Infringement: interesting rulings on the doctrine of equivalents in the UK Patents Court

Five years since the doctrine of equivalents was introduced by the Supreme Court decision in *Actavis v Eli Lilly* [2017] UKSC 48, there are still questions as to its scope (ironically) in the UK. We dive into three decisions handed down in 2022 to see how the doctrine has progressed.

Teva v Novartis [2022] EWHC 2847 (Pat). In this decision His Honour Judge Hacon (sitting in the High Court) addressed a question that had not been considered by the Supreme Court in *Actavis*: how should numerical ranges be approached in the context of infringement by equivalence?

The invention concerned a swallowable film coated tablet for the treatment of iron overload. Claim 1 provided for a pharmaceutical formulation "*comprising deferasirox or a pharmaceutically acceptable salt thereof present in an amount from 45% to 60% by weight based on the total weight of the tablet* […]". Although the precise figures for Teva's formulation were confidential, on a normal construction Teva's allegedly infringing product, Teva DFX, fell outside the claim because its deferasirox content was higher than the claimed range. There was therefore no literal infringement. An infringement finding would thus have to be based under the doctrine of equivalents.

The parties differed as to the what the inventive concept of the patent was: Teva argued it was "*almost entirely about the 45–60% range*"; whereas Novartis argued it was the "*unexpected increased bioavailability and reduced food effect*" of the formulation ('food effect' being the ability to take the tablet with a light meal), with the 45–60% range not featuring. The Judge rejected both. Novartis's inventive concept was held to import technical effects that were not present in the claims. Teva's was too simplistic. The Judge came to his own formulation of the inventive concept that largely followed the claim language that included the various other excipients, and, crucially, the range of deferasirox.

Turning to the evaluation of a numerical range in the context of equivalence, the Judge cautioned against a strict approach whereby a numerical range "*invariably implies strict compliance*". To do so, would mean that "*a product or process 0.1% outside the range could never be an equivalent. Alternatively, what about 1% or 5%?*". Grappling with the issue, the Judge turned back to the Court of Appeal decision in *Smith & Nephew v Convatec* [2015] EWCA Civ 607, later endorsed by *Jushi v OCV Int. Capital* [2018] EWCA Civ 1416, which held that "*… the approach to be adopted to the interpretation of claims containing a numerical range is no different from that to be adopted in relation to any other claim*". There was therefore no 'one-size-fits-all' approach: compliance with the numerical range could be given more or less weight, depending on all relevant facts.

The Judge's assessment focussed on the first and third *Actavis* questions. On the first – does the variant achieve substantially the same result in substantially the same way as the invention (i.e., is the inventive concept the same) – he said "No". Although the skilled formulator has leeway regarding the other excipients if the deferasirox content is in the range, if the deferasirox content is outside the range, there was no evidence before the Court on the corresponding changes to the other claimed

excipients to show that they, too, would work in the combination claimed by the invention. Alleged similarities in bioavailability of the parties' products was no answer to this first *Actavis* question.

On the third question – would such a reader of the patent have concluded that the patentee none the less intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention – he said "Yes". On the facts in this case the skilled formulator would adhere strictly to the 45–60% range of deferasirox. On that basis, Teva DFX would fall outside the claims on a normal construction and under the doctrine of equivalents, as a result of its claimed numerical range. The patent was in any event also found invalid over the prior art.

Advanced Bionics v Med-El [2022] EWHC 1345 (Pat). In this case before Mr Campbell Forsyth (sitting as a Deputy Judge), the technology concerned rotating disk magnets in implantable cochlear devices that are MRI-safe. On a normal (purposive) construction of the claims, Advanced Bionics' device was held to infringe the patent under s. 60(1). The Judge went on to consider equivalents, in case he was wrong on literal infringement. Like *Novartis*, the equivalence case fell down on the third of the *Actavis* questions: the patentee did intend strict compliance with the claim language. In this instance, that meant the magnets rotating in one plane parallel to the coil housing, whereas the allegedly infringing product's magnets had the ability to also rotate off-parallel. This case shows how a product can be infringing when claims are assessed purposively, but not when approached as an equivalent.

Vernacare v Moulded Fibre Products [2022] EWHC 2197 (IPEC). This case provided a successful invocation of the so-called *Formstein* defence to infringement by equivalence. Vernacare's patent covered a paper pulp wash bowl that could be lifted easily and without fear of disintegration. MFP's washbowl did not infringe on the normal interpretation due to differences in the ridge design. Faced with the doctrine of equivalents, the Judge agreed with MFP that either: the broadening of the claim to catch the 'equivalent' was such that the ridge design was part of the common general knowledge (i.e., the patent was obvious); or, under the third limb of *Actavis*, the patentee intended strict compliance with its ridge design and the product was not equivalent. The case takes UK case law on *Formstein* beyond the *obiter* decisions of Birss LJ and HHJ Hacon in *Facebook v Voxer* [2021] EWHC 1377 and *Technetix v Teleste* [2019] EWHC 126 (IPEC), respectively, and further aligns the UK's position on the availability of such a defence with other European Patent Convention countries.

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