

Kluwer Patent Blog

Roche successfully shields its bevacizumab patents from Pfizer's Arrow – Pfizer v Roche [2019] EWHC 1520 (Pat)

Philipp Widera (Vossius & Partner) · Wednesday, July 24th, 2019

The case at hand concerned an application by Pfizer for *Arrow*-declarations in relation to its proposed launch of its bevacizumab product (it will be branded “Zirabev”) for the treatment of various cancers in combination with other drugs.

Since Pfizer was unable to show a “useful purpose”, the complaint was dismissed. The mere prospect of using an *Arrow*-declaration in foreign courts is insufficient.

The facts of the case in a nutshell

Pfizer had no problem waiting for launch until expiry of the basic patent SPC in June 2020. However, Pfizer was concerned about Roche’s “thicket of second-line patents and patent applications” relating to combinations of bevacizumab with other known drugs essentially hindering its intended product launch due to the alleged uncertainty caused. For this reason, Pfizer requested declaratory relief that its intended product lacked novelty and/or inventive step at the earliest priority date of Roche’s patents and applications.

However, at the time of trial, Roche had no relevant UK patent and it was undisputed that Roche had “abandoned any prospect of obtaining such a UK patent in future”. Nevertheless, it is important to note that Pfizer planned to supply the UK market from Belgium. In this regard, Pfizer argued that the supply of the patent-free UK market could be hindered by Roche through legal actions in Belgium. Hence, it was Pfizer’s goal to use the UK judgment to influence potentially arising Belgian court actions.

Legal background regarding *Arrow*-declarations

The underlying jurisdiction was established in *Arrow Generics v Merck & Co Inc [2007] FSR 39* and approved by the Court of Appeal in *Fujifilm v AbbVie [2017] EWCA Civ. 1*. Accordingly, English courts have the power to grant declarations that certain acts would have been obvious in light of the prior art at a particular date. In other words, it is admissible for the claimant to seek a declaration that it can rely on a *Gillette*-defence.

At the end of the day, it depends on whether this type of declaratory relief sought serves a “useful purpose”. The existence of pending applications in this regard is necessary but itself insufficient.

Grounds for decision

In assessing the requirement of a “useful purpose”, the following factors were taken into account:

While Birss J only looked at the **prima facie merits of the technical case** (interestingly, Roche did not even try to defend the case on the technical side), given (only) Pfizer’s expert reports, he nevertheless saw a “compelling case” in favour of a *Gillette*-defence.

Regarding **Roche’s conduct**, Birss J conceded that “[n]othing Roche has done is unlawful”. In fact, he assumed that Roche had a bona fide belief in managing to get a valid patent. But still, he saw Roche’s motive for de-designating the UK in **shielding its portfolio from scrutiny** by English courts. The latter assumption was indeed principally sufficient to render an *Arrow*-declaration.

Finally, Birss J saw at least a **commercial value for Pfizer** in the fact that a Belgian court would take into account a UK judgment. Nevertheless, this was insufficient here because there are **no pending UK applications** in any of the relevant patent families. Hence, Birss J did not see any outstanding uncertainty at all relating to UK rights. In his view, there remained uncertainty in Belgium but Belgian courts were better suited to rule on Belgian patents and Belgian law. Any other decision would have amounted to forum shopping.

Outlook

Even though the case was dismissed, the threshold for granting *Arrow*-declarations seems to be rather low. If Roche’s conduct was lawful and it was “entitled to try (...) to get a valid patent”, it is not comprehensible as to why there should be room for *Arrow*-declarations in such circumstances at all. It seems at least questionable whether a mere assumption by the court (even if based only on evidence by the claimant) that the defendant is trying to shield its patent from scrutiny by English courts can be sufficient. There are certainly various reasons for de-designating the UK from one’s patents or applications.

Nevertheless, clear and unambiguous de-designations of the UK from all relevant EP applications very likely impede claims for *Arrow*-declarations even though Birss J concluded that other factors might also justify such declarations, e.g. as assistance in settlement talks. However, these other factors are rather difficult to substantiate.

For a non-UK lawyer, however, what is most striking about the case is the High Court’s acceptance of the fact that “UK courts are in no better position to rule on [Belgian law]” than Belgian courts. Unlike in the *Unwired Planet*-case concerning the determination of FRAND-rates (allowing English courts to become a very attractive forum for FRAND/SEP issues), in the case at hand Birss J carefully seemed to want to avoid any possibility of (future) forum shopping to the UK for pharma matters as well. Given the fact that in most EPC-countries (including Germany) requests for *Arrow*-declarations are inadmissible, a decision to the contrary would have likely caused yet another push in patent matters for English courts.

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