

Court of Appeal refuses Arrow declaratory relief for Teva in a stand against forum shopping and jurisdictional overreach

Teva v Novartis [2022] EWCA Civ 1617

The fingolimod saga continues between Teva and Novartis. In a hearing dated 28 November 2022 before Arnold, Nugee, and Floyd LLJ, Teva appealed the decision of Bacon J in Teva v Novartis [2022] EWHC 2779 refusing the grant of a declaration of non-infringement, better known as an Arrow declaration^[1], against the imminent infringement of Novartis's second medical use patent for 0.5mg fingolimod, European Patent 2, 959, 894 ("EP 894"), the same patent whereby the Court of Appeal upheld a finding in May 2022 to refuse Novartis's application for a preliminary injunction against Teva. Our article summarising that matter can be accessed [here](#). Notably, the Düsseldorf Regional Court also refused a parallel application for injunctive relief brought by Novartis against two other generic drug manufacturers in Germany.

The litigation history

Teva, as well as several other generics seeking to enter the fingolimod market in the UK, commenced proceedings in February 2022 seeking a declaration of non-infringement. This was followed by proceedings commenced by Novartis in March 2022 whereby Novartis sought interim injunctive relief prior to the grant EP 894, which was refused by Roth J and upheld by the Court of Appeal in May 2022 on the basis that damages were sufficiently quantifiable despite concluding that the court had jurisdiction to grant injunctions prior to the grant of a patent.^[2]

Teva gave undertakings not to supply generic fingolimod until the conclusion of the patent validity / infringement trial scheduled for August 2022. Prior to trial, however, Novartis announced its intention to withdraw the UK designation so that EP 894 will not grant in the UK. Following this, Teva sought permission to amend its pleadings, which Meade J allowed in Teva v Novartis [2022] EWHC 2366 but said were a complete replacement of its basis for declaratory relief. Meanwhile, Novartis had reached settlement with the other generics seeking to enter the fingolimod market.

Bacon J heard Teva's new application for declaratory relief with respect to EP 894 and its divisional, European Patent Application No. 3 797 765 ("EP 765"), in October 2022, but after ruling out the need for declaratory relief in order to redress market uncertainty in the UK, found that Teva had no compelling justification for the grant of such relief as its purpose would solely be to influence a foreign court on an issue governed by the law of that foreign court. Teva appealed that decision on the basis that the judge had incorrectly applied the law regarding Arrow declarations. The Court of Appeal dealt with each of Teva's submissions by applying the legal principles below.

Declaratory relief and Arrow relief

The Patents Court has the discretion to decide whether Teva would infringe EP 365 before its grant and without having to decide its validity. The benefit Teva would enjoy were it granted declaratory relief would be a Gillette defence to any subsequent claim for patent infringement in relation to its generic fingolimod products. [3] However, since Novartis abandoned the UK designation for EP 894 and EP 765, Teva could not rely on its non-infringement position alone in order to pre-emptively establish a Gillette defence. As such, the only option open to Teva was to rely on other reasons for the grant of declaratory relief.

Declarations in respect of foreign patents

In the appropriate case, the Patents Court can grant declaratory relief with respect to a foreign patent. Although such a finding requires the application of foreign law, the English court can make the substantive decision on infringement. [4]

"Spin-off value" of judgments of the Patents Court

As a Contracting State of the European Patent Convention, English courts generally follow, but are not bound by, the settled case law of the Boards of Appeal of the EPO and other Contracting States (and vice versa). Such influence, or "spin-off value", may be considered persuasive by other European courts, with this case focusing on its persuasiveness on the German court.

Declaratory relief in aid of foreign proceedings

While the Court of Appeal accepted the relevance of spin-off value in the context of patents or patent applications designated in the UK where the Patents Court can decide the issue applying foreign law, Teva's application sought to use an Arrow declaration for the sole purpose of influencing a foreign court applying its own law to an issue before it. In the absence of a UK designation, the Court of Appeal looked to four cases which have previously considered the issue as to whether the Patents Court should make a declaration for use in foreign proceedings:

1. Fujifilm v AbbVie^[5] – granted

The court found special reasons which supported the grant of the declarations, including AbbVie's conduct of threatening infringement whilst abandoning proceedings at the last moment, the large sum of damages that would be available to Fujifilm if they were to launch at risk, and the need for commercial certainty considering AbbVie's threats to sue for infringement in the UK and globally. A further reason the declarations would serve a useful purpose was the likelihood of preliminary injunctions being granted by foreign courts affecting Fujifilm's supply chains for the UK market, but that was not the sole purpose.

2. Pfizer Ltd v F. Hoffmann-La Roche AG^[6]– refused

The court considered Roche's motive for de-designating the UK from its patents was to shield the patents from risk of an adverse decision in the Patents Court, and that an Arrow declaration would reduce Pfizer's commercial uncertainty across the European market by assisting it to resist a claim for patent infringement brought by Roche from where Pfizer intended to supply the UK market (Belgium). The court, however, refused to grant a declaration on the basis that there was no outstanding uncertainty related to UK rights, distinguishing it from Fujifilm. Further, the market uncertainty related to goods to be supplied in the UK from Belgium, and so allowing UK ruling would be a form of forum shopping.

3. TQ Delta LLC v ZyXEL Communications UK Ltd^[7]– refused

The Court of Appeal found that although an Arrow declaration would have utility in foreign jurisdictions where there were proceedings for injunctive relief with respect to patent infringement, it was considered "an exercise in jurisdictional imperialism"^[8] for an English court to make such a determination where such issues are far better decided in a foreign court.

4. Lisa Dräxhmaier GmbH v BOS GmbH & Co KG^[9]– refused

p4

The court found that a claim for declaration of non-infringement under section 71 of the 1977 Act brought “solely or essentially for the purpose of the decision being used to influence a foreign court ... should be struck out as an abuse, or at the very least stayed on case management grounds”,^[10] and that the claim should never have been brought before an English court as the claimant's essential purpose was to influence the German court.

Conclusion of the Court of Appeal regarding foreign proceedings

In light of the case law, and on the presumption that the parties had and have full and unimpeded access to the foreign court, the Court of Appeal ultimately decided that it was wrong for an English court to make a declaration solely for the purpose of influencing a decision by a foreign court on an issue governed by the law of the foreign court. Further, it was considered irrelevant that the English court and foreign court would be applying the same basic law on the basis that “comity requires restraint on the part of the English courts”.^[11]

Teva's other reasons

Teva submitted a slew of other reasons with respect to market uncertainty in support of its claim for declaratory relief, each of which the Court of Appeal agreed were correctly dismissed. The first was that Novartis should be restrained from further conduct following its withdrawal of the UK designation directly before trial after seeking injunctive relief with respect to the same patents just months prior. Though the court considered it was relevant to the “useful purpose” test, Novartis's past conduct alone was not enough to warrant declaratory relief. Teva also submitted that an Arrow declaration would assist the NHS in removing uncertainty as to the status of the market for 0.5mg fingolimod, but as Novartis had notified the NHS of its abandonment of the UK for its patents, the court found such uncertainty unlikely. Teva further submitted that although it was presented with undertakings by Novartis, they were too ambiguous to provide Teva with any certainty with respect to the UK market. However, as Novartis had since rectified the alleged ambiguity in the undertakings, the court found there to be no ongoing uncertainty.

Finally, Teva argued that the supply chain for Teva's generic product would involve transit through confidential “Country A”, and that an injunction against Teva in Country A would disrupt the supply chain to the UK market. Following Birss J's approach in *Pfizer v Hoffmann-La Roche*, Bacon J considered that this did not change the fact that the purpose of the Arrow declaration was to use it in foreign courts rather than to obtain or

enforce any right in the UK.

p5

Court of Appeal dismisses Teva's appeal

In agreement, the Court of Appeal considered that once the judge had found that a declaration was not required in order to redress uncertainty in the UK market, the only purposes which could be served by a declaration was to assist foreign court (Germany and Country A) in deciding issues under their own laws, which the Court of Appeal repeated is not a legitimate reason for the grant of declaratory relief.

[1] Arrow Generics Ltd v Merck & Co Inc [2007] EWHC 1900 (Pat), [2008] Bus LR 487.

[2] Novartis AG v Teva UK Ltd & Ors [2022] EWHC 959 (Ch).

[3] Gillette Safety Razor Co v Anglo-American Trading Co Ltd (1913) 30 RPC 465.

[4] Actavis Group HF v Eli Lilly & Co [2012] EWHC 3316 (Pat).

[5] [2017] EWHC 395.

[6] [2019] EWHC 1520.

[7] [2019] EWCA Civ 1277.

[8] Ibid, [52] per Floyd LJ.

[9] [2022] EWHC 2823.

[10] Ibid, [77] per Sir Anthony.

[11] [51] per Arnold LJ.