

Even more on pemetrexed

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by Nicholas Round

At the start of this month, the UK Supreme Court took a break from its recent post-Brexit work interpreting (and developing) constitutional principles to hear an intellectual property matter. This rare Supreme court foray for a patent produced a ripple of excitement across the UK IP litigation community not least because (uniquely among our courts) Supreme court hearings are televised and can be watched live. Too many arguments were put before the five law Lords sitting for a comprehensive analysis of the two-and-a-half day hearing so what follows is a summary of the main issues and a selection of some points which, in the authors' view, are particularly interesting.

By way of recap, the outline facts of this case are that Eli Lilly hold a patent with a Swiss form claim relating to the use of pemetrexed, in a disodium salt, in combination with vitamin B12 for inhibiting tumour growth. Actavis sought a declaration of non-infringement (DNI) in respect of its products which use pemetrexed in different salt forms, one of which was pemetrexed dipotassium. Furthermore, Actavis requested DNIs from the UK court in relation to France, Spain and Italy as well as the UK. In the case's last outing, the Court of Appeal upheld the first instance decision that Actavis' product was not directly infringing Lilly's patent but reversed the finding in relation to indirect infringement with the result that Actavis did infringe the patent indirectly unless it used dextrose as a diluent (this is for technical reasons relating to the form of the pemetrexed when it is in solution). Lilly appeals the finding in relation to direct infringement whilst Actavis is appealing the decision on indirect infringement.

Lilly argue direct infringement on the footing that, when properly construed Actavis' products do fall within claim 1 of the patent, in view of the equivalence between pemetrexed disodium and the salt forms Actavis use. Much of the hearing was therefore taken up by submissions on the proper approach to take on claim construction in view of EPC 2000 and the seminal UK cases of *Catnic* [1982] R.P.C. 183, *Improver* [1990] F.S.R. 181 and *Kirin-Amgen* [2004] UKHL 46. Lilly emphasised that the invention of its patent was the combination of the pemetrexed (which was already known to be effective at inhibiting tumour growth) with vitamin B12 (which Lilly had discovered to reduce the toxicity of pemetrexed to safe levels) and was not related to the salt-form of the pemetrexed. Lilly argued that in the field of the patent, the skilled person would readily appreciate that other salt-forms existed that would work in exactly the same way as pemetrexed disodium and so - if used in combination with vitamin B12 - would be making use of the disclosed invention. Thus, on a purposive construction, the patent is directly infringed.

In dialogue with Lilly's counsel their Lordships appeared concerned by whether this reading of the patent was a construal or, separately, made use of a doctrine of equivalents. It was put to Lilly that "pemetrexed disodium" cannot be construed as "pemetrexed dipotassium" in the way that "vertically" was construed in *Catnic* since disodium is not a qualitative word/concept - it is a specific entity. Lilly returned that it need be borne in mind, as it would be by the skilled person reading the patent, that the particular-type of salt used was not an essential element of the patent and this is why the wider reading should be given. A similar exchange occurred with Actavis' counsel and Lord Neuberger and the analogy of a dinner invitation stating "Come at 8:00 on 23 June". The invitee would readily understand that arrival on 23 June, and not another day, was an essential element of the message but that the time of arrival could be interpreted more flexibly.

Lilly also emphasised policy considerations in an empirical field, such as chemistry, were in favour of interpreting the patent so as to include equivalents. Furthermore the patentee would expect, under EPC 2000, that equivalents were included in the scope of its claims as they are in other European jurisdictions. Lilly submitted it was unfair to expect the patentee to work out all possible equivalent salts and include them in the patent and therefore, unless equivalents did fall within the claims of the patent it would effectively mean that chemical/pharmaceutical inventions received relatively less protection than inventions in other fields (and

such “discrimination” is forbidden under TRIPS). Support for this could be seen by the fact Actavis had, very frankly, stated that the only reason it did not use a disodium salt-form was so as not to infringe the patent.

Interestingly, Actavis argued that EPC 2000 was not as prescriptive on the harmonisation of European patent law as suggested by Lilly. Instead EPC 2000 provides a framework that continues to allow a degree of national variability. Counsel for Actavis contrasted this with the forthcoming UPC regime which will aim for complete harmonisation. Additionally, Actavis argued that it was dangerous to look at procedure in other jurisdictions and drift towards an alternative practice without a very comprehensive analysis of that other system and, in particular, any counterbalances included within it. By way of example, the doctrine of equivalents is established in US law but is curtailed by prosecution-history estoppel, which prevents overly broadening the patent scope following grant. Additionally, the US pursues a literal patent construction followed by consideration of equivalents; Actavis submitted that Lilly were hoping for a purposive construction as well as equivalents, and that this effectively amounted to “double counting”.

Further to this, and in relation to prosecution history, Actavis argued that it was a relevant consideration that during prosecution of the patent Lilly had been required to set out a specific salt-form. Actavis submitted, extending a line of argument expressed in *Virgin* [2009] EWCA Civ 1062 on the knowledge of patent law that the skilled person is deemed to possess, that the skilled person was aware of the patent file and could look at the prosecution history to help them interpret the patent. They would then see that a specific salt-form was required before grant of the patent and conclude that this meant the claim should be narrowly construed to only protect the particular salt-form claimed. Unsurprisingly, Lilly disagreed with this submitting that the “life’s too short to look at the prosecution history” principle applied.

Clearly there is much for the Supreme Court to digest before handing down judgment in this complex area. However, whichever way the learned judges decide, it seems certain that “*in accordance with the principles set out in Eli Lilly v Actavis*” will soon be a recurring phrase for UK patent litigators when setting out their arguments on claim construction. We will be reporting on this as soon as the judgment is given.