de Rechtspraak

Pregabalin UCL

Plausibility, 2nd medical use and late amendments -

The Dutch perspective after UK SC 14 Nov 2018 pregabalin case

Judge Edger F. Brinkman, senior judge, Court of The Hague

de Rechtspraak

Plausibility

- Not a separate concept in Dutch law
- First real case probably Angiotech-cases
- We mostly see it as an objection in the assessment of:
- The patent in the context of inventive step or sufficiency of disclosure
- The priority document
- The prior art

Plausibility ii

- CoA The Hague, Leo/Sandoz
- Pharmaceutical composition comprising calcipotriol andbetamethasone for treating psoriasis
- The patentee argues that the combination has a synergistic effect

de Rechtspraak

Plausibility iii – Leo/ Sandoz

- The patent monopoly should correspond to the technical contribution to the art
- The contribution to the state of the art must be assessed from the perspective of the average skilled person at the application date
- Effects that the average skilled person would have considered not plausible at the application date must be disregarded in the context of the assessment of inventive step

de Rechtspraak

Plausibility iv – Leo/ Sandoz

- Burden of proof lies with the party claiming that the effect is not plausible
- Definitive proof not required
- Statements that the average skilled person would consider speculative are not enough
- No general standard of plausibility
- Depends on the content of the patent(application) and the common general knowledge

Plausibility v – Leo/ Sandoz

- Explicit statement and substantiation of the effect in the patent is not required if the effect was evident to the skilled person at the application date
- Stricter requirements if the effect was not expected by the skilled person at the application date
- synergistic effect of calcipotriol and betamethasone not plausible
- synergistic effect unexpected on the basis of the prior art
- No statement on or substantiation of a synergistic effect in the patent

Plausibility – possible differences NL - UK

- UKSC weighs the “facts”, DSC only law
- Some lords perhaps more strict, requiring *prima facie* evidence
- In UK seems issue of sufficiency, not so much inventive step

de Rechtspraak

2nd medical use claim (SMU)

- DSC Merck v. Teva 3 Nov 2017, main points:
- Direct infringement SMU if objectified foreseeability
- By the skilled person
- on the basis of the SmPC, leaflet or some other circumstance,
- that the substance is (also) intended for and suited to that treatment.
- If foreseeable, then the generic manufacturer or seller should implement all effective measures that can reasonably be required to prevent use of SMU.
- carve-out generally not sufficient

de Rechtspraak

2nd medical use claim

- DSC Merck v. Teva 3 Nov 2017, entire consideration on objectified foreseeability:
- foresees or ought to foresee that the generic substance he manufactures or offers will intentionally be used for treatment covered by the second medical indication patent. This requires that the average person skilled in the art, on the basis of the SmPC and/or the product information leaflet or some other circumstance, will consider that the substance is (also) intended for or suited to that treatment. The manufacturer or seller will then have to take all effective measures that can reasonably be required of him to prevent his product from being dispensed for the patented second medical indication. The mere circumstance of a carve-out in the SmPC and product information leaflet of the generic drug – as in the present case – is generally not sufficient to rule out direct infringement.

2nd medical use claim (SMU), more main points DSC Merck v. Teva

- direct infringement and indirect infringement of second medical use claims possible
- Indirect infringement if gm supplies or offers where he knows or it is obvious given the circumstances, that the drug is suitable and intended for the patented second medical indication
- No objection that at same time both directly and indirectly infringe 2muc patent. See inter alia UKSC Eli Lilly
- EPC 2000/1973 2muc give same protection, see G2/08 and Explanatory Notes cited

de Rechtspraak

2nd medical use – possible differences NL - UK

- UKSC seems more limited protection for SMU, DSC wider
- Foreseeability in UK seems no factor any more, in NL main consideration
- In NL for generic company much more difficult to know what he has to do to sell for unpatented first indication, but not infringe SMU
- In UK gm skinny label and carve-out may be sufficient, in NL not yet

de Rechtspraak

Late amendments DSC High point v. KPN

- 138(3) EPC does not mean national procedural rules cannot limit the possibility to amend claims – in appeal after one written statement by either party: no more amendments
- Seems UK and NL align here on 138(3), but in NL appeal de novo
- Incidentally, in NL centralised limitation re 105a EPC possible, even after appeal decision but before SC decision (DSC Scimed v. Medinol, 6 March 2009)