

## **TWO SENSIBLE, AND COMMERCIALY VERY IMPORTANT, UK PATENT CASES**

Two recent UK court decisions have hit the headlines because the products in question are commercially very important. However, in our opinion, the decisions simply confirm, or at most clarify, existing patent practice in the UK.

### *“Lipitor” atorvastatin*

The first decision was in the High Court and concerned the anti-cholesterolaemia drug atorvastatin, sold by Pfizer as “Lipitor”<sup>®</sup>. A generic pharmaceutical manufacturer, Ranbaxy, sought a declaration of non-infringement on the basis that their intended drug was a single enantiomer whereas, they contended, the structural formula in the patent claim should be construed as being limited to the racemic mixture. The judge accepted that the formula would conventionally have been used to denote the racemate. However, he took into account the description in the patent and the common general knowledge of the intended reader, who would have been aware that the activity in drugs of this chemical class generally resides in only one enantiomer:

*“In my view, a proper approach to construction of this claim (is) to ask why the patentee, who has covered a two-element composition for use in a drug, would not wish to cover one element of that composition which any reader would know was the effective element and which could be isolated using routine techniques. Of course, clear words would be conclusive, but there are no clear words. I can see that to ask this question would not be justified if the skilled reader did not have a clear understanding that the claimed material would have a component that was new and useful, but there is every difference between on the one hand an omission that was surprising but for which the patentee might have reasons, and on the other an omission that is both surprising and would in the eye of the reader immediately deprive the patent of any commercial effect.”*

He therefore concluded that the claim did cover the single enantiomer and that therefore Ranbaxy would infringe the patent.

However, Ranbaxy were successful in establishing that a later Pfizer patent, directed specifically to the calcium salt of a single enantiomer of atorvastatin, was anticipated by one of Pfizer's earlier patent applications and was obvious over another one. More specifically, the claim was held to lack novelty over an earlier disclosure of the racemate, together with general instructions for how to resolve the enantiomers, and a list of preferred salts that included calcium; and it was held to be obvious over a very similar earlier disclosure partly on the basis that, although the calcium salt was better than the sodium salt that was used in the specific example of the earlier document, the person skilled in the art would have screened a number of different salts (calcium being specifically mentioned in the document) in order to find the best one.

Since the patent in question had been granted following an EPO Board of Appeal decision, in which essentially the same prior art was considered, the judge needed to explain why he differed from the EPO. In part, he did this by criticising the EPO's problem-and-solution approach but mainly he did so by pointing out that the EPO decision was *ex parte*; had the Board seen the same evidence that he had seen (showing that those in the art routinely screened different salts for hygroscopicity, which was the improved property asserted for the calcium salt by Pfizer), he felt that they would have made the same decision. Moreover, he noted that the advantage of decreased hygroscopicity was not asserted in the Pfizer patent but was only discovered later. Hence, it should not be allowed to support the inventive step in the patent. Although the particular EPO board had not taken this into consideration, it is nevertheless a part of EPO practice (as in T867/95) and so the judge felt that his decision was not inconsistent with EPO practice.

*“Seroxat” paroxetine*

The second case involved a GlaxoSmithKline patent on the crystalline form of its antidepressant paroxetine, sold as Seroxat<sup>®</sup> and Paxil<sup>®</sup>. The rival company Synthon had filed an earlier patent application on similar subject matter, which had not been published when GSK filed its application. The House of Lords confirmed that, for an earlier document to be novelty-destroying, (i) it must disclose the claimed subject matter and (ii) the disclosure must be “enabling”, these two concepts being separate requirements. The Synthon specification had given the wrong infrared spectrum of the crystals and the specific example did not work, since the wrong solvent had been used. Nevertheless, the original trial judge had decided that the person skilled in the art could easily (based purely on common general knowledge) find a suitable solvent and, since paroxetine crystals are monomorphic, the wrong IR spectrum would be irrelevant; the GSK-claimed crystals would inevitably result. The House of Lords upheld that original judgement and overturned the intervening judgement of the Court of Appeal, which was criticised as confusing the separate requirements for disclosure and enablement.

The information in this Newsletter was correct at the date of release. More up to date information is available by contacting Eric Potter Clarkson. All comments contained here are of a general nature and full professional advice should be sought on any specific problem.

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