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Fluticasone: District Court The Hague Lectures on Inventive Step

Rik Lambers (Brinkhof) · Wednesday, January 26th, 2011

The District Court of The Hague passed judgment today in a case between Sandoz and Glaxo regarding a combination patent held by Glaxo. The judgment comprises an extensive "lecture" on the assessment of inventive step and may become a benchmark for future cases.

Sandoz requested revocation of Glaxo's patent and supplementary protection certificate ("SPC") for a composition containing the beta-agonist salmeterol and the corticosteroid fluticasone proprionate for simultaneous inhalation in the treatment of respiratory diseases (e.g. asthma). .

In the UK (2004), Germany (2010) and Ireland (2010) the equivalent national parts of the patent were revoked for lack of inventive step. The District Court shows it awareness of these foreign decisions, but concludes that the patent is invalid based on its own reasoning. As a springboard to this conclusion, the Court discussed the appropriate test for inventive step in the Netherlands. Interestingly, the District Court takes UK case law *ex officio* into consideration.

The Court considers that Dutch courts "usually (and only exceptionally not") use the *problem-and-solution approach* (PSA) to assess inventive step. The Court sees no reason to make an exception in this case, which is "well suited for the structured approach of this approach". In a foot note to this consideration, the District Court states (para. 4.4 judgment):

> "It is considered *ex officio* that exceptions such as recently indicated by Jacob LJ in *Fluvastatin* [2010] EWCA *Civ* 82 at 35-37 where the PSA falters in his view, as in case of "problem" inventions and the "5 ¼ inch plate paradox" do not occur here, while the reformulation of the objective technical problem is minimal in this case, as will be developed hereafter."

The District Court rejects Glaxo's approach to the assessment of inventive step, which does not take one document as the closest prior art, but takes the state of the art as a whole into consideration, including – so-called by Glaxo – positive and negative *pointers*. The District Court therefore starts – in line with the PSA – with one closest prior art document.

Again, the District Court puts this in a pan-European (UK) perspective (para. 4.5 judgment):

> "Moreover, it is very doubtful whether the different approaches to assess inventive step in Europe would still lead to different outcomes. As far as the method of assessment pleaded by Glaxo would essentially focus on the more *traditional* English coloured "state of the art" approach from the *Pozzoli/Windsurfing* case law, the District Court considers the following. In English patent case law it is repeatedly indicated that, although usually a strict PSA as established in the case law of the TBA's is not applied there, the "English" assessment of inventive step is essentially not different and should not lead to different outcomes. Incidentally, Jacob LJ *did* remarkably (also) apply the PSA in so many words recently in the *Fluvastatin* case."

In a footnote to this last sentence the District Court notes that

> "In the case about the parallel English patent, Jacob LJ has also indicated this in his refusal to allow appeal under 4: *I can detect no real difference in approach between the EPO and the UK on obviousness – in the end it all (as it must) comes back to the statutory question*."

Thereafter the District Court systematically discusses the various steps of the PSA (closest prior art, objective technical problem, could-would test) within the EPO framework, citing EPO case law and the EPO guidelines. Topping its general introduction, the Court stresses the recognition in Dutch case law of the importance of the could-would distinction and the avoidance of hindsight, referring to the Supreme Court's *Rockwool/Isover* case and citing the related opinion of the Supreme Court's advisor in that case.

Application of the PSA, and specifically the could-would test, on the case at hand, leads the District Court to reject Glaxo's argument that the skilled person starting from the closest prior art document would not be able to see the wood for trees (i.e. the many publications). The District Court considers that it is the could-would-test that helps the skilled person to overcome this last (visibility) problem (para. 4.23):

> "Indeed, the skilled person does not have before him a roadmap to the solution on the reference date. In his search for a solution to a technical problem he will have to find his way in all available publications, which are not selected and which sometimes refer in another direction. Precisely because Barnes has so much "filtered out" in his review article [the closest prior art document – author], this provides the skilled person an unambiguous incentive in the indicated direction which he, in the judgment of the court (following the judgment of the English, German and Irish courts) *would* walk."

The District Court deals with two other subjects: the *bonus effect* and (the existence of a) prejudice.

As to the bonus effect, Glaxo argued that the patented invention concerns a synergetic and therefore surprising effect by the interaction of the two components salmeterol and fluticasone. The District Court considers this a bonus effect, noting that in the patent nothing of substance regarding this effect is disclosed. The language referred to by Glaxo is too general to refer to specific effects.

According to the District Court, (para. 4.27):

> "The reasoning of Glaxo would open wide the door to "wish patents" in which the applicant could suffice by submitting unsubstantiated characterisations such as *highly effective, significant improvement* and *particularly compatible and complementary in their activity and thus highly effective* in order to link a later found surprising effect to it. By connecting the synergistic effects that were found long after the priority date and date of grant (2003) to these vague passages, Glaxo employs a reasoning which only takes her preferred colour with hindsight of the appeared synergy of the invention combination – in view of the court a *hindsight* reasoning which should not be followed."

In a last UK nod, the District Court discusses the clear difference between understandably setting out the advantages in a patent (application) and the English pre-*Angiotech* inventive step test, "which was abolished by Lord Hoffmann in the House of Lords-decision in that case".

As to the existence of a prejudice, Glaxo argued that if next to *positive* pointers (in the closest prior art document) there are *negative* pointers (in other publications), in sum the skilled person would not get a *general* directional pointer / general guidance to the claimed solution. Therefore, following the positive pointers in the closest prior art notwithstanding the negative pointers would still be inventive.

The District Court dismisses Glaxo's calculations (para. 4.34):

> "Assessment of inventive step is not a sum of negative and positive pointers. For inventive step this is only relevant if the "negative *pointers*" put forward by Glaxo can be qualified as technical prejudices and such is not the case. […] there is nothing inventive in following a "positive" *pointer*, even if there are concerns or anxieties in the state of the art thereabout or indications in another direction, at least as long as there is no prejudice."

All in all, the District Court's judgment provides a clear and extensive read on the assessment of inventive step.

The English translation of the judgment can be found here.

The Dutch version can be found here.

Dislaimer: the author's firm represented Sandoz in this case.

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