Kluwer Patent Blog

Report from the Fordham Conference (2)

Brian Cordery, Andrew Bowler (Bristows) · Monday, April 4th, 2016

Friday 1st April was the final day of the Fordham conference. This short report summarises one of the more interesting patent-focused sessions which dealt with second medical use issues.

Brian Cordery from Bristows set the scene. He briefly referred to some of the recent European decisions on Swiss-type claims, particularly the pregabalin and pemetrexed cases. He pointed out the apparent distinction between an approach to construction adopted by some European judges which heavily focuses on the manufacturing element of Swiss-type claims and an approach to construction by other judges in which the claims are viewed as a series of steps. Brian thought the latter approach was more in keeping with a purposive approach to claim construction, particularly bearing in mind that in Swiss-type claims the novel and inventive step is the new use of a known medicament. Brian finished his talk with some real examples of action being taken by pharmaceutical companies to limit the prescription of skinny-label generic medicines for patented indications so as to deal with the problem of cross label use.

Sir Robin Jacob spoke next and said that the topic of second medical use patents was the “biggest subject” on this year’s Fordham agenda. He made the point that the patent system by itself was not adequate to resolve the issues that arise when a new use has been found for a known medicament. For example, if a doctor has spotted a side effect when a patient takes a drug and published some work on it, it may not be possible subsequently to obtain patent protection for this new use. He also thought that there were difficult issues regarding originators bringing proceedings against generic companies in this context, particularly as regards what would be appropriate remedies.

A key issue is to gather data relating to how often the medicament is prescribed for the patented indication. Sir Robin couldn’t see any particular concern if prescriptions actually stated the indication. In most circumstances, the pharmacist would be aware in any event of the disease that the patient was suffering from as the prescribed medicine was only used to treat one disease. Healthcare authorities could produce a databank which might be useful in own right.

Dr Juergen Dressel of Novartis reiterated the need to incentivise originators to innovate, including developing new indications for known medicaments. Appropriate means to enable the developer to recoup its expenditure – be it through patents or other forms of exclusivity – is an important issue for originators. Juergen explained that all stakeholders need to work together to find a solution to the difficulty of cross-label use. The key is to doing so is to ensure that already over-worked doctors are not burdened with additional bureaucracy by prescribing the branded medicine for the protected indication and a generic medicine for the non-protected indications. Mark Ridgway from

Allen & Overy in London agreed with this observation and, later in the session, sounded a degree of optimism that the various stakeholders concerned would pull together to achieve a satisfactory outcome in most circumstances.

Rian Kalden from the Dutch Court of Appeal agreed that patent law is not the best solution but that, in the meantime, we are stuck with having to consider Swiss-type claims. Rian thought that much of the difficulty on construction resulted from interpreting Swiss-type claims as purpose limited process claims rather than as purpose limited product claims. Given that novelty and inventive step is assessed by reference to the new use, the latter approach might be more consistent with the purposive approach outlined by Lord Hoffmann in Kirin Amgen.

Marleen Van den Horst noted that two arms of the zoledronate litigation are still active in the Netherlands; the preliminary injunction proceedings are to be heard by the Supreme Court and the first instance court has asked for submissions on the issue of direct infringement. She noted that remedies needed to be effective, reasonable and proportionate as well as being permissible under EU completion law. She looked at various aspects of relief including possible financial remedies.

Dr Christine Kanz was the last to speak and gave a neat summary of the interpretation of second medical use claims in Germany and the historic propensity of the Court to look at the wording of the PIL (even if patients were in fact being treated for the patented indication). However, the pregabalin litigation showed that the German Courts were becoming more flexible in their approach and considering how the product was used in practice.

In conclusion, the panel are looking forward to further clarity from the senior courts of several European states on the construction and infringement of second medical use claims, whilst recognising that the issues at stake are much broader than simply reaching a consensus on the correct construction such patents. To ensure that second medical use patents are respected, all stakeholders must work together and it is encouraging to see recent signs of such cooperation. However, at the end of the day, patents are probably not the right tool to ensure that further uses for existing medicines are researched and developed and further work remains to be done to ensure that potential new uses for existing medicines are investigated thoroughly.

This entry was posted on Monday, April 4th, 2016 at 1:11 pm and is filed under United States of America
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.