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Case Nos: CA-2022-002097, 002098

IN THE COURT OF APPEAL (CIVIL DIVISION) ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (ChD), PATENTS COURT Mrs Justice Bacon [2022] EWHC 2779 (Pat)

Royal Courts of Justice Strand, London, WC2A 2LL

Date: 8 December 2022

Before :

LORD JUSTICE ARNOLD LORD JUSTICE NUGEE and SIR CHRISTOPHER FLOYD

Between :

(1) TEVA UK LIMITED
 (2) TEVA PHARMACEUTICAL INDUSTRIES

 LIMITED
 - and NOVARTIS AG

<u>Claimants/</u> <u>Appellants</u>

Defendant/ Respondent

(1) NOVARTIS AG <u>Claimants/</u> (2) NOVARTIS PHARMACEUTICALS UK LIMITED <u>Respondents</u> - and -TEVA UK LIMITED Defendant/

<u>Defendant/</u> <u>Appellant</u>

Justin Turner KC and Katherine Moggridge (instructed by Pinsent Masons LLP) for the Appellants Andrew Waugh KC and Geoffrey Pritchard (instructed by Bristows LLP) for the Respondents

Hearing date : 28 November 2022

Approved Judgment

This judgment was handed down by the Court remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for hand-down is deemed to be 10:30 on 8 December 2022.

Lord Justice Arnold:

Introduction

1. Is it proper for the courts of England and Wales 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? That is the question raised by this appeal. On 19 October 2022 Bacon J dismissed the Appellants' ("Teva's") claim for a so-called *Arrow* declaration for the reasons given in her judgment of the same date ([2022] EWHC 2779 (Pat)). On 28 November 2022 this Court dismissed Teva's appeal for reasons to be given in writing. This judgment sets out my reasons for concluding the appeal should be dismissed.

Factual background

- 2. The Respondents ("Novartis") market fingolimod, an S1P receptor modulator, for the treatment of relapsing-remitting multiple sclerosis ("RRMS") throughout the European Union and in the United Kingdom under the trade mark Gilenya. The market for Gilenya is a very valuable one, worth some \$2.8 billion worldwide. It is Novartis' second biggest selling product in the UK with annual sales of £46 million.
- 3. Gilenya was authorised by the European Medicines Agency on 17 March 2011. Until October 2018 fingolimod was protected in the UK by European Patent (UK) No. 627 406 and Supplementary Protection Certificate SPC/GB11/026 owned by Mitsubishi Tanabe and licensed to Novartis. Regulatory data exclusivity for Gilenya expired on 22 March 2022 (having been extended by a year due to the approval of an additional indication).
- 4. Novartis own a number of families of patents and patent applications protecting formulations of, and dosage regimes for, fingolimod. These include a family claiming a daily dose of 0.5 mg fingolimod administered orally for the treatment of RRMS. The members of this family include:
 - i) International Patent Application No. WO2008/000419 filed on 25 June 2007 claiming priority from 27 June 2006.
 - ii) European Patent Application No. 2 037 906 deriving from the International Application. There was no limitation with respect to dosage in any of the original claims, but in March 2009 amended claims were filed which included dependent claims to wide ranges of active ingredient. Novartis withdrew this application in April 2015.
 - iii) A first divisional application, European Patent Application No. 2 698 154, was filed in September 2013, but deemed withdrawn in May 2016.
 - iv) A second divisional application, European Patent Application No. 2 959 894 ("EP894"), was filed in July 2015. As filed, EP894 claimed the use of an S1P receptor modulator in the preparation of a medicament for preventing, inhibiting or treating neoangiogenesis associated with demyelinating disease e.g. multiple sclerosis. On 29 June 2016 the claims were amended to restrict them to the use of fingolimod for the treatment of RRMS at a daily dosage of

0.5 mg p.o. On 29 November 2020 EP894 was refused by the Examining Division of the European Patent Office for lack of novelty over a Novartis press release. On 8 February 2022 the Technical Board of Appeal allowed Novartis' appeal for reasons given in writing on 3 June 2022 (Case T 108/21). On 18 August 2022 the EPO issued notice of its intention to grant EP894. EP894 was granted on 12 October 2022. Ten parties, including Teva, have so far filed oppositions. Given that the period for opposition does not expire until 12 July 2023 and the likelihood that any decision of the Opposition Division will be appealed to the Technical Board of Appeal, it is probable that the opposition proceedings will not be finally determined for some years.

- v) A third divisional application, European Patent Application No. 3 797 765 ("EP765"), was filed in November 2020. This also claims fingolimod at a daily dose of 0.5 mg p.o. for the treatment of RRMS.
- 5. Teva have obtained a marketing authorisation for generic fingolimod. On 25 February 2022 Teva commenced a claim in the Patents Court seeking an *Arrow* declaration that the importation, disposal, use and keeping by Teva of generic fingolimod in the UK for use in the treatment of RRMS at a daily dosage of 0.5 mg p.o. would have been obvious as at 27 June 2006 (i.e. the priority date of EP894) in light of three items of prior art.
- 6. On 2 March 2022 Novartis commenced a cross-claim against Teva and five other manufacturers or suppliers of generic drugs, and applied for an interim injunction to prevent the marketing of generic fingolimod in the UK. Teva and three of the other defendants counterclaimed for *Arrow* declaratory relief.
- 7. Novartis' application for an interim injunction was heard by Roth J on 17 and 18 March 2022. On that application, Novartis contended that they had standing to apply for an interim injunction even though EP894 had not yet been granted because, as a result of the decision of the Board of Appeal, it was certain that EP894 would be granted, and when it was granted EP894 would have effect back to the publication of the application in December 2015 pursuant to section 69 of the Patents Act 1977. At the end of the hearing Roth J reserved judgment. Teva and three other defendants gave undertakings not to supply generic fingolimod in the UK pending judgment in return for a cross-undertaking in damages from Novartis.
- 8. On 26 April 2022 Roth J refused Novartis' application for an interim injunction for the reasons given in his judgment of the same date ([2022] EWHC 959 (Ch), [2022] Bus LR 888), but granted Novartis an injunction to prevent the defendants from supplying generic fingolimod in the UK until the determination of their application for permission to appeal, again subject to a cross-undertaking in damages. Roth J also ordered an expedited trial of the two sets of proceedings to be heard together, commencing on or around 3 October 2022.
- 9. On 25 May 2022 Birss LJ refused Novartis permission to appeal from Roth J's refusal of the interim injunction for the reasons given in his judgment of that date ([2022] EWCA Civ 775).

- 10. On 10 August 2022 Novartis informed Teva that they were removing the UK designation from EP894 and EP765. On 11 August 2022 Novartis applied to discontinue their infringement claim against all of the defendants.
- 11. On 2 September 2022 Novartis applied in effect to strike out Teva's claim and counterclaim for an *Arrow* declaration. On 6 September 2022 Teva applied to amend their statements of case in both actions. On 16 September 2022 Meade J declined to strike out Teva's claims and allowed the amendments subject to further particularisation ([2022] EWHC 2366 (Pat)). Meade J also directed a two-day trial on 17 and 18 October 2022 of Teva's claim for an *Arrow* declaration confined to the issue of whether, as a matter of discretion, a declaration should be granted in circumstances where Novartis do not have patent protection for a 0.5 mg dosage regime in the UK.
- 12. As regards the technical question of whether the subject-matter of the claim is obvious, Novartis have not put in any evidence and have said that they will not cross-examine Teva's witnesses or make submissions to defend the inventiveness of what is claimed in EP894. Meade J therefore directed that the trial of the discretionary issue would proceed on the assumption that Teva are correct that the relevant subject-matter is obvious. If the court concluded that it was appropriate to exercise its discretion to grant a declaration, then there would be a further short hearing to determine the question of obviousness.
- 13. On 19 October 2022 Bacon J gave judgment refusing to grant an *Arrow* declaration. Bacon J refused permission to appeal, but on 8 November 2022 I granted permission to appeal and expedited the appeal at Teva's request. The reason for expediting the appeal is that on 12 October 2022 Novartis commenced proceedings for infringement of EP894, and applied for preliminary injunctions, against Teva in a number of EU Member States, including Germany. The application in Germany is due to be heard on 15 December 2022. Teva wished, if successful on the appeal and on the subsequent determination of the issue as to obviousness, to be in a position to rely upon the *Arrow* declaration and upon the court's reasoned judgment on the issue of obviousness at that hearing.
- 14. Although Teva have, for reasons of procedural economy, only adduced expert evidence as to the extent to which the German courts would have regard to an English judgment, Teva are also concerned about the possibility of a preliminary injunction in Country A. Teva's supply chain for their generic fingolimod product involves the product passing through Country A before reaching the UK. The identity of Country A is confidential.

Applicable legal principles

Declaratory relief

15. The High Court, which includes the Patents Court, has an inherent jurisdiction (the existence of which is confirmed by CPR rule 40.20) to make a declaration, including a negative declaration, that is to say, a declaration that a party is not under a liability. The foundation for the modern law as to the exercise of this jurisdiction is the judgment of Lord Woolf MR, with whom Hale LJ and Lord Mustill agreed, in *Messier-Dowty Ltd v Sabena Ltd* [2000] 1 WLR 2040 at [41]:

"Lord Wilberforce and Lord Denning M.R. differed in the circumstances of [an earlier] case as to whether the declaration would serve a *useful* purpose. However, if it would, that it would then be appropriate to grant a declaration was agreed. The approach is pragmatic. It is not a matter of jurisdiction. It is a matter of discretion. The deployment of negative declarations should be scrutinised and their use rejected where it would serve no useful purpose. However, where a negative declaration would help to ensure that the aims of justice are achieved the courts should not be reluctant to grant such declarations. They can and do assist in achieving justice. ... So in my judgment the development of the use of declaratory relief in relation to commercial disputes should not be constrained by artificial limits wrongly related to jurisdiction. It should instead be kept within proper bounds by the exercise of the court's discretion."

16. Another much-cited statement is that of Neuberger J in *Financial Services Authority v Rourke* [2002] CP Rep 14 where he said, after citing *Messier-Dowty*:

"It seems to me that, when considering whether to grant a declaration or not, the court should 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."

Arrow declarations

- 17. Arrow declarations take their name from the seminal decision of Kitchin J (as he then was) in Arrow Generics Ltd v Merck & Co Inc [2007] EWHC 1900 (Pat), [2008] Bus LR 487. An Arrow declaration is a declaration that a product, process or use was lacking in novelty or obvious as at the priority date of a patent application. The point of such declaration is that it is in effect a declaration that the claimant will have a *Gillette* defence to any subsequent claim for patent infringement in relation to that product, process or use: see *Gillette Safety Razor Co v Anglo-American Trading Co Ltd* (1913) 30 RPC 465. Thus it enables the court pre-emptively to determine a patent infringement case before the patent has even been granted without having to decide whether the patent would be invalid, or not infringed because the claimant's product, process or use would not fall within the claims, if and when granted.
- 18. The jurisdiction of the Patents Court to grant an *Arrow* declaration was confirmed by this Court in *Fujifilm Kyowa Kirin Biologics Co Ltd v AbbVie Biotechnology Ltd* [2017] EWCA Civ 1, [2018] Bus LR 228, where Floyd LJ giving the judgment of the Court (himself, Longmore and Kitchin LJJ) said at [98]:

"We have said enough to explain why we do not consider that there is any issue of principle which prevents the granting of *Arrow* declarations in appropriate cases. Drawing the threads together: (i) A declaration that a product, process or use was old or obvious at a particular date does not necessarily offend against section 74 of the 1977 Act. (ii) Such a declaration may offend against the 1977 Act where it is a disguised attack on the validity of a granted patent. (iii) Such declarations do not offend against the scheme of the EPC or the Act simply because the declaration is sought against the background of pending divisional applications by the counter-party. (iv) On the other hand the existence of pending applications cannot itself be a sufficient justification for granting a declaration. (v) Whether such a declaration is justified depends on whether a sufficient case can be made for the exercise of the court's discretion in accordance with established principles."

19. One of the submissions made by counsel for AbbVie in that case (see [73(vi)]) was that to allow *Arrow* declarations "would be to open the floodgates, so that a claimant faced with patent problems in, say, Romania could come to the English court for a declaration that a product is obvious, because it would be useful for him in connection with his business there". The Court rejected this submission at [95] for the following reasons:

"We are not persuaded that declarations in the *Arrow* form will open any floodgates. The *Arrow* decision is now of some age, and has not resulted in many such cases being brought. The circumstances in which such declarations will be justified, will, we would have thought, be uncommon. [Counsel for AbbVie]'s example of a business problem in Romania would be unlikely to justify the grant of a declaration by the English court."

- 20. In *Glaxo Group Ltd v Vectura Ltd* [2018] EWCA Civ 1496, [2019] Bus LR 648 Floyd LJ (with whom Birss J, as he then was, agreed) said:
 - "24. In my judgment paras 98(iv) and 98(v) of this court's judgment in the Fujifilm case [2018] Bus LR 228 need to be read together, taking into account what was said in para 93. The statutory remedy of revocation (and I would add the declaration of non-infringement) are remedies which are available if a relevant patent exists. Thus 'any person' may bring a revocation action by identifying a granted patent and without the need to show any particular commercial interest: see section 72 of the Patents Act 1977 and Cairnstores Ltd v Aktiebolaget Hässle [2002] FSR 35. Similarly a person wishing to obtain a declaration of non-infringement needs to do no more than identify the patent and provide the statutory particulars of his proposed act: see section 71 of the Patents Act 1977. The person seeking revocation, or a declaration of non-infringement, does not need to justify the need for the relief any further. As Jacob LJ said in Nokia Corpn v Interdigital Technology Corpn [2007] FSR 23, para 17:

'Section 71 requires no claim of right nor even any intention by the applicant for a declaration to make or do the acts, the subject matter of the declaration he seeks. Normally, of course, the applicant will at least have in mind the possibility of doing those acts but whether he does or not is irrelevant. The only question is whether the patent covers what is described in the full particulars called for by section 71(1)(a).

- 25. The jurisdiction to grant an *Arrow* declaration is by contrast discretionary. Identification of a relevant application is a necessary but not sufficient condition for an application for such relief. It is necessary to go further and examine whether it would serve a useful purpose. The point being made by paras 98(iv) and 98(v) in the *Fujifilm* case is the contrast between a remedy which depends only on the existence of a patent (or application) and one whose availability turns on a critical examination of the purpose which its grant would serve."
- 21. When the *Fujifilm v AbbVie* case reached trial, Henry Carr J decided to exercise his discretion to grant an *Arrow* declaration: [2017] EWHC 395 (Pat), [2018] RPC 1. By contrast, Birss J refused to grant an *Arrow* declaration in *Pfizer Ltd v F. Hoffmann-La Roche AG* [2019] EWHC 1520 (Pat), [2019] RPC 14. I shall consider their reasons for reaching these conclusions below.
- 22. It will be appreciated that, although EP894 was still a pending application at the date when Teva commenced their claim for an *Arrow* declaration, it has subsequently proceeded to grant. It is not in dispute that the Patents Court has jurisdiction to make an *Arrow* declaration even though EP894 has proceeded to grant (cf. *Mexichem UK Ltd v Honeywell International Inc* [2020] EWCA Civ 473, [2020] RPC 11 at [31] (Floyd LJ, with whom Lewison LJ agreed)). This is for two reasons. First, although section 74(1) of the 1977 Act provides that the validity of a patent can only be put in issue in certain specified types of proceedings, that is not an obstacle since neither EP894 nor EP765 designate the UK. Secondly, EP765 has not yet proceeded to grant.
- 23. It follows, however, that Teva cannot invoke the Patents Court's jurisdiction to grant an *Arrow* declaration in order pre-emptively to establish a *Gillette* defence to any claim for patent infringement, because Novartis have abandoned any possibility of obtaining patent protection in the UK in respect of the 0.5 mg daily dosage regime. Instead, Teva must rely upon other reasons for the grant of declaratory relief.

Declarations in respect of foreign patents

24. The Patents Court has the power in an appropriate case to make a declaration as to whether or not a foreign patent has been or will be infringed. For example, in *Actavis Group HF v Eli Lilly & Co* Actavis sought a declaration of non-infringement in respect of the UK, French, German, Italian and Spanish designations of a European patent owned by Lilly. Actavis did not challenge the validity of the patent. Lilly challenged the jurisdiction of the Patents Court in respect of the foreign patents on *forum non conveniens* grounds, arguing that the courts of the countries in question were better placed to apply their respective national laws to the issue of infringement, but that challenge was rejected ([2012] EWHC 3316 (Pat)), as was an appeal on other grounds ([2013] EWCA Civ 517, [2013] RPC 37). Although such a claim requires foreign law to be applied, the substantive decision on infringement is taken by the English court.

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

- 25. The UK is a Contracting State of the European Patent Convention. As such, it has aligned much of its patent law, and in particular the provisions of the 1977 Act concerning the validity and scope of protection of patents, with the corresponding provisions of the EPC. In addition, the courts of the UK, including the courts of England and Wales, generally follow the settled case law of the Boards of Appeal of the EPO even though such case law is not binding upon them. The same is true of the other Contracting States. The UK also implemented the key provisions of the CPC never came into force, as did a number of EU Member States. It follows that, to a large extent, the courts of EPC Contracting States, and even more so the courts of the States which implemented the CPC, apply the same basic law.
- 26. As well as applying the same basic law, these courts are often called upon to adjudicate parallel disputes concerning different national designations of the same European patent. In most cases the different designations are identical, and only differ as to the territory in which they have legal effect.
- 27. It follows that, where one court in Europe has given judgment concerning an issue as to the validity or infringement of a European patent, its reasoning is likely to be relevant to the determination of the same issue by other courts in Europe. In principle, the courts should be in a position to give the same answers to the questions before them. In reality, this is less straightforward than theory might suggest, for a number of reasons. Although the substantive law is substantially harmonised, it is not completely harmonised due to the persistence of differing national traditions and the absence of a supranational court to give binding rulings upon the interpretation of the EPC (let alone the CPC). Even if the substantive law is often different, and the arguments of the parties may also differ. Thus the outcome in one country does not dictate the outcome in other countries. The courts of most countries in Europe do, however, have regard to the judgments of the courts of other countries when made aware of them (which does not always happen).
- 28. There is a body of English case law which establishes that, in some circumstances, it is legitimate for the court to take into account what has been referred to as the "spin-off value" of a judgment of the Patents Court, that is to say, its value to the successful party going beyond the legal effect of the judgment within the UK. There are two kinds of "spin-off value" which are commonly referred to. The first is that the judgment of the Patents Court, as a respected specialist court which gives detailed reasons for its conclusions, may assist the parties to negotiate a wider settlement of their dispute, that is to say, a settlement which embraces other countries within Europe (or even the whole world). The second is that the judgment of the Patents Court may, for the reasons explained above, be considered persuasive by the courts of other countries in Europe. It is the second kind of "spin-off value" which is relevant for present purposes.
- 29. Although a judgment of the Patents Court may have "spin-off value" in many European countries, experience shows that in many cases the parties are most interested in its potential "spin-off value" in Germany. There are two main reasons for this. First, Germany is the largest market in Europe for many kinds of goods.

Secondly, for constitutional reasons Germany has a bifurcated system for adjudicating upon patent disputes. An infringement claim must be brought before a Landgericht (Regional Court), whereas a claim for revocation must be brought before the Bundespatentgericht (Federal Patent Court). In general, the Regional Courts are quicker than the Federal Patent Court. Furthermore, it is not possible to attack the validity of a European patent (DE) either before the expiry of the opposition period (9 months after grant) or, if an opposition is filed at the EPO, until the conclusion of those proceedings. These features of the German system lead to the so-called "injunction gap", whereby it can happen that the Regional Court grants an injunction to restrain infringement of a patent which is later found to be invalid by the Federal Patent Court. (Appeals lie from both courts (in the case of the Landgericht, via an Oberlandesgericht (Higher Regional Court)) to a common apex court, the Bundesgerichtshof (Federal Court of Justice)). Under German law an injunction was formerly an automatic remedy for a finding of patent infringement. Recently the German Patents Act has been amended to introduce a proportionality test, but it seems unlikely that this will lead to injunctions being refused in many cases. The Regional Courts do, however, have discretion to stay the injunction pending the determination of invalidation proceedings if persuaded that there is a high likelihood of the patent being found invalid. A judgment of the Patents Court finding a European patent invalid may be of particular utility for this purpose. A judgment of the Patents Court finding that a European patent has not been infringed may also be of some value in seeking to persuade the Regional Court to reach the same conclusion, but in general judgments of the Patents Court are less likely to have persuasive force on questions of infringement than on questions of validity, because the Regional Court has equal competence to determine issues of infringement of a European patent to the Patents Court, whereas it is not competent to determine issues of validity.

- 30. The "spin-off value" of a judgment of the Patents Court has been taken into account in a number of different contexts. First, it is common for parties seeking an expedited or early trial of a patent dispute to rely upon this in support of their application for expedition or for an early date to be fixed. I know of no case in which this has been the sole reason for the Patents Court granting expedition or fixing an early trial date, but there have been numerous cases in which it has been a factor in the decision. Perhaps the high-water mark of this line of authorities is the decision of Henry Carr J in *Takeda UK Ltd v F. Hoffmann-La Roche AG* [2018] EWHC 2155 (Ch) to order an early trial date for Takeda's claim for revocation and a potential counterclaim by HLR for infringement. Although Takeda relied upon its general desire for commercial certainty as soon as possible, it particularly wanted a trial date in June 2019 in the hope of getting a judgment in time to put before the Düsseldorf Regional Court at a hearing on 18 July 2019. As to that, Henry Carr J said:
 - "11. In my view, it is important to give Takeda at least the opportunity of obtaining a judgment from the UK court, which may have some influence on the Düsseldorf court hearing the infringement action. By a decision of the Bundesgerichtshof, dated 15th April 2010, Xa ZB 10/09, *Roll-Forming Machine*, the Federal Supreme Court held that:

'The German courts are required to consider decisions rendered by organs of the European Patent Office and courts in other EPC contracting states and pertaining to a largely similar issue and, where appropriate, address the reasons leading to a diverging result in the earlier decision. Insofar as points of law are concerned, this also applies, for instance, to the question of whether the subject-matter of a property right was obvious in the light of prior art.'

- 12. The UK courts are always very interested to see decisions of our German colleagues and judges of other EPC Contracting States pertaining in particular to equivalent patents. If I were hearing an infringement case in the UK, I would be very interested to see what decision the German courts had reached."
- 31. It may be worth recording what happened subsequently, however. Birss J gave judgment on 17 July 2019 finding the European patent in suit invalid ([2019] EWHC 1911 (Pat), [2019] RPC 18). The Düsseldorf Regional Court took the judgment into account, but was not persuaded that it demonstrated that there was a high likelihood that the patent would be held invalid. As the Court stated in its judgment dated 20 September 2019 4b O 7/18 at [211] (in translation):

"The fact that the hearings of an expert led the English court to the conclusion that the patent in the suit did not make a technical contribution to progress did not itself constitute a circumstance that would render the EPO decision manifestly incorrect. At most, there are two conflicting decisions on this point with regard to the inventive step, although in this situation the board cannot predict with sufficient certainty which result the Federal Patent Court will reach."

I understand that the parties subsequently settled the dispute.

- 32. Secondly, "spin-off value" has been taken into account when deciding whether to stay English proceedings pending the determination of opposition proceedings in the EPO. In this context the focus has been upon the first kind of "spin-off value" described in paragraph 28 above, rather than the second kind: see in particular *Glaxo Group Ltd v Genentech Inc* [2008] EWCA Civ 23, [2008] Bus LR 888 at [33] (Mummery LJ giving the judgment of the Court of Appeal, the other members of the Court being Ward and Jacob LJJ) and *IPCom GmbH & Co KG v HTC Europe Co Ltd* [2013] EWCA Civ 1496, [2014] Bus LR 187 at [56] (Floyd LJ, with whom Rafferty and Patten LJJ agreed). In principle, however, it seems to me that it may be possible in an appropriate case for the party attacking the validity of a European patent to rely upon the second kind of "spin-off value", as suggested in *Terrell on the Law of Patents* (18th ed) at 19-213.
- 33. Thirdly, "spin-off value" has been taken into account when deciding whether a claim brought in the Patents Court is an abuse of process. In *TNS Group Holdings Ltd v Nielsen Media Research Inc* [2009] EWHC 1160 (Pat), [2009] FSR 23 the claimant brought a claim for revocation of a European patent (UK). The defendant applied to strike out the claim as an abuse of process on two distinct bases. The first was that,

having regard to a licence offered by the defendant, the claim constituted pointless and wasteful litigation. I rejected this basis on the ground that section 72(1) of the 1977 Act provides that "any person" may apply to revoke a patent, and it is settled that a claimant does not need to have any interest in revoking the patent. The second basis was that the claim had been brought for an improper or collateral purpose, relying upon evidence given on behalf of the claimant that a decision of the Patents Court would be of value to it because (among other reasons) the decision could be "exported' to other national courts". I rejected this basis for the reasons I gave at [26]:

"In my judgment, those authorities demonstrate that it is perfectly legitimate for the claimant to seek to obtain a judgment of this court on the validity of the patent in suit in the hope that it will lead to a settlement of the dispute between the parties throughout Europe. Nor, in my judgment, would it be in any way illegitimate for the claimant, absent such a settlement being achieved, to seek to rely upon the judgment of the English court in proceedings before the courts of other contracting states or the European Patent Office. It is commonplace for parties litigating on the same European patent in a number of contracting states to put before the courts of one contracting state decisions arrived at in one or more other contracting states. I do not see that such conduct can possibly be stigmatised as an abuse of process. That is particularly so given that such judgments may come to the attention of courts in other contracting states in any event. The courts of all the contracting states are seeking to apply the same substantive law. It would be most unfortunate if anything were to be done which made it more difficult for the courts of the contracting states to arrive at common answers to common questions."

34. On the other hand, "spin-off value" does not justify the expenditure of substantial resources on trying academic questions, such as whether specific grounds for revocation are established when the patentee has consented to revocation: see *Fresenius Kabi Deutschland GmbH v Carefusion 303 Inc* [2011] EWHC 2959 (Pat).

Declaratory relief in aid of foreign proceedings

- 35. It is one thing for a party to rely upon the "spin-off value" of a judgment of the Patents Court concerning a patent or patent application designating the UK. It is quite another for a claimant to seek a declaration from the Patents Court for the sole purpose of influencing a foreign court applying its own law to an issue before it (as opposed to the Patents Court itself deciding the issue applying the foreign law).
- 36. I emphasise that I am considering the position where the issue before the foreign court is governed by the law of that country, albeit that the relevant foreign law is substantially harmonised with the relevant UK law. Different considerations arise where an English court is asked to determine an issue of English law for the assistance of a foreign court, particularly if there is a contractual provision conferring jurisdiction upon the courts of England.

- 37. That was the position in *Deutsche Bank (China) Co Ltd v Bright Food Hong Kong Ltd* [2017] EWHC 3543 (Comm). In that case, the claimant ("DBSH") was a Chinese subsidiary of Deutsche Bank AG ("DBAG") and the defendant ("BFHK") was a Hong Kong company. BFHK and DBAG had entered into a series of currency swap transactions on the terms of a 2002 ISDA Master Agreement which provided for English law to be the applicable law and included a non-exclusive English jurisdiction clause. BFHK had brought proceedings against DBSH in Shanghai contending that DBSH was a party to the transactions and owed BFHK certain duties in relation to them. DBSH brought proceedings in the Commercial Court claiming a declaration that it had never been a party to any of the transactions or owed any duties to BFHK. BFHK did not contest jurisdiction and did not file a defence. DBSH applied for summary judgment. Cockerill J was satisfied that the grant of a declaration was appropriate as a matter of discretion for the following reasons:
 - "29. ... Given the proceedings in the People's Republic of China courts, there is reason to believe that a declaration of the position as a matter of English law given by an English court may be of utility to the claimant and it may also be of utility to the courts of People's Republic of China In those circumstances, one might say that a negative declaration would help to ensure that the aims of justice are achieved, that being one of the criteria which the authorities establish.
 - 30. So far as the recent caution to this court to be careful when granting declarations for a foreign court it is said that this is not simply a declaration which is sought in relation to a foreign court. In any event the declaration may be of utility to the claimant in the United Kingdom and this is a rather different case to the kinds of cases where the court has been wary about granting a declaration in relation to circumstances which are likely to be predominantly debated before a foreign court. There is, it is said, no element of forum shopping here because there is a non-exclusive English jurisdiction clause and the contracts are governed by English law. It is not a question of there being a number of possible fora which could be equally appropriate.
 - 31. I accept this submission. This is a case where DBSH should be entitled to seek a declaration in any event, because the case is uniquely within this court's ability to judge the position so far as the contract is concerned because it is an English law contract. It may be of utility here, even if its obvious use is for a foreign court. It is not a forum shopping case. ..."
- 38. Other than the present case, the issue as to whether the Patents Court should make a declaration for use in foreign proceedings has been considered in four cases. I shall consider them in chronological order.
- 39. The first is *Fujifilm v AbbVie*. As discussed above, that was a claim for an *Arrow* declaration. Henry Carr J said at [374]:

"I accept that the spin-off value of a judgment in a contracting state can be very valuable, and it is legitimate for parties to rely upon such judgments in other contracting states. However, it is important not to extend this principle too far. Statements as to the spin-off value of UK judgments have been made in the context of applications to stay pending resolution of EPO oppositions, or of applications to expedite trials. Those cases are very different from the present. It is also important to guard against forum shopping, where a declaration from the UK court is sought in cases which have no connection with this jurisdiction."

- 40. He went on to hold at [394]-[410] that an *Arrow* declaration would serve a useful purpose in that case because: (i) AbbVie had abandoned its UK patents in order to shield them from scrutiny by the UK courts; (ii) AbbVie had created commercial uncertainty in the UK market by making threats that it would enforce its patents against biosimilar competition anywhere in the world and that uncertainty would impede the marketing of the claimants' products in the UK; (iii) the undertakings offered by AbbVie would not dispel that uncertainty, whereas an *Arrow* declaration would do, which was why AbbVie had not submitted to judgment or provided an acknowledgement in the same form; (iv) the declaration would protect the claimants' supply chains for the UK market because it would make injunctive relief in other jurisdictions less likely; and (v) it was reasonably foreseeable that the grant of the declaration would promote a settlement on a European or even worldwide basis.
- 41. He concluded his assessment of useful purpose by saying:
 - "411. I now turn to the question of spin-off value. The claimants submit that the declarations will be influential in other European Courts and tribunals, and will make it more difficult for AbbVie to obtain preliminary injunctions, particularly in jurisdictions where validity cannot be challenged whilst patents are under opposition in the EPO.
 - 412. I accept that the spin-off value of a judgment in a contracting state can be very valuable, and it is legitimate for parties to rely upon such judgments in other contracting states. However, on reflection and having regard to the legal principles which I have set out above, I have not taken this into account other than to the extent that this issue may have an impact on the UK market"
- 42. Having concluded that it was just to the claimants to grant a declaration and that there was no injustice to AbbVie, he turned to consider whether there were special reasons for or against granting it and said at [416]:

"I consider that, on the most unusual facts of this case, there are special reasons which support the grant of the declarations. These include 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 launch at risk; and the need for commercial certainty, having regard to AbbVie's threats to sue for infringement throughout the world."

- 43. It can be seen from Henry Carr J's reasoning that the effect of the declaration on the likelihood of preliminary injunctions being granted by foreign courts which affected the claimants' supply chains for the UK market was one of the reasons why he concluded that it would serve a useful purpose. It was not the sole reason, however. Moreover, as I read his judgment, it was not the most important reason either. Rather, the most important reason was that the declaration would dispel the uncertainty in the UK market which AbbVie had created and which AbbVie was not prepared voluntarily to take sufficient steps to resolve.
- 44. The second case is *Pfizer v Hoffmann-La Roche*. This was another claim for an *Arrow* declaration. Birss J considered the applicable principles at [61]-[88]. As he recorded at [64], counsel for Roche submitted that:
 - "i) The court has no jurisdiction to grant declarations where there was no dispute about UK legal rights or disputes of facts that were relevant to UK legal rights.
 - (ii) In the alternative, if that argument fails, there was a 'hard-edged' point of principle that precluded the court from granting declarations in such circumstances. The 'useful purpose' test (see FSA v Rourke) therefore related to a purpose that was useful in the context of a UK legal dispute.
 - (iii) In the further alternative and in any event, the circumstances in this case do not justify granting a declaration for two reasons. First because in fact there is nothing in Roche's conduct to date which justifies exercising the jurisdiction as a matter of fact. Second because the only 'useful purpose' relied on by Pfizer is the spin-off value of a UK judgment in foreign jurisdictions; and that is not enough."
- 45. Birss J's analysis of these submissions was as follows:
 - "86. Taking stock, in my judgment the position is the following. Roche's first submission (set out at [64(i)] above) is wrong because it purports to place a limit on the court's power to grant a declaration even when it would serve a useful purpose. That is not right because the only relevant limitation is concerned with useful purpose. I would characterise Henry Carr J. in *FujiFilm* as a case illustrating why the first point is wrong. The fact that analytically, by the time the question came to be decided, it was true that there was no longer a dispute before the court about the existence or scope of AbbVie's UK legal rights, did not mean the declaration would serve no useful purpose.

- 87. As for Roche's second submission ([64(ii)] above), the first part of it is wrong for the same reasons as the first submission. The second part of the second submission is that the useful purpose test must be related to a purpose that is useful in the context of a UK legal dispute. The *Deutsche Bank* case shows why that is not correct. At least as long as one is not concerned with forum shopping, the fact that the purpose is useful in relation to a dispute in a foreign court may justify granting a declaration. On the other hand *Deutsche Bank* is a long way on the facts from the present case, because there the foreign court was going to have to decide issues arising under a contract governed by English law.
- 88. Roche's third point ([64(iii)]) is not really a submission of law or principle. The true principle in my judgment is that in considering all the circumstances and the issue of useful purpose, the court will wish to identify what the real purpose of the declaration is. There may be more than one purpose. The court will look carefully at a case in which the only or predominant purpose of the declaration sought is to use the court's judgment in foreign jurisdictions."
- 46. Birss J found at [111] that Roche's motive for de-designating the UK from its patent portfolio was to shield the portfolio from the risk of an adverse decision in the Patents Court. He also found at [115]-[117] that an *Arrow* declaration would be of real commercial value for Pfizer because it would reduce the uncertainty which Pfizer faced in relation to its launch of bevacizumab all over Europe, and in particular it would help Pfizer to resist a patent infringement claim brought by Roche in Belgium, from where Pfizer intended to supply the UK market. He nevertheless refused to grant a declaration for the following reasons:
 - "118. If today there were pending UK applications in any of the families, this would be a plain case for an Arrow declaration and I would go on to examine the merits of the Gillette defences in detail. However given the complete absence of the possibility of UK rights in future, the reality is that the commercial value of an Arrow declaration to Pfizer is the utility it might have (along with a reasoned judgment) in helping Pfizer defend itself against suits brought by Roche in other European countries. This case is unlike FujiFilm in that in relation to bevacizumab there is no outstanding uncertainty at all relating to UK rights. Pfizer does not need the Patents Court to tell it or anyone else that it can freely sell bevacizumab in this country without risk from the Roche patent families.
 - 119. There is uncertainty relating to the UK market but that derives from the fact that the goods are to be supplied from a separate jurisdiction (Belgium) in which the uncertainty remains. Now what Pfizer really wants is a UK judgment so as to use it in Belgium. In *Deutsche Bank* the issue which was to come

before the foreign court was about a UK contract and UK law and so the UK court was naturally in a better position than a foreign court to rule on such a point, and so obtaining a ruling here to use abroad was not forum shopping. However the position here is different because the issue which will come before the Belgian court (if it ever does) will be about a Belgian patent and Belgian law. The fact that a Belgian court would take a judgment of this court into account does not alter the fact that the UK courts are in no better position to rule on those points of the patent law. It is true that under the EPC we apply the same law in Belgium and in the UK but that is not a sufficient justification for embarking on the exercise of deciding the technical issues.

- 120. What will happen in Belgium is likely to affect the UK market but that is only because of the local effect in Belgium of a Belgian designation of the European patent. It is nothing to do with any UK legal right.
- 121. Another way a declaration could be useful would be to assist settlement. That can often be a useful factor, and I think it probably applies in this case, but on these facts it is not enough to make a difference.
- 122. When the action began it was not forum shopping at all. There were pending UK applications which provided a basis for considering an *Arrow* declaration. However now they have gone. There might have been other factors which justified *Arrow* relief such as arose in *Fujifilm* but on examination in this case, there are not. There is no evidence of uncertainty about UK patent rights. The true purpose of an *Arrow* declaration in this case would be for it to be used in foreign courts. I am not persuaded that that is enough."
- 47. The third case is *TQ Delta LLC v ZyXEL Communications UK Ltd* [2019] EWCA Civ 1277, [2020] FSR 10. That was a case about the obligation to license standard-essential patents ("SEPs") on reasonable and non-discriminatory ("RAND") terms. The defendant waived its right to enforce the obligation in respect of all UK SEPs in the claimant's portfolio. Despite this, the claimant attempted to pursue claims for the determination of RAND terms and for a declaration that the defendant was an unwilling licensee. This Court struck out those claims. As to the latter, the utility of the declaration was said to be that it would have effect as *res judicata* in proceedings in foreign jurisdictions were the claimant to seek injunctive relief for patent infringement in those jurisdictions.
- 48. Floyd LJ, with whom Lewison LJ agreed, identified a number of serious problems with this case at [48], noted the large costs that would be required to determine it at [50] and expressed scepticism as to the concern which was said by the claimant to underlie the claim at [51]. He concluded at [52]:

"These considerations force me strongly to the conclusion that the questions on which the court's declaratory judgment is sought are far better decided in the foreign court where those questions arise, if they ever do. It would be an exercise in jurisdictional imperialism to foist this court's view as to whether ZyXEL were unwilling licensees, or holding-out on an unknown foreign jurisdiction. Far less can it be said that it is in the interests of justice for it to do so."

- 49. The fourth case is Lisa Dräxlmaier GmbH v BOS GmbH & Co KG [2022] EWHC 2823 (Pat). In that case the claimant sought a declaration of non-infringement pursuant to section 71 of the 1977 Act in respect of a European patent (UK) owned by the defendant. Both the claimant and the defendant were German companies. By the time the case came before the Patents Court it was common ground that the claim no longer served a useful purpose and should be brought to an end. The issue before the court was as to the manner in which it should be brought to an end, and the real dispute was as to the costs. Sir Anthony Mann found at [32]-[35] that the claimant's predominant motive by a long way for bringing and maintaining the claim was to obtain a declaration for the purpose of placing it before a German court. Having considered TNS v Nielsen, Fujifilm v AbbVie, Takeda v Hoffmann-La Roche, Fresenius v Carefusion and certain other authorities (but not Pfizer v Hoffmann-La Roche, TO Delta v ZvXEL or the judge's judgment in the present case, none of which appear to have been cited to him), Sir Anthony concluded at [77] that "an infringement claim, or its counterpart DNI claim ... 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". He went to conclude at [80]-[85] that (i) whether or not it had been an abuse of process when originally launched, the claim had become an abuse once the defendant had made its position clear after service, and (ii) the claim should never have been brought, whether it was an abuse or not.
- 50. Sir Anthony distinguished *TNS v Nielsen* on the basis that it concerned validity whereas his case concerned a declaration of non-infringement. I note, however, that he was not referred to *Glaxo v Vectura*. In my judgment, the true distinction is that in *TNS v Nielsen* the primary purpose of the claim was to extinguish a UK legal monopoly, although the claimant admitted that it also wanted the "spin off" value of the judgment, whereas Sir Anthony found that in his case the claimant's essential purpose was to influence the German court.
- 51. The conclusion I reach having considered these cases is that, as a matter of principle, it is 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. It is not the function of the courts of England and Wales to provide advisory opinions to foreign courts seised of issues which fall to be determined in accordance with their own laws. The English courts have no special competence to determine such issues. If anything, it is likely that they have less competence than the local courts. It makes no difference that the English court and the foreign court are applying the same basic law. Furthermore, comity requires restraint on the part of the English courts, not (to adopt Floyd LJ's graphic phrase) jurisdictional imperialism. Otherwise the English courts would be enabling forum shopping.

52. In saying this, I am assuming that the parties have full and unimpeded access to the foreign court. I recognise that the position might possibly be different if that were not the position; but it is not necessary to consider this further for the purposes of the present case, since there is no suggestion that either of these parties lacks full and unimpeded access to the courts of Germany or Country A.

The judge's judgment

- 53. The judge reviewed the applicable legal principles at [19]-[32], citing *Messier-Dowty*, *FSA v Rourke*, *Arrow v Merck*, *Fujifilm v AbbVie* (both Court of Appeal and Henry Carr J), *Pfizer v Hoffmann-La Roche* and two other authorities (she was not referred to *TQ Delta v ZyXEL*, and *Lisa Dräxlmaier v BOS* post-dated her decision).
- 54. At [34] she recorded that Teva had advanced five reasons why a declaration should be granted:
 - "i) First, Novartis' aggressive enforcement of EP 894, including the fact that it had obtained injunctive relief.
 - ii) Secondly, that a declaration would provide clarity to Teva's customer in the UK, the NHS.
 - iii) Thirdly, the inadequacy of Novartis' undertakings in dispelling the uncertainty on the UK market.
 - iv) Fourthly, the potential utility of a UK judgment to a decision in Germany on whether to grant a preliminary injunction against Teva.
 - v) Fifthly, the fact that Teva's supplies to the UK transited through Country A, such that an injunction against Teva in that country would threaten that supply chain."
- 55. At [40] the judge noted that Novartis had declined to provide any explanation for dedesignating the UK in respect of EP894 and EP765, and inferred that the motive for doing so was to shield the portfolio from the risk of an adverse decision in the Patents Court. There is no challenge by Novartis to that finding.
- 56. So far as Teva's first reason was concerned, the judge noted at [42] that counsel for Teva had accepted during the course of argument that this was not a stand-alone reason for the grant of a declaration, but rather a factor in the assessment of useful purpose, and agreed with this at [43].
- 57. As for Teva's second reason, the judge found at [44]-[49] that there was no evidence of uncertainty on the part of the NHS, or elsewhere in the UK market. There is no challenge by Teva to that finding.
- 58. In relation to Teva's third reason, the judge explained at [50]-[54] that Novartis had offered undertakings which had been clarified during the course of the hearing to address a concern raised by Teva, and concluded that the revised undertakings were not ambiguous or lacking in clarity such as to create or perpetuate uncertainty in the market. Again, there is no challenge by Teva to that assessment.

59. The judge considered Teva's fourth reason at [55]-[62]. Having considered the expert evidence as to German law which had been adduced by the parties, she found at [59] that the German courts would undoubtedly take account of the declaration and would give it such weight as considered appropriate alongside the other evidence available, which would necessarily include the EPO decision and any judgments of other courts in EPC Contracting States. There is no challenge by either side to that finding. The judge went on at [61]:

"... whatever the nuances of the views of the experts on this point, the fundamental problem with this aspect of Teva's case is that the case-law discussed above consistently establishes that if the only or predominant purpose of the declaration sought is to use the judgment for a foreign court, this court will look carefully at the justification for the declaration. In such a case, a declaration is only likely to be granted in unusual cases where [there is] a very compelling justification for doing so."

- 60. The judge considered Teva's fifth reason at [63]-[76]. She accepted Teva's evidence that an injunction in Country A would be disruptive of their supply chain to the UK and that a declaration by the Patents Court might well have an impact on this, but was not persuaded that this was sufficient:
 - "71. The question is, however, whether that is enough. I do not think that it is. Given the prevalence of global supply chains, it is not surprising that, in this case, as no doubt in very many others in this sector, the decision of the relevant foreign courts as to whether to injunct a product is likely to have a knock-on impact on the supply of that product to the UK, but the fact that a decision in Country A will therefore affect the UK market indirectly by having an impact on Teva's supply route to the UK does not change the fact that the purpose of an *Arrow* declaration in this jurisdiction will be to use it in the courts of Country A and other countries, rather than to obtain or enforce any right in the UK.
 - •••
 - 75. ... The point of principle in both *Pfizer* and the present case is that the purpose of the declaration was and is to influence a foreign court whose decision is likely to impact upon the supply of the product to the UK, whether or not that supply has already commenced at the time that the declaration is sought. Birss J's assessment in *Pfizer* was that the decision of the Belgian courts was 'likely' to affect supplies to the UK market. That is similar to the conclusion I have reached in this case. ...
 - 76. The question I have to ask, therefore, is whether there are particular unusual circumstances in the present case which provide a compelling justification for the grant of the injunction sought by Teva. In my judgment, there are not. As I have already noted, there is nothing unusual in the fact of a global supply chain with the result that a decision in one

country may impact upon the supply of product to another, specifically the UK. Nor, in my judgment, does Novartis' conduct in this case tip the balance in favour of granting an injunction in the present case, in circumstances where, as I have found, unlike in *Fujifilm*, it cannot be said that this conduct has resulted in any continuing uncertainty on the UK market."

61. Finally, the judge considered at [77]-[78] whether making the declaration sought would assist the parties to reach a settlement, and concluded that the prospect of a settlement was not a sufficient reason to grant a declaration. There is no challenge by Teva to that assessment.

The appeal

- 62. As is common ground, the judge's decision involved an exercise of discretion. It follows that this Court is only entitled to reconsider the issue if she erred in law or principle, took a factor into account which she should not have, failed to take into account a factor which she should have or was plainly wrong.
- 63. Teva contend that the judge erred in principle at [61] and [76]. Teva argue that she should have asked herself (i) whether the declaration would serve a useful purpose and (ii) whether there were any special reasons for or against the grant of a declaration, and that she was wrong to ask whether there was "a very compelling justification" for granting one. In the alternative, Teva argue that the judge was wrong to conclude that there was no "very compelling justification" given (i) the impact that a declaration was likely to have in Germany and in Country A and (ii) Novartis' conduct in attempting to enforce EP894 by applying for an interim injunction and then abandoning protection for the UK.
- 64. In my judgment the only error the judge made was in adopting an approach that was too favourable to Teva. Once she had found that a declaration was not required in order to redress uncertainty in the UK market, it followed that, as the judge recognised, the only purposes which could be served by a declaration were to assist the courts of Germany and Country A in deciding issues under their own laws. The judge essentially followed Birss J's approach to that question in *Pfizer v Hoffmann-La Roche*. As explained above, however, I have concluded that assisting a foreign court to decide an issue under its own law is not a legitimate reason for the grant of declaratory relief.
- 65. It follows that the judge was correct to dismiss Teva's claim. I would add two points. The first is that counsel for Teva placed particular reliance upon the fact that the grant of an injunction in Country A would affect the supply of Teva's product in the UK. As the judge pointed out, however, that would simply be a knock-on consequence of the courts of Country A applying their own law within their territory.
- 66. The second point concerns Teva's reliance upon Novartis' conduct in applying for an interim injunction before subsequently abandoning their claim to patent protection in the UK. I agree with the judge that this is not a factor which in itself justifies the grant of a declaration. Rather, it is a matter to be addressed by enforcing Novartis' cross-undertakings in damages and by awards of costs.

Lord Justice Nugee:

67. I agree.

Sir Christopher Floyd:

68. I also agree.