonio de esta resolución a los efectos procedentes.

Así por esta nuestra sentencia, que se insertará en la COLECCIÓN LEGISLATIVA pasándose al efecto las copias necesarias, lo pronunciamos, mandamos y firmamos.- Francisco Marín Castán.- José Ramón Ferrándiz Gabriel.- Ignacio Sancho Gargallo.- Francisco Javier Orduña Moreno.- Sebastián Sastre Papiol.- Firmado y Rubricado.

PUBLICACIÓN.- Leída y publicada fue la anterior sentencia por el EXCMO. SR. D. **Ignacio Sancho Gargallo**, ponente que ha sido en el trámite de los presentes autos, estando celebrando Audiencia Pública la Sala Primera del Tribunal Supremo, en el día de hoy; de lo que como secretario de la misma, certifico.

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T R I B U N A L S U P R E M O
Sala de lo Civil

Presidente Excmo. Sr. D. Francisco Marín Castán

SENTENCIA

Sentencia Nº: 223/2015
Fecha Sentencia*:* 29/04/2015
CASACIÓN E INFRACCIÓN PROCESAL
Recurso Nº*:* 556/2013
Fallo/Acuerdo: Sentencia Desestimando
Votación y Fallo: 08/04/2015
Ponente Excmo. Sr. D.*:* Rafael Sarazá Jimena
Procedencia: Sección 15.ª de la Audiencia Provincial de Barcelona
Secretaría de Sala*:* Ilmo. Sr. D. José María Llorente García
Escrito por*:* MRP
Nota:

Recurso extraordinario por infracción procesal. El recurso extraordinario por infracción procesal no convierte a esta Sala en una tercera instancia. Improcedencia de identificar cualquier vulneración procesal con la infracción del art. 24 de la Constitución La impugnación de la recurrente a la suficiencia de la prueba practicada para acreditar un hecho relevante no supone que la sentencia recurrida haya vulnerado las reglas de la carga de la prueba.
Recurso de casación. Patentes de invención. Acción por infracción. Doctrina de los equivalentes. La infracción por equivalencia: la obviedad de la alternativa

ADMINISTRACION DE JUSTICIA

CASACIÓN E INFRACCIÓN PROCESAL Num.: **556/2013**
Ponente Excmo. Sr. D.: **Rafael Sarazá Jimena**
Votación y Fallo: **08/04/2015**
Secretaría de Sala: **Ilmo. Sr. D. José María Llorente García**

TRIBUNAL SUPREMO
Sala de lo Civil

SENTENCIA Nº: **223/2015**

Excmos. Sres.:

D. Francisco Marín Castán
D. Francisco Javier Orduña Moreno
D. Rafael Sarazá Jimena

En la Villa de Madrid, a veintinueve de Abril de dos mil quince.

La Sala Primera del Tribunal Supremo, constituida por los magistrados indicados al margen, ha visto los recursos extraordinario por infracción procesal y de casación núm. 556/2013, interpuesto por el procurador D. Ángel Quemada Cuatrecasas, asistido por el letrado D. Miquel Montañá Mora, en nombre de "H. Lundbeck A/S" y de "Lundbeck España S.A.", representada ante esta Sala por la procuradora D.ª M.ª Dolores Girón Arjonilla, contra la sentencia núm. 434/2012, de 19 de diciembre, dictada por la sección decimoquinta de la Audiencia Provincial de Barcelona, en el recurso de apelación núm. 54/2012, dimanante de las actuaciones de procedimiento ordinario núm. 6572010, seguidas ante el Juzgado de lo Mercantil núm. 4 de Barcelona. Han sido recurridos los laboratorios "Adamed Sp. Z.O.O." y "Adamed Laboratorios S.L.U.", representados ante esta Sala por D.ª Rosa Sorribes Calle y asistidos por la letrada D.ª Rita Reyes Ríos, "Laboratorios Cinfa, S.A.", "Galenicum Health, S.L.", "Laboratorios Normon, S.A.", "Sandoz Farmacéutica, S.A.", "Lannacher Heilmittel GMBH", "Ratiopharm España, S.A", "Laboratorios Milo, S.A.", "Bexal Farmacéutica, S.A.", "Acost Comercial Generic Pharma, S.L.", "Laboratorio Stada, S.L.", "Kern Pharma, S.L.", "Actavis Spain, S.A.", representados ante esta Sala por el procurador D. Anibal Bordillo Huidobro, bajo la asistencia letrada de D. Javier Huarte Larrañaga, y "Germed Farmaceútica", antes "Uso Racional, S.L", representada ante esta Sala por el Procurador D. Javier Zabala Falcó y asistida por el letrado D. Jaime Enrique Cuevas Martínez, "Mylan Pharmaceuticals, S.L.", representada ante esta Sala

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por la procuradora D.ª Rosa Sorribes Calle y asistida por el letrado D. Miguel Vidal-Quadras Trias de Bes, y "Cantabria Pharma, S.L.", no personada ante esta Sala.

ANTECEDENTES DE HECHO

PRIMERO.- "H. Lundbeck A/S" y de "Lundbeck España S.A." presentaron ante el Decanato de los Juzgados de Barcelona, con fecha 25 de enero de 2010, demanda de juicio ordinario contra "Galenicum Health, S.L.", "Laboratorios Cinfa, S.A.", "Laboratorios Normon, S.A.", "Sandoz Farmacéutica, S.A.", "Lannacher Heilmittel GMBH" y "Ratiopharm España, S.A." que, una vez repartida, tuvo entrada en el Juzgado de lo Mercantil núm. 4, cuyo suplico decía: *«[…] dicte sentencia por la que, dando lugar a los pedimentos de mis principales, SE DECLARE que:*

1. *H.LUNDBECK A/S es titular del Certificado Complementario de Protección Núm. C 200300019 sobre la patente europea EP 347.066 B1 (publicada en España con el número ES 2.986.891) y LUNDBECK ESPAÑA, S.A. es licenciataria para España de dicho Certificado Complementario de Protección.*
2. *Los medicamentos genéricos "Escitalopram Cinfa" (Núm. Reg. 71430. 71428, 71425 y 71419), "Escitalopram Goibela (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz" (Núm. Reg. 71585, 71586 y 71584) y 'Escitalopram Lannacher"(Núm. Reg. 71317, 71318 y 71319) invaden el ámbito de protección del Certificado Complementario de Protección Núm. C 200300019.*
3. *El ofrecimiento, la introducción en el comercio o la utilización, antes de la fecha de caducidad del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891, de Escitalopram obtenido mediante cualquier procedimiento que se encuentre comprendido dentro del ámbito de protección de la patente ES 2.068.891, o la importación o posesión de dicho producto para alguno de los fines mencionados supone la infracción del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891.*
4. *La transmisión de las autorizaciones de comercialización de los medicamentos genéricos "Escitalopram Cinfa" (Núm. Reg. 71430. 71428 71425 y 71419), Escitalopram Goibela (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon (Núm. Reg. 71417, 71421 y 71426), Escitalopram Sandoz (Núm. Reg. 71585, 71586 y 71584) y/o Escitalopram Lannacher" (Núm. Reg. 71317, 71318 y 71319), constituye un acto de contribución y/o cooperación a la infracción del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891.*
5. *Las demandadas han realizado actos de infracción del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 de H. LUNDBECK A/S. Con carácter subsidiario, para el caso de que no quedara acreditada la realización de concretos actos de explotación del objeto de la patente ES 2.068.891, se declare que han realizado actos que constituyen una amenaza de infracción del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891.*
6. *Las demandadas han realizado actos de competencia desleal por obstaculización y/o por imitación que comportan un riesgo de aprovechamiento indebido del esfuerzo ajeno.*
7. *En particular, la fabricación, importación, posesión, ofrecimiento e introducción en el comercio de los medicamentos genéricos "Escitalopram Cinfa" (Núm. Reg. 71430, 71428, 71425 y 71419), "Escitalopram Goibela" (Núm. Reg. 71420,*

71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz" (Núm. Reg. 71585, 71586 y 71584) y/o "Escitalopram Lannacher" (Núm. Reg. 71317, 71318 y 71319) constituye un acto de competencia desleal por obstaculización y/o por imitación que comporta un riesgo de aprovechamiento indebido del esfuerzo ajeno.

8. *Las demandadas han causado a H. Lundbeck A/S y Lundbeck España, S.A. unos daños y perjuicios ciertos y efectivos, cuya determinación deberá realizarse a lo largo del procedimiento (o, subsidiariamente, en ejecución de sentencia), consistentes en todos los gastos incurridos por mis principales con relación a los actos de infracción del Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 o, subsidiariamente, preparatorios para la inminente infracción, llevados a cabo por las demandadas, entre los que se enuncian, a título de ejemplo, los gastos derivados del asesoramiento de profesionales especializados, de la preparación de traducciones, de la realización de pruebas analíticas, de las horas dedicadas por el personal de dichas empresas a preparar y atender el litigio, viajes realizados con dicho fin y cualquier otro concepto que resulte acreditado en autos.*
9. *Las demandadas han causado a H. Lundbeck A/S y Lundbeck España, S.A. unos daños y perjuicios ciertos y efectivos, cuya determinación deberá realizarse a lo largo del procedimiento (o, subsidiariamente, en ejecución de sentencia), conforme a las siguientes bases:*
    - *(a) Los beneficios que H. Lundbeck A/S y Lundbeck España, S.A. habrían obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la infracción de las demandadas, lo que incluye tanto los beneficios adicionales que H. Lundbeck A/S y Lundbeck España, S.A. habrían obtenido de comercializar ellas las unidades de medicamentos poseídos, ofrecidos y/o comercializados por las demandadas, como cualquier pérdida. como, por ejemplo, la derivada de la eventual inclusión del producto en el sistema de precios de referencia; y*
    - *(b) Los beneficios que las demandadas hayan obtenido de la explotación de la invención objeto de la patente ES 2.068.891 titularidad de H. Lundbeck A/S.*

Y se condene a las demandadas a:

1. *Estar y pasar por las anteriores declaraciones.*
2. *Abstenerse de ofrecer, introducir en el comercio, utilizar, importar y poseer, mientras el Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 esté en vigor, y, en el supuesto de que alguno de dichos actos de infracción ya hubiera sido realizado, cesar en el ofrecimiento, introducción en el comercio, utilización, importación y posesión, mientras el Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 esté en vigor, de:*
    - *(a) Escitalopram obtenido por cualquier procedimiento que se encuentre comprendido dentro del ámbito de protección de la patente ES 2.068.891; y*
    - *(b) En particular, abstenerse de ofrecer, introducir en el comercio, utilizar, importar y poseer los medicamentos genéricos "Escitalopram Cinfa (Núm. Reg. 71430, 71428, 71425 y 71419). "Escitalopram Goibela' (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz (Núm. Reg. 71585, 71586 y 71584) y "Escitalopram Lannacher" (Núm. Reg. 71317. 71318 y 71319), en cualquiera de sus presentaciones, así como cualquier otro medicamento genérico de Escitalopram autorizado en base al mismo dossier de registro y/o dossieres en los que figure el mismo procedimiento de fabricación, y que llegue a obtener precio de venta al público.*

3. *Retirar del tráfico económico y de sus locales, incluso si ello exige la recompra a sus poseedores u otro negocio jurídico, de:*
   (a) *Todo Escitalopram obtenido mediante cualquier procedimiento que se encuentre comprendido dentro del ámbito de protección de las reivindicaciones de la patente ES 2.068.891;*
   (b) *En particular, todas las unidades de venta de los medicamentos genéricos "Escitalopram Cinfa (Núm. Reg. 71430, 71428, 71425 y 71419). "Escitalopram Goibela' (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz (Núm. Reg. 71585, 71586 y 71584) y "Escitalopram Lannacher" (Núm. Reg. 71317, 71318 y 71319), en cualquiera de sus presentaciones, así como cualquier otro medicamento genérico de Escitalopram autorizado en base al mismo dossier de registro y/o dossieres en los que figure el mismo procedimiento de fabricación, y que llegue a obtener precio de venta al público.*
4. *Al embargo y destrucción de los objetos producidos o importados con violación de los derechos de patente de H. Lundbeck A/S y Lundbeck España, S.A. y de los medios principalmente destinados a tal producción o a la realización de la infracción y, en particular, al embargo y destrucción de:*
   (a) *Todo Escitalopram obtenido mediante cualquier procedimiento que se encuentre comprendido dentro del ámbito de protección de las reivindicaciones de la patente ES 2.068.891;*
   (b) *En particular, todas las unidades de venta de los medicamentos genéricos Escitalopram Cinfa (Núm. Reg. 71430, 71428, 71425 y 71419). "Escitalopram Goibela' (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz (Núm. Reg. 71585, 71586 y 71584) y "Escitalopram Lannacher" (Núm. Reg. 71317, 71318 y 71319), en cualquiera de sus presentaciones, así como cualquier otro medicamento genérico de Escitalopram autorizado en base al mismo dossier de registro y/o dossieres en los que figure el mismo procedimiento de fabricación, y que llegue a obtener precio de venta al público.*
5. *A abstenerse de transferir a terceros la titularidad y/o derechos de utilización y. en el supuesto de que hayan procedido ya a su transmisión a terceros, procedan con carácter inmediato a la ejecución de todos los actos necesarios para recuperar la titularidad y/o derechos de utilización, de:*
   (a) *Las autorizaciones de comercialización relativas a Escitalopram obtenido mediante cualquier procedimiento que se encuentre comprendido dentro del ámbito de protección de la patente ES 2.068.891; y*
   (b) *En particular, las autorizaciones de comercialización relativas a los medicamentos genéricos"Escitalopram Cinfa (Núm. Reg. 71430, 71428, 71425 y 71419). "Escitalopram Goibela' (Núm. Reg. 71420, 71423, 71427 y 71415), "Escitalopram Normon" (Núm. Reg. 71417, 71421 y 71426), "Escitalopram Sandoz (Núm. Reg. 71585, 71586 y 71584) y "Escitalopram Lannacher" (Núm. Reg. 71317, 71318 y 71319), en cualquiera de sus presentaciones, así como cualquier otro medicamento genérico de Escitalopram autorizado en base al mismo dossier de registro y/o dossieres en los que figure el mismo procedimiento de fabricación, y que llegue a obtener precio de venta al público.*
6. *A resarcir a H. Lundbeck A/S y Lundbeck España, S.A. por los gastos y daños y perjuicios causados por las demandadas en la cuantía que se determinen en período de prueba o, en su caso, en fase de ejecución aplicando las bases fijadas en la Sentencia. Para el cálculo de la indemnización de daños y perjuicios habrán de tomarse las siguientes bases:*
   (a) *Todos los gastos incurridos por H. Lundbeck A/S y Lundbeck España, S.A. con relación a los actos de infracción de la patente ES 2.068.891 llevados a*

cabo por las demandadas, o los actos encaminados a su inminente infracción, entre los que enunciamos, a título de ejemplo, los gastos derivados de (i) los análisis realizados para comprobar la realidad de dichos actos; (ji) el asesoramiento de profesionales especializados; (iii) traducciones. (iv) las horas dedicadas por el personal de dichas empresas a preparar y atender el litigio, (y) viajes realizados con dicho fin; y (vi) cualquier otro concepto que resulte acreditado en autos;

(b) Además, deberán tomarse en consideración también las siguientes bases:

(i) El número de unidades vendidas por las demandadas;

(ii) Los beneficios que H. Lundbeck A/S y Lundbeck España, S.A. habrían obtenido previsiblemente de la explotación de la invención protegida por el Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 si no hubiera existido la infracción de las demandadas, lo que incluye tanto los beneficios adicionales que H. Lundbeck A/S y Lundbeck España, S.A. habrían obtenido de vender ellas las unidades de medicamentos genéricos poseídos, ofrecidos y/o comercializados por las demandadas, como cualquier pérdida derivada de la eventual inclusión de Escitalopram en el sistema de precios de referencia; y

(iii) Los beneficios que las demandadas hayan obtenido de la explotación de la invención protegida por el Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891.

7. A notificar la Sentencia, a costa de las demandadas, a:

(a) La Agencia Española del Medicamento y Productos Sanitarios, con domicilio en Parque Empresarial Las Mercedes, Edificio 8, Campezo 1, 28022 Madrid, al objeto de que proceda a anotar la Sentencia en el Registro de Medicamentos;

(b) Al Ministerio de Sanidad y Política Social, y en particular a su Dirección General de Farmacia y Productos Sanitarios y a su Secretaría General Técnica (con domicilio en Paseo del Prado, 18-20, E-28071, Madrid) y a la Comisión Delegada del Gobierno para Asuntos Económicos (con domicilio en Paseo de la Castellana, 162, Planta 18, 28046 Madrid), al objeto de que, en el marco de la debida colaboración con los Tribunales de Justicia, asegure la efectividad práctica de lo acordado por la Sentencia y, en este sentido, mientras el Certificado Complementario de Protección Núm. C 200300019 sobre la patente ES 2.068.891 esté en vigor, tenga en cuenta la prohibición a la que se refiere el Pedimento de Condena 2 anterior en el momento de aplicar el Sistema de Precios de Referencia y al tiempo de nutrir y mantener las bases de datos denominadas Nomenclator Digitalis y Nomenclator de Facturación.

10. A la publicación íntegra de la sentencia condenatoria, a costa de las demandadas, en las publicaciones Diario Médico y Correo Farmacéutico, de conformidad con lo previsto en el artículo 63 (f) de la Ley de Patentes.

Todo ello, con imposición de costas a las demandadas.»

SEGUNDO.- Admitida a trámite la demanda, se acordó emplazar a la parte demandada para su contestación.

TERCERO.- Los demandantes presentaron, con fecha 28 de enero de 2010, ampliación de la demanda contra “Cantabria Pharma, S.L.” “Laboratorios Adamed SP. Z.O.O.”, “Laboratorios Milo, S.A.”, “Bexal Farmacéutica, S.A.”, “Acost Comercial Generis Pharma, S.L.” y “Mylan Farmaceuticals, S.L.” , que fue admitida y trasladada a los demandados.

CUARTO.- De nuevo, los demandantes ampliaron la demanda, para dirigirla contra Adamed Laboratorios, S.L.U.

QUINTO.- Los demandantes volvieron a ampliar la demanda, esta vez contra "Kern Pharma, S.L.", "Alchemia, LTD", "Actavis Spain, S.A." y "Uso Racional, S. L."

SEXTO.- De las ampliaciones de demanda se dio traslado a las demandadas para su contestación.

La entidad "Mylan Farmaceuticals, S.L." presentó escrito de contestación a la demanda, de fecha 30 de octubre de 2010, que terminaba suplicando: *«[…] dicte sentencia desestimando íntegramente la demanda, con expresa imposición de costas a la parte actora.»*

Mediante escrito de 13 de mayo de 2010, "Mylan Farmacéuticals, S.L." se opuso a la ampliación subjetiva de la demanda y solicitó: «*[…] sae deniegue la ampliación subjetiva solicitada por Lundbeck A/S y Lundbeck España, S.A., en coherencia con la excepción formulada por esta parte en el Fundamento de Derecho Procesal Primero de la contestación a la demanda de fecha 30 de marzo de 2009, rechazando la competencia de este juzgado para conocer dicha demanda.*

"Laboratorios Milo, S.A.", tras contestar a la demanda, solicitó: «*[…] dictar Sentencia por la que se desestime íntegramente la demanda, absolviendo a Laboratorios Milo, S.A. de todos los pedimentos de la misma, con imposición de costas a las actoras.*»

"Laboratorios Cinfa, S.A.", "Laboratorios Normon, S.A.", "Sandoz Farmacéutica, S.A.", "Bexal Farmacéutica, S.A.", "Acost Comercial Generic-Pharma S.L." "Lannacher Heilmittel GmbH", "Ratiopharm España, S.A.", "Galenicum Health, S.L." y "Laboratorio Stada, S.L.", contestaron a la demanda y suplicaron: *«[…] dictar Sentencia por la que se desestime íntegramente la demanda, absolviendo a Cinfa, Normon, Sandoz, Bexal, Acost, Lannacher, Ratiopharm, Galenicum y Stada de todos los pedimentos de la misma, con imposición de costas a las actoras.»*

Asimismo, "Actavis Spain, S.A." y "Kern Pharma, S.L." contestaron a la demanda y solicitaron: *«[…] dictar Sentencia por la que se desestime íntegramente la demanda, absolviendo a Actavis y Kern de todos los pedimentos de la misma, con imposición de costas a las actoras.»*

La entidad "Uso Racional, S.L.", a través de su procuradora, se opuso a la demanda y suplicó: *«[…] dicte sentencia por la que se desestime la demanda en todas sus pretensiones y se absuelva a mi representada de todos los pedimentos deducidos en su contra, con expresa imposición a la parte actora.»*

"Adamed Laboratorios, S.L.U.", en su escrito de contestación a la demanda, solicitó: *«[…] dicte sentencia desestimando íntegramente la demanda, con expresa imposición de costas a la parte actora.»*

"Cantabria Pharma, S.L." presentó escrito de oposición a la ampliación subjetiva de la demanda y solicitó: *«[…] se deniegue la ampliación subjetiva solicitada por Lundbeck A/S y Lundbeck España, S.A., desestimando íntegramente la demanda, con expresa imposición de costas a la parte actora, y declaración de temeridad en lo que respecta a la interposición de la demanda contra Cantabria Pharma, S.L. por las circunstancias expuestas en el cuerpo del presente escrito.»*

SÉPTIMO.- "Mylan Farmaceuticals, S.L." presentó escrito mediante el que solicitó: *«[…] se deniegue la ampliación subjetiva solicitada por Lundbeck A/S y Lundbeck España, S.A., en coherencia con la excepción formulada por esta parte en el fundamento de derecho procesal primero de la contestación a la demanda de fecha 30 de marzo de 2009, rechazando la competencia de este juzgado para conocer dicha demanda.»*

Asimismo, "Cantabria Pharma, S.L.", se opuso a la ampliación subjetiva de la demanda y suplicó: *«[…] se deniegue la ampliación subjetiva solicitada por Lundbeck A/S y Lundbeck España, S.A., desestimando íntegramente la demanda, con expresa imposición de costas a la parte actora, y declaración de temeridad en lo que respecta*

a la interposición de la demanda contra "Cantabria Pharma, S.L." por las circunstancias expuestas en el cuerpo del presente escrito.»

OCTAVO.- "Laboratorios Adamed SP Z.O.O." y "Alchemia, LTD" fueron declarados en situación de rebeldía procesal.

NOVENO.- Mediante auto, que resolvió el recurso de reposición interpuesto por "Cantabria Pharma, S.L.", "Mylan Farmaceuticals, S.L." y "Adamed Laboratorios, S.L.U", se acordó dejar sin efecto la declaración de rebeldía de "Laboratorios Adamed SP, Z.O.O.".

DÉCIMO.- "Adamed SP, Z.O.O." contestó a la demanda y suplicó: *«[…] dicte sentencia desestimando íntegramente la demanda, con expresa imposición de costas a la parte actora.»*

UNDÉCIMO.- En la audiencia previa, se admitió la intervención voluntaria de "Laboratorio Stada, S.L.", en condición de demandada. Por su parte, "Uso Racional" alegó su absorción por otra compañía

DUODÉCIMO.- Tras seguir los trámites oportunos, se dictó sentencia de fecha 1 de agosto de 2011, con el siguiente fallo: *«[…] Desestimar las demandadas formuladas por el procurador D. Ángel Quemada, en representación de Lundbeck A/S y Lundbeck España, S.A. y, en consecuencia, absolver a los demandados Cinfa, Normon, Sandoz, Bexal, Acoswt, Ratiopharm, Stada, Alchemia LTD, Actavis, Kern, Milo, Cantabria, Mylan y Germen Farmaceútica SL (antes Uso Racional), condenando a las actoras solidariamente al pago de las costas.»*

DÉCIMO TERCERO.- "H. Lundbeck A/S" y "Lundbeck España, S.A." solicitaron aclaración de la sentencia, que fue acordada mediante auto, con la siguiente parte dispositiva: *«Decido: Aclarar la Sentencia dictada en fecha 1 de agosto de 2011, en el sentido de:*

1. *En el Antecedente de Hecho quinto: Se ha de incluir que emplazados los demandados el Procurador Sr. Antonio Mª de Anzizu Furest compareció en representación de las codemandadas Cantabria Pharma, S.L., bajo la dirección de la letrada Ana Palao Benabeu y Adamed Laboratorios, S.L.U. bajo la dirección letrada de Rita Reyes Ríos, para oponerse a la demanda, negar la infracción y pedir la desestimación de la demanda, con imposición de costas a la actora.»*
2. *En el Fundamento de Derecho 1: Se ha de incluir que Adamed Laboratorios, S.L.U., no es titular de las autorizaciones de comercialización tal y como se ilustra en el cuadro de la página 7 de la Sentencia.*
3. *En el fallo de la Sentencia: Se ha de incluir entre los demandados absueltos a Galenicum Health, S.L., Lannacher Heilmittel GMBH, Laboratorios Adamed, S.P. Z.O.O. y Adamed Laboratorios S.L.U. »*

Tramitación en segunda instancia

DÉCIMO CUARTO.- Los demandados formalizaron recurso de apelación contra la sentencia dictada en primera instancia y, tras alegar lo que tuvieron por conveniente, suplicaron: «[…] *se sirva remitir el mismo, junto con los autos de los que trae causa, a la Audiencia Provincial de Barcelona (Sección 15ª) a fin de que ésta, previos los trámites legales oportunos, estimando el recurso de apelación de esta parte, revoque la Sentencia de 1 de agosto de 2011 y dicte una nueva Sentencia ajustada a Derecho en la que se acuerde estimar íntegramente la demanda instada por mis representadas, condenando a las demandadas a abonar a mis representadas los daños y perjuicios causados, cuyo importe deberá actualizarse en ejecución de Sentencia, todo ello con imposición de costas a las demandadas.»*

DÉCIMO QUINTO.- Del recurso interpuesto se dio traslado a las entidades apeladas.

"Laboratorios Cinfa, S.A.", "Laboratorios Normon, S.A.", "Sandoz Farmacéutica, S.A.", "Lannacher Heilmittel GMBH", "Laboratorio Stada S.L.", "Ratiopharm España, S.A.", "Bexal Farmacéutica, S.A.", "Acost Comercial Generic Pharma, S.L.", "Galenicum Health S.L." "Laboratorios Milo, S.A.", "Actavis Spain, S.A." y "Kern Pharma, S.L" se opusieron al recurso formulado de contrario y solicitaron al Juzgado: *«[…] se dicte Sentencia desestimatoria del recurso de apelación, con imposición de costas a las apelantes.»*

"Germed Farmaceútica, S.L.U.", presentó, asimismo, escrito de oposición y suplicó: *«[…] dicte resolución por la que acuerde desestimar el recurso de apelación interpuesto de adverso, confirmando la resolución impugnada, con expresa condena en costas para la parte apelante.»*

"Laboratorios SP. Z.O.O." y "Laboratorios S.L.U.", tras oponerse al referido recurso, solicitaron a la Audiencia Provincial: *«[…] dicte Sentencia por la que se desestime íntegramente el recurso de apelación interpuesto de contrario, confirmándose la Sentencia objeto de apelación en todos sus extremos, con imposición de las costas a la adversa y expresa declaración de temeridad al haberse obligado a esta parte a defenderse en un proceso inútil y carente de fundamento.»*

"Cantabria Pharma, S.L." presentó escrito de oposición al reiterado recurso, que terminaba suplicando a la Audiencia Provincial: *«[…] dicte Sentencia por la que se desestime íntegramente el recurso de apelación interpuesto de contrario, confirmándose la sentencia objeto de apelación en todos sus extremos, con expresa imposición de las costas a la adversa y expresa declaración de temeridad por cuanto mi representada aún aportando la prueba que acredita la ausencia de infracción de la patente, ésta se ha ignorado por Lundbeck interponiendo también contra mi representada recurso de apelación.»*

"Mylan Pharmaceuticals, S.L." se opuso al recurso y suplicó a la Sala: *«[…] dicte Sentencia por la que se desestime íntegramente el recurso de apelación planteado de contrario, confirmándose la Sentencia objeto de apelación en todos sus extremos, con expresa imposición de las costas a la adversa y con expresa mención de temeridad al haber interpuesto la demanda contra mi principal con base en unos hechos que no le afectaban y sabiendo perfectamente que el producto del origen MYLAN tenía otra procedencia industrial. No es de recibo acudir a los tribunales para obtener de ellos una satisfacción sobre la base de hechos que se conoce que no son ciertos como es el origen industrial diferente de un determinado producto.»*

DÉCIMO SEXTO.- La resolución del recurso de apelación correspondió a la sección decimoquinta de la Audiencia Provincial de Barcelona, que lo tramitó con el núm. de rollo 54/2012 y, tras seguir los correspondientes trámites, dictó la sentencia núm. 434/2012, de 19 de diciembre, cuyo fallo disponía: *«Se desestima el recurso de apelación interpuesto por H. Lundbeck A/S y Lundbeck España, S.A. contra la sentencia del Juzgado Mercantil 4 Barcelona de 1 de agosto de 2011, dictada en el juicio ordinario 65/2020, seguido por H. Lundbeck A/S y Lundbeck España, S.A. contra*

las siguientes demandadas: Laboratorios Cinfa, S.A., Laboratorios NORMON, S.A., Sandoz Farmaceútica, S.A., Lannacher Heilmittel GMBH, Laboratorio Stada, S.L., Ratiopharm España, S.A., Bexal Farmacéutica, S.A., Acost Comercial Generic Pharma, S.L., Galenicum Health, S.L., Actavis Spain, S.A., Kern Pharma, S.L. Adamed Sp Z.O.O., Adamed Laboratorios S.L.U., Laboratorios Mylan Pharmaceuticals, S.L., salvo en lo que afecta a las costas de la primera instancia.

Se revoca parte del pronunciamiento de costas. No se imponen a la parte actora las costas de la primera instancia causadas a Laboratorios Cinfa, S.A.; Laboratorios Normon, S.A., Sandoz Farmacéutica, S.A., Laboratorio STADA, S.L., Ratiopharm España, S.A., Bexal Farmacéutica, S.A., Acost Comercial Generic Pharma, S.L., Actavis Spain, S.A., Kern Pharma, S.L., Cantabria Pharma, S.L. y Mylan Pharmaceuticals, S.L.

Se confirma la sentencia del juzgado en todos los restantes pronunciamientos.

No se imponen las costas de la segunda instancia.»

Interposición y tramitación de los recursos extraordinario por infracción procesal y de casación

DÉCIMO SÉPTIMO.- "H. Lundbeck A/S" y de "Lundbeck España S.A." interpusieron recurso extraordinario por infracción procesal contra la sentencia dictada en apelación, que fundamentó en los siguientes motivos:

» Primero.- La sentencia de la Audiencia Provincial de Barcelona recurrida infringe el derecho a la tutela judicial efectiva del artículo 24 de la Constitución al valorar la prueba practicada de forma manifiestamente ilógica y errónea (469.1.4º LEC)

» Segundo.- La sentencia recurrida infringe las normas procesales reguladoras de la sentencia, y en particular la regla de las presunciones judiciales del artículo 386 de la LEC en relación con el artículo 24 de la Constitución, al presumir a partir de un hecho admitido (el que Lundbeck no denunciara la falta de trazabilidad de los lotes aportados por Cinfa et Altri antes del acto del juicio) otro (el que "Lundbeck no discutía esa correspondencia") respecto al que no existe un enlace preciso y directo según las reglas del criterio humano (469.1.4º LEC)

» Tercero.- La sentencia recurrida infringe normas legales que rigen los actos y garantías del proceso, en particular el artículo 433.2 de la LEC, al obligar a Lundbeck a valorar la exhibición documental de Cinfa Et Altri antes del juicio (¡Incluso antes de que se practicara!, lo cual ha producido indefensión a esta parte (469.1 3º LEC)

» Cuarto.- La sentencia recurrida infringe las normas procesales reguladoras de la sentencia, y en particular las reglas de la carga de la prueba de los artículos 61.2 de la Ley de Patentes y de los Apartados 2,3 y 7 del artículo 217 de la LEC, pues la carga de probar el principal hecho controvertido pesaba sobre Cinfa et Altri (469.1.2º LEC)

Asimismo, formalizó recurso de casación contra la referida sentencia, que basó en un único motivo, que a continuación se transcribe: *«Único.- La sentencia recurrida infringe el artículo 69 del Convenio de la Patente Europea y el artículo 2 del Protocolo interpretativo de dicho precepto.»*

DÉCIMO OCTAVO.- La Audiencia Provincial remitió las actuaciones a esta Sala, con emplazamiento de las partes. Personadas las mismas, se dictó auto de 14 de enero de 2014, cuya parte dispositiva decía: «*La Sala acuerda:*

»1º) Admitir el recurso extraordinario por infracción procesal y el recurso de casación interpuestos por la representación procesal de H. Lundbeck A/S y Lundbeck España, S.A., contra la sentencia dictada, con fecha 19 de diciembre de 2012, por la

Audiencia Provincial de Barcelona (sección 15ª), en el rollo de apelación nº 54/2012, dimanante de los autos de juicio ordinario nº 65/2010 del Juzgado de lo Mercantil nº 4 de Barcelona.

» 2º) Y entréguese copia del [de los] escrito[s] de interposición de los recursos formalizados, con sus documentos adjuntos, a las partes recurridas personadas para que formalicen su oposición por escrito en el plazo de veinte días, durante los cuales estarán de manifiesto las actuaciones en la Secretaría.»

DÉCIMO NOVENO.- "Germen Farmacéutica, S.L.U.", presentó escrito de oposición a los recursos formulados de contrario y solicitó: *«[…] sea dictada sentencia por la que se:*

Acuerde la inadmisión de los recursos de casación y extraordinario por infracción procesal.

Subsidiariamente a lo anterior, desestime el recurso extraordinario por infracción procesal y recurso de casación interpuestos.

En cualquiera de los supuestos anteriores, con expresa imposición de costas a la parte recurrente.»

"Laboratorios Cinfa, S.A.", "Galenicum Health, S.L.", "Laboratorios Normon, S.A.", "Sandoz Farmacéutica, S.A.", "Lannacher Heilmittel GMBH", "Ratiopharm España, S.A", "Laboratorios Milo, S.A.", "Bexal Farmacéutica, S.A.", "Acost Comercial Generic Pharma, S.L.), "Laboratorios Stada, S.L.", "Kern Pharma, S.L.", "Actavis Spain, S.A.", se opusieron, asimismo, a los referidos recursos, y suplicaron a esta Sala: *«[…] dictar sentencia por la que se desestimen ambos recursos, con imposición de costas a las recurrentes.»*

"Mylan Pharmaceuticals, S.L." presentó escrito oponiéndose a los recursos interpuestos de adverso y solicitó: *«[…] se confirme la sentencia de 19 de diciembre de 2012 de la Sección 15.ª de la Audiencia Provincial de Barcelona, todo ello con expresa condena en costas a la parte recurrente.»*

"Adamed Sp. Z.O.O." y "Adamed Laboratorios S.L.U.", también se opusieron a los reiterados recursos y suplicaron a esta Sala: *«[…] se confirme la sentencia de 19 de diciembre de 2012 de la Sección 15.ª de la Audiencia Provincial de Barcelona, todo ello con expresa condena en costas a la parte recurrente y expresa declaración de temeridad en lo que respecta al recurso interpuesto contra Adamed Sp. Z.O.O. y Adamed Laboratorios S.L.U.»*

VIGÉSIMO.- Se designó ponente al Excmo. Sr. D. Ignacio Sancho Gargallo y se acordó resolver el presente recurso, previa votación y fallo, señalándose el día 13 de noviembre de 2014 para que éstos tuvieran lugar.

VIGÉSIMO PRIMERO.- Comunicada por el Excmo. Sr. Ponente su abstención por concurrir la causa prevista en el artículo 219.10ª de la Ley Orgánica del Poder Judicial, se acordó estimarla justificada y se suspendió el señalamiento para votación y fallo.

VIGÉSIMO SEGUNDO.- Se designó nuevo magistrado ponente al Excmo. Sr. D. Rafael Sarazá Jimena y se señaló nuevamente la votación y fallo del presente recurso para el día 26 de febrero de 2015.

VIGÉSIMO TERCERO.- Por necesidades del servicio, se suspendió la votación y fallo señalados.

VIGÉSIMO CUARTO.- El Excmo. Sr. magistrado D. Sebastián Sastre Papiol comunicó su abstención a la Sala, por concurrir la causa prevista en el artículo 219.2ª de la Ley Orgánica del Poder judicial, abstención que se acordó estimar justificada.

VIGÉSIMO QUINTO.- Asimismo, se acordó justificada la abstención del Excmo. Sr. magistrado D. José Ramón Ferrándiz Gabriel, por darse la causa prevista en el artículo 219.2ª de la Ley Orgánica del Poder judicial.

VIGÉSIMO SEXTO.- Mediante providencia de 12 de marzo de 2015, se señaló nuevamente para votación y fallo del presente recurso el día 8 de abril de 2015 y se acordó que junto al ponente, el Excmo. Sr. D. Rafael Sarazá Jimena, formaran Sala el Excmo. Sr. presidente de la misma D. Francisco Marín Castán y el Excmo. Sr. magistrado D. Francisco Javier Orduña Moreno.

Ha sido ponente el Excmo. Sr. D. **RAFAEL SARAZÁ JIMENA**,

FUNDAMENTOS DE DERECHO

PRIMERO.- Antecedentes del caso

1.- Para entender mejor lo que debe ser resuelto en esta sentencia es necesario resumir los hitos principales del proceso y las cuestiones controvertidas en el mismo.

Las entidades “H. LUNDBECK A/S” y “LUNDBECK ESPAÑA, S.A.” (en lo sucesivo, cuando no sea necesario distinguirlas, nos referiremos a ellas indistintamente como LUNDBECK, la demandante o las demandantes, la recurrente o las recurrentes) presentaron el 25 de enero de 2010 demanda contra las siguientes entidades: “GALENICUM HEALTH, S.L.” (en lo sucesivo, GALENICUM), “LABORATORIOS CINFA, S.A.” (CINFA), “LABORATORIOS NORMON, S.A.” (NORMON), “SANDOZ FARMACÉUTICA, S.A.” (SANDOZ), “LANNACHER HEILMITTEL GMBH” (LANNACHER) y “RATIOPHARM ESPAÑA, S.A.” (RATIOPHARM).

2.- Las demandantes, “H. LUNDBECK A/S” y “LUNDBECK ESPAÑA, S.A.”, accionaban como titular y licenciataria en España, respectivamente, del certificado complementario de protección CCP 200300019, sobre la patente europea EP 347.066 B1, publicada en España con el número ES 2.086.891 (ES '891), por la infracción del referido certificado complementario de protección (CCP). También accionaban por competencia desleal, si bien tal cuestión ha quedado fuera de los recursos extraordinarios.

Como fundamento de su demanda, LUNDBECK alegaba, en síntesis y en lo que aquí interesa, que:

1) La reivindicación primera (para la que la Audiencia utiliza la abreviatura R1) de la patente ES '891 protege un procedimiento para la preparación del principio activo escitalopram, que era un producto nuevo en la fecha de prioridad de la patente ES '891, 14 de junio de 1988.

2) En virtud del CCP, la patente extendía sus efectos en España hasta el 1 de junio de 2014.

3) En los últimos meses de 2009, NORMON, CINFA, SANDOZ B.V. y LANNACHER habían obtenido de la Agencia Española del Medicamento y Productos Sanitarios (AEMPS) numerosas autorizaciones para comercializar en España medicamentos genéricos cuyo principio activo es el escitalopram.

4) Inmediatamente después, las demandadas citadas solicitaron a la Dirección General de Farmacia y Productos Sanitarios, del Ministerio de Sanidad y Política Social (DGFPS), la inclusión de sus medicamentos genéricos de

escitalopram en el Sistema Nacional de Salud (SNS). Algunas de estas entidades habían obtenido ya la fijación del precio de venta de laboratorio (PVL) para sus medicamentos genéricos de escitalopram, que habían sido incluidos en el SNS, en el Nomenclátor Digitalis y en el Nomenclátor de Facturación del Ministerio de Sanidad y Política Social, y habían realizado actos de ofrecimiento a mayoristas y oficinas de farmacia, y otras estaban realizando las gestiones para conseguirlo.

5) Al ser escitalopram un producto nuevo a la fecha de prioridad de la patente de LUNDBECK, pesaba sobre las demandadas la carga de probar cuál era el procedimiento utilizado efectivamente en la fabricación del escitalopram incorporado a sus medicamentos genéricos, así como probar que dicho procedimiento no invadía el ámbito de protección de la patente ES '891 de LUNDBECK, conforme al artículo 61.2 de la Ley de patentes.

6) Además, LUNDBECK había podido adquirir y analizar "escitalopram NORMON" y resultaba que: i) contenía impurezas de un compuesto intermedio (diol) que permitían confirmar la utilización del procedimiento de LUNDBECK, y ii) presentaban una pureza enantiomérica que solamente puede conseguirse utilizando el proceso objeto de la patente de la actora.

La demanda solicitaba una serie de declaraciones, entre las que se encontraba, con carácter principal, la relativa a que las demandadas habían infringido el CCP de LUNDBECK y habían realizado actos de competencia desleal. Pedía la condena de las demandadas a abstenerse de realizar actos de infracción; a cesar en ellos; a retirar del tráfico el producto infractor; el embargo y destrucción del producto; a indemnizar a LUNDBECK los daños y perjuicios causados y a la publicación de la sentencia en determinados medios.

3.- El 28 de enero de 2010, LUNDBECK presentó una ampliación de su demanda inicial contra “CANTABRIA PHARMA, S.L.” (CANTABRIA), “LABORATORIOS ADAMED Sp. Z.O.O.” (ADAMED Sp), “LABORATORIOS MILO, S.A.” (MILO), “BEXAL FARMACÉUTICA, S.A.” (BEXAL), “ACOST COMERCIAL GENERIC PHARMA, S.L.” (ACOST) y “MYLAN PHARMACEUTICALS, S.L.” (MYLAN). El 25 de febrero de 2010 amplió la demanda para dirigirla contra “ADAMED LABORATORIOS, S.L.U.” (ADAMED). El 23 de marzo de 2010 amplió de nuevo la demanda contra “KERN PHARMA, S.L. “(KERN), “ALCHEMIA, LTD” (ALCHEMIA), “ACTAVIS SPAIN, S.A.” (ACTAVIS) y “USO RACIONAL, S.L.” (USO RACIONAL), posteriormente denominada “GERMED FARMACÉUTICA S.L.U.“ (GERMED).

4.- Las entidades demandadas que se personaron negaron la infracción y solicitaron la desestimación de la demanda. ALCHEMIA no compareció ni contestó, por lo que fue declarada en rebeldía.

5.- Tras la tramitación del proceso en primera instancia, el Juzgado Mercantil dictó sentencia en la que desestimó la demanda y condenó a LUNDBECK al pago de las costas.

6.- LUNDBECK interpuso recurso de apelación contra la sentencia. La Audiencia Provincial fijó como hechos no controvertidos los que a continuación se reproducen resumidamente:

a) H. LUNDBECK A/S es titular de la patente europea EP 347.066 B1, cuya traducción ha sido publicada en España con el número ES 2.986.891 (en adelante, ES '891), y titular del certificado complementario de protección (CCP) número C 200300019, que extiende los efectos de la patente mencionada hasta el 1 de junio de 2014. LUNDBECK ESPAÑA, S.A. es licenciataria no exclusiva de la patente y el CCP.

b) La patente ES '891 lleva por título "nuevos enantiómeros y su aislamiento" y tiene por objeto un procedimiento para la obtención del principio activo escitalopram, un agente indicado para el tratamiento de la depresión y de diversos trastornos mentales.

c) Escitalopram es la denominación común internacional del compuesto químico (S)-(+)-1-(3-dimetilaminopropil)-1-(4'-fluorofenil)-1,3-dihidroisobenzofuran-5-carbonitrilo.

d) La patente tiene dos reivindicaciones de procedimiento, de las cuales solo la primera es relevante para el proceso.

e) En la reivindicación primera (R1) se protege:

"Un método para la preparación de (+)-1-(3-dimetilaminopropil)-1-(4'-fluorofenil)-1,3-dihidroisobenzofuran-5-carbonitrilo que tenga la fórmula general [sigue un gráfico] y de sus sales de adición de ácido no tóxicas que comprende convertir (-)-4-[(4-dimetil-amino)-1-(4'-fluorofenil)-1-hidroxi-1-butil]-3- (hidroximetil) benzonitrilo o un monoéster suyo que tiene la fórmula [sigue otro gráfico]. Donde R es H o un grupo éster lábil, de una forma estereoselectiva y, luego aislar el compuesto de Fórmula I como tal o como una de sus sales de adición de ácido no tóxicas".

f) El escitalopram era un producto nuevo en la fecha en la que se solicitó la patente europea. H. LUNDBECK ESPAÑA, S.A. y Almirall comercializan medicamentos de escitalopram en España desde 2003 (con los nombres comerciales de Cipralex y Esertia) fabricados por LUNDBECK.

g) Las compañías demandadas, excepto GALENICUM, que es el representante de DR. REDDY'S LABORATORIES LTD (en adelante, REDDY'S), y ADAMED LABORATORIOS S.L.U., son titulares de las preceptivas autorizaciones de la Agencia Española del Medicamento y Productos Sanitarios (AEMPS) de comercialización de medicamentos con el principio activo escitalopram, por haberlas obtenido directamente o haberlas adquirido de otra entidad.

h) REDDY'S figura como fabricante del principio activo escitalopram para las demandadas CINFA, NORMON, SANDOZ, BEXAL, ACOST, RATIOPHARM, STADA, ALCHEMIA, ACTAVIS, KERN, MILO y CANTABRIA.

i) NATCO PHARMA LIMITED (en adelante, NATCO) consta como fabricante de escitalopram de MYLAN y USO RACIONAL (actualmente, GERMED FARMACÉUTICA).

j) En los expedientes administrativos de autorización de comercialización, SANDOZ, BEXAL, ACOST, RATIOPHARM, STADA, ALCHEMIA, ACTAVIS, KERN, MILO y CANTABRIA han declarado, además de REDDY'S, otro fabricante del principio activo (concretamente, SANDOZ PRIVATE LIMITED, filial del grupo SANDOZ en la India, los tres primeros; MATRIX LABORATORIES LIMITED, los dos segundos y HETERO LABS LIMITED, los últimos). Las demandadas citadas han declarado que el escitalopram de dichos fabricantes alternativos únicamente se utilizaría con posterioridad a la caducidad del CCP de autos (a partir de 1 de junio de 2014) o en el supuesto de que el CCP fuera revocado.

k) El procedimiento descrito en el DMF de REDDY'S es diferente del procedimiento reivindicado por LUNDBECK en la patente ES '891, y no hay controversia sobre que no infringe la patente.

l) En el pleito cabe distinguir dos grupos de demandadas:

i) El primero lo integran aquellas entidades que, en el procedimiento de autorización de los medicamentos, han declarado como fabricante a REDDY'S, y que son: CINFA, NORMON, SANDOZ, BEXAL, ACOST, RATIOPHARM, STADA, ALCHEMIA, ACTAVIS, KERN, MILO y CANTABRIA. En relación con estas demandadas, se discute el procedimiento seguido realmente para la fabricación del escitalopram utilizado. LUNDBECK acepta que el procedimiento de REDDY'S descrito en DMF aportado no infringe la patente ES '891. Lo que alega es que ese no es el único procedimiento utilizado en la fabricación del principio activo de los medicamentos de las demandadas citadas pues también se estaría utilizando un

procedimiento infractor de la patente y, sobre todo, niega que estas hayan probado con el grado de certeza que les imponen los artículos 61.2 Ley de Patentes y 217.1 de la Ley de Enjuiciamiento Civil que solo han utilizado el procedimiento de REDDY'S.

ii) El segundo grupo lo constituyen las demandadas MYLAN y GERMED, que han declarado como fabricante a NATCO. Respecto de estas demandadas, LUNDBECK reconoce expresamente que el principio activo escitalopram se fabrica por el procedimiento declarado por NATCO y considera que ese procedimiento infringe su patente ES '891.

7.- La Audiencia Provincial dictó sentencia en la que desestimó el recurso de apelación, salvo en lo relativo a la imposición de las costas de primera instancia a las demandantes respecto de algunas de las demandadas. Respecto del primer grupo de demandadas, consideró, como había hecho el Juzgado Mercantil, que las pruebas practicadas prueban que el procedimiento utilizado fue el REDDY'S y no el que, por entrar en el ámbito de protección de la patente ES '891, la infringía. Respecto del segundo grupo de demandadas, la Audiencia consideró que el procedimiento declarado por NATCO no infringe la patente ES '891

8.- LUNDBECK ha interpuesto recurso extraordinario por infracción procesal, basado en cuatro motivos, y recurso de casación, basado en un solo motivo, contra la sentencia de la Audiencia Provincial. La formulación de uno y otro recurso viene precedida por una amplia exposición de "antecedentes de hecho", que ocupa las páginas 4 a 21 del escrito, en la que se reproducen extensamente diversos particulares del proceso, tales como proposiciones de prueba, alegaciones de las partes y del Juez en la audiencia previa, alegaciones hechas en una comparecencia, escritos de alegaciones, alegaciones formuladas en el juicio por partes y peritos, incluso se incluye, escaneado, un envase de medicamento, etc.

Recurso extraordinario por infracción procesal

El recurso extraordinario por infracción procesal afecta exclusivamente al primer grupo de demandadas, esto es, a las entidades que, en el procedimiento de autorización de los medicamentos, han declarado como fabricante a REDDY'S, y que son: CINFA, NORMON, SANDOZ, BEXAL, ACOST, RATIOPHARM, STADA, ALCHEMIA, ACTAVIS, KERN, MILO y CANTABRIA.

SEGUNDO.- Formulación del primer motivo del recurso extraordinario por infracción procesal

1.- El primer motivo del recurso extraordinario por infracción procesal tiene el siguiente epígrafe: «*La sentencia de la Audiencia Provincial de Barcelona recurrida infringe el derecho a la tutela judicial efectiva del artículo 24 de la Constitución al valorar la prueba practicada de forma manifiestamente ilógica y errónea (469.1.4º LEC)*».

2.- El motivo se desarrolla entre las páginas 22 a 47 del escrito de interposición del recurso. Se estructura en diversos subapartados que a su vez llevan los siguientes epígrafes:

«*I. Introducción. Valoración manifiestamente ilógica y errónea de los certificados de análisis y hojas de fabricación de los 25 lotes de escitalopram aportados por CINFA et altri, la única prueba que llevó al Tribunal "a quo" a formarse la convicción de que el escitalopram incorporado a los medicamentos genéricos de dichas compañía se fabrica siguiendo exclusivamente el procedimiento de DRL».*

«II. La valoración de la prueba "de las restantes demandadas que declaran el procedimiento de Reddy's" contenida en el Fundamento de Derecho 11 de la Sentencia recurrida es manifiestamente ilógica».

«III. La Sentencia parte de la errónea premisa de que los certificados de análisis y hojas de fabricación de DRL aportados por CINFA et altri "fue la documentación que LUNDBECK requirió de la parte demandada en el acto de la audiencia previa"».

«IV. La Sentencia es manifiestamente ilógica al entender que, como antes de la celebración del juicio, LUNDBECK, "que sí cuestionó el número de hojas de fabricación exhibidas, en ningún momento puso de manifiesto que esa documentación no permitía vincular los lotes del principio activo y los lotes de medicamentos", ello "pudo interpretarse de manera lógica en el sentido de que LUNDBECK no discutía esa correspondencia."»

«V. La Sentencia incurre en un error manifiesto y en una evidente contradicción al afirmar que "los términos en que quedó planteada la controversia- visto el contenido de la demanda y de las medidas cautelares, de los dictámenes aportados por la actora y, sobre todo, de la audiencia previa (fijación de hechos controvertidos y proposición de prueba de la parte actora)- permitieron entender razonablemente a la parte demandada –y al juez- que lo discutido era si el procedimiento utilizado efectivamente por Reddy'" invadía la patente de LUNDBECK"».

La recurrente centra su impugnación en los certificados de análisis y hojas de fabricación de veinticinco lotes de escitalopram aportados por CINFA y otros demandados que alegaban utilizar el procedimiento que hemos denominado REDDY'S.

En el desarrollo del motivo, la recurrente, con invocación de los "antecedentes de hecho" que preceden la formulación de los motivos, reproduce transcripciones parciales de interrogatorios realizados en el juicio, escritos e instructas de las partes, alegaciones de la audiencia previa, actas de comparecencia, y asimismo realiza remisiones a diversos particulares de los autos de primera instancia.

TERCERO.- Decisión de la Sala. El recurso extraordinario por infracción procesal no convierte a esta Sala en una tercera instancia

1.- La jurisprudencia de esta Sala, en sentencias que por su abundancia y reiteración es innecesario precisar, ha declarado que los recursos extraordinarios por infracción procesal y de casación no constituyen una tercera instancia que permita exigir la total revisión fáctica y jurídica de las cuestiones litigiosas, como sí es posible hacer ante un tribunal de apelación. Por el contrario, estos recursos extraordinarios constituyen un grado de enjuiciamiento jurisdiccional "limitado y peculiar", que exige que el recurrente identifique con claridad y precisión la norma que entiende infringida y razone por qué se ha infringido, individualizando con claridad el problema jurídico planteado para que este Tribunal cumpla la función nomofiláctica que le asigna nuestro sistema. Ello obliga a los recurrentes a observar determinadas reglas exigidas por la configuración de los recursos extraordinarios por infracción procesal y de casación.

2.- Esta Sala ha declarado también de forma reiterada que la valoración de la prueba es función soberana y exclusiva de los órganos judiciales de instancia, y no es revisable en el recurso extraordinario por infracción procesal, salvo cuando se conculque el artículo 24.1 de la Constitución por incurrirse en error de hecho palmario, irracionalidad o arbitrariedad, lo que impide, si no se demuestra de modo patente la existencia de una infracción de las reglas del discurso lógico aplicables, tratar de desvirtuar una apreciación probatoria mediante una valoración conjunta efectuada por el propio recurrente para sustituir el criterio del tribunal por el suyo

propio, por acertado que pueda parece. Así se ha afirmado en sentencias como las núm. 88/2011, de 16 de febrero, y 635/2012, de 2 de noviembre.

3.- Las recurrentes no han respetado estas exigencias al formular este motivo, de modo que han pretendido plantear de nuevo la problemática fáctica en toda su amplitud, para que esta Sala realice una revisión completa de la actividad probatoria del proceso, no solo en su valoración, también en su proposición y práctica, así como de las alegaciones de las partes relativas a la actividad probatoria. Para ello, el recurso mezcla alegaciones relativas a la valoración de la prueba con otras referentes a la carga de la prueba, que son cuestiones de distinta naturaleza, y con referencias a la normativa sectorial de los laboratorios farmacéuticos, lo que explica la desmesurada extensión del motivo y de los particulares a que se remite, y la falta de claridad y precisión en el planteamiento de la impugnación.

4.- La sentencia recurrida responde expresamente a la impugnación de la valoración de la prueba hecha por el Juzgado Mercantil, y al hacerlo y confirmar lo resuelto por el Juzgado no incurre en la infracción denunciada. El recurso pretende una reinterpretación no solo de la valoración de la prueba, sino del complejo "iter" de proposición y práctica de la misma, conforme a sus particulares intereses, a la "sana crítica" tal como es entendida por la parte demandante. Pero no existe error de hecho palmario, irracionalidad o arbitrariedad en el enjuiciamiento de la actividad probatoria por parte de la sentencia, sino una simple discrepancia de las recurrentes con en enjuiciamiento realizado por la Audiencia Provincial, que no es apta para fundar un recurso extraordinario. El carácter ilógico que el recurso atribuye al razonamiento de la sentencia de la Audiencia Provincial (coincidente con el del Juzgado Mercantil) no es otra cosa que la disconformidad de la parte demandante con dicho razonamiento y la pretensión de que sea sustituido por el postulado por ella.

No es admisible la técnica utilizada, que descontextualiza expresiones de la sentencia para imputarles una contradicción que no existe.

El razonamiento de la Audiencia Provincial cuando analiza en qué términos se produjo la solicitud de exhibición documental formulada por la parte demandante, cómo se cumplimentó dicho requerimiento por las demandadas concernidas, y valora el resultado de dicha prueba a la vista de lo anterior, y a la vista de cómo estaba planteada la controversia entre las partes, no es ilógico, está razonado en la resolución, y no incurre en ningún error notorio. Por tanto, podrá compartirse o no (es evidente que la recurrente no lo comparte), pero no se ha infringido el art. 24 de la Constitución.

El motivo debe ser desestimado.

CUARTO.- Formulación del segundo motivo del recurso extraordinario por infracción procesal

1.- El segundo motivo se encabeza con el siguiente título: «*La sentencia recurrida infringe las normas procesales reguladoras de la sentencia, y en particular la regla de las presunciones judiciales del artículo 386 de la LEC en relación con el artículo 24 de la Constitución, al presumir a partir de un hecho admitido (el que Lundbeck no denunciara la falta de trazabilidad de los lotes aportados por Cinfa et Altri antes del acto del juicio) otro (el que "Lundbeck no discutía esa correspondencia") respecto al que no existe un enlace preciso y directo según las reglas del criterio humano (469.1.4º LEC)*».

2.- En el motivo, por el cauce del art. 469.1.4º de la Ley de Enjuiciamiento Civil, se alega que la sentencia de la Audiencia Provincial infringe el art. 24 de la Constitución y en particular la regla sobre presunciones judiciales del art. 386 de la Ley de Enjuiciamiento Civil por entender que antes de la celebración del juicio,

LUNDBECK, que sí cuestionó el número de hojas de fabricación exhibidas, en ningún momento puso de manifiesto que esa documentación no permitía vincular los lotes del principio activo y los lotes de medicamentos, lo que pudo interpretarse de manera lógica en el sentido de que no discutía esa correspondencia, cuando, alega en el recurso, el silencio de la demandante sobre la falta de trazabilidad en la documentación aportada se debió a que no había podido ver ni valorar tal documentación. Que LUNDBECK no dijera nada hasta el día del juicio no implicaría por tanto desinterés por la documentación que permitiría establecer la trazabilidad de los lotes aportados.

QUINTO.- Decisión de la Sala. Inexistencia de infracción del art. 24 de la Constitución

1.- LUNDBECK ha formulado el motivo por el cauce del art. 469.1.4º de la Ley de Enjuiciamiento Civil, esto es, por haberse producido una vulneración, en el proceso civil, de derechos fundamentales reconocidos en el artículo 24 de la Constitución. Tal vulneración habría consistido en la infracción de la regla sobre presunciones judiciales del art. 386 de la Ley de Enjuiciamiento Civil.

El recurso incurre en el error de identificar cualquier vulneración procesal con la infracción del art. 24 de la Constitución. Tal confusión no es admisible. El art. 24 de la Constitución contiene una serie de garantías fundamentales del proceso, que no pueden identificarse con todas y cada una de las reglas procesales. Que se hubiera aplicado incorrectamente la norma sobre las presunciones judiciales no significa que se haya infringido el art. 24 de la Constitución.

El enfoque del recurso supone convertir el recurso extraordinario por infracción procesal, a través del cual solo pueden denunciarse determinadas infracciones procesales de especial trascendencia, en un recurso ordinario mediante el que la parte puede plantear ante el Tribunal Supremo cualesquiera cuestiones procesales. Este enfoque no es admisible.

2.- La Audiencia Provincial, al realizar el razonamiento que se impugna, no aplica la regla de las presunciones judiciales, sino que valora el resultado de la prueba en relación a cómo se propuso y cómo se comportaron las partes a través del complejo proceso de proposición y práctica de la prueba, lo cual es cuestión diferente de las presunciones del art. 386 de la Ley de Enjuiciamiento Civil.

3.- La cuestión suscitada en el motivo no es más que un aspecto de lo planteado en el primer motivo del recurso extraordinario por infracción procesal, por lo que nos remitimos a lo expuesto en el mismo. La Audiencia Provincial valoró la falta de alegación sobre la insuficiencia de la documentación aportada desde la entrega de la documentación, varias semanas antes del juicio, hasta el trámite de conclusiones, tomando en consideración cómo se había propuesto la prueba y cómo estaban planteadas las posiciones de las partes, atribuyendo una determinada significación a ese silencio, que no se presenta como ilógica ni arbitraria. La recurrente no comparte la significación dada por la Audiencia Provincial a su conducta, pero eso no supone la infracción del art. 24 de la Constitución, como se pretende, ni tampoco, como se ha dicho, una infracción del art. 386 de la Ley de Enjuiciamiento Civil.

SEXTO.- Formulación del tercer motivo del recurso

1.- El tercer motivo del recurso se encabeza así: «*La sentencia recurrida infringe normas legales que rigen los actos y garantías del proceso, en particular el artículo 433.2 de la LEC, al obligar a Lundbeck a valorar la exhibición documental de*

Cinfa Et Altri antes del juicio (¡Incluso antes de que se practicara!, lo cual ha producido indefensión a esta parte (469.1 3º LEC)».

2.- El motivo se encuadra en el art. 469.1.3º de la Ley de Enjuiciamiento Civil y se fundamenta alegando que la Audiencia Provincial contraviene el art. 433.2 al exigir que LUNDBECK hubiera valorado la exhibición documental antes del juicio, produciendo indefensión a la demandante.

SÉPTIMO.- Decisión de la Sala. Inexistencia de la infracción alegada

1.- El motivo se formula a través del art. 469.1.3º de la Ley de Enjuiciamiento Civil, que consiste en la infracción de las normas legales que rigen los actos y garantías del proceso cuando la infracción determinare la nulidad conforme a la ley o hubiere podido producir indefensión.

Es necesario, por tanto, no solo que se hayan infringido las normas reguladoras de los actos y garantías del proceso, sino que la infracción determine la nulidad o haya podido producir indefensión.

Para justificar la producción de indefensión no basta con la invocación formal de la misma, sino que es preciso que la parte explicite cómo se le ha impedido u obstaculizado gravemente la realización de alegaciones o la práctica de pruebas, y la parte recurrente no lo ha hecho. Por tanto, incluso aunque hubiera existido alguna infracción procesal, el motivo no podría estimarse porque no se ha justificado que haya producido indefensión a la parte.

2.- De nuevo se plantea un aspecto de lo que constituyó el objeto del primer motivo del recurso, relacionado también con el anterior motivo, y de nuevo la Sala debe remitirse a lo allí explicitado.

OCTAVO.- Formulación del cuarto motivo del recurso extraordinario por infracción procesal

1.- El cuarto y último motivo de infracción procesal se encabeza con el siguiente epígrafe: «*La sentencia recurrida infringe las normas procesales reguladoras de la sentencia, y en particular las reglas de la carga de la prueba de los artículos 61.2 de la Ley de Patentes y de los Apartados 2,3 y 7 del artículo 217 de la LEC, pues la carga de probar el principal hecho controvertido pesaba sobre Cinfa et Altri (469.1.2º LEC)*».

2.- El motivo se formula por el cauce del art. 469.1.2º de la Ley de Enjuiciamiento Civil, y se fundamenta en que la sentencia infringe los preceptos invocados porque la carga de probar que los medicamentos comercializados por las demandadas en España contiene únicamente el principio activo fabricado por REDDY'S (y no por un procedimiento infractor de la patente) pesaba sobre ellas, y la sentencia no ha presumido, a falta de prueba en contrario, que dicho principio activo ha sido obtenido por el procedimiento patentado por la demandante, puesto que las pruebas practicadas no han acreditado tal extremo.

NOVENO.- Decisión de la Sala. La impugnación de la recurrente a la suficiencia de la prueba practicada para acreditar un hecho relevante no supone que la sentencia recurrida haya vulnerado las reglas de la carga de la prueba

1.- Es doctrina reiterada de esta Sala la que afirma que las reglas de la carga de la prueba solo entran en juego cuando no se ha considerado probado un determinado extremo relevante, y el mismo no había sido admitido por la parte a

quien perjudica, ni podía considerarse notorio. Pero no se vulneran esas reglas porque la parte considere insuficientes las pruebas que han servido para que el tribunal considere acreditado el extremo controvertido.

2.- La sentencia de la Audiencia Provincial, como antes la del Juzgado Mercantil, ha considerado probado que el principio activo utilizado por las demandadas del primer grupo en la producción de sus medicamentos era el producido por REDDY'S. La recurrente ha empleado los tres primeros motivos de su recurso en combatir esta conclusión de la sentencia recurrida.

Por tanto, es inconsistente que en el cuarto motivo se alegue la vulneración de las reglas de la carga de la prueba, las generales del art. 217 de la Ley de Enjuiciamiento Civil y la específica del art. 61.2 de la Ley de Patentes. Las alegaciones sobre la insuficiencia o inadecuación de la prueba practicada por las demandadas de este primer grupo son irrelevantes para fundar un motivo basado en la infracción de las reglas de la carga de la prueba.

El motivo debe ser desestimado, y con ello, el recurso extraordinario por infracción procesal.

Recurso de casación

DÉCIMO.- Formulación del único motivo de casación

1.- El recurso de casación se refiere exclusivamente al segundo grupo de demandadas (MYLAN y GERMED). Respecto de estas, y una vez aceptada por ambas partes que el procedimiento utilizado para la elaboración del escitalopram es el denominado NATCO, por ser este el fabricante que lo emplea, la cuestión controvertida se refiere a si la utilización del bromo-diol enantiopuro como producto de partida para la elaboración del escitalopram infringe por equivalencia la patente ES '891 de LUNDBECK, cuya reivindicación primera solo menciona el ciano-diol enantiopuro como producto de partida, y estriba en si dicha alternativa puede considerarse obvia.

2.- El recurso se inicia con una extensa introducción en la que alega la existencia de interés casacional porque existe jurisprudencia contradictoria entre Audiencias Provinciales. Según LUNDBECK, la sentencia recurrida, al afirmar que la obviedad es la ausencia de actividad inventiva, estaría equiparando el enjuiciamiento propio de la infracción al correspondiente al análisis de la actividad inventiva como requisito de patentabilidad, con lo que sería extremadamente exigente con el requisito de la obviedad. Esta línea se opondría a la observada por la Audiencia Provincial de Madrid en dos resoluciones, que habría propuesto un análisis de la obviedad autónoma, menos exigente que la Audiencia Provincial de Barcelona para considerar que ha existido obviedad y, por tanto, infracción por equivalencia.

3.- Tras esta justificación del interés casacional del recurso, y una remisión a los antecedentes de hecho realizados al principio del escrito, LUNDBECK formula el único motivo del recurso de casación, que se encabeza con este epígrafe: «*La sentencia recurrida infringe el artículo 69 del Convenio de la Patente Europea y el artículo 2 del Protocolo interpretativo de dicho precepto*».

4.- El motivo se fundamenta alegando que la Audiencia Provincial, al afirmar en su sentencia que «*si la variante no era obvia, es decir, es inventiva, no hay equivalencia*», equipara la noción de obviedad de la segunda pregunta del test "Improver" a la ausencia de actividad inventiva, lo que le lleva a concluir que solo es obvia la variante cien por cien segura, esto es, la que a priori no plantea al experto

duda alguna. Por tanto, no habría obviedad (ni por tanto infracción) cuando la alternativa presentara una expectativa razonable de que se conseguirá hacerla funcionar. Esta exigencia de demostración de que el experto no tendría ninguna duda, de que estaría seguro al cien por cien de la eficacia de la alternativa utilizada para que la misma pudiera considerarse “obvia” y, como tal, infractora de la patente, no se ajustaría a Derecho.

Cita la recurrente diversas sentencias de esta Sala en la que se aplica la doctrina de los equivalentes al interpretar el art. 48.3 del Estatuto de la Propiedad Industrial, en las que se mantenía el criterio de la insustanciabilidad o de las diferencias esenciales, así como otras resoluciones de Audiencias Provinciales, que en su opinión habrían utilizado un criterio menos estricto de la obviedad al aplicar el test “Improver”.

Según LUNDBECK, la equiparación de la obviedad de la segunda pregunta del test “Improver” a la ausencia de actividad inventiva no estaría justificada, al enmarcarse en dos análisis (de infracción y de patentabilidad, respectivamente) que carecen de simetría. Es posible que la alternativa utilizada por la realización cuestionada tenga actividad inventiva (por descubrir alguna ventaja adicional que no fuera previsible) pero que infrinja la patente porque reproduzca sus elementos, literalmente o por equivalencia, con lo que constituiría una patente dependiente. A continuación, señala cuáles son a su juicio las diferencias entre el examen de la actividad inventiva a efectos de validez de la patente, y el de la obviedad, a efectos de la infracción. Aplicando estas diferencias, para enjuiciar la actividad inventiva de la patente de LUNDBECK lo relevante sería determinar si en su fecha de prioridad un experto se habría sentido motivado, con expectativas de éxito, a resolver el precursor ciano-diol y, una vez resuelto, a transformarlo de manera estereoselectiva en escitalopram sin alterar la estereoquímica del precursor resuelto; mientras que para enjuiciar la obviedad en la infracción por equivalencia del procedimiento de NATCO, lo relevante sería si para el experto en la materia, la sustitución del precursor ciano-diol (cuya eficacia enseñaba la patente de LUNDBECK) por un precursor bromo-diol era una variante obvia del modo de realización explícitamente protegido en la patente de LUNDBECK.

Tras esos razonamientos, la recurrente alega que incluso admitiendo que cupiera enjuiciar la obviedad en sede de equivalencia mediante el test de la actividad inventiva aplicado en sede de patentabilidad, el test relevante sería si el tercero “habría contemplado” la variante con expectativas razonables de éxito, y no si habría tenido la certeza absoluta de que dicha variante funcionaría. La tesis acogida por la sentencia recurrida, alega, sería inadmisible por cuanto solo habría considerado obvia (y por tanto infractora) la alternativa cuyo funcionamiento “no planteara duda alguna”. Lo correcto, según la recurrente, sería que la obviedad estaría justificada si se acreditara que el experto, aun no estando seguro al 100% de que la alternativa funcionaría, la probaría al “tener una expectativa razonable de que funcionará”.

La recurrente invoca otras resoluciones de la Audiencia Provincial de Barcelona, las directrices de examen de la Oficina Europea de Patentes y decisiones de la Cámara de Recursos de dicha institución, y las directrices de examen de la Oficina Española de Patentes y Marcas, que según sostiene la recurrente, considerarían que la obviedad no solo existe cuando los resultados con claramente predecibles, sino cuando hay una expectativa razonable de éxito.

Tras ello, la recurrente argumenta que si la Audiencia Provincial hubiera interpretado la noción de obviedad como “tener una expectativa razonable de que se conseguirá hacer funcionar” en vez de “no tener ninguna duda de que la variante funcionará”, habría llegado a la conclusión de que el procedimiento de NATCO infringía su patente, puesto que conforme al Juzgado Mercantil el cambio del ciano por el bromo era la única alternativa prevista en la patente US 4.136.193 y el procedimiento NATCO sigue los mismos pasos descritos en los dos primeros párrafos del ejemplo 2 de la descripción de la patente ES ‘891, por lo que dicho

Juzgado concluyó que la variante del procedimiento de NATCO era una alternativa perfectamente probable a la vista de la patente US 4.136.193. En consecuencia, concluye la recurrente, «*en la fecha de la publicación de la patente de LUNDBECK el experto no solo podía sino que habría intentado esta alternativa –como hizo NATCO- con una expectativa razonable de que también le permitiría obtener escitalopram. Y ello máxime a la vista de la potencial recompensa comercial inherente a la obtención de un producto tan exitoso como el escitalopram…*».

UNDÉCIMO.- La infracción por equivalencia: la obviedad de la alternativa

1.- Para realizar el enjuiciamiento necesario para determinar si la realización cuestionada infringe la patente es necesario, en primer lugar, determinar el ámbito de protección conferido por la patente.

Tanto en la patente nacional como en la patente europea, las reivindicaciones cumplen una doble función: de una parte, definen el objeto para el que se solicita la protección, conforme a los arts. 84 del Convenio sobre concesión de Patentes Europeas, hecho en Munich el 5 de octubre de 1973 (en lo sucesivo, Convenio de la Patente Europea) y 26 de la Ley de Patentes, indicando para ello las características técnicas de la invención necesarias para ejecutar el procedimiento o definir el producto en que consiste la invención, y que permiten resolver el problema técnico anunciado en la memoria descriptiva; y de otra, determinan la extensión de la protección conferida por la patente o por la solicitud de patente, de acuerdo con los arts. 69.1 del Convenio de la Patente Europea y 60.1 de la Ley de Patentes, tomando en consideración la descripción y los dibujos.

Esta segunda función, la de delimitar el ámbito de exclusiva de la patente, es la esencial para decidir si se ha producido la violación de la patente. Para ello, será preciso interpretar la reivindicación o reivindicaciones afectadas, a fin de conocer su sentido técnico y jurídico relevante, y así poder determinar el alcance de la protección que otorga la patente. Tras esto, ha de hacerse una comparación entre lo que la patente reivindica tal como fue concedida, según su correcto alcance, y la realización cuestionada.

2.- De acuerdo con los arts. 69.1 del Convenio de la Patente Europea y 60.1 de la Ley de Patentes, el alcance de la protección que otorga la patente estará determinado por las reivindicaciones. No obstante, la descripción y los dibujos servirán para interpretar éstas.

El art. 1 del Protocolo interpretativo del art. 69 (que conforme al art. 164.1 del Convenio de la Patente Europea, forma parte de dicho Convenio), establece:

> «*El artículo 69 no deberá interpretarse en el sentido de que el alcance de la protección que otorga la patente europea haya de entenderse según el sentido estricto y literal del texto de las reivindicaciones y que la descripción y los dibujos sirvan únicamente para disipar las ambigüedades que pudieran contener las reivindicaciones. Tampoco debe interpretarse en el sentido de que las reivindicaciones sirvan únicamente de línea directriz y que la protección se extienda también a lo que, en opinión de una persona experta que haya examinado la descripción y los dibujos, el titular de la patente haya querido proteger. El artículo 69 deberá, en cambio, interpretarse en el sentido de que define entre esos extremos una posición que garantiza a la vez una protección equitativa para el solicitante de la patente y un grado razonable de certidumbre a terceros*»

Lo anterior supone que el objeto de la interpretación son las reivindicaciones, que definen el objeto de la invención y la extensión de la protección, y que la descripción y los dibujos deben tenerse en cuenta en la labor interpretativa.

3.- Como se indicó en el primer fundamento de esta resolución, la patente ES '891 lleva por título "nuevos enantiómeros y su aislamiento" y tiene por objeto un procedimiento para la obtención del principio activo escitalopram, que es la

denominación común internacional del compuesto químico (S)-(+)-1-(3-dimetilaminopropil)-1-(4'-fluorofenil)-1,3-dihidroisobenzofuran-5-carbonitrilo. La primera reivindicación de procedimiento de la patente, que es la relevante para este recurso porque es la que se alega ha sido infringida, protege:

«*Un método para la preparación de (+)-1-(3-dimetilaminopropil)-1-(4'-fluorofenil)-1,3-dihidroisobenzofuran-5-carbonitrilo que tenga la fórmula general* [sigue un gráfico] *y de sus sales de adición de ácido no tóxicas que comprende convertir (-)-4-[(4-dimetil-amino)-1-(4'-fluorofenil)-1-hidroxi-1-butil]-3- (hidroximetil) benzonitrilo o un monoéster suyo que tiene la fórmula* [sigue otro gráfico]. *Donde R es H o un grupo éster lábil, de una forma estereoselectiva y, luego aislar el compuesto de Fórmula I como tal o como una de sus sales de adición de ácido no tóxicas*».

La Audiencia Provincial considera que la lectura de la descripción de la patente muestra que «*lo sorprendente (la invención) no es (solamente) que se haya podido resolver el ciano-diol en sus enantiómeros, sino (también) que esos enantiómeros del ciano-diol se hayan podido convertir después de forma estereoselectiva en los enantiómeros del citalopram y, en concreto, en el enantiómero (S), escitalopram, que tiene la acción farmacológica deseada. Ahora bien, la R1 no incluye la etapa de la resolución del precursor, ciano-diol, aunque los ejemplos de la patente ilustran tanto la resolución de la mezcla racémica de ciano-diol como la posterior etapa de ciclación*».

Para la Audiencia Provincial, «*la patente no reivindica la resolución del racemato del diol, sino que su R1 tiene como punto de partida el enantiómero (S) (+) del ciano-diol, por lo que la parte del procedimiento de Natco que interesa en la comparación es la que comprende los últimos pasos, es decir, la transformación estereoselectiva de ese enantiómero inicial*».

Es aceptado por las partes, y así lo afirman también las sentencias de primera y segunda instancia, que la reivindicación primera de la patente menciona solo el ciano-diol enantiopuro como producto de partida.

4.- Definido el ámbito de protección conferido por la patente, el segundo paso necesario para decidir si ha existido infracción de la patente consiste en valorar si la realización cuestionada cae dentro del ámbito protegido por la patente, para lo cual ha de hacerse una comparación entre la invención patentada y la realización cuestionada.

Esta comparación ha de realizarse elemento por elemento. Solo cuando todos los elementos de la invención patentada sean reproducidos por la realización cuestionada se habrá producido una vulneración del derecho conferido por aquélla. Es lo que se denomina regla de la simultaneidad de todos los elementos, que ha sido aceptada por la moderna doctrina, y se desprende de la previsión del art. 2º del Protocolo de interpretación del art. 69 del Convenio de la Patente Europea, conforme al cual «*para determinar la extensión de la protección otorgada por la patente europea, deberá tenerse debidamente en cuenta todo elemento equivalente a un elemento indicado en las reivindicaciones*»

Consecuencia de lo anterior es que bajo la normativa vigente no es aceptable la doctrina de la “esencialidad” que podía encontrar cierta base en los arts. 46 y 48.3 del Estatuto de la Propiedad Industrial, que hacían mención a las “condiciones esenciales” o a que se “modifiquen sustancialmente las cualidades”. Correlativamente, pierde vigencia la jurisprudencia de esta Sala que acogía esa doctrina de la “esencialidad” y que es invocada por la recurrente para justificar el interés casacional.

5.- La reproducción de todos los elementos de la invención patentada, necesaria para que la realización cuestionada sea considerarse infractora, puede producirse por identidad (infracción literal) o por equivalencia (infracción por equivalencia).

En el caso objeto del recurso, la diferencia fundamental entre el procedimiento patentado y el cuestionado consiste en que mientras el primero utiliza como producto de partida el ciano-diol enantiopuro, el segundo utiliza el bromo-diol enantiopuro.

La parte demandante admite que el procedimiento empleado por NATCO, el fabricante del principio activo escitalopram que utiliza el segundo grupo de demandadas, no infringe literalmente su patente, pero considera que se produce una infracción por equivalencia.

La sentencia de la Audiencia Provincial, al igual que hizo la del Juzgado, consideró adecuado utilizar el test de las tres preguntas utilizado en la jurisprudencia británica, fundamentalmente en los casos “Catnic” e “Improver”, para determinar si ha existido infracción por equivalencia. La recurrente no cuestiona la corrección de utilizar este test en el caso enjuiciado. Lo que impugna es cómo se ha aplicado, en concreto el segundo de sus pasos.

De acuerdo con la sentencia de la Audiencia Provincial, las tres preguntas serían:

i) Si el procedimiento de la demandada altera sustancialmente el funcionamiento de la invención descrita en la patente de la actora. En caso afirmativo, no hay equivalencia. Si es negativo (no altera el funcionamiento), debe responderse a la pregunta siguiente.

ii) Si la alternativa propuesta por el procedimiento de la demandada era obvia para el experto en la materia que leyera la patente a la fecha de la publicación. Si la variante no era obvia, es decir, es inventiva, no hay equivalencia. Si la respuesta es afirmativa, todavía es necesario hacerse la tercera pregunta.

iii) Si este mismo experto en la materia, a la vista del texto de las reivindicaciones y de la descripción de la patente, habría entendido que el titular quiso que la sujeción al estricto sentido de los términos de la reivindicación fuera un requisito esencial de la invención.

6.- Para la Audiencia Provincial, en el caso enjuiciado, la primera pregunta del test debe responderse afirmativamente, en el sentido de que el procedimiento de la realización cuestionada (sustitución del ciano-diol enantiopuro de la patente ES '891 por el bromo-diol enantiopuro de NATCO) no altera sustancialmente el funcionamiento de la invención descrita en la patente. Habría que pasar por tanto a la segunda pregunta del test.

El núcleo de la controversia se encontraría en esta segunda pregunta, esto es, en la obviedad de la alternativa utilizada en el procedimiento empleado por NATCO para la obtención del principio activo, y en concreto, si la utilización como producto de partida del bromo-diol enantiopuro era una alternativa obvia para el experto en la materia que leyera la patente a la fecha de la publicación.

7.- La Audiencia Provincial indica que existe discrepancia incluso sobre el propio significado de la obviedad, concepto fundamental en la formulación de esta segunda pregunta.

Así, mientras que el Juzgado Mercantil, en su sentencia, consideró que para el experto, una alternativa sería obvia si no le planteara duda alguna sobre su funcionamiento en el procedimiento patentado, si fuera una variante fácil y rápida de encontrar, y ello explica que un titular no incluya literalmente esa alternativa en las reivindicaciones de su patente, en cambio LUNDBECK negaba que la obviedad consistiera en la ausencia de "duda alguna", y afirmaba que bastaría una expectativa razonable de éxito para que existiera obviedad en la alternativa utilizada por la realización controvertida.

La Audiencia Provincial no aceptaba el entendimiento menos exigente de la “obviedad” que LUNDBECK defendía en su recurso de apelación, y consideraba que «*obvio es algo fácil de ver o de comprender. Conforme a su etimología (obvius): que sale al paso, que se encuentra en el camino. Desde otro punto de vista, predecible*».

8.- La Audiencia Provincial considera que las pruebas periciales han puesto de manifiesto que la sustitución de la resolución del racemato de ciano-diol, presupuesto indispensable del procedimiento reivindicado en la patente de LUNDBECK, por la resolución del racemato de bromo-diol, empleada en el procedimiento de NATCO, para obtener el principio activo de escitalopram, no puede considerarse predecible y, por tanto, obvia. Los peritos coinciden en que el proceso experimental de resolución de un racemato es empírico e impredecible, pues no existe nunca certeza de que la mezcla de diastereoisómeros o diastereómeros formada en la primera etapa, al realizar la conversión química de los dos enantiómeros en diastereoisómeros o diastereómeros, podrá separarse.

Estas consideraciones de los informes periciales de los doctores Torres, March y Zea llevaron a la Audiencia Provincial a considerar que no podía afirmarse que la alternativa consistente en utilizar el bromo-diol como producto de partida, en vez del ciano-diol, fuera obvia para el experto en la materia.

9.- Para la Audiencia, otro argumento reforzaba la conclusión anterior. La sentencia del Juzgado Mercantil había considerado que el experto estaría desincentivado para probar la opción del bromo-diol por cierta consideración que el titular de la patente USA 4.136.193 incluyó en la patente ES 545.885, en la que se describe la ruta sintética para obtener citalopram a partir del ciano-diol racémico. Se decía, respecto de la ruta que utiliza el bromo-diol racémico, que «*se ha encontrado que el método descrito en la patente de EE.UU nº 4.136.193 para la preparación de este compuesto plantea algunos problemas a escala ampliada a producción comercial, y esto ha necesitado más investigación en un intento de descubrir una ruta más corta para este compuesto y de evitar el riesgo implicado en la etapa de metalación usada anteriormente*».

La Audiencia consideró que la constancia de esos prejuicios técnicos (*teaching away*, una enseñanza en otra dirección, esto es, una enseñanza que lleva al experto a alejarse de un comportamiento en vez de a acercarse a él) juega en contra de la obviedad de la variante. Tres años antes de la patente cuya infracción se alega, LUNDBECK había descartado la ruta del bromo-diol, por las razones expuestas.

En cuanto a la recompensa comercial que, según la apelante, tras la publicación de la patente ES '891 habría motivado al experto a comprobar si un proceso que no era muy conveniente antes de la obtención del escitalopram, pudiera serlo ahora, la Audiencia Provincial considera que tal argumento pertenece a un terreno distinto al de la obviedad. La recompensa comercial puede constituir una motivación poderosa, pero no simplifica la búsqueda.

Por último, la Audiencia Provincial descartó que la denegación de patentabilidad, por falta de actividad inventiva, que las Oficinas de Patentes de Suecia y Estados Unidos hicieron, en un informe de examen preliminar, a la solicitud de patente de un procedimiento para la obtención de escitalopram a partir de la variante del bromo-diol formulada por LUNDBECK años después de obtener la patente ES ‘891, supusiera, como pretendía LUNDBECK, que la alternativa que usaba como producto de partida el bromo-diol fuera obvia para un experto en la materia. La Audiencia consideró que, a la vista de la prueba practicada, carecía de datos suficientes para valorar el contenido de las solicitudes.

Por todo ello, la Audiencia Provincial confirmó la decisión del Juzgado Mercantil de desestimar la existencia de infracción por equivalencia, por considerar que la alternativa empleada por NATCO en su procedimiento de obtención del escitalopram no era obvia.

10.- El recurso de casación alude a una expresión de la sentencia de la Audiencia Provincial («*si la variante no era obvia, es decir, es inventiva, no hay*

equivalencia») para resaltar que la expresión «*es decir, es inventiva*» no es utilizada por la sentencia del tribunal inglés en el caso "Improver", y para imputar a la sentencia de la Audiencia Provincial una equiparación entre la noción de obviedad de la segunda pregunta del test "Improver" y la ausencia de actividad inventiva propia del examen de validez de la patente (o sea, es obvio lo que no es inventivo, la obviedad es la ausencia de actividad inventiva). Y que esta equiparación habría excluido indebidamente la existencia de infracción.

La argumentación del recurso no se acepta. En primer lugar, que la Audiencia Provincial pueda haberse apartado del literal de la sentencia del caso "Improver" no supone que haya incurrido en la infracción legal denunciada, única que puede fundamentar la estimación del recurso. La doctrina de los tribunales extranjeros puede ser útil en ciertos casos, como pueden serlo otros elementos doctrinales. Pero el recurso de casación no puede fundarse en que exista una divergencia entre lo afirmado por el tribunal español y el británico, pues solo puede basarse en la infracción de la ley aplicable, en este caso, el Convenio de la Patente Europea y la Ley de Patentes. Por otra parte, los propios tribunales ingleses matizan la aplicación de las diversas reglas o test establecidos en casos anteriores, adaptándolos a las exigencias de los supuestos objeto de cada litigio, por lo que carece de sentido insistir en esa divergencia.

En segundo lugar, varios de los argumentos utilizados en el recurso son artificiosos. Es artificiosa la alegación del interés casacional por la contraposición con la doctrina que emanaría de dos sentencias de la Sección 28ª de la Audiencia Provincial de Madrid (la más significativa de las cuáles, según el parecer de la recurrente, no sería siquiera una sentencia, sino un auto que resolvió una apelación contra un auto de medidas cautelares), puesto que intenta presentar como sustentadora de su tesis, que sostiene un concepto laxo de obviedad, lo que es, en la resolución de la Audiencia de Madrid, una interpretación restrictiva de la obviedad que impide hacer una aplicación extensiva de la infracción por equivalencia. Las resoluciones invocadas no extienden la infracción por equivalencia a soluciones alternativas "posibles" sino que, por el contrario, afirman que no es necesario que una alternativa reúna el requisito de actividad inventiva en el sentido de absoluta imprevisibilidad, absoluta falta de obviedad, para que no sea infractora.

Asimismo, al justificar la pretendida infracción legal en que ha incurrido la sentencia recurrida, la recurrente tergiversa lo dicho por la sentencia de la Audiencia Provincial, al poner en afirmativo ("es obvio") lo que la sentencia enuncia en negativo («*si la variante no era obvia*»), y en negativo ("lo que no es inventivo") lo que la sentencia enuncia en afirmativo («*es decir, es inventiva*»).

El recurso atribuye a la sentencia recurrida afirmaciones que esta no contiene. La sentencia de la Audiencia Provincial no dice que para decidir si concurre el requisito de la obviedad necesario para que exista infracción por equivalencia, hayan de aplicarse los mismos criterios que para determinar si concurre actividad inventiva en el análisis de la validez de una patente. La Audiencia Provincial no equipara el análisis de infracción al análisis de patentabilidad.

El recurso, para desacreditar una equiparación de este tipo y exponer que una realización posterior puede ser inventiva y, sin embargo, infractora de una patente prioritaria, alude a supuestos en que la actividad inventiva de la realización posterior se debe a que soluciona, de modo imprevisto, un problema técnico distinto, de modo añadido al solucionado por la patente, aunque pueda estar relacionado con él, pero en los que la alternativa utilizada respecto de un elemento de las reivindicaciones de la patente no altera el funcionamiento de la invención patentada y era obvia para solucionar el problema técnico objeto de la patente (como puede suceder por ejemplo en el caso de las patentes dependientes), por lo que, entiende la recurrente, en tal caso hay infracción por equivalencia.

No es ese el caso de la realización cuestionada en el litigio objeto del presente recurso, en el que el problema técnico que soluciona el elemento técnico

utilizado de modo alternativo (el bromo-diol como producto de partida) es el mismo que el que soluciona el elemento de la reivindicación (el ciano-diol como producto de partida), por lo que todas las alegaciones que se hacen al respecto son irrelevantes.

11.- El recurso atribuye a la sentencia de la Audiencia Provincial haber afirmado que el procedimiento alternativo solo es obvio cuando es cien por cien seguro, cuando su funcionamiento «*no plantea duda alguna*» al experto y que esta tesis infringiría el art. 69 del Convenio de la Patente Europea y su protocolo al restringir indebidamente la infracción por equivalencia..

El recurso, al utilizar este argumento, tergiversa de nuevo lo declarado por la sentencia de la Audiencia Provincial. Ciertamente LUNDBECK en su recurso negaba que la obviedad consistiera en la ausencia de "duda alguna" (esto es, negaba la tesis de que si existía la mínima duda de éxito de la alternativa utilizada en la realización controvertida, ya no era obvia, y por tanto se excluía la infracción por equivalencia), y afirmaba que bastaría una expectativa razonable de éxito para que concurriera el requisito de la obviedad. La Audiencia Provincial rechazó la tesis de LUNDBECK, pero no porque afirmara, como pretende el recurso, que para que el procedimiento alternativo no fuera obvio y, por tanto, infringiera la patente, sería preciso que no hubiera duda alguna de éxito (de modo que si el competidor acometía una alternativa con alguna mínima posibilidad de fracaso, ya no había obviedad), sino porque negó que bastara una simple perspectiva razonable de éxito (que es lo que sostiene la recurrente) y requirió algo más exigente para que pudiera afirmarse la existencia de obviedad, necesaria para que existiera infracción por equivalencia. Lo que la Audiencia Provincial exigió fue que la alternativa utilizada en la realización controvertida en sustitución del elemento de la invención no realizado de forma idéntica fuera fácil de ver o de comprender, que fuera predecible, tesis que esta Sala considera correcta.

Por tanto, todos los argumentos del recurso que se dedican a combatir esta cuestión parten de una base incorrecta.

12.- Tras los anteriores razonamientos, la recurrente alega que incluso admitiendo que cupiera enjuiciar la obviedad en sede de infracción por equivalencia aplicando los criterios de la actividad inventiva aplicados en sede de patentabilidad, el test relevante sería si el tercero “habría contemplado” la variante con expectativas razonables de éxito, y no si habría tenido la certeza absoluta de que dicha variante funcionaría. Según la recurrente, la tesis acogida por la sentencia recurrida sería inadmisible por cuanto solo habría considerado obvia (y por tanto infractora) la alternativa cuyo funcionamiento “no planteara duda alguna”. Lo correcto, según la recurrente, sería que la obviedad estaría justificada si se acreditara que el experto, aun no estando seguro al 100% de que la alternativa funcionaría, la probaría al “tener una expectativa razonable de que funcionará”.

Como se ha expuesto anteriormente, no es correcto sostener que la sentencia recurrida afirma que para que exista obviedad a efectos de apreciar la infracción por equivalencia, el experto en la materia debería haber tenido la certeza absoluta de que la variante utilizada funcionaría para resolver el problema técnico abordado con éxito por la invención patentada y, por tanto, que solo consideraba obvia (y por tanto infractora) la alternativa cuyo funcionamiento “no planteara duda alguna”.

La recurrente sostiene que el test relevante para determinar que existía obviedad sería que el tercero “habría contemplado” la variante con expectativas razonables de éxito, que la obviedad estaría justificada si se acreditara que el experto, aun no estando seguro al cien por cien de que la alternativa funcionaría, la probaría al “tener una expectativa razonable de que funcionará”.

Esto es realmente lo rechazado la Audiencia Provincial en su sentencia, al exigir un entendimiento más exigente de la obviedad, no porque pretenda que para que exista obviedad el experto en la materia ha de estar seguro al cien por cien de

que la alternativa funcionará, sino por entender que «*obvio es algo fácil de ver o de comprender. Conforme a su etimología (obvius): que sale al paso, que se encuentra en el camino. Desde otro punto de vista, predecible*». Tesis que, como se ha dicho y se razonará más adelante, esta Sala considera correcta.

13.- La recurrente, tras afirmar de modo artificioso que la Audiencia Provincial realiza una equiparación entre el enjuiciamiento de la infracción y el de la patentabilidad, dice aceptar "a efectos dialécticos" que se enjuicie la obviedad en sede de infracción por equivalencia aplicando el test de actividad inventiva propio del examen de patentabilidad, e intenta que se apliquen rigurosos criterios del examen de patentabilidad según su interpretación de las directrices de examen de la Oficina Europea de Patentes y de las resoluciones de su Cámara de Recursos, de modo que si la alternativa utilizada por la realización controvertida, la sustitución del ciano-diol por el bromo-diol como producto de partida, no fuera suficiente para alcanzar el nivel de actividad inventiva exigido para que una invención fuera patentable, sería obvia a efectos de la infracción por equivalencia.

El argumento vuelve a ser artificioso, no solo porque se pretende aceptar una argumentación de la sentencia recurrida (la equiparación entre el juicio de infracción y el juicio de patentabilidad), cuando tal argumentación no ha sido empleada por la Audiencia Provincial, para justificar un enjuiciamiento de la obviedad más riguroso, sino también porque la cita que hace de las directrices de examen de la Oficina Europea de Patentes es sesgada.

Lo que exigen estas directrices para excluir la actividad inventiva no es solo que en el estado de la técnica hubiera alguna enseñanza que «*podía haber impulsado*» ("could") al experto en la materia a modificarlo o adaptarlo teniendo en cuenta dicha enseñanza para solucionar el problema técnico: se exige que esa enseñanza «*habría impulsado*» ("would"), lo que supone un grado mayor de exigencia en la predecibilidad del resultado satisfactorio. Es tras utilizar esta expresión de mayor exigencia cuando se añade la matización sobre las expectativas razonables de éxito, expresión que no puede descontextualizarse como hace la recurrente. Este es el contexto en el que deben valorarse las resoluciones de la Cámara de Recursos de la Oficina Europea de Patentes que se invocan por la recurrente. La matización de que es suficiente una "expectativa razonable de éxito" para que exista actividad inventiva se introduce por dicha Cámara de Recursos en sede de control de los requisitos de patentabilidad (en concreto, de la actividad inventiva), no en sede de infracción (que es cuestión sobre la que dicho organismo carece de competencias), y tras recordar que no es suficiente que las enseñanzas del estado de la técnica "hubieran podido empujar" al experto en la materia a esa alternativa, pues para excluir la actividad inventiva se exige que dichas enseñanzas "habrían empujado" al experto en la materia a esa alternativa.

En todo caso, el juicio de patentabilidad es distinto del juicio de infracción, como se expondrá más adelante, y las directrices de examen de la Oficina Europea de Patentes no son más que eso, directrices que esa oficina da a sus examinadores, por lo que no vinculan a los tribunales de justicia. Las resoluciones de la Cámara de Recursos emanan de un organismo de la Oficina Europea de Patentes, y no puede olvidarse que pese a que dicha Oficina pueda aceptar la patentabilidad de una determinada invención, son los tribunales de cada Estado los que deben decidir, con plena independencia de lo resuelto por la Oficina Europea de Patentes, sobre la validez de una patente cuando se plantea su nulidad, por vía de acción, excepción o reconvención, y que cuando declaran la nulidad de una patente contradicen el criterio de la Oficina Europea de Patentes que la ha otorgado.

14.- Por otra parte, como ya se ha adelantado, que la variante utilizada en la realización cuestionada no alcance el umbral de patentabilidad, y concretamente, que no cumpla el requisito de la actividad inventiva, puede deberse a razones distintas de

la obviedad en la alternativa utilizada respecto de un concreto elemento técnico de la patente prioritaria.

El examen de la actividad inventiva necesaria para reconocer la patentabilidad de una variante que se pretende inventiva es diferente del examen de la obviedad en el juicio de infracción por equivalencia de esa misma variante. Son valoraciones que persiguen finalidades distintas y que, en consecuencia, utilizan parámetros diferentes.

El examen de la actividad inventiva que se realiza para determinar la patentabilidad de una invención no se realiza elemento por elemento, sino sobre la invención como tal, considerada de modo conjunto, y es respecto de este conjunto del que debe decidirse si resulta o no del estado de la técnica (en la que se integra la patente prioritaria, pero también otras divulgaciones) de un modo evidente para el experto en la materia. Esto es, no se enjuicia la actividad inventiva de sus características técnicas tomadas de forma aislada, sino de la solución global en que la invención consiste.

En el juicio de infracción por equivalencia, el examen y la comparación han de realizarse elemento por elemento, por lo que la obviedad de un elemento de la variante ha de referirse al elemento pretendidamente equivalente de la invención prioritaria.

Por tanto, puede suceder que una realización posterior, en el juicio de patentabilidad, supere el nivel exigible de actividad inventiva, pero infrinja una patente prioritaria, en cuyo caso se trata de una patente dependiente, que soluciona, además del problema técnico resuelto por la patente prioritaria, otro problema técnico distinto, pero en la que la alternativa utilizada respecto de una determinada característica técnica de la patente prioritaria era obvia para solucionar el problema técnico cuya solución perseguía dicha patente prioritaria.

Y, en sentido inverso, puede suceder también que una realización posterior no supere el umbral de actividad inventiva necesario para ser patentable porque, en su conjunto, para un experto en la materia, resulte de un modo evidente del estado de la técnica más próximo al momento determinante de su prioridad, pero que sin embargo no infrinja la patente anterior porque la alternativa empleada para sustituir una de las características técnicas de las reivindicaciones, pese a no alterar el funcionamiento de la invención, no pudiera haber sido considerada obvia por un experto en la materia en el momento determinante de la prioridad de la patente supuestamente infringida.

De lo expuesto se deduce que también es distinto el momento temporal a tener en cuenta en el examen de la obviedad propio del juicio de infracción por equivalencia y en el juicio de la actividad inventiva propio del examen de patentabilidad de la variante. Mientras que para el juicio de infracción, la sustitución del elemento técnico por otro que realice la misma función para solucionar el mismo problema técnico debía ser obvia para un experto en la materia en la fecha de prioridad de la patente que se alega infringida, para la valoración de la actividad inventiva ha de determinarse si la variante resultaba del estado de la técnica, de un modo evidente para el experto en la materia, en la fecha de prioridad de la patente solicitada.

En consecuencia, el momento temporal relevante para enjuiciar la obviedad en el juicio de infracción por equivalencia sería anterior al relevante para enjuiciar la actividad inventiva de la nueva variante.

Por tanto, no se aceptan los argumentos empleados por la recurrente, que llevarían a equiparar toda variación que no alcanzara la actividad inventiva suficiente para superar el umbral de la patentabilidad con un equivalente obvio y por tanto infractor.

15.- La diferencia entre lo que afirma la sentencia recurrida y lo que sostiene la demandante en su recurso es que mientras que la Audiencia Provincial considera

que para que exista obviedad es necesario que para el experto en la materia sea predecible que la alternativa utilizada en la realización controvertida respecto de uno de los elementos técnicos de la patente, que no altera el funcionamiento de la misma, solucionará el problema técnico abordado por la patente, en cambio para la recurrente basta con que el experto en la materia probaría o intentaría esa alternativa al tener una expectativa razonable de que funcionará.

La Sala considera que es más acertada la tesis más exigente de la Audiencia, al requerir que la expectativa razonable de que la alternativa funcionará alcance el umbral de la predecibilidad. Esta predecibilidad debe ser entendida no como un cien por cien de seguridad en el éxito (que en estos campos de la ciencia y de la técnica es difícil poder alcanzar) pero sí como una probabilidad muy elevada de éxito. No es suficiente, como pretende la recurrente, que el experto en la materia habría contemplado la variante con expectativas de éxito. Es necesario que el experto en la materia "habría" contemplado que la variante (el elemento equivalente) era una alternativa obvia, esto es, que el éxito de la sustitución, para resolver el problema técnico abordado satisfactoriamente por la patente, era predecible.

Por tanto, no basta la simple posibilidad de que el experto en la materia hubiera adoptado la solución al problema técnica a la vista del estado de la técnica más reciente (podía, "could"), sino que se exige una alta probabilidad de que lo hubiera hecho (habría, "would").

16.- Consecuencia de lo expuesto es que para el juicio de obviedad en la infracción por equivalencia, es más acertado el estándar de "predecibilidad" utilizado por la Audiencia Provincial que el menos exigente de mera "posibilidad de éxito", de que el experto en la materia "se habría sentido motivado a intentar" la alternativa "con expectativas de éxito", defendido por la recurrente.

17.- Por último, la recurrente, que hasta ahora ha realizado toda la crítica de la sentencia recurrida en un plano abstracto, cuando alude al supuesto concreto enjuiciado, lo hace transcribiendo pasajes aislados tanto de la sentencia de la Audiencia Provincial como de la sentencia del Juzgado Mercantil, con lo que pretende justificar que la alternativa utilizada por la realización controvertida era obvia, en tanto que la no alteración del funcionamiento de la invención por la sustitución del producto de partida (lo que en la patente era ciano-diol enantiopuro, en la realización controvertida sería bromo-diol enantiopuro) sería evidente para un experto en la materia, que conocería la patente USA 4.136.193.

La recurrente, al realizar estas citas de pasajes descontextualizados, prescinde del enfoque global que la sentencia de la Audiencia Provincial da a esta cuestión. Como se ha expuesto, la Audiencia considera que la sustitución de la resolución del racemato de ciano-diol, presupuesto indispensable del procedimiento reivindicado en la patente de LUNDBECK, por la resolución del racemato de bromo-diol, empleada en el procedimiento de NATCO, para obtener el principio activo de escitalopram, no puede considerarse predecible y, por tanto, obvia, pues la prueba pericial arroja el resultado de que el proceso experimental de resolución de un racemato es empírico e impredecible, pues no existe nunca certeza de que la mezcla de diastereoisómeros o diastereómeros formada en la primera etapa, al realizar la conversión química de los dos enantiómeros en diastereoisómeros o diastereómeros, podrá separarse. Además, añadía la sentencia recurrida, en el estado de la técnica existía constancia de prejuicios (*teaching away*) que jugaban en contra de la obviedad de la variante, pues la ruta que utilizaba el bromo-diol racémico para la obtención de citalopram planteaba algunos problemas a escala ampliada a producción comercial, hasta el punto de que LUNDBECK había descartado la ruta del bromo-diol por esas razones.

Por tanto, el nivel de probabilidad de que un experto en la materia utilizara la alternativa del bromo-diol para obtener el escitalopram no alcanzaba el umbral necesario para considerar que la alternativa era obvia.

Coincide también la Sala con la Audiencia Provincial en que la potencial recompensa comercial inherente a la consecución de un producto tan exitoso como el escitalopram no es un elemento relevante en el enjuiciamiento de la infracción por equivalencia, puesto que no hace que la alternativa intentada sea más o menos obvia.

18.- La conclusión de lo expuesto es que la Audiencia Provincial no ha infringido el art. 69 del Convenio de la Patente Europea ni su protocolo cuando ha dado al requisito de obviedad necesario para realizar el enjuiciamiento de la infracción por equivalencia un alcance que, sin exigir una certeza absoluta por parte del experto en la materia de que la variante empleada respecto de un elemento técnico de las reivindicaciones funcionaría adecuadamente, considera que no basta con que dicho experto tenga una expectativa razonable de que funcionará, pues es necesario que concurra la nota de predecibilidad.

Más aún en un caso como el enjuiciado, en el que la sustitución del producto de partida (ciano-diol por bromo-diol) no hacía predecible para el experto en la materia que pudiera obtenerse el principio activo de escitalopram por el carácter empírico e impredecible del proceso experimental de resolución de un racemato, y porque la ruta que utilizaba el bromo-diol racémico para la obtención de citalopram planteaba algunos problemas a escala ampliada a producción comercial.

19.- La sentencia recurrida reconoce que antes de la patente ES '891 nadie había conseguido resolver el racemato de citalopram. Después de esa patente, el experto ya sabía que se obtenía escitalopram mediante la transformación estereoselectiva del enantiómero del ciano-diol. Las incertidumbres se estrecharon, sin duda, pero no hasta convertir en obvia la ruta del bromo-diol utilizada. Que NATCO, o cualquier experto en la materia, tras la patente ES '891 tuviera más información y más posibilidades de éxito en la transformación (por el cambio en el estado de la técnica) no significa que se infringiera la patente por equivalencia.

Las consideraciones de la Audiencia Provincial son correctas. La exigencia de simultaneidad de todos los elementos para que exista infracción de la patente permite que los demás aprendan de la patente, de algunos de sus aspectos, que puedan operar en el mismo campo de la ciencia y de la técnica, pero que no la infrinjan al sustituir alguno de sus elementos por otro que no sea equivalente.

Se trata de una consecuencia del equilibrio que se debe preservar dentro de la tensión existente entre el monopolio que el derecho de exclusiva atribuye a su titular, que recibe la protección de los poderes públicos, y la legítima aspiración de los restantes operadores económicos a intervenir en el mismo mercado al que se refiera la invención protegida, con un grado de certidumbre suficiente. Este equilibrio es consecuencia de la correspondencia existente entre la exigencia de publicidad de la patente, en términos suficientemente precisos como para que pueda ser ejecutada, y la protección que el inventor obtiene. Las enseñanzas de la patente son públicas, y no cualquier aprovechamiento es infractor, solo aquel que reproduce la invención patentada elemento por elemento, bien literalmente, bien por equivalencia.

Por lo expuesto, la sentencia recurrida, al establecer este criterio para determinar cuándo es obvia la variante utilizada, ha alcanzado un equilibrio adecuado entre la protección equitativa del titular de la patente y un grado razonable de certidumbre a terceros, dando por tanto cumplimiento al art. 69 del Convenio de la Patente Europea que se cita como infringido, en el sentido previsto en el art. 1 del protocolo interpretativo de dicho precepto.

Por lo expuesto, el recurso de casación debe ser desestimado.

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DUODÉCIMO.- **Costas y depósitos**

1.- De acuerdo con lo previsto en el artículo 398.1 en relación con el 394.1, ambos de la Ley de Enjuiciamiento Civil, las costas de los recursos extraordinario por infracción procesal y de casación deben ser impuestas a la recurrente.

2.- Procede acordar también la pérdida de los depósitos constituidos de conformidad con la disposición adicional 15ª, apartado 9, de la Ley Orgánica del Poder Judicial, introducida por la Ley Orgánica 1/2009, de 3 de noviembre, complementaria de la Ley de Reforma de la Legislación Procesal para la implantación de la Nueva Oficina Judicial.

Por lo expuesto, en nombre del Rey y por la autoridad conferida por el pueblo español.

F A L L A M O S

1.- Desestimar los recursos extraordinario por infracción procesal y de casación interpuestos por "H. Lundbeck A/S" y de "Lundbeck España S.A.", contra la sentencia núm. 434/2012, de 19 de diciembre, dictada por la sección decimoquinta de la Audiencia Provincial de Barcelona, en el recurso de apelación núm. 54/2012.

2.- Imponer la parte recurrente las costas de los recursos extraordinario por infracción procesal y de casación que desestimamos, así como la pérdida de los depósitos constituidos.

Líbrese al mencionado tribunal la certificación correspondiente, con devolución de los autos y del rollo de Sala.

Así por esta nuestra sentencia, que se insertará en la COLECCIÓN LEGISLATIVA pasándose al efecto las copias necesarias, lo pronunciamos, mandamos y firmamosFrancisco Marín Castán. Francisco Javier Orduña Moreno. Rafael Sarazá Jimena. FURMADO Y RUBRICADO

PUBLICACIÓN.- Leída y publicada fue la anterior sentencia por el EXCMO. SR. D. **Rafael Sarazá Jimena**, ponente que ha sido en el trámite de los presentes autos, estando celebrando Audiencia Pública la Sala Primera del Tribunal Supremo, en el día de hoy; de lo que como secretario de la misma, certifico.

ADMINISTRACION
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Cabecera	
Remitente:	[2807911004] TRIBUNAL SUPREMO CIVIL SALA 1A. SECCION 4A. de Madrid, Madrid
Asunto:	Resolucion
Fecha LexNET:	13/05/2015 13:56:00
Datos particulares	
Remitente:	[2807911004] TRIBUNAL SUPREMO CIVIL SALA 1A. SECCION 4A. de Madrid, Madrid
Destinatario:	SORRIBES CALLE, ROSA [617] ZABALA FALCO, JAVIER EVARISTO [1273] BORDALLO HUIDOBRO, ANIBAL [557] GIRON ARJONILLA, MARIA DOLORES [212]
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Tipo procedimiento:	CIP
Descripción:	NOTIFICACION
NIG:	2807911120130000720
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Archivos adjuntos	
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Anexos:	
Lista de Firmantes	
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