Parties divided on Humira® dosage regime divisionals

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Case reported and summarised by Gregory Bacon, Bristows LLP
Mr Justice Carr has issued an interesting interim judgment regarding the jurisdiction of the English Court to grant negative declarations in relation to patent applications before the EPO (*Fujifilm Kyowa Biologics v Abbvie Biotechnology* [2016] EWHC 425 (Pat)). The case concerns an application by Fujifilm Kyowa Biologics (FKB) to revoke certain dosage regime patents in the name of AbbVie to adalimumab, sold under the trade mark Humira®. FKB commenced an action to revoke two such patents, both deriving from a single patent application, in advance of anticipated launch of its biosimilar adalimumab product ("FKB327") on expiry of the SPC granted under Abbvie's basic patent for adalimumab on 15 October 2018.

Both European patents in suit included second medical use claims to adalimumab at a dose of 40 mg given every other week by subcutaneous injection for various indications. A number of divisionals had also been applied for by AbbVie. One of the two patents in suit was granted in June 2013 following which 15 oppositions were filed at the EPO. Six days after the English proceedings were issued, AbbVie wrote to the EPO stating that it no longer approved the text of the granted patent and the EPO revoked the patent. On the same day that AbbVie wrote to the EPO, the Office published a further divisional application of the revoked patent which claimed essentially the same subject matter as the revoked patent. FKB also identified a further six pending divisional patent applications concerning the treatment of different indications by adalimumab in accordance with subcutaneous administration of a dose of 40 mg every other week.

As a result, FKB sought to amend its case to seek negative declaratory relief, that "*products containing a biosimilar monoclonal antibody to the antibody adalimumab for the treatment of rheumatoid arthritis, psoriatic arthritis and/or psoriasis by the administration of 40mg every other week by subcutaneous injection*" would have been anticipated or obvious at the priority dates of the two patents. This was with a view to preventing AbbVie from commencing infringement proceedings in the UK against FKB327 under any pending applications if granted by creating a squeeze between infringement and validity such that an action for infringement could not succeed in the UK. AbbVie resisted the application.

FKB relied on the interim judgment of Kitchin J (as he then was) in *Arrow Generics v Merck* [2007] EWHC 1900 (Pat) as support for the jurisdiction of the English Court to grant such declarations, as well as the subsequent full judgment of the Court of the Hague in *Merck Sharpe & Dohme v Ratiopharm & Ors* (February 13 2008 case number/docket number 288241/HA ZA 07-1689). Readers less familiar with the English precedent system should know that first instance judgments are not binding on other judges at first instance, and that interim judgments have even less precedential value. In response, AbbVie argued that the *Arrow* interim judgment, whereby Kitchin J allowed Arrow to seek the declaration at trial, was wrongly decided and that the English Court should not follow its Dutch brethren. AbbVie also argued that even if the English Court had jurisdiction to grant such declarations, the circumstances of the case did not justify the relief sought.

The main argument raised by AbbVie against jurisdiction was section 74 of the Patents Act 1977, which Merck has also raised in the earlier Arrow case. This lists the types of actions in which the validity of a patent (including a European patent) may be put in issue and states that the validity of a patent may not be put in issue in other proceedings, including proceedings seeking only a declaration as to the validity or invalidity of a patent. The Judge held that the wording of section 74 meant that it did not extend to patent applications, only granted patents. The judge also distinguished the declaratory relief sought from a pre-grant opposition (which is not available either before the UK IPO or EPO) on the basis that the relief sought was that the claimant's **product** was anticipated or obvious as opposed to the **patent** sought being anticipated or obvious. In contrast, the judge was of the view that the English Court will not make declaration that no valid patent could be granted on a divisional application which is being prosecuted before the EPO, as this would usurp the function of the EPO in its examination of European patent applications. In concluding, the Judge noted that if there was no jurisdiction to grant declarations of this nature, then it would be impossible for parties who wished to clear the way for the launch of a product to do so without facing years of commercial uncertainty posed by cascading divisional pending before the EPO. This would be so even where a patent had already been revoked or abandoned in the jurisdiction of intended launch, as the patentee could seek to re-monopolise essentially the same subject matter by filing further divisionals.

Having held that the jurisdiction existed, Carr J warned that it needed to be exercised with caution. On the facts, he held that there was a good arguable case that the declaration sought would serve a useful purpose. FKB had filed a confidential estimate of potential loss of revenue if FKB327 was not launched that, given the sales figures for Humira, was very substantial. FKB had also shown in its evidence that there was a real likelihood that it would be ready to launch FKB327 in the fourth quarter of 2018, and the judge was satisfied that AbbVie would enforce its patent rights that might be granted in the future by seeking injunctive relief. The judge concluded that these facts, as well as the conduct of the patentee in abandoning one of the patents, meant there was a realistic prospect that the trial judge would exercise their discretion to grant the relief sought. One point to note is that on the question of whether the product would have been anticipated or obvious, the Judge held that although he was not in a position on an application of this nature to accept FKB's submission that it had a very strong case, he was satisfied that the FKB had a real prospect of success (which is a relatively low hurdle) in establishing this at trial.

The Judge also noted that the costs and burden to AbbVie in allowing this cause of action to go to trial did not outweigh the potential injustice to FKB if could not clear the way before launch, in particular as AbbVie already faced a trial on the other patent which concerns very similar subject matter. In addition, the commercial value of Humira meant that costs of litigation would operate as a deterrent to AbbVie in pursuing a vigorous defence of the claims made.

We are also aware that, on handing down judgment, the Judge refused AbbVie's application for permission to appeal to the Court of Appeal, noting that it was open to AbbVie to argue at the trial of this action that the Court should not grant the declaration sought. The result of his judgment was merely that there was a good arguable case that the declaration sought would serve a useful purpose and therefore that FKB should be entitled to have its application for a negative declaration proceed to trial. The merits of granting the declaration will have to be decided at trial.