

On the job harmonisation of European Patent Law?

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Outline

- Introduction: what is harmonisation on the job?
- young EPLAW harmonisation on the job?
Case study – anondronate
- Real life: harmonisation on the job?
- Conclusions

Introduction: what is harmonisation on the job?

- Brief background:
 - community patent
 - EPLA and Venice Conferences
- European patent litigation – an ongoing story
- Hypothesis I: harmonisation on the job by patent judges
- Hypothesis II: harmonisation on the job by (young) patent practitioners
- What about these hypotheses...?

Young EPLAW v. “Old” EPLAW

- Hypothesis II:

Initiatives such as EPLA, EPLAW, Young EPLAW, but also the internet and IP Blogs have created much more awareness of patent litigation abroad amongst young European patent litigators.

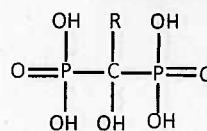
Testing the hypothesis: a case study - *anondronate*

- Case: invention + prior art: new?, inventive?
- The rules of the game:
 - country-by-country
 - spokesperson
 - voting ballots

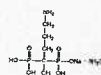
Testing the hypothesis: a case study - *anondronate*

- Background to the invention:

- disease osteoporosis occurs in elderly (women)
- known treatment with bisphosphonates

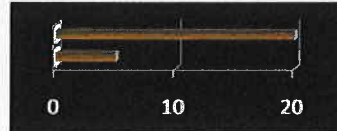


Alendronate: R = C₃H₆NH₂



Testing the hypothesis: a case study - *anondronate*

- The invention: Anondronate ($R=C_4H_8NH_2$)
- Better oral absorption in the body when administered in the form of pellets (20% v. 1-5% prior art)
- Claims (as granted by the EPO):
 1. The substance anondronate.
 2. Pellet containing anondronate.



Testing the hypothesis: a case study - *anondronate*

- Claim:
 1. The substance anondronate.
 2. Pellet containing anondronate.
- Prior art:
 - D1: method for preparation of bisphosphonates, examples for the preparation of pamidronate ($R=C_2H_4NH_2$) and alendronate ($R=C_3H_6NH_2$)
 - D2: alendronate and neridronate ($R=C_5H_{10}NH_2$) are suitable as anti-osteoporosis agents and have an oral absorption of 1-5%

Novel?

Inventive?

Testing the hypothesis: a case study - *anondronate*

- Claims (as granted by the EPO):
 1. The substance anondronate.
 2. Pellet containing anondronate.
- Suppose claim 1 is invalid and claim 2 provides a valid fall-back position...

Are you allowed to amend in the context of litigation?

Testing the hypothesis: a case study - *anondronate*

- The inventors have also surprisingly found that for elderly patients over the age of 70, a very good absorption of all bisphosphonates (10% v. 1-5%) is obtained with a dosage regime of 70 mg / week.



Assume novel and inventive: Is this patentable?

Testing the hypothesis: a review of Pan-European cases: novelty of enantiomers and the requirement of reasonable expectation of success

Vienna Convention on the Law of Treaties (1969)

- Art 31 under 3(b) regarding interpretation:
- A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose
- There shall be taken into account, together with the context:
(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

Pfizer/Ranbaxy (Atorvastatine)

- Bundespatentgericht October '07:
- "Diesen bewertungen [*of the EPO*] , denen sich ein sehr enger – mitunter als "photografisch" bezeichneter – Neuheitsbegriff zugrunde liegt (...) kann sich der Senat unter Berücksichtigung der Rechtsprechung des Bundesgerichtshof zur Neuheit chemischer Verbindungen nicht anschliessen"
- "Der Ansicht der Beklagten, die Patentfähigkeit des Streitpatents dürfe im Interesse der gebotenen Harmonisierung des nationalen und europäischen Patentrechts durch eine möglichst einheitliche Rechtsabwendung nicht abweichend von der Entscheidung der [TBA and Examining Division] bewertet werden, kann sich der Senat nicht anschliessen."

Bundespatentgericht in Atorvastatine ctd.

- "Es kann auch nicht festgestellt werden dass sich hinsichtlich der hier relevanten Frage der Neuheit in der Mehrheit der Vertragsstaaten des Europäischen Patentübereinkommens eine mit den Bewertungsmaßstäben des Europäischen Patentübereinkommens übereinstimmende Rechtsanwendung als Übung herausgebildet hätte, die nach den entsprechend heranzuziehenden Auslegungsgrundsätzen des Wiener Übereinkommens 1969 maßgeblich zugrunde zu legen wäre."

Pfizer/Ranbaxy - Dutch Court of Appeals

- The Dutch Court of Appeals agrees with EPO case law.

“The EPO tends – in order to avoid said negative consequences – to examine whether the claimed species is ‘known as such’ (in individualised form) in the document describing the genus. In this context the observation that in selection inventions in the field under consideration of, put succinctly, racemates versus enantiomers, the EPO generally speaking takes ‘literal’ or ‘photographic’ novelty as a point of departure...”

Lundbeck v. Generics

- UK Court of Appeal:
 - It is settled jurisprudence in the European Patent Office that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers

Lundbeck v. Generics

- Dutch Court of First Instance:

“The court takes the line followed by the European Patent Office and the Dutch patent courts which followed suit, in the assessment of the novelty of an enantiomer vis-à-vis a racemate.”

Lundbeck v Generics

- Bundespatentgericht:

“Eine chemische Verbindung mit einem asymmetrischen Kohlenstoffatom ist in Form eines ihrer Enantiomeren nicht mehr neu, wenn dem Fachmann in einer Vorveröffentlichung ein konkreter Hinweis auf die Enantiomere gegeben wird und er aufgrund dieses Hinweises und sein allgemeinen Fachwissens in der Lage ist, die Verbindung herzustellen.”

Intermezzo: Daiichi (levofloxacin)

- UK Court:
- “Interestingly, the Bundespatentgericht has recognised its approach is out of step with the EPO “
- “The difficulty I have with the German approach is that it appears to conflate the issues of novelty and obviousness “
- “I feel reinforced in this conclusion by the decision of the Court of Appeal in *Generics v Lundbeck*- Although the point was not argued, Lord Hoffmann noted with apparent approval at [9] what he described as the settled jurisprudence of the EPO that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers.”

Intermezzo: Olanzapine

- Bundespatentgericht:

Soweit der noch zum Patentgesetz 1968 ergangenen Entscheidung „Fluoran“, in der der *Senat* sich im Rechtsbeschwerdeverfahren an die Feststellung des *Patentgerichts* gebunden gesehen hat, dem Fachmann seien durch eine allgemeine Formel fast 2000 unter die betreffende Formel fallende Einzelverbindungen als herstellbar offenbart, etwas anderes zu entnehmen sein sollte, **wird daran für das geltende Recht nicht festgehalten.**

Intermezzo: Olanzapine

- Als offenbart kann eine nicht ausdrücklich genannte Einzelverbindung vielmehr nur dann gelten, wenn der Fachmann sie im vorstehend ausgeführten Sinne „mitliest“, etwa weil sie ihm als die übliche Verwirklichungsform der genannten allgemeinen Formel geläufig ist und sich ihm daher sofort als jedenfalls auch gemeint aufdrängt, wenn er die allgemeine Formel liest.

Intermezzo: Olanzapine

- Der *Senat* sieht sich mit dieser allgemeinen Beurteilung des Offenbarungsgehalts chemischer Formeln im Wesentlichen in Einklang mit der - auch vom *High Court für England und Wales* (Floyd J.) in dem das Streitpatent betreffenden Nichtigkeitsverfahren zu Grunde gelegten ([2008] EWHC 2345 [Pat]) - Rechtsprechung der Beschwerdekammern des EPA, nach der nur solche technische Lehren neuheitsschädlich sind, die einen Stoff als zwangsläufiges Ergebnis eines vorbeschriebenen Verfahrens oder in spezifischer, d.h. individualisierter, Form offenbaren

Lundbeck v Generics

- Dutch Court of First Instance:

“Kitchin J. has a different view on this and holds that the average skilled person would not deem the Baldwin Rules applicable to unsaturated systems. For the reasons set out above, on the basis of what the parties have presented to the court in this case – which differs from the English case – this court comes to a different conclusion, so that it '***respectfully disagrees***' with the English judgment on this point. This aspect was subsequently not dealt with anymore by the Court of Appeal and the House of Lords.”

Inventive Step “obvious to try”?

- UK approach: obvious to try
- Continental (EPO) approach: obvious to try **with a reasonable expectation of succes**

Conor v Angiotech

- UK House of Lords:
 - There is still no European Patent Court.
 - But when the question is one of principle, it is desirable that so far as possible there should be uniformity in the way the national courts and the EPO interpret the European Patent Convention (“EPC”). In this case, as Pumfrey J made clear in his judgment, there is a question of principle at stake. It is about how you identify the concept embodied in the invention which may constitute the “inventive step” for the purposes of article 56 of the EPC and section 1(1)(b) of the Patents Act 1977

Conor v Angiotech

UK House of Lords:

- “There is no requirement in the EPC or the statute that the specification must demonstrate by experiment that the invention will work or explain why it will work. As the Dutch court said (at paragraph 4.17): “...it is not required in the view of the court that experimental data concerning such use of taxol stents in humans and the actual prevention of restenosis be included in the patent to further substantiate [the claim].”

Conor v Angiotech

UK House of Lords:

- He (Jacob J) correctly summarised the authorities, starting with the judgment of Diplock LJ in *Johns-Manville Corporation's Patent* [1967] RPC 479, by saying that the notion of something being obvious to try was useful only in a case in which there was a fair expectation of success.

Conor/Angiotech

UK House of Lords:

- "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.**"

Harmonisation on the Job?

- European Judges refer to each other's decision and "explain" why they "respectfully disagree"
- Remaining differences caused by different evidence in the proceedings
- Today's results ???