Kluwer Patent Blog

MSD v. Mylan: conflicting views

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MSD's European Patent for treating baldness, EP 0 724 444 ('EP 444'), has been the subject of a number of (in)validity decisions throughout Europe, with differing outcomes. The Dutch chapter in this saga is a decision of the District Court The Hague, which holds that – contrary to the German, French and Italian courts –the patent is valid and infringed.

Claim 1 of EP 444 is a Swiss-type claim for the use of finasteride for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg. Androgenic alopecia is a type of baldness occurring in men and women caused by hyper androgenic stimulation. In addition to alopecia, hyper androgenic stimulation also causes benign prostate dysplasia ('BPH'). No opposition was filed against the patent.

EP (UK) 444 was initially revoked in 2007 by the England & Wales High Court. This verdict was subsequently overruled by the Court of Appeal by decision of 21 May 2008. In short, the Court of Appeal held that novelty in a Swiss-type claim may reside in the dosage regime. That is, the fact that it was known at the priority date that finasteride could be used in the treatment of androgenic alopecia, with a prescribed dosage regime of 5mg/day, did not mean that the claimed dosage regime of "about 0.05 to 1.0 mg" was not novel. In doing so the CoA, in its own words, followed the decision of the EPO's Enlarged Board of Appeal in G 5/83, which had become established case law.

That was not the end of it, however. On 26 June 2008 the German Federal Patent Court revoked the German part of EP 444 (decision 3 Ni 58/06). The Court referred to earlier case law of the German Federal Patent Court (Carvedilol II, GRUR 2007, 404), in which it was decided that a dosage regime in a treatment step is not patentable, being a method for treatment of the human body (Article 53(c) EPC). According to the Federal Patent Court, the dosage regime specified in claim 1 did not relate to the preparation of the medicament but to the treatment of the patient with said medicament. The Federal Patent Court did not rule on whether this meant that claim 1, a Swiss-type claim, was as a whole excluded from patentability, or whether a claimed dosage regime may not be taken into account when assessing novelty and inventive step of the claimed subject matter. Even if the latter was the case, EP 444 would be invalid for lack of novelty over prior art disclosing the use of finasteride in the treatment of androgenic alopecia, but in higher dosage amounts than claimed in EP 444. The appeal to the German Federal Court of Justice was

withdrawn after Actavis and MSD reached a settlement.

In its decision, the Federal Patent Court did not refer to either the UK decisions on EP 444 or EPO case law. It should be noted that the German Federal Court of Justice has since determined that the German Courts must give account of EPO and foreign decision where these concern essentially the same questions ("Walzenforgebungsmachine", covered on this blog).

On 19 February 2010, the Enlarged Board of Appeal held in its decision G2/08 that a claimed dosage *did* have to be taken into account when assessing validity of a patent. This decision was prompted, at least in part, by the German Federal Court of Justice's decision Carvedilol II and the decision of the UK CoA on EP 444 discussed above.

Next, the French Tribunal de Grand Instance de Paris argued in its decision of 28 September 2010, in the words of Pierre Véron, who covered this decision for the Kluwer Patent Blog, that "*the EPO is not a court so that its decisions even issued by the Enlarged Board of Appeal are merely indications of the analysis made by the EPO*", expressly rejecting G2/08 and opting instead to adopt the reasoning of the German Federal Patent Court which it found convincing. This author can't help but wonder if the Federal Patent Court would not have come to a different conclusion had G2/08 been available at the time of its decision.

EP 444 was also litigated in Spain, were it was nullified by the Commercial Court of Madrid, and Italy, where the case was settled after court experts concluded that the patent was valid.

All this just to set the stage for the Dutch case…

The District Court The Hague started with construction of the claim. It considered that the skilled person would understand the claimed dosage regime to be daily dosages, despite the fact that the express language that the dosage amounts were daily was no longer present in the claims (it had been present in the priority application, but was removed when amended claims were filed with the EPO). As a consequence, Mylan's added matter, enabling disclosure and non-infringement arguments were rejected, all being based on the construction that the claimed dosage amounts were absolute (rather than daily).

On novelty, the District Court considered that – following G2/08 – a specific dosage regime *was* patentable and that the reasoning of the German Federal Patent Court was outdated in light of this decision. Since none of the prior art documents (more specifically international application WO 225) directly and unambiguously disclosed a dosage range of about 0.05 to 1.0 mg, this range was novel. It was not for lack of trying on Mylan's part that the Court came to this conclusion. Mylan pointed to several different values mentioned in WO 225 to argue that the claimed range was in fact disclosed in WO 225. However, to do so Mylan first converted a dosage expressed in mg/kg body weight to an absolute dosage, assuming an average body weight of 50kg, used a value that was disclosed as a lower limit as an upper limit, and finally took values from different experiments, one of which was on monkeys. The District Court argued that the values thus obtained were not, in fact, disclosed in combination with each other.

The patent was also held to be non-obvious. The District Court noted that on this point it differed from the England & Wales High Court, the German Federal Patent Court and the Spanish court. The District Court consequently held the patent valid and infringed. MSD was granted an injunction and Mylan was required to render accounts and to issue a recall on finasteride products already sold.

The fate of EP 444 in the various European courts is a testament to the fact that, despite material European patent law being harmonized through the European Patent Convention, national courts may have diverging opinions on essential provisions of that convention, leading to conflicting decisions on the validity of different national parts of the same patent. For now we have to live with that but it does not change the fact that the French approach to EPO case law is rather disappointing. Also, it would be good if the Dutch courts would, like in the UK and Germany, adopt as a standard approach that they motivate if they deviate from earlier foreign decisions (which they already often do).

The decision of the District Court The Hague has also been summarized for Kluwer IP Law. This summary goes into more detail on the reasoning of the Court on novelty and inventive step in particular.

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This entry was posted on Saturday, October 25th, 2014 at 12:51 pm and is filed under Netherlands, Novelty, Validity
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