English Patents Court grants declaratory relief in relation to Humira® dosage regimes

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by Laura Von Hertzen

On 3 March 2017, the English Patents Court (Henry Carr J) issued a decision (here) in the joined claims filed by Fujifilm Kyowa Biologics (FKB) and Samsung Bioepis/Biogen (S/B) against AbbVie Biotechnology Limited (AbbVie) for so-called Arrow declarations in relation to dosage regimes of adalimumab (sold by AbbVie under the brand name Humira) for the treatment of rheumatoid arthritis and psoriasis/psoriatic arthritis.

Arrow Declarations

An *Arrow* declaration is a declaration that a product (or process) was old or obvious at a particular date (here the earliest claimed priority date of AbbVie's patents/patent applications for the dosage regimes in question). Its main purpose is to provide a so-called *Gillette* defence – a short-cut for an alleged infringer, as if it can show that the product (or process) in question was either disclosed in the prior art or is an obvious modification, that product (or process) cannot infringe any validly-granted claim with that priority date, no matter the claim's form. The name for the declaration derives from *Arrow Generics v Merk* [2007] EWHC 1900 (Pat), in which such a declaration was first sought and in which it was held that it

was at least arguable that they could be granted.

Readers may recall that in March 2016, Henry Carr J confirmed, in an interim judgment in the present case, that it was arguable that the jurisdiction for such declarations existed (see earlier post here). That decision was upheld in January this year by the English Court of Appeal, which clarified that as a matter of principle, the English Courts have the power to grant such declarations in appropriate circumstances.

The purpose of FKB and S/B's claims is to clear the way for their biosimilar products by the date of expiry of compound patent protection for adalimumab in October 2018. FKB and S/B had initially sought the revocation of granted patents. However, in the course of the proceedings AbbVie had abandoned those patents – making it impossible for the revocation actions to proceed – whilst at the same time filing and/or maintaining divisional applications at the EPO covering the same subject matter, and indicating that it intended to vigorously enforce its patent portfolio on expiry of the basic patent.

Having found that the dosage regimens in question were old or obvious at the relevant priority dates, Henry Carr J had to consider whether a sufficient case could be made out for the exercise of the court's discretion for granting the declarations sought, and in doing so take into account "justice to the claimant, justice to the defendant, whether the declaration would serve a useful purpose and whether there are any other special reasons why or why not the court should grant the declaration" (per Neuberger J. in *Financial Services Authority v Rourke* [2002] C.P. Rep. 14, a case on the general power of the Court to grant declarations).

Henry Carr J held that, in the unusual circumstances of the case, it was in the interests of justice to grant the declarations sought. There were special reasons to grant the declarations; these included AbbVie's conduct of threatening infringement whilst abandoning proceedings at the last moment (in order to shield its patent portfolio from scrutiny), the amount of money at stake for the claimants in terms of investment in clinical trials and potential damages if they launched at risk, and the need for commercial certainty, having regard to AbbVie's threats to sue for infringement throughout the world.

On useful purpose, the Judge held that the question was whether the declarations would serve a useful purpose in the UK, as a declaration that is sought solely for

the benefit of foreign courts would rarely be justified. The issue arose because AbbVie had offered undertakings that it would not obtain any patent protection in the UK that would be infringed by FKB and S/B's biosimilar products as a result of their use of the dosage regimes for the indications specified in the declaration sought; in light of this, AbbVie argued that the declarations sought would serve no useful purpose.

Henry Carr J disagreed. First, the declarations would dispel commercial uncertainty in the UK (and European) market, which AbbVie's threats of patent enforcement against biosimilar competition had created. They would provide clarity for third parties in the UK; this was necessary given AbbVie's conduct to date, and was not provided by AbbVie's undertakings, which were complicated and not easily understandable for companies seeking to do business with the claimants in respect of their biosimilar products.

Second, the declarations would protect the claimants' supply chain for the UK market; they would make injunctive relief in other jurisdictions in respect of that supply chain less likely, and this would be of direct benefit to the UK market. Finally, foreseeable promotion of settlement, in combination with these other facts, would provide a useful purpose for granting the declarations.

Importantly, Henry Carr J stressed that in his decision he had not taken the spin-off value of a judgment into account, other than to the extent that it may have an impact on the UK market.

Henry Carr J also noted that the main purpose of an Arrow declaration is to provide a Gillette defence to an infringement claim in the UK and, given the particular circumstances of this case and how the proceedings developed, referring to the declarations sought by the claimants as "*Arrow* declarations" would be "*misleading shorthand*", as their purpose was different from those sought in the Arrow case.

Priority

It is worth mentioning that the case also dealt with an interesting issue of entitlement to priority, as FKB and S/B challenged the chain of title by which entitlement to priority to one of AbbVie's European patents was claimed. FKB and S/B alleged that Abbott Laboratories (Bermuda) Ltd ("Abbott Bermuda"), the applicant for the PCT application which resulted in the European patent, was not entitled to claim priority from a US application, because it was not the successor in

title to the applicants for the US application who were, as US law required at the time, the inventors. This was important because, although the European patent was no longer in issue in the proceedings (it had been abandoned by AbbVie), FKB and S/B sought a declaration as at the date from which that patent was entitled to priority.

AbbVie had submitted that it was unnecessary to examine the chain of title because the inventors (and applicants for the US application) were also joint applicants for the PCT application (with Abbott Bermuda) and, although when the PCT application was filed the inventors may no longer have owned the substantive rights to the invention, they still owned legal title to the invention. This argument was rejected by Henry Carr J, who held that where a right to claim priority has been assigned, the assignor cannot subsequently make a claim himself; the judge considered that Article 4A of the Paris Convention contemplates a claim to priority either by the original applicant or his successor in title, and not by both. Furthermore, the Judge found that the only part of the PCT application that was material to the priority claim at hand was the claim in respect of "all designated states except the US"; this was made by Abbott Bermuda, and not by the inventors, who the PCT application identified as the applicants for the "US only". In doing so he rejected AbbVie's claim that this distinction made no difference because at the time when a PCT application is filed (the point when priority is assessed), it is a single international application.

Nevertheless, having considered the chain of title and following *Edwards Lifesciences v Cook Biotech* [2009] EWHC 1340 (Pat), in which the court held that to make a valid claim for priority as successor in title it is necessary to be a successor in title at the time of filing the application, and *KCI v Smith & Nephew* [2010] EWHC 1487 (Pat), in which the court held that "successor in title" includes a person who was a recipient of the beneficial interest in the invention, Henry Carr J found that on the facts, the challenge to the chain of title failed, and therefore held that Abbott Bermuda was "successor in title" to the invention. The noteworthy fact in this part of the case was that one of the inventors was an employee under German employment law, which provides an employee with the right to claim a service invention, i.e. created in the course of employment. Under this law, an employee is under a duty immediately to provide written notice to their employer of all service inventions which an employer may claim by written statement to the employee no later than four months after receipt of the report. The claimants had

initially argued that the filing of the US priority application constituted written notice such that the employer’s entitlement to claim the invention had expired before the filing of the PCT. However, this argument was abandoned by the end of trial. As the time for the employer to claim the service invention had not started to run, it retained the right to claim the invention at the time of filing the PCT and thus was, in substance, the owner of the invention for the purpose of claiming priority even if legal title resided at that time with the employee.