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# Headings

- “Classical” absolute product protection - general discussion
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- General learnings/recommendations
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- Discussion of BRCA cases

# “Classical” absolute product protection - general discussion (1)

- Small chemical synthesized molecules – e.g. small molecule drugs
- A first patent describes the synthesis of novel small molecules and demonstrates they can be used for treatment of cancer.
- First patent claim 1 is a product claim like “A chemical compound having the structure (e.g. a so-called Markush)”
- Second patent discovers that the chemical compounds can be used for treatment of allergy – it claims use of the compounds for treatment of allergy.
- Due to absolute protection of first patent => owner of second patent shall pay a license to owner of first patent.

# “Classical” absolute product protection - general discussion (2)

- Overall speaking – one may see the basic legal “philosophy” behind allowing absolute protection for chemical synthesized molecules (e.g. small molecule drugs) as that in first patent was for the first time “provided to the world” these laboratory made “not natural” small molecules and demonstrated that these small molecules could be used for e.g. treatment of cancer.
- This novel knowledge then “opens the door” for e.g. other companies to work with these small molecules and maybe identify that they also could be used for treatment of allergy and thereby file a second patent of this specific use.

# “Classical” absolute product protection - general discussion (3)

- One may say that for DNA sequences the basic situation could be seen as different.
- Many times one knows that the “natural” DNA sequence is there and the work is “just” to clone/isolate this “natural” DNA sequence – i.e. one needs not to synthesize novel “not natural” compounds as such.
- For instance – it may be known that there on e.g. a human chromosome (i.e. in the human genome) is a gene important for development of breast cancer and the work is “just” to clone/isolate this “natural” human DNA sequence and then e.g. to identify specific “good/bad” allelic variants (mutations) – see e.g. the BRCA cases discussed below.
- Or for instance – it is known that people e.g. needs a EPO hormone to win Tour de France.. ☺ – i.e. the work is “just” to clone/isolate the “natural” human EPO DNA sequence.

# “Classical” absolute product protection - general discussion (4)

- In view of these “differences” a number of people in the patent “community” have for years argued that DNA sequences are “different” – i.e. for DNA sequences there should not be absolute product protection but only protection for the uses of the DNA sequences as plausible indentified/demonstrated in the patent application as filed.

# European Court of Justice (ECJ) - C-428/08 (1)

- In short – the “story” behind this case was that Monsanto isolated/cloned from a bacteria a gene encoding an enzyme giving resistance to a so-called Roundup herbicide.
- They then made transgenic soy plants, where the gene was inserted to make so-called Roundup Ready soy plants – i.e. Roundup Ready soy plants that can grow in the presence of the herbicide Roundup – other “unwanted” weed/plants on the field would “die”.
- In Argentina there was/is no patent protection – accordingly other companies cultivated such Roundup Ready soy plants - harvested them and made soy meal (all done in Argentina).

# European Court of Justice (ECJ) - C-428/08 (2)

- Cefetra and others then imported (sold) the soy meal (made in Argentina) into different EU countries.
- There had been some discussions about this – but in the present context it is assumed that the soy meal comprises “impurities” of the DNA sequence giving the Roundup resistance.
- However, it was evident to everybody – that the DNA sequences present in the meal are not doing anything of herein relevance – i.e. the DNA sequences as present in the meal as such are not giving Roundup resistance to the soy meal as such.

# European Court of Justice (ECJ) - C-428/08 (3)

- The herein relevant Monsanto patent was EP546090B1 – where relevant claim 6 in question essentially reads: “An isolated DNA sequence encoding [the Roundup resistance] enzyme.”
- If the scope of this DNA claim would be “classical” absolute protection – the soy meal could maybe infringe this DNA product claim – recall the DNA sequence as such is present as an “impurity” in the soy meal.
- A Dutch court then referred this issue to ECJ – essentially asking if there, in view of the EU Biotech Directive 98/44/EC, is “classical” absolute protection for such a DNA sequence claim.

# European Court of Justice (ECJ) - C-428/08 (4)

- Today we still do not have an EU patent court – personally I hope we will get it in my life-time... ☺
- Since scope of protection of EP patent claims then still generally is a matter of national/local EU courts – the ECJ has hitherto rarely (if ever) had a “chance” to give an opinion about the scope of protection of EP patent claims as such.
- However, since this case related to scope of protection in view of the EU Biotech Directive – the ECJ could give an opinion.

# European Court of Justice (ECJ) - C-428/08 (5)

- The so-called ECJ Opinion of the Advocate General was published 9 March 2010 – this preliminary opinion essentially said that there in EU is no “classical” absolute protection for a DNA sequence product claim.
- Monsanto and the relevant parties thereafter settles the case.
- Even though, the ECJ gave its final full decision the 6 of July 2010 – by many in the patent “community” this have been interpreted as that the ECJ wanted to give a “message”.
- In the EPO Official Journal (OJ, 8-9/2010, pages 428-447) was the ECJ final full decision published.

# European Court of Justice (ECJ) - C-428/08 (6)

- The ECJ final decision of 6 of July 2010 reads (emphasis added):
- Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.
- Accordingly, the soy meal made in Argentina could still be sold in EU.

# European Court of Justice (ECJ) - C-428/08 (7)

- Article 9 of the Directive reads (emphasis added):
- “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material ... in which the product is incorporated and in which the genetic information is contained and performs its function.”
- The ECJ decision reads (emphasis added):
- “45 Since the Directive thus makes the patentability of a DNA sequence subject to indication of the function it performs, it must be regarded as not according any protection to a patented DNA sequence which is not able to perform the specific function for which it was patented.”
- The phrase “the specific function for which it was patented” is in my opinion (and many others) to be interpreted as the specific uses/functions mentioned in the patent application as filed – in view of e.g. A123(2), EPC one can not get a granted EP claim to a function/use not mentioned in the application as filed.

# European Court of Justice (ECJ) - C-428/08 (8)

- Accordingly, if first patent description only mentions/claims use of the DNA sequence for treatment of e.g. cancer – a later filed second patent of e.g. a competitor company claiming use of the DNA sequence for treatment of e.g. allergy will go “free” – i.e. the competitor company of the second patent will not have to “pay” to the owner of the first patent.
- Here it will be “irrelevant” that first EP patent comprises a product claim to the DNA sequence as such.

# European Court of Justice (ECJ) - C-428/08 (9)

- The ECJ decision further reads (emphasis added):
- “47 An interpretation to the effect that, under the Directive, a patented DNA sequence could enjoy absolute protection as such, irrespective of whether or not the sequence was performing its function, would deprive that provision of its effectiveness. Protection accorded formally to the DNA sequence as such would necessarily in fact extend to the material of which it formed a part, as long as that situation continued.
- Here again made clear – that in EU there is NO absolute protection as such for DNA sequence claims.

# European Court of Justice (ECJ) - C-428/08 (10)

- The ECJ decision reads (emphasis added):
- Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.
- Here essentially said that individual EU countries can not “save” this absolute protection issue in their local national patent law.

# European Court of Justice (ECJ) - C-428/08 (11)

- The ECJ decision reads (emphasis added):
- Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.
- Here essentially said this ECJ decision (i.e. NO absolute protection) is also applicable to EP patents granted before the adoption the EU Biotech Directive – i.e. it applies to all EP patents currently in force and of course also to all future granted EP patents.

# Recommendations in view of the ECJ decision (1)

- I have asked several people with “inside” knowledge – I understand that EPO has not said anything about that they will not continue to grant EP patents with DNA sequence product claim as such.
- Further, when one drafts e.g. a priority founding application – one generally not only “think” about Europe. In other jurisdictions (e.g. JP, CN) one may still get absolute protection for DNA sequence product claims as such. In view of a recent (March 2010) US decision it may in some cases be complicated in USA (for “natural” DNA sequences – see below).
- In short, when drafting the patent application I see no reason not to continue to include DNA sequence product claim as such.

# Recommendations in view of the ECJ decision (2)

- When the “product” on the market may be seen as the DNA sequence as such is it quite evident that the ECJ decision will have an impact on scope of protection in EU.
- Examples of such situations, wherein the “product” on the market is the DNA sequence as such could e.g. be:
  - (a) PCR primers in a method for diagnosing a disease essentially comprising determining if a person has ”good” or ”bad” specific allelic variants (mutations) – see e.g. BRCA cases discussion below;
  - (b): Gene therapy – where a “healthy” gene is inserted into a patient.

# Recommendations in view of the ECJ decision (3)

- In such cases – wherein “product” on the market may be seen as the DNA sequence as such – the scope of EP claims in EU will only cover the uses/functions of the DNA sequence as such as described/claimed in the EP patent. For business I personally find this OK and objectively quite fair.
- E.g. PCR primers used in a diagnostic method to amplify a gene in e.g. human to determine if a person has “good” or “bad” specific allelic variants (mutations) – seems to me in practice only to have this commercial relevant use.
- Similarly – a DNA sequence for gene therapy - seems to me in practice only to have this commercial relevant use.

# Recommendations in view of the ECJ decision (4)

- It is evident that the ECJ does not say one can not get a product claim to the transgenic plant comprising the Roundup resistance gene (DNA sequence).
- At least when the transgenic plant is cultivated on the field – the gene (DNA sequence) performs its function – i.e. gives resistance to the Roundup herbicide.

# Recommendations in view of the ECJ decision (5)

- In the future – I find it quite evident that people will try to be quite “creative” when “speculating” about possible uses/functions of a DNA sequence as such.
- However, I find it here relevant to be aware of the EPO BA important T1329/04 (Factor-9/JOHN HOPKINS) decision – it essentially says that a “postulated” effect (here the uses/functions of the DNA sequence as such) shall be “plausible” based on the technical content of the EP application AS FILED – if not => EPO will NOT accept later filed data (e.g. later made experimental data).
- For instance – if data in application as filed only relates to use of the DNA sequence for treatment of cancer – I find it difficult to argue that it is also “plausible” that it would work for treatment of e.g. allergy.

# Recommendations in view of the ECJ decision (6)

- Many times the commercial “product” on the market as such is not the DNA sequence as such but the protein (e.g. EPO or an insulin variant/analogy) encoded by the DNA sequence.
- I have discussed this issue with a number of people – in short different people have different opinions about the impact of the ECJ decision in such cases.
- As discussed above – the ECJ decision was essentially based on Article 9 of the Directive that reads (emphasis added):
  - “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material ... in which the product is incorporated and in which the genetic information is contained and performs its function.”
- One may argue that the protein as such is not “genetic information” – i.e. not covered by Art. 9 and therefore not “affected” as such by the ECJ decision.

# Recommendations in view of the ECJ decision (7)

- My personal “feeling” is that the ECJ decision could maybe in the future form basis for a new ECJ decision that maybe also could limit the scope of a product as such claim to an isolated composition comprising a natural (e.g. human) protein encoded by a natural human DNA sequence.
- However, for business the solution of this possible “problem” could, in my opinion, be “solved” by having e.g. a broad claim relating to a method for recombinant production of the protein.
- By properly drafting – the relevant process steps could end with something like “step (x): isolating the protein to get a composition comprising the protein in a pure/isolated form”.
- The “end” product as directly obtained by such a recombinant method claim will then be the commercial product on the market – i.e. the composition (e.g. a pharmaceutically product) comprising the protein in some kind of a pure/isolated form.
- Accordingly, in view of Article 64(2), EPC – one could then argue that one would here have a nice absolute kind of protection for the recombinant produced protein in EU – even though e.g. a competitor actually recombinantly produces the protein in a country out-side EU (e.g. in India).

# Recommendations in view of the ECJ decision (8)

- A big Danish based company (Novo) has today a big commercial success by selling so-called insulin analogs – these may be seen as not natural variants/mutations of human insulin
- The product on the market is then a not natural protein/polypeptide – in my opinion, there clearly should be continued to be absolute product protection for such a not natural protein/polypeptide product – i.e. such a not natural product is not something you “just” have to isolate from nature (e.g. from a human)
- A similar situation may be laboratory made novel antibodies.

# Recommendations in view of the ECJ decision (9)

- The Monsanto EP546090B1 patent does not contain a method claim for making the soya meal as such.
- It comprises claims relating to the “the isolated DNA sequence”; “A method for making the transgenic Roundup resistant soya plants”; “the transgenic plants as such”; “cultivation of the transgenic plants in the presence of the Roundup herbicide”.
- If the Monsanto EP546090B1 would have comprised e.g. a claim to a method for making soya meal comprising (i) cultivation of the transgenic plants; (ii) harvesting them and (iii) isolating the soya meal – then I believe Monsanto could have argued that the product DIRECTLY obtained by such a method would be the soya meal as such – the “Argentina” produced soya meal could maybe have infringed such a claim in EU in view of A64(2), EPC.
- Generally (independently of the ECJ decision) it is always recommendable to think about claims directed to the different possible commercial products – see e.g. UK discussion below.

# Discussion of corresponding Monsanto court cases in Spain and UK (1)

- The *Monsanto v Sesostris* decision of the Audiencia Provincial de Madrid dated 10 of March 2009.
- In short, this Spanish court decision essentially arrived at the same conclusion as the ECJ – or depending on how one looks at it - the ECJ arrived at the same conclusion as the Spanish court.
- As the ECJ - the Spanish court concluded that the soy meal made in Argentina could still be sold in Spain, since the Roundup resistance DNA sequence is not doing its function in the soya meal as such.

# Discussion of corresponding Monsanto court cases in Spain and UK (2)

- The UK *Monsanto v Cargill* decision dated 10 of October 2007 ([2007] EWHC 2257 (Pat))
- In short, the UK court essentially resolved the “problem” by an interpretation of the term “isolated” in the claim “An isolated DNA sequence encoding [the Roundup resistance] enzyme.”
- The UK court essentially interpreted the term “isolated” as “what it conveyed was that the sequence had been separated out as a fragment for further cloning and amplification in a plasmid DNA” (*see e.g. point 74 and 77 of the UK decision*)
- The DNA sequence “impurities” present in the soya meal are not in such a “fragment for further cloning” form – one needs to take the DNA sequence out from the soya meal before it will be in such a form => no infringement for the soya meal as such.

# Discussion of corresponding Monsanto court cases in Spain and UK (3)

- Of herein interest is that the UK decision was not “worried” about the ECJ essential part – i.e. that the DNA sequence does not have any function in the soya meal as such.
- The UK decision reads (emphasis added):
- “89. I should also deal with a *de minimis* point. The DNA present in the meal, such as it is, is entirely irrelevant to the meal as an animal feedstuff, is present in small, variable, quantities and may not be present at all if processing conditions are changed. It is not in any serious sense genetic material. It is just the remains of the material which was in the soybeans from which the meal was extracted. **This, it seems to me, is irrelevant.** It may raise a question on damages, that there is no causative relationship between acts of infringement, as opposed to acts which are not infringing by English law, and the loss suffered by Monsanto, but this was not argued. **There is, generally, no authority in favour of trace quantities of infringing material being held not to infringe, and some authority against it.**
- Accordingly, at least in UK a product comprising small amounts of unwanted “impurities” may infringe a product claim covering these “impurities”
- I understand that in Germany there is a decision saying the contrary – i.e. unwanted “impurities” may not be an infringement – I also understand this issue may not be finally settled in Germany.

# Discussion of corresponding Monsanto court cases in Spain and UK (4)

- Article 64(2) of EPC reads (emphasis added):
- If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.
- The UK court interpreted the term “directly” in relation to a Monsanto claim relating to “A method for making the transgenic Roundup resistant soya plants”
- The UK court essentially confirmed the strict/limited interpretation of the term of the earlier UK important landmark decision *Pioneer v Warner* [1997] RPC 759
- Accordingly, the UK court said that the product directly obtained from this method claim is the transgenic plants – the soya meal does not infringe since the soya meal does “no longer retains its [the plant] essential characteristics”.
- Monsanto could maybe have won on this A64(2) issue – if their EP patent had comprised a claim to a method for making soya meal (see above).

## BRCA cases (1)

- So-called BRCA1 cases: EP699754B2 (T80/05); EP705902B2 (T1213/05); EP705903B2 (T666/05) – all EP patents share same priorities and all was filed 11/8-1995. The EPO Board of Appeal (T-) decisions were published in 2007 or 2008.
- Essentially, the "story" behind all these BRCA cases was that prior art had shown that allelic variants (mutations) in a so-called BRCA1 gene located on chromosome 17q are responsible for development of breast cancer – however, the BRCA1 gene was not cloned and specific "good/bad" allelic variants (mutations) were therefore also not known.
- Proprietor Myriad Genetics cloned the BRCA1 gene and e.g. EP705902B1 comprises broad granted claims covering the cloned/isolated BRCA1 gene as such (product claim) and all allelic variants thereof and EP699754B1 claim 1 relates to a method for diagnosing predisposition of breast cancer essentially comprising determining if a person has "good" or "bad" allelic variants (mutations) as such.

## BRCA cases (2)

- Essentially – for substantial patent law reasons (i.e. not the EU Biotech Directive as such), the EPO Board of Appeal limited all the granted BRCA1 patents to essentially only cover a method for diagnosing predisposition of breast cancer comprising determining if a person has specific (i.e. not all possible) ”bad” allelic variants (mutations) .
- Some of the BA allowed amended claims (e.g. EP705902B2) are product claims relating to specific nucleic acid probes (i.e. not the cloned BRCA1 gene as such) suitable to detect/determine the ”bad” allelic variants (mutations).
- In practice it is difficult to imagine that these specific probes can be used for anything else than determining the corresponding ”bad” allelic variants – however, in case they could – I believe that in view of the herein discussed ECJ decision it is evident that actual scope in EU would not be more than use of these probes to detect/determine the ”bad” allelic variants (mutations).

## BRCA cases (3)

- EP785216B1 is a later filed patent and relates to a so-called BRCA2 gene located on chromosome 13.
- In short, the “story” of this BRCA2 may be seen as similar to the BRCA1 “story”.
- EP785216B1 was granted with broad claims (e.g. covering isolated/cloned BRCA2 gene as such) – the Opposition Division limited the claims for substantial patent law reasons (i.e. not the EU Biotech Directive as such) - to only cover a method for diagnosing predisposition of breast cancer comprising determining if a person has specific (i.e. not all possible) ”bad” BRCA2 allelic variants (mutations)
- The case was not appealed - EP785216B2 was published with the OD allowed claim 1 (only claim allowed).

## BRCA cases (4)

- US District Court of New York decision (09 Civ. 4515) dated March 29, 2010 also relates to these BRCA1 and BRCA2 cases
- The US court revoked the US granted claims covering the cloned/isolated BRCA1 gene as such (product claim).
- The court said on page 135 of the decisions: “Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C §101”.
- Here relevant to note – that this US decision is focused on claims covering “natural” DNA sequences – i.e. not said that one could not get absolute product protection for “not natural” DNA sequences – i.e. encoding a “not natural” mutated variant of e.g. a “natural” human protein such as e.g. an insulin analog.

## BRCA cases (5)

- The US District Court also revoked broadly defined method claims – e.g. method claims that essentially broadly covered a method to identify e.g. “bad” BRCA1 allelic variants (mutations) as such by “simply” comparing BRCA sequences from healthy and sick persons.
- It is here important to note that a number of more limited claims were not attacked as such in this US decision (see e.g. page 80 of the US decision) – e.g. a number of more limited claims with a scope corresponding to the BA allowed claims in Europe were not attacked.
- In my personal opinion are the BA EP allowed claims valid and should, in my opinion, also be considered valid in the US
- This US decision will maybe be appealed (if not already appealed).