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MADRID

IS THERE ONLY ONE WAY OF ASSESSING ART. 56 EPC?

Dr. Joachim Renken

www.HoffmannEitle.es

Inventive Step: Article 56 EPC

"AN INVENTION SHALL BE CONSIDERED AS INVOLVING AN INVENTIVE STEP IF, HAVING REGARD TO THE STATE OF THE ART, IT IS NOT OBVIOUS TO A PERSON SKILLED IN THE ART".

Article 52 EPC – Invention

(1) European Patents shall be granted for any inventions, in all fields of technology, provided that there are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business and programs or computers;
(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which the European patent application or European patent relates to such subject-matter or activities as such.

Article 54 (2) EPC – State of the Art

THE STATE OF THE ART SHALL BE HELD TO COMPRISE EVERYTHING MADE AVAILABLE TO THE PUBLIC BY MEANS OF A WRITTEN OR ORAL DESCRIPTION, BY USE, OR IN ANY OTHER WAY, BEFORE THE DATE OF FILING OF THE EUROPEAN PATENT APPLICATION

Rule 42 EPC– Technical Problem and its Solution

(1) *THE DESCRIPTION SHALL:*

…

(C) DISCLOSE THE INVENTION, AS CLAIMED, IN SUCH TERMS THAT THE TECHNICAL PROBLEM, EVEN IF NOT EXPRESSLY STATED AS SUCH, AND ITS SOLUTION CAN BE UNDERSTOOD, AND STATE ANY ADVANTAGEOUS EFFECTS OF THE INVENTION WITH REFERENCE TO THE BACKGROUND ART

Who is the person **skilled** in the art?

What does **obviousness** having regard to the state of the art mean?

EPO

THE SKILLED PERSON:
WHO IS HE OR SHE?

- Presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date (C-IV, 9.6)

- Does not possess inventive capability (T39/93)

- May be a group of people (T141/87; T99/89)

THE FRAMEWORK: „PROBLEM-AND-SOLUTION-APPROACH“

1. Determine the closest prior art
2. Assess the technical difference between the closest prior art and the claimed subject matter (i.e. the differing features)
3. What is the resulting technical effect of these differing features?
4. Formulate the objective technical problem on the basis of this effect
5. Was it obvious for the skilled person to use the differing features to solve the objective technical problem?

THE CLOSEST PRIOR ART

- The closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention (T 606/89)

- Another criterion is the most promising springboard being represented by the prior art which would have most easily enabled the skilled person to make the invention (T656/90)

- In case there is more than one candidate for the closest prior art (either within the same or in different documents): Inventiveness should be established in view of either of them

THE OBJECTIVE TECHNICAL PROBLEM

- Starting point: The specific problem set out in the description
- What happens if this problem was not solved vis-à-vis the CPA by the application (i.e. at the filing date)?
- Is it possible to generate supporting evidence after the filing date?
- Is it possible to reformulate the problem? (If so, how?)
- Or has an inventive step to be denied in such a case?

THE SITUATION

- The application concerned Polynucleotide encoding “Growth Differentiation Factor-9” (GDF-9), allegedly a new member of the TGF-β-superfamily
- GDF-9 exhibits major structural differences to the known members of this family
- The application did not contain any evidence that GDF-9 has the effects expected for a member of this family
- Such evidence was firstly provided in the form of post-published experimental data

THE DECISION

- Problem to be solved: *Provision of a new member of the TGF-β-superfamily*.

- Solution according to the application: GDF-9, but…
  - No respective data or evidence in the application
  - Because of the large structural differences, it is not plausible that GDF-9 is a member of the TGF-β-superfamily
  - Post-published documents are the only evidence going beyond speculation; this was considered to be insufficient for acknowledging inventive step

- Problem not plausibly solved: Inventive Step denied!

HEADNOTE

T 1329/04 Factor-9

"The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve."

CONCLUSION

T 1329/04 Factor-9

- The application must make it plausible that the addressed problem is indeed solved
- This means that the application as filed must either contain experimental evidence that the desired technical effect is achieved by the claimed subject matter,
- or the solution must be plausible when reading the application with the skilled person's technical background knowledge
- Demonstration of plausibility only by post-published data is not sufficient!

THE SITUATION

T 108/09 Fulvestrant

- The patent concerned the use of fulvestrant for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed such previous treatments
- Patent contains protocol for a clinical trial, but not its results
- Results of clinical trials provided (post-published)
- Problem to be solved was defined as the provision of a method which allows treatment of patients with breast cancer who have previously been treated with an aromatase inhibitor and with tamoxifen and have failed with such previous treatments
- Opponent: Not plausible that problem was solved

THE DECISION

T 108/09 Fulvestrant

Board 3.3.02

In decision T 1329/04, there had been prima facie ***serious doubts*** that the polypeptide denominated GDF-9 belonged to the TGF-ß superfamily and thus solved the problem of the invention. … In the present case, however, it was already known that fulvestrant was effective as a second-line agent in the treatment of breast cancer. Regarding the use of fulvestrant as a third-line agent, which constitutes the contribution of the present invention to the state of the art, the patent in suit contains, as was mentioned above detailed information as to how fulvestrant has to be formulated and administered in order to obtain the desired effect. Document (10) is therefore far from being the only source of information regarding the question whether fulvestrant is useful as a third-line agent, so that the data contained therein may be used in the evaluation of whether or not the problem underlying the present invention has been plausibly solved.

THE SITUATION

- The invention the combination of enalapril sodium and micronized nitredipine
- Claim 1 differs from CPA in that the claimed association specifies that enalapril is in the form of sodium salt and that nitrendipine is in a micronized form
- The patent does not emphasize explicitly any improved features of the claimed association as compared to the prior art formulation. The technical effect obtained by the claimed invention is described in the patent as to achieve good stability of the enapril and a good solubility of the nitrendipine
- Patentee submitted (post-published) data showing that a combination of enalapril sodium and micronized nitredipine showed a synergistic effect with regard to the solubility of nitredipine

THE SITUATION

- The Opposition Division considered the synergistic effect in the formulation of the OTP and ruled that the patent fulfils the requirement of inventive step.

Is a reformulation of the (originally stated) problem always possible?

- *The extent to which such reformulation of the technical problem is possible has to be assessed on the merits of each particular case. As a matter of principle any effect provided by the invention may be used as a basis for the reformulation of the technical problem,* ***as long as said effect is derivable from the application as filed*** *(see T 386/89). It is also possible to rely on new effects submitted subsequently during the proceedings by the applicant,* ***provided that the skilled person would recognise these effects as implied by or related to the technical problem initially suggested*** *(see G-VII, 11 and T 184/82)* (see Guidelines)

THE DECISION

- Board of Appeal

Prima facie therefore, the board is satisfied that the "comparative examples" seem to support the presence of a synergistic effect on the dissolution rate of nitrendipine of a particular association falling within the ambit of claim 1.

However:

(…) the board is not in a position to accept that the "comparative examples" submitted with the letter dated 16 July 2002 are unambiguously supportive of a synergistic effect of the specific use of enalapril in the form of its sodium salt on the dissolution rate of micronized nitrendipine.

Inventive step denied! Why?

Inventive step denied! Why?

The reason for this is that it has for long been a generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art (see T 409/91, OJ EPO 1994, 653 , reasons Nos. 3.3. and 3.4, and T 435/91, OJ EPO 1995, 188, reasons Nos. 2.2.1 and 2.2.2).

Now, whereas in both the above decisions this general legal principle was applied in relation to the extent of the patent protection that was justified by reference to the requirements of Articles 83 and 84 EPC, the same legal principle also governs the decision that is required to be made under Article 56 EPC, for everything falling within a valid claim has to be inventive. If this is not the case, the claim must be amended so as to exclude obvious subject-matter in order to justify the monopoly.

FIRST CONCLUSIONS

i. Article 56 EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art (Agrevo)

ii. If the patent specification does not make plausible that the originally stated problem is solved, there may be no inventive step; this is particularly so if there are doubts that the originally stated problem is not solved (John Hopkins)

iii. A technical effect may be shown by post-published evidence, provided that the effect is related to the originally stated problem

THE EPO APPROACH TO INVENTIVE STEP

iv. Once it is established that in comparison to the closest prior art, the claimed subject matter exhibits:

- a technical effect, which
- has its origin in the distinguishing features,
- is achieved over the whole scope claimed, and
- is derivable from the application as filed

then the objective technical problem to be solved in view of the closest prior art relates to the provision of this technical effect.

iv. If there is no technical effect, the objective technical problem relates to a <u>provision of an alternative</u> to the closest prior art

v. And remember: The technical problem is determined objectively, i.e. on the basis of the available evidence. Different bodies (Examining Divisions/Opposition Divisions/Appeal Boards) may come to different oonclusions in their evaluation of the available evidence!

Does this mean that one has to prove the alleged effect for every embodiment covered by the claim?

No, this must be merely plausible, which can be achieved by proper comparative testing!

COMPARATIVE EXPERIMENTS: SUPPORT FOR NON-OBVIOUSNESS

- Should be derived from tests comparing the claimed subject matter to the closest prior art.

- Should serve to establish unexpected and advantageous effects resulting from the technical difference(s) between the claimed subject matter and the closest prior art.

COMPARATIVE EXPERIMENTS

1. Structurally closest approximation

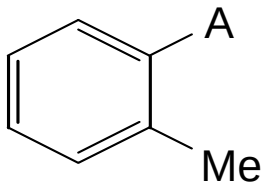
- Prior art compound or composition used for comparison should be that Example of the closest prior art which is most similar to the claims.

- Claimed compound or composition which is used for comparison should be that which is most similar to the prior art compound/composition used for comparison.

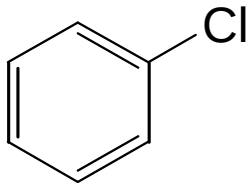
- If the application uses a general chemical formula to define the claimed subject matter then the compound falling under this formula which is structurally closest to the prior art should be used for comparison.

EXAMPLE: STRUCTURALLY CLOSEST APPROXIMATION

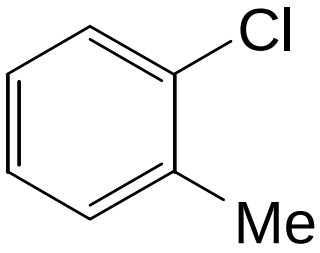
Claim: A compound of the following formula, wherein A represents a halogen atom, a C_{1-6} alkyl group or a C_{1-6} alkoxy group:



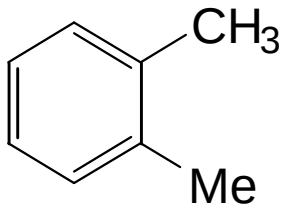
Closest prior art compound:



Claimed compound to be used for **comparison** test:



not:



COMPARATIVE EXPERIMENTS

2. Concept of the Experiments

- The embodiments of the prior art and of the invention which are used for the comparative experiments should differ only with regard to the technical feature(s) matching the difference between the claimed subject matter and the disclosure of the closest prior art.

- The testing conditions should be the same for the prior art embodiment and the embodiment of the claimed invention.

- The tested properties should be the same as described in connection with the advantages of the invention and/or tested in the Examples of the application.

COMPARATIVE EXPERIMENTS

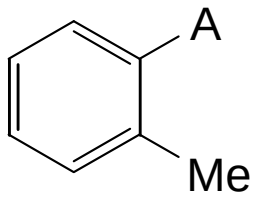
3. Scope of the Effect

- The technical effect of the invention must be plausibly shown to exist for all compounds/the entire composition range which are/is claimed.

- This applies to both, the technical effect claimed in the application and that observed with regard to the closest prior art compound or composition (if these effects should differ from each other).

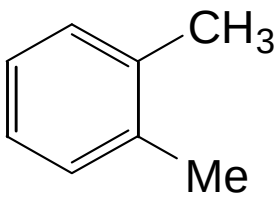
EXAMPLE: SCOPE OF THE EFFECT

- **Claim**: A compound of the following formula, wherein A represents a halogen atom, a C_{1-6} alkyl group or a C_{1-6} alkoxy group:



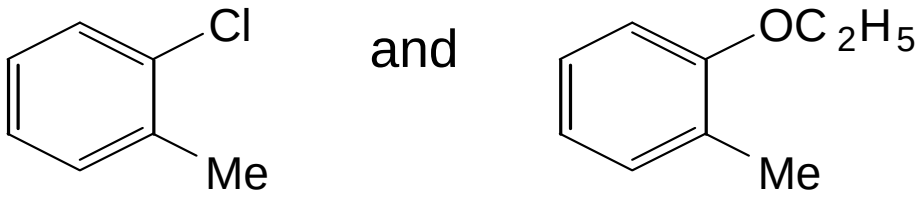
- Application claims antibacterial effect for the claimed compounds

- The effect is shown in the application on the basis of test data to exist for:



EXAMPLE: SCOPE OF THE EFFECT

- Need to provide exemplary evidence that the effect also exists for the other compounds falling under the scope of the claims, e.g. effect shown to also exist for:



- A generalization of the existence of the effect to comparable functional groups (i.e. any halogen atom, any C_{1-6} alkyl or any C_{1-6} alkoxy group) will typically be accepted by the EPO.

OBVIOUSNESS OF THE SOLUTION

Art. 56: Was the invention obvious, having regard to the state of the art, to the skilled person?

Problem/solution approach: Was the solution to the objective technical problem vis-à-vis the CPA obvious to the skilled person?

Remember: The skilled person is presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date.

Does this mean that only the skilled person's common general knowledge is to be considered for obviousness?

OBVIOUSNESS OF THE SOLUTION

No!

A **skilled person would**, as well as considering the state of the art in the specific technical field of the application**, look for suggestions in neighbouring fields or a broader general technical field** if the same or similar problems arose, and if he could be expected to be aware of such general fields (T176/84).

The relevant prior art also includes prior art in a non-specific (general) field dealing with the solution of any general technical problem which the application solved in its specific field (T195/84).

T 2/83 Simethicone tablet/Rider

- Prior art : tablet with antacid and simethicone adsorbed on solid
- Prior art: gastro-intestinal formulations separating liquid simethicone from solid antacid with a barrier
- Invention: tablet with antacid separated from simethicone adsorbed on solid by a barrier

"Proper question to be asked was not whether the skilled man could have provided the barrier but whether he would have done so in expectation of some improvement or advantage".

Decision also known for introducing the expression "one way street" into the patent lexicon

OBVIOUSNESS OF THE SOLUTION

The question is whether there is any teaching in the prior art as a whole that **would** (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves (see G-VII, 4).

Even an implicit prompting or implicitly recognizable incentive is sufficient to show that the skilled person would have combined the elements from the prior art (see T 257/98 and T 35/04). This must have been the case for the skilled person before the filing or priority date valid for the claim under examination (Guidelines).

T16/04

The jurisprudence of the Boards of Appeal has indicated that a technical effect of a claimed invention may be considered a "*bonus effect*" only when the skilled person has no alternative other than arriving at the claimed subject-matter in order to solve another reasonable technical problem (see, for instance, the "one-way street" situation described in decision T 192/82, OJ EPO 1984, 415, also mentioned in the section of the Case Law of the Boards of Appeal of EPO, 4th Edition 2001, cited by the Appellant).

UK

It is often convenient, but by no means essential, to consider an allegation of obviousness using the structured approach explained in Pozzoli vs. BDMO...

WINDSURFING INTERNATIONAL *VS*. TABUR MARINE (UK)

- GB-B-1,258,317
- Priority: 27 March 1968
- Windsurfing alleged *infringement*
- Tabur Marine sought *revocation*

- Inventive concept – Bermuda rig
- with a wishbone spar
- 2 key pieces of prior art:
    - prior use by Mr. Chilvers in 1958/9
    - ‘Sailboarding – Exciting New Water Sport’

APRIL 1982
WITFORD J

- Anticipated by prior use (Mr. Chilvers)
  - non-arcuate booms, but became arcuate in use
- Obvious from prior art document
  - disclosed a square-rigged sail
  - Bermuda-rigged sail held to be an obvious improvement
- Windsurfing appealed

JANUARY 1984
OLIVER LJ

4-step test to **assess obviousness**:

1) Identify the inventive concept embodied in the patent.

2) Impute to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date.

3) Identify the differences, if any, between the matter cited and the alleged invention.

4) Decide whether those differences, viewed without any knowledge of the alleged invention, constituted steps which would have been obvious to the skilled addressee or whether they required any degree of invention.

The *Windsurfing* test in action:

a) The inventive concept was the free-sail concept.

b) At the priority date the skilled man would be familiar with Bermuda rigs, square rigs, the benefits of the former over the latter, and wishbone booms.

c) The only difference between the prior art document and the alleged invention was the square rig in place of a Bermuda rig held by a wishbone boom.

d) The skilled man would have immediately recognised that the disadvantages of the square rig could be addressed by replacing it with a Bermuda rig and a wishbone boom.

WINDSURFING INTERNATIONAL *VS*. TABUR MARINE – COURT OF APPEAL

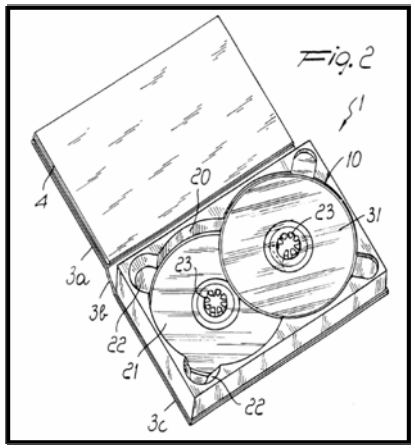
- Patent held invalid: both anticipated and obvious

- Benefits of the *Windsurfing* test:
  - standardised approach
  - aids objectivity

- The identity of the skilled person and their common general knowledge is critical

POZZOLI SPA *VS*. BDMO SA

- EP (UK) 0 676 763
- Priority: 15 July 1994
  - multi-CD case
  - dimensions less than 2:1
  - more convenient storage



- Pozzoli alleged infringement
- BDMO sought revocation for obviousness

June 2006
Lewison J

- Inventive concept = overlapping and spatially separating the discs

- *Windsurfing* Step 4:

  Was it obvious in 1994 to the design team who were aware of pre-existing CD storage methods to partially overlap and spatially separate the discs such that the central axes were offset?

- Yes!
- Patent held to be invalid

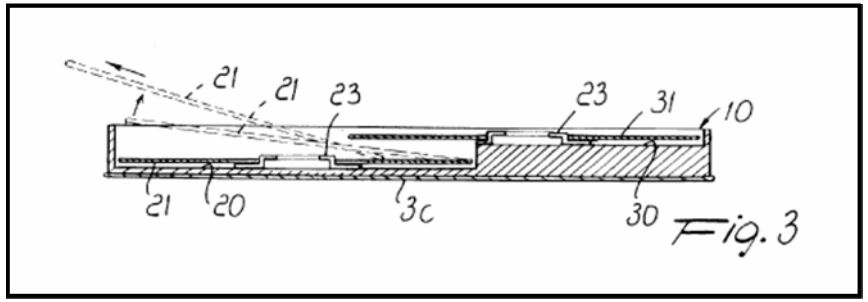


Fig. 3

June 2007
Jacob LJ

- *Windsurfing* test as reformulated in *Pozzoli*

1.) a) Identify the notional 'person skilled in the art';
b) Identify the relevant common general knowledge of that person;

2.) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

3.) Identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim as construed;

4.) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

POZZOLI SPA *VS*. BDMO SA – COURT OF APPEAL

- Inventive concept viewed by skilled addressee
- Skilled addressee identified before assigning knowledge
- Emphasis on the invention as claimed

POZZOLI SPA *VS*. BDMO SA – COURT OF APPEAL

- Case turned on the common general knowledge
- Pozzoli argued it would include a *technical prejudice* against overlapping CDs
- But the 'Brilliant Box' was commonplace

- Patent held to be obvious

Lord Hoffmann:

„...*the patentee is entitled to have the question of obviousness determined by reference to the claim and not to some vague paraphrase based upon the extent of his disclosure in the description*.“

EUROPEAN APPROACH – SIMILARITIES AND DIFFERENCES

- Similarities: – use the same state of the art
  – skilled person/addressee
- Differences:

Feature		
Primary Document	Anything	CPAD
Secondary Document	Only exceptionally, usually CGK	Can be combined with CPAD if it adresses the same problem
Inventive ‘Step’	Are differences obvious over prior art?	Is the solution to the objective technical problem obvious?

Lord Justice Floyd:

I would summarize the position thus far in the following way:

i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;

ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used to formulate the question for the purposes of judging obviousness;

…

v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;

vi) Later evidence may be adduced to support a technical effect made plausible by the specification;

…

EUROPEAN APPROACH – PROS AND CONS

- Cost ✓
- Predictable results ✓
- Approach realistic ?
- Fit for purpose ✓

- Cost !!!
- Predictable results ?
- Approach realistic ✓
- Fit for purpose ✓

Germany

WHERE TO START? – THE ANSWER OF THE FCJ

When assessing the obviousness of a patent-protected subject matter, the **„closest“ prior art** cannot always be taken as the sole starting point.

The selection of a starting point (or even several starting points) rather requires **specific justification** that is as a rule derived from the efforts undertaken by the person skilled in the art to find a better solution – or even just a different solution – for a specific purpose than is provided by the prior art (…).

The European Convention does not provide any foundation for exclusively taking the „closest“ prior art as a basis either.

FCJ Fischbissanzeiger
(„Fishbite Indicator“, GRUR 2009, 1039)

SELECTION OF STARTING POINT

Fischbissanzeiger

- Fishbite indicator enabling an angler to adjust the indicator‘s sensitivity to suit prevailing winds, wind undertow and water movement
- British patent application D14 merely focussed a particular aspect, namely unequal biting behaviour of different fish species.

Is **D14** a realistic starting point?

FCJ: Yes!

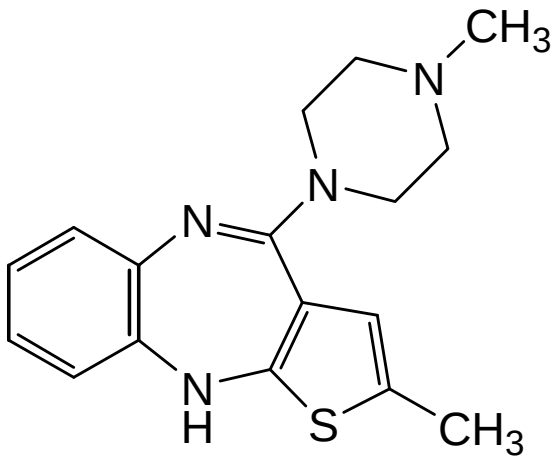
Probably doubtful closest prior art candidate at the **EPO**

THE OLANZAPINE CASE

The Patent-in-Suit

- Claim 1 directed to olanzapine compound or acid addition salt thereof

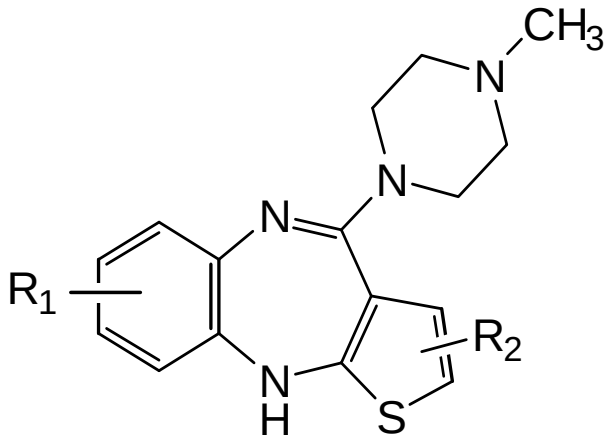
- Olanzapine is a schizophrenia medicament



THE OLANZAPINE CASE

D1 – Chakrabarti *et al*.
(J. Med. Chem. **1980**, 23, 878)

- Scientific research paper
- Showing general formula (I)
- Providing animal test data for 59 compounds
- 45 thereof with olanzapine-related structure
- Olanzapine not expressly mentioned



(I)

THE OLANZAPINE CASE

1st Selection Decision:

EP-A-…

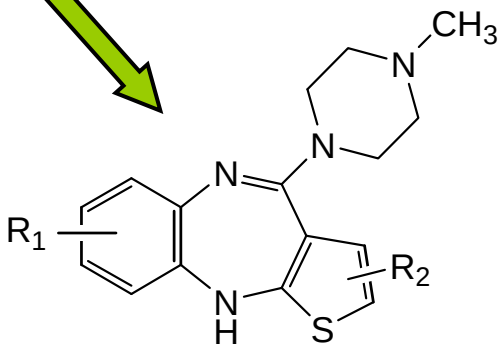
D1 Chakrabarti

GB 1 533 235

US…

...

2nd Selection Decision:



...

(I)

FCJ: Selection of starting point requires justification

TECHNICAL PROBLEM

- What is **objectively** achieved by the invention?
- Definition of technical problem is part of the interpretation of the claim
- Object indicated in patent can give some guidance

FCJ KOSMETISCHES SONNENSCHUTZMITTEL III

As starting point for assessing inventive step one shall not exclusively consider the „problem“ indicated in the patent in dispute; one shall rather consider whether providing a solution to a(nother) problem belonging to the tasks of the skilled person was obvious.

FCJ BETRIEB EINER SICHERHEITSEINRICHTUNG

For the use of an approach to a problem that deviates from the previous approaches to be seen as not only possible, but as **obvious** to the expert, there must as a rule be – except in those cases in which the expert sees immediately what is to be done – additional i**mpulses, stimuli, suggestions or other motives** going beyond the discernibility of the technical problem to prompt the expert to solve the technical problem by inventive means.

FCJ FETTSÄUREZUSAMMENSETZUNG (15.04.2010)

Fatty acid composition comprising omega-3 fatty acids including EPA, DHA and other omega-3 C20, C21 und C22 fatty acids,

- wherein the fatty acid composition contains at least 80 wt.% of the omega-3 acids,
- wherein EPA and DHA are present in relative amounts of more than 1:1 to 2:1 and constitutes at least 75 wt.% of the total fatty acid content, and
- wherein the other omega-3 fatty acids constitute

  3 – 9,9 wt.% of the total fatty acid content.

FCJ FETTSÄUREZUSAMMENSETZUNG

- Known: Maxepa®
- Lower concentration of EPA and DHA in Maxepa®
- Omacor® is more effective using the same amount of active ingredient. However, this data was not in the patent.

FCJ FETTSÄUREZUSAMMENSETZUNG

It was known at the priority date that fatty acid compositions containing EPA and DHA have advantageous properties on the risk factors specified in the patent.

In light of this, it is was obvious for the skilled person to first consider known compositions when searching for improved formulations. As confirmed by the court expert, it belonged to the obvious possibilities of optimization to find the active ingredients in known formulations and to concentrate them. For ***experiments*** *in this direction an active ingredient composition such as Maxepa…*

FCJ FETTSÄUREZUSAMMENSETZUNG

At the priority date, there existed no problems which would have made it impossible for the skilled person to obtain the claimed concentrations, or which at least would have prevented him to perform ***experiments*** *in this direction.*

Against this background (…) the fact that the administration of a combination of EPA and DHA in higher concentraton surprisingly shows a higher efficacy (…) cannot justify an inventive step. According to the jurisprudence of the FCJ, an additional, albeit unexpected and surprising effect cannot jusfity the inventive step of a combination of known compounds, if the provision of such a combination is obvious to the skilled person in light of the prior art and if means for obtaining the combination were available to him (Kosmetisches Sonnenschutzmittel I; Escitalopram).

FCJ FETTSÄUREZUSAMMENSETZUNG

Conclusion:

- The Court defined the problem of the patent to be the provision of a composition showing advantageous effects with regard to the risk factors for cardiovascular diseases.
- In essence, the Court concluded that it was obvious to concentrate DHA and EPA in known compositions such as Maxepa® because there existed a motive to do so.
- The higher efficacy did not justify an inventive step, even if unexpected.

EUROPEAN APPROACH – SIMILARITIES AND DIFFERENCES

- Similarities: – use the same state of the art
  – skilled person/addressee
- Differences:

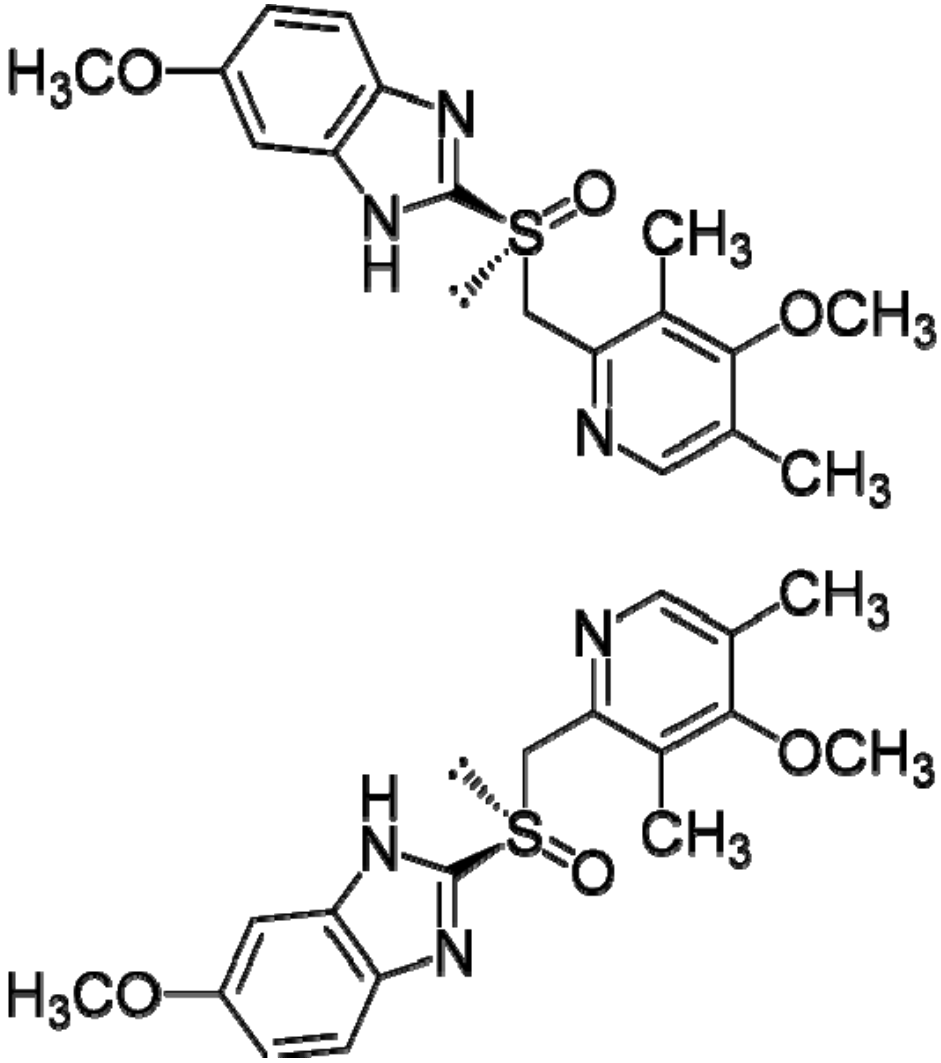
Feature		
Primary Document	Starting point not (necessarily) CPAD, but needs to be justified	CPAD
Secondary Document	Can be combined with starting point if it helps to solve the problem	Can be combined with CPAD if it helps to solve the problem
Inventive ‘Step’	Was it obvious to solve (one of) the technical problems as claimed?	Is the solution to the objective technical problem obvious?

AND WHAT ABOUT SPAIN?

- The jurisprudence of the Spanish courts follow EPO's problem-solution approach incl. determination of the prior art and could/would approach
- A recent example is *Derprosa Film vs. Brilloworld*, Juzgado Mercantil 4 Barcelona, April 29, 2013

Obvious to try

with a reasonable expectation of success



Regulatory authorities generally encourage the investigation of single enantiomers of racemic drugs.

So it is obvious to try to resolve the racemate. Does this render one enantiomer obvious?

In view of the wording of the statute, if the state of the art makes something obvious to try, why should that something need to be associated with a reasonable expectation of success in order for it to negate the inventive step of a patent?

A judicial answer to this conundrum was provided by Lord Justice Kitchin in paragraph 90 of the MedImmune Ltd v. Novartis judgement :

One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious …

… On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.

The concept of obvious to try with a reasonable expectation of success might be considered to constitute a weakening of the inventive step requirement in research-dependent, empirical technical fields.

An expectation of improvement or advantage flowing from the prior art was evolved from T 2/83 in T 149/93 (Retinoids/Kligman) as being an indicator of obviousness:

In accordance with the case law of the Boards of Appeal, a course of action can be considered obvious within the meaning of Article 56 EPC, if the skilled person would have carried it out in expectation of some improvement or advantage (see e.g. T 2/83, OJ EPO 1984, 265, Reasons; point 7). In other words, obviousness is not only at hand when the results are clearly predictable but also when there is a reasonable expectation of success.

What is success?

- A successful experiment?
- Obtaining an unexpected effect?

Can the obvious experiment lead to a patentable invention?
Can a predictable result lead to a patentable invention?

	Predictable result	**Unpredictable result**
Experiment suggested	No	?
Experiment not suggested	?	Yes

Paragraph 28.5 of Decision T 694/92 (Modifying plant cells/Mycogen)

The relevant question in respect of inventive step is whether the skilled person, starting from the oral disclosure of Dr. Kemp … would have carried out the experiment referred to in it with a reasonable expectation of success. In this respect, the statement in Decision T 296/93 (above), that "a reasonable expectation of success" should not be confused with the understandable "hope to succeed" is of relevance. In fact, while it can be said that, in the light of [Kemp], the experiment in question was "obvious to try" for the skilled person, it is not necessarily true that this person would have had any reasonable expectation of success when embarking on it … The question to be decided is whether the average skilled person was in a position to reasonably predict its successful conclusion, on the basis of the existing knowledge, before starting the experiment.

After further refinement, this branch of case law was summarised in Section 7 of T 333/97 (Somatic changes/Monsanto) as follows:

According to established case lase, in cases where the prior art provides suggestions or incentives to do something and thus it may seem obvious for the skilled person to follow the indicated path, the question may arise whether the said skilled person, based on a scientific evaluation of the facts at hand, would thereby have had a "reasonable expectation of success". Generally speaking, the more unexplored a technical field of research is, the more difficult is the making of predictions about the successful conclusion of a given endeavour and, consequently, the lower the expectation of success. However, in order to be considered, any allegation of factors putting in jeopardy the reasonable expectation of success must be based upon technical facts.

Section 31 of T 1241/03 (Human growth hormone/Genentech)

In spite of the understandable uncertainties which always characterise experiments using biologic compounds like proteins, the skilled person had no reason to adopt a sceptical attitude. He/she would have had either some expectations of success or, at worst, no particular expectations of any sort, but only a "try and see" attitude, which (as pointed out in Decision T 333/97) does not equate with the absence of a reasonable expectation of success.

Envisageable products

A product which could be envisaged as such with all characteristics determining its identity including its properties in use, i.e. an otherwise obvious entity, might nevertheless become non-obvious and claimable as such, if there was no known way or applicable (analogous) method in the art for making it and the claimed methods for its preparation were therefore the first to achieve this and do so in an inventive manner (T494/90; T268/98; T441/02)

Routine experiments

Enhanced effects cannot support an inventive step if they emerged from obvious tests.

Example: T296/87

...it was generally known to specialists that, in physiologically active substances with an asymmetrical carbon atom enabling them to occur in the form of a racemate or one of two enantiomers, one of the latter frequently has a quantitatively greater effect than the other or than the racemate. If – as here – the aim is therefore to develop agents with increased physiological activity from a physiologically active racemate the obvious first step is to produce the two enantiomers in isolation and test whether one or the other is more active than the racemate. Such tests are routine. Under established Board case law, an enhanced effect cannot be adduced as evidence of inventive step if it emerges from obvious tests.

T 1677/11 ((-)-Omeprazole Na/AstraZeneca) decision dated 27 November 2012 on a patent having a priority date of 28 May 1993.

Prior Art: Racemic Omeprazole and various of its salts (including the sodium salt) known to treat reflux esophagitis. **D1** taught a method for resolving Omeprazole to an optical purity of 92%. Regulatory authorities were acknowledged generally to encourage the investigation of single enantiomers of racemic drugs at the patent's priority date.

Claim 1: Na(-)-Omeprazole with an optical purity of at least 99.8%.

Claim 1 held by the EPO Appeal Board to be patentable based on the enantiomer having a proven improved therapeutic profile compared to the racemate (cf. T 296/87).

D1 held not to be a "*realistic, feasible or legitimate starting point for the assessment of inventive step in view of the problem posed in the patent in suit*".

"The skilled person would have had no expectation that an improvement in therapeutic profile would result from the use of the resolved enantiomers, and would therefore have no reason to explore this avenue" essentially because the metabolic pathway of Omeprazole had been elucidated and self-evidently was not dependent on the chirality of the drug.

Current approach of the UK Courts with reference to MedImmune v. Novartis (10 October 2012)

http://www.bailii.org/ew/cases/EWCA/Civ/2012/1234.html

and Novartis v. Generics (12 December 2012)

http://www.bailii.org/ew/cases/EWCA/Civ/2012/1623.html

MedImmune v. Novartis

EP(UK) 2 055 777 (MedImmune) whose claims were directed to an antibody phage display method was held to be obvious by J Arnold in the UK Patents Court.

MedImmune appealed to the Court of Appeal who, unusually, decided to hear full argument on the issue of obviousness. Whilst the leading judgement rejecting MedImmune's appeal was delivered by LJ Kitchin, the concurring judgement of LJ Lewison provides an authoritative analysis from a British perspective of the "obvious to try with a reasonable expectation of success" test.

In paragraph 178:

So at bottom the question is simply whether the invention is obvious. Any paraphrase or other test is only an aid to answering the statutory question.

In paragraph 181:

It cannot be said too often that the statutory question is: was the invention obvious at the priority date? It is not: was it obvious to try? In my judgement too much elaboration of the statutory question has been attached to it. The questions of the degree of expectation of success and the length of time thought to be needed to undertake a trial have taken on lives of their own. I think that this happened in our case. Insistence on the statutory question is not a novel thought. It is also an obvious one.

And continuing

The question of obviousness must be considered on the facts of each case. The Court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.

In Kitchin's judgement a similar sentiment is expressed in paragraph 93:

Ultimately the Court has to evaluate all the relevant circumstances in order to answer a single and relatively simple question of fact: was it obvious to the skilled but unimaginative addressee to make a product or carry out a process falling within the claim.

Each case depends upon the invention and the surrounding facts. No formula can be substituted for the words of the statute. In every case the Court has to weigh up the evidence and decide whether the invention was obvious.

Novartis v. Generics

GB 2 203 040 (Novartis) with claims directed to Rivastigmine, the (-)enantiomer of a previously disclosed racemic mixture which had been proposed to treat Alzheimer's disease, had been held to be obvious by J Floyd in the Patents Court. Novartis appealed this decision to the Court of Appeal where LJ Kitchin again delivered the leading judgement a little more than 2 months after the above MedImmune decision.

In dismissing the appeal, LJ Kitchin held in paragraph 55:

In deciding whether the invention was obvious to the skilled but unimaginative addressee at the priority date the Court will have regard to all the circumstances of the case including, where appropriate, whether it was obvious to try a particular route with a reasonable or fair expectation of success. What is a reasonable or fair expectation of success will again depend upon all the circumstances and will vary from case to case. Sometimes, … it may be appropriate to consider whether it is more or less self-evident that what is being tested ought to work.

So … simply including something in a research project in the hope that something might turn up is unlikely to be enough. But I reject the submission that the Court can only make a finding of obviousness where it is manifest that a test ought to work. That would be to impose a straightjacket upon the assessment of obviousness which is not warranted by the statutory test and would, for example, preclude a finding of obviousness in a case where the results of an entirely routine test are unpredictable.

SUMMARY OF THE UK POSITION

- Obvious to try with a reasonable expectation of success acknowledged to be an approach “which it may be appropriate to take into account”.
- But as just one factor amongst several others including motivation, the number and extent of research avenues and the effort required.
- The two overriding factors are the facts of the case and the statutory question: was the invention obvious at the priority date?
- In principle, this position is the same as that of the EPO but in practice the UK Courts may be more austere.

FCJ ESCITALOPRAM (10.09.2009)

If individual enantiomers had proven to be advantageous in other active ingredients and it had not been clarified in detail to what this phenomenon was due, ***it made sense to carry out such experiments*** *also with citalopram that had hitherto only been available as a racemate and had proven to be effective as an antidepressant.*

…the relations causing the different modes of action of individual enantiomers had not been clarified to such an extent that another result could be considered precluded or even not obvious. The existing deficits in knowledge rather ***argued in favour of examining the effectiveness of the enantiomers by way of experiments*** *instead of making numerous theoretical observations.*

FCJ ESCITALOPRAM

*…the teaching of patent claim 1 is ba**sed on inventive merit not already for the reason that escitalopram**, according to Defendant's assertion, **leads to unexpected therapeutic advantages** (improved healing prospects, reduced healing time and a more rapid onset of effect). According to the case law of the Federal Court of Justice, an additional, albeit unexpected and surprising effect cannot substantiate the inventive merit of a combination of known substances if the provision of this combination was rendered obvious to the person skilled in the art by the prior art and there was actually a way for him to obtain the combination.*

FCJ ESCITALOPRAM

*On the other hand, the person skilled in the art had no **motive (Anlass)** to pursue his efforts to obtain citalopram enantiomers at any cost. If the person skilled in the art had not been able to obtain the enantiomers **with a reasonable amount of effort**, he would have sensibly given up this approach **in view of the uncertain expectation of success** and would have looked for other possibilities that were simpler to realise.*

German courts look at the **motive** (Anlass)

If more than reasonable efforts are required, there is no **expectation of success**.

- But does a motive require an expectation of success?
- What is the degree of expectation?
  (Reasonable? Certainty?)
- What is success?
  (Only the solution to the objective technical problem?)

FCJ DIHYDRODIPICOLINATE SYNTHASE (08.01.2013)

Claim (simplified):

- A DNA coding for a dihydropicolinate synthase (DPPS) originating from *Escherichia* having a mutation selected from the group consisting of mutation A, mutation B, and mutation C.

Effect:

- No feed-back inhibition by lysin.

Known:

- Genetically modified strains of E.coli containing DPPS from a Corynebacterium (NK11). NK11 concludes that DPPS catalyses the rate-limiting step of the biosynthesis of lysin.

FCJ DIHYDRODIPICOLINATE SYNTHASE

As already stated by the Panel in connection with a different patent also relating to a method for preparing lysine, ***a person skilled in the art was merely motivated to look at those factors which were known or sufficiently likely to have a limiting effect,*** *i.e. are not available to a sufficient degree in the known processes (Federal Court of Justice, judgement of 7 February 2012 "Transhydrogenase" - X ZR 115/09, as published in GRUR 2012, 479)….*

If one step of the synthesis pathway is identified as limiting and a person skilled in the art has several promising pathways at his disposal to overcome this effect, there may be a motive in principle to consider all of these pathways as long as their total number is manageable.

FCJ DIHYDRODIPICOLINATE SYNTHASE

*However, certain **clues** that the elimination of feedback inhibition of lysine may be considered as an alternative were found in citation NK11 (Oh et al.)…*

*This provided certain **clues** that it might be worthwhile to examine the influence of this inhibition in greater detail. This is true not only for the dapA gene of Corynebacterium glutamicum. In view of the temperature sensitivity of this foreign gene described to be known also in the specification of the Patent in Suit, there was a certain motivation to carry out corresponding tests also with the dapA gene of Escherichia coli the basic suitability of which was already documented by NK7…*

*An additional **incentive** may have been provided by the disadvantages of foreign genes vis-à-vis homologous genes shown by the Private Expert W.*

FCJ DIHYDRODIPICOLINATE SYNTHASE

Despite these indications, however, ***there were not enough prospects to be able to modify the dapA gene*** *of Escherichia coli with conventional tools in such a manner that the expressed DDPS becomes insensitive against feedback inhibition by lysine.*

It is true (…) that the pathway of selection by means of AEC disclosed in the specification of the Patent in Suit corresponds to another approach successfully used for other micro-organisms for quite some time (…). ..however, ***there were clear indications from NK7 that it was not possible to isolate desensitised mutants*** *with a view to the dapA gene at the time (1982) and that especially selection by means of AEC is not promising in this respect.*

FCJ DIHYDRODIPICOLINATE SYNTHASE

Against this background, a person skilled in the art had no reason to look at this approach again, especially since two feasible routes for improving the synthesis step influenced by DDPS had been shown in NK7 and NK11 and ***there was therefore not much motivation to look for further routes offering little prospects of success on the basis of what was known on the priority date****.*

FCJ DIHYDRODIPICOLINATE SYNTHASE

Conclusion:

- The Court thus concluded that there existed *clues* and *indications* to perform experiments to mutate DPPS in *E.coli*.
- However, there were no *prospects* (expectation of success) that these experiments would render DDPS insensitive against feedback inhibition by lysine because a prior art reference was discouraging to do so.
- Inventive step was thus acknowledged.

SUMMARY OF THE DE POSITION

- German court look for motives to modify the prior art, which appears similar to the EPO's could/would approach.
- German courts assess whether there existed a reasonable expectation/prospects of success to solve the technical problem.
- There is no prospect of success if the experiments require an unreasonable amount of effort or a (single) prior art reference was discouraging.
- However, German courts may deny inventive step even if there existed no reasonable expectation to achieve all advantages of the claimed invention.
- The German approach is thus similar to the UK approach.

CASE STUDY: CALCIPOTRIOL MONOHYDRATE

- The Parties
- The Issue in Dispute
- Factual Background
- The National Decisions
- Summary and Conclusions

FACTS

- Leo Pharmaceuticals is owner of EP Patent ‘154 directed to Calcipotriol monohydrate
- Calcipotriol as such was a known Vitamin D3 derivative useful in the treatment of certain skin diseases including psoriasis
- Novelty and inventive step of EP ‘154 were argued to be in the monohydrate of Calcipotriol
- Leo also owned two prior art patents directed to Calcipotriol per se (D5) and new formulations/uses including a suspension cream formulation of Calcipotriol (D4). They have meanwhile expired
- Leo marketed a Calcipotriol suspension cream and an ointment

- Leo's earlier patents did not specify in which form the calcipotriol was present, but data in D5 suggests it was in the anhydrous form
- After expiry of these earlier patents Sandoz (Defendant and Nullity Plaintiff) wanted to market its own ointment and cream products containing (anhydrous) Calcipotriol
- Sandoz bought solid anhydrous Calcipotriol from a supplier and put it into its own ointment and cream formulations
- Leo tested these formulations and found presence of small amount of monohydrate crystals
- Leo sued Sandoz for patent infringement in the UK, NL and Germany

- Sandoz argued that (a) it did not use Calcipotriol monohydrate and (b) that it just reproduced the teaching of the prior art (D4), since its cream formulation was extremely similar to the one of D4

- Infringement and nullity lawsuits ensued in UK, NL, DE, IT, SE

- Sandoz counterclaimed that EP ‘154 is invalid for lack of novelty over D4

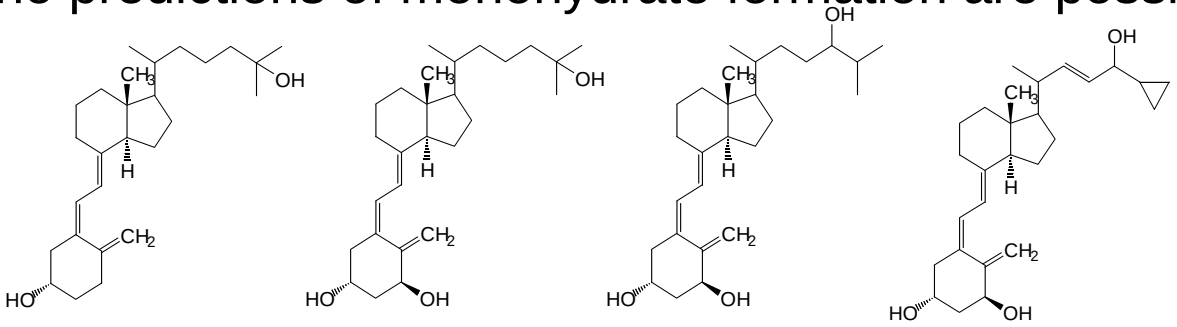
- Sandoz’ novelty attack was based on inherent formation of Calcipotriol monohydrate when reproducing the teaching of D4. Evidence was provided by various experimental reports, putting anhydrous Calcipotriol of various manufacturers into the cream formulation of D4

- Leo argued that this Calcipotriol used by Sandoz was not the same Calcipotriol as the one available at the priority date (impurity profile, method of preparation etc.)
- Leo showed that the Calcipotriol starting material used in some of the experiments contained monohydrate from the outset
- Sandoz counter-argued and submitted experiments showing that whichever anhydrous Calcipotriol is used, the result is always monohydrate when you contact it with water
- On novelty, most courts found in favour of Leo and held that Sandoz had not met its burden of proof

- With regard to inventive step, Sandoz argued that EP ‘154 is obvious over D4 or D5 in combination with any of D8-D10, each disclosing stable monohydrates of other vitamin D3 derivatives.

- EP ‘154 disclosed that the monohydrate was more stable than the anhydrate. Sandoz argued that a skilled person wanting to produce a more stable form of Calcipotriol would have tried to form a stable monohydrate in analogy with other vitamin D3 derivatives (D8-D10) where stable monohydrates are also formed.

- Leo argued that (a) anhydrous Calcipotriol had no real stability problem and that (b) no predictions of monohydrate formation are possible.



25-Hydroxy-Cholecalciferol D8 | 1α,25-Dihydroxy-Cholecalciferol D9 | 1α,24-Dihydroxy-Cholecalciferol D10 | Calcipotriol Ni 4/5 and EP’154

The Results (so far)

PRELIMINARY INJUNCTION PROCEEDINGS

- **England**
  - Preliminary Injunction granted by first instance
  - Leave for Appeal granted by Court of Appeal with promising brief reasoning
  - Appeal rejected and injunction maintained
  - Main reasons: Status quo before infringement should be preserved. Patentee had to give cross-undertaking for damages caused by the injunction
- **Italy**
  - Preliminary Injunction denied by first instance judge due to doubts to validity
  - Preliminary Injunction granted on a appeal by full panel court
  - Injunction revoked as a result of main proceedings

MAIN PROCEEDINGS

- **England**
  - Infringement and Validity heard together and affirmed by Floyd J
  - Appeal dismissed by Jacob LJ
- **Italy**
  - Infringement and validity denied by Court of Turine
  - Appeal dismissed. Further Cassation Appeal pending
- **Netherlands**
  - Patent held valid and infringed by first instance court
  - Appeal successful: Patent revoked by Court of Appeal
- **Germany**
  - Federal Patent Court revoked patent for lack of inventive step
  - Federal Court of Justice agreed and rejected the appeal
- **Sweden**
  - Stockholm Tingsrätt held patent valid and infringed. No appeal

Patents Court (UK High Court) / Court of Appeal

- EP‘154 Patent held valid and infringed by Floyd J.
- Sandoz‘ appeal dismissed by Jacob LJ.
- Floyd J. affirmed both novelty and inventive step essentially for the following reasons:
  - Lack of novelty by inherent formation of monohydrate not sufficiently proven.
  - Sandoz should have reproduced D5 process from the scratch and used this calcipotriol in the formulation experiments.
  - Inventive Step: Skilled person would have looked into whether calcipotriol would form a monohydrate, but it was not proven that he would have found it.

- Both pharmacological and regulatory reasons motivated skilled person to look into monohydrate formation

- However, Floyd J. had doubts that skilled person would have actually found monohydrate:

  - Patents disclosing Vitamin D3 analogues were not used as main references in the UK proceedings
  - Finding a monohydrate was a research programme that would be carried out in the hope of finding out something valuable, but with no particular expectation of success
  - Judge found that experts were not asked which tests they would have performed and what would be the outcome
  - Judge did not believe that acetone/water and ethyl acetate/water mixtures would have been „part of the limited check for hydrates“

Federal Patent Court

Inventive Step denied

- Problem: find a form of calcipotriol that is more stable than the anhydrate, e.g. during storage
- Skilled person HAD to look around in the class of vitamin D3 derivatives whether there are any hints to solve this problem
- Structurally related vitamin D3 derivatives of K8-K10 offered guidance to the skilled person of what he could and should try
- Fact that only 3 of 600 derivatives in Chemical Abstract databank were registered as monohydrates is irrelevant, since most vitamin D3 derivatives were never investigated for hydrate formation
- Only the pharmacologically relevant ones described in a paper by Kragballe K24 were tested – and found to from a monohydrate
- Skilled person could not predict whether monohydrate would form, but he was at least motivated to try it out, and would have easily found it using analogous procedures

Bundesgerichtshof (Karlsruhe)
Federal Court of Justice

Appeal dismissed – Patent invalidated

- BGH appointed a Court Expert who confirmed that a skilled person would have to investigate monohydrate formation when exposing calcipotriol to an aqueous medium in a cream
- First instance decision was fully confirmed; Leo's attacks were dismissed
- Decisions of UK, NL and SE courts were taken note of and cited in the judgment
- Problem: (i) find a form of calcipotriol that is more stable than the anhydrate, (ii) improve wettability of calcipotriol crystals to allow easier processing of calcipotriol (wet-ball milling)
- Mentioning of stability in the patent is part of the problem, not of the solution; since it is not prima facie apparent how the stability problem can be solved

Appeal dismissed – Patent invalidated

- Skilled person might have tried to improve wettability problems by adding a surfactant, but he would have soon realized that this would increase the foaming problem.
- He would therefore have tried to find another form of calcipotriol that is better wettable.
- Skilled person was also motivated to investigate hydrate formation because hydrates are less soluble in water than anhydrous forms and unwanted precipitation of calcipotriol would have to be avoided or controlled
- Investigation of hydrate formation is a “central problem” in the formulation of aqueous cream/ointment systems
- K8-K10 disclosed simple processes for preparing hydrates
- Compounds were considered as structurally close
- Hydrate formation is simple

Appeal dismissed – Patent invalidated

- Since skilled person was motivated to investigate hydrate formation and had a precedent of how to do it, it does not matter that there is no explicit hint in the prior art that wettability of calcipotriol could be improved by monohydrate form.
- Argument of Stockholm court that skilled person would not have looked for a further crystal form was considered, but dismissed
- Court noted that 1/3 of all pharmaceutical substances form hydrates and that investigation of hydrates is critical to find the pseudopolymorphic form that is most stable
- Predictability is no requirement for obviousness. If skilled person had a reasonable expectation of success, this is sufficient.
- Such expectation existed here: the Vitamin D3 derivatives of K8-K10 were structurally similar and the hydrate formation experiment was simple, promising and not burdensome.


5 : 4

CONCLUSIONS

- Inventive Step is difficult
- Problem-Solution-Approach widely applied, but opinions can differ:
  - What is the problem?
  - Was skilled person motivated or not motivated?
  - How much is required for a „reasonable“ expectation of success?
- Even seemingly simple technical judgments can be difficult:
  - Same chemical compounds considered as structurally related by one court and unrelated by another.
  - One court even thought it is difficult to find a hydrate when looking for it, whereas others saw no such problem.

CONCLUSIONS

Jacob J in Leo vs. Sandoz

Different results in different countries based on different cases is, of course, explicable. It is an unfortunate state of affairs, curable only b a single European Patent Court.

QUESTIONS?

JRENKEN@HOFFMANNEITLE.COM