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Case No: HP-2022-000005
HP-2022-000006

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

7 Rolls Building
Fetter Lane, London
EC4A 1NL

Date: 19 October 2022

Before:

MRS. JUSTICE BACON

Between:

(Case No. HP-2022-000005)

TEVA UK LIMITED **TEVA PHARMACEUTICAL INDUSTRIES LIMITED**	**Claimants**
- and -	
NOVARTIS AG	**Defendant**

And between:

(Case No. HP-2022-000006)

(1) NOVARTIS AG **(a company incorporated in Switzerland)** **(2) NOVARTIS PHARMACEUTICALS UK LIMITED**	**Claimants**
- and -	
(1) TEVA UK LIMITED **(2) DR REDDY'S LABORATORIES LIMITED** **(3) GLENMARK PHARMACEUTICALS EUROPE LIMITED** **(4) TILLOMED LABORATORIES LIMITED** **(5) ZENTIVA PHARMA UK LIMITED** **(6) ARISTO PHARMA GMBH** **(a company incorporated in Germany)** **(7) VIATRIS UK HEALTHCARE LIMITED**	**Defendants**

DR JUSTIN TURNER KC and MS KATHERINE MOGGRIDGE (instructed by **Pinsent Masons LLP**) on behalf of **Teva**

MR ANDREW WAUGH KC and MR GEOFFREY PRITCHARD (instructed by **Bristows LLP**) appeared on behalf of **Novartis**

Approved Judgment

Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd.,
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MRS. JUSTICE BACON:

Introduction

1. This is the hearing of an application by Teva for what is referred to as an *Arrow* declaration, that its proposed acts of importing and selling generic fingolimod to treat relapsing-remitting multiple sclerosis (**RRMS**) at a daily dose of 0.5 mg p.o. was obvious at the priority date of European Patent EP 2 959 894 (**EP 894**), for which Novartis AG is the registered proprietor.

2. The application is what is left of two separate sets of proceedings between Teva and Novartis concerning Teva's right to launch a generic version of fingolimod in the UK, in competition with Novartis' branded product Gilenya.

3. Gilenya was launched in the UK in 2011, and has been protected by an extensive patent portfolio. These proceedings relate to the patent EP 894, claiming a daily 0.5 mg dose of fingolimod for treating RRMS. EP 894 was the second divisional patent application following Novartis' parent application, which was originally filed in June 2007, but withdrawn in 2015.

4. The EP 894 patent application was initially refused by the Examining Division of the European Patent Office in November 2020 for lacking novelty. Novartis then filed an appeal to the Technical Board of Appeal of the EPO, which allowed the appeal on 8th February 2022, and decided that the patent would proceed to grant.

5. Regulatory marketing exclusivity for Gilenya expired on 22nd March 2022. A month before that occurred, on 25 February 2022, Teva commenced its claim seeking an *Arrow* declaration in order to clear EP 894 out of the way and allow the launch of generic fingolimod. On 2 March 2022 Novartis in turn commenced proceedings against Teva and other manufacturers or suppliers of generic drugs, claiming interim injunctive relief to prevent the sale of generic fingolimod in the UK. Teva and three of the other defendants then counterclaimed for *Arrow* declaratory relief.

6. Roth J refused Novartis' application for an injunction ([2022] EWHC 959 (Ch)), and on 25 May 2022 Birss LJ refused permission to appeal ([2022] EWCA Civ 775). Roth J did, however, order an expedited trial of the two sets of proceedings to be heard together, commencing on or around 3 October 2022. There was a brief skirmish about specific disclosure in June, leading Novartis to apply to adjourn the trial. That was resolved by agreement and Novartis withdrew its application.

7. Thereafter, trial preparation proceeded on both sides until 10 August 2022, when Novartis informed Teva that it was de-designating the UK from EP 894 so that it would not proceed to grant in the UK. Novartis also, at the same time, removed the UK designation from a third divisional patent application that had been sought for the same family. The next day, Novartis applied to discontinue its infringement action against all of the defendants.

8. The effect of that was that when EP 894 was eventually granted by the EPO on 12 October 2022, it did not apply in the UK and the UK is therefore now a generic market. Novartis has subsequently either settled or reached agreement in principle with all of the defendants to its infringement action, other than Teva.

9. Teva, however, maintains its application for an *Arrow* declaration on the basis that it will continue to serve a useful purpose. In order to do so, Teva applied to amend its pleadings in both actions. Novartis resisted that application. On 16 September 2022 Meade J allowed the amendments, subject to further particularisation of the pleading and amplification of Teva's evidence ([2022] EWHC 2366 (Pat)). Meade J also directed that the trial of Teva's application for an *Arrow* declaration should be confined to the issue of whether, as a matter of discretion, a declaration should be granted in circumstances where Novartis does not have patent protection for its 0.5 mg dose in the UK.

10. As regards the technical question of whether the subject-matter of the claim is obvious, Novartis has not put in any evidence on that point and has said that it will not be cross-examining Teva's technical witnesses or making submissions to defend the inventiveness of what is claimed in EP 894. Meade J, therefore, directed that the present trial of the discretionary issue would proceed on the assumption that Teva is correct that the relevant subject-matter is in fact obvious. If I find following this hearing that on the basis of that assumption it is appropriate to grant the declaration that Teva seeks, then there will be a subsequent hearing of the technical issue of obviousness. Given Novartis' position on that, however, the hearing is likely to be rather short.

11. The sole issue for this hearing is, therefore, whether, as a matter of discretion, the court should grant the declaration sought by Teva.

Witnesses

Teva's witnesses

12. Teva relied upon the evidence of two factual witnesses. Mr Christopher Sharp, a solicitor at Pinsent Masons, representing Teva in these proceedings, gave evidence regarding the history of these proceedings and the status of proceedings to enforce EP 894 in various other countries. Following objection by Novartis to some of the passages of his witness statement, those passages were withdrawn. The remainder of his evidence is not controversial and Novartis did not seek to cross-examine him.

13. Secondly, Teva relied upon the evidence of Ms Claudia Kulla, a commercial portfolio manager at Teva. She gave evidence as to the logistics of supplying Teva's fingolimod product to the UK, and said that it would be highly disruptive to the supply of that product if the supply chain had to be changed because Teva's supply into a particular transit country were to be injuncted because of EP 894's patent protection outside the UK. The identity of that transit country is confidential and has been referred to in the redacted versions of the materials before me as Country A.

14. At the PTR before me on 11 October 2022 Novartis applied, rather belatedly, to cross-examine Ms Kulla. I granted that application on condition that she would give evidence remotely from Germany, where she is currently resident. Following the hearing, however, it transpired that the necessary authorisations for Ms Kulla to do so would not be able to be obtained in time from the German authorities. On that basis, Novartis agreed that it would not cross-examine Ms Kulla, but would confine itself to making submissions as to the reliability and weight to be attached to her evidence.

15. Finally, Teva relied on an expert report, supplementary report and reply report from Dr Anna Wolters-Höhne, a German attorney and patent litigator. The sole issue addressed in her evidence was the weight that the German courts would give to a decision of the UK courts granting an *Arrow* declaration on the terms sought by Teva. Novartis did not seek to cross-examine Ms Wolters-Höhne. Indeed, Novartis said that her evidence was put in such limited terms that it was ultimately supportive of Novartis' case.

Novartis' witnesses

16. Novartis, for its part, relied on factual evidence from Dr Gregory Bacon, a solicitor at Bristows, representing Novartis in these proceedings. He responded to Mr Sharp's evidence by providing further details on a limited number of points, including the status of the proceedings in other countries. As with Mr Sharp, his evidence was not disputed and he was not cross-examined.

17. Novartis' second factual witness was Mr Alexander Denoon, also a solicitor at Bristows, who gave evidence on the regulatory position concerning the supply of Teva's fingolimod product into the UK. His position was that from a regulatory perspective, appointing a new importer from another country should be relatively straightforward and not materially disruptive. In light of Novartis' confirmation that it was content not to cross-examine Ms Kulla, Teva agreed that it would likewise not cross-examine Mr Denoon.

18. Novartis' German-law expert was Professor Christopher Ann, the Chair of Intellectual Property Law at the Technical University of Munich. He responded to the evidence of Dr Wolters-Höhne as to the status of foreign case-law in the German courts. Teva did not seek to cross-examine Professor Ann, but made some submissions about the scope of some of his evidence.

Legal framework

19. An *Arrow* declaration is a particular type of negative declaration which takes its name from the judgment of Kitchin J in *Arrow Generics v Merck* [2007] EWHC 1900 (Pat). Arrow had sought (among other things) declarations that its own product was obvious at the priority date of pending divisional patent applications in circumstances where Merck had threatened patent infringement proceedings on the basis of those divisional applications. Kitchin J considered that the court had jurisdiction to grant the declarations sought and refused to strike out the claim. He considered, in particular, that the declarations would serve a useful purpose in providing Arrow with the certainty that its product would not infringe Merck's patent rights arising from the pending divisional applications.

20. The court's power to grant an *Arrow* declaration was confirmed by the Court of Appeal in *Fujifilm v AbbVie* [2017] EWCA Civ 1, again in the context of an application to strike out a claim for such a declaration. Unlike the *Arrow* case, the declarations were specifically sought in relation to patents which AbbVie had either abandoned for all designations or, in one case, had de-designated in the UK since the commencement of the proceedings.

21. Delivering the judgment of the court, Floyd LJ cited at §59 the comments of the court in *Messier-Dowty v Sabena* [2001] 1 All ER 275, §§41–42, that the grant or refusal of declaratory relief should be kept in "proper bounds" by the exercise of the court's discretion; that negative remedies are an unusual remedy; but that subject to appropriate circumspection there should be no reluctance to grant negative declarations when useful to do so.

22. The court went on to endorse the approach taken by Neuberger J in *Financial Services Authority v Rourke* [2002] CP Rep 14, 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 whether there are any other special reasons why or why not the court should grant the declaration."

23. Floyd LJ went on to note that circumstances in which *Arrow* declarations would be justified were likely to be uncommon, noting that a business problem in a foreign jurisdiction would be unlikely to justify the grant of a declaration by the English court (§95). Nevertheless, on the facts of the case, the court did not think that the claim for a declaration should be struck out. In particular, given the way that AbbVie had apparently acted, there was a case for the court to intervene by way of declaration to provide FKB with a measure of "useful commercial certainty" (§100).

24. There followed a three-week trial of the action, following which, Henry Carr J granted the declaration sought. It is evident that he considered the facts of the case to be very unusual. In particular, he referred to the fact that AbbVie had not only abandoned its UK patent protection shortly before trial, but had a "long record of similar conduct", the purpose being, he found, to shield the claims of its patents from scrutiny in both the EPO and the UK courts (§§392–395).

25. Against that background, the judge's reasoning can be summarised as follows:

    i) The court should be concerned with whether the declaration sought will serve a useful purpose in the UK. A declaration which is sought solely for the benefit of foreign courts will rarely be justified (§377). This was, however, a case where AbbVie had abandoned its UK patent protection shortly before trial. It was not a case which had never had any connection with the UK, but was being brought purely for influence foreign courts (§392).

    ii) If the declarations did not serve a useful purpose, there was no coherent explanation of why AbbVie refused to submit to judgment or give undertakings in the same form as the declarations. AbbVie would not have invested the considerable resources required for the trial unless there was a good commercial reason to resist the declarations. Absent any alternative explanation, it could be inferred that the declarations would be more damaging to AbbVie's strategy in relation to its patent portfolio than the undertakings it had offered (§§386–7).

    iii) AbbVie had called no evidence in relation to either useful purpose or any other factors that might be relevant to the discretion to grant the declarations. FKB's evidence, therefore, stood unchallenged (§378). That evidence suggested, and

the court found, that the objective effect of AbbVie's conduct was to shield its patent portfolio from examination of validity while continuing to file divisional applications and threaten infringement proceedings. That perpetuated commercial uncertainty which the declaration sought would serve a useful purpose in dispelling (§§388, 394–7, 406).

iv) AbbVie's undertakings were complicated, long and difficult to follow. They did not provide the clarity that was necessary given AbbVie's conduct (§§398–9).

v) The declarations would also serve a useful purpose in protecting FKB's supply chain for the UK market in circumstances where despite the UK being patent-free, the rest of the EU remained subject to the threat of potential patent litigation. In practice, most manufacturers would be unable to confine their supply chain to the UK, such that the UK market might not be able to be exploited without being at risk of AbbVie's patents in other jurisdictions. The grant of a declaration would, therefore, not solely have spin-off value in other jurisdictions, but would be of direct benefit to the UK market (§§401–5).

vi) The grant of the declarations might also promote settlement (§§407–9).

26. The judge's conclusion was that on the "most unusual facts of this case", it was in the interests of justice to grant the declaration sought and there were, indeed, special reasons to do so. Those included, in particular, AbbVie's conduct of threatening infringement whilst abandoning proceedings at the last moment in order to shield its patent portfolio from scrutiny and the need for commercial certainty having regard to AbbVie's threats to sue for infringement throughout the world (§416).

27. An *Arrow* declaration was granted by Arnold J in *Glaxo v Vectura* [2018] EWHC 3414 (Pat), but on facts that are quite different to those of the present case.

28. More recently, however, in *Pfizer v Hoffman-La Roche* [2019] EWHC 1520 (Pat), Birss J refused an *Arrow* declaration. As in the *Fujifilm* case, Roche had de-designated the UK from the relevant pending EP patent applications after the action for a declaration was commenced. In those circumstances, Roche contended that the grant of declarations would serve no useful purpose.

29. Birss J rejected Roche's arguments that there was a hard-edged point of either law or principle precluding the court from granting a declaration where there was no dispute about UK legal rights or facts relevant to UK legal rights. If correct, he said that would place a limit on the court's power to grant a declaration, even when it would serve a useful purpose, whereas the only relevant limitation was concerned with useful purpose (§§86–7). Nor, he considered, was there any principle that the useful purpose test must concern a purpose that was useful in the context of a UK legal dispute. The fact that the purpose was useful in relation to a dispute in a foreign court might, in principle, justify granting a declaration. The court should, however, look carefully at a case in which the only or predominant purpose of the declaration sought was to use the court's judgment in foreign jurisdictions (§§87–8).

30. On the facts of the case, Birss J inferred (as in the *Fujifilm* case) that Roche's motive for de-designating the UK was to shield its portfolio from the risk of an adverse decision in the English courts (§111). Nevertheless, he held that although an *Arrow* declaration would be of real commercial value for Pfizer by reducing the uncertainty which Pfizer faced in relation to its launch of the product in Europe, the reality was that the value to Pfizer was its utility in helping Pfizer defend itself in other European countries. There were no pending UK applications in any of the relevant patent families and the only uncertainty relating to the UK market, therefore, derived from the fact that Pfizer planned to supply its product from Belgium, where uncertainty as to the status of the patent would remain. The issue that would come before the Belgian court, however, would be about a Belgian patent and Belgian law and the fact that a Belgian court would take a judgment of the English court into account was not a sufficient justification for the English court to decide the technical issues (§§115–19, 122).

31. In addition to the leading authorities of *Fujifilm* and *Pfizer*, Mr Waugh KC, for Novartis, also placed some emphasis on Aikens LJ's summary in *Rolls-Royce v Unite the Union* [2009] EWCA Civ 387, §120, of the bases on which declarations should be granted. In particular, Mr Waugh noted the comments that:

    i) There must, in general, be a real and present dispute between the parties before the court as to the existence or extent of a legal right between them. The claimant does not, however, need to have a present cause of action against the defendant: §120(2).

    ii) The court must be satisfied that all sides of the argument will be fully and properly put. It must therefore ensure that all those affected are either before it or will have their arguments put before the court: §120(6).

32. Aikens LJ's judgment was dissenting in that case, but his summary was approved by the Court of Appeal in *Milebush Properties v Tameside MBC* [2011] EWCA Civ 270, §46 (Mummery LJ). Dr Turner KC, for Teva, noted that in the same case Moore-Bick LJ had commented that Aikens LJ's summary was expressed somewhat too narrowly, as Birss J also noted at §73 of *Pfizer*. He also noted Birss J's rejection of a hard-edged requirement for a UK legal dispute, which I have summarised above. Ultimately, however, Dr Turner did not dispute the propositions above; rather, his submission was that they were met on the facts of this case.

Assessment in the present case

33. Unsurprisingly, Teva places particular reliance on the *Fujifilm* judgment of Henry Carr J while Novartis relies on the approach taken by Birss J in *Pfizer*. Attempting to draw analogies can, however, only go so far. As Birss J emphasised at §66 of *Pfizer*, each case turns on its own facts.

34. In the present case, Teva advanced essentially five reasons why, in its submission, 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.

35. Before I address those points, I will make a few preliminary comments.

Preliminary comments

36. First of all, regarding the question of whether the declaration is sought in the context of a dispute as to UK legal rights, as Birss J made clear in his extended discussion of this point, at §§70–82 of *Pfizer*, this cannot be construed too narrowly. The dispute may concern an issue of fact, a legal right which might come into existence in the future or a question of whether a UK legal right arises at all. Birss J clearly regarded it as sufficient that, as in the facts of the *Fujifilm* case, there had been uncertainty about the scope of the relevant patent rights which the declaration would address: see his comments at §81.

37. In the present case, it is likewise contended by Teva that there is residual uncertainty on the UK market which a declaration will dispel. Novartis is, moreover, not submitting to judgment on the declaration, but resists it. Dr Turner is, therefore, in my judgment, correct to say that, on any basis, there is a real dispute between the parties. The court is not being asked to opine on a purely academic or theoretical issue.

38. Secondly, although Mr Waugh initially suggested that this would not be a case where all sides of the argument were put, he ultimately retreated from that proposition. In my judgment, he was right to do so. Aikens LJ's comments in *Rolls-Royce* were made in the context of an industrial dispute where individual employees who would be directly affected by any declaration were not involved in the litigation.

39. The facts of the present case are entirely different. The parties affected by the declaration sought are both before this court and Novartis has had every opportunity to put its case on all of the issues relevant to the declaratory relief claim. While it has chosen not to engage with the technical issue of obviousness, that is its considered litigation strategy. As Birss J noted, at §12 of *Pfizer*, in similar circumstances, no party who contests a case is obliged to disagree with every point raised by their opponent; and the fact that they do not do so does not mean that they are not fully contesting the case. It cannot, moreover, be the case that a party can avoid declaratory relief simply by failing to engage with one or more of the issues relevant to the grant of that relief.

40. Thirdly, as in the *Fujifilm* and *Pfizer* cases, Novartis has declined to provide any explanation of why it withdrew its UK patent designation after these proceedings commenced, but before trial. As in both of those cases, I infer that the motive for doing so was to shield the portfolio from the risk of an adverse decision in this court.

41. There is no doubt, therefore, that Novartis does have a commercial motive in resisting the declaration sought by Teva. That does not, however, mean that a declaration should inevitably be granted. Rather, it is necessary to consider Teva's specific reasons in support of such a declaration, to which I now turn.

Novartis' enforcement of EP 894

42. Teva's first reason turns on Novartis' conduct and, particularly, the fact that Novartis initially sought to enforce its patent in the UK to the point of seeking interim injunctive relief before ultimately abandoning the UK designation only months before trial. While Dr Turner initially suggested that Novartis' conduct should be regarded as a stand-alone reason supporting the grant of a declaration, irrespective of the question of whether a declaration would serve a useful purpose, ultimately, his position was that this was a relevant factor in the assessment of useful purpose.

43. I consider that to be the right approach. There is no suggestion in the case law that even when a declaration would serve no useful purpose a court might, nevertheless, grant a declaration in order to censure the conduct of the defendant and discourage such conduct in future. Rather, it is clear from Henry Carr J's judgment in *Fujifilm* that the reason why the conduct of AbbVie was relevant was that it had created and perpetuated commercial uncertainty in the UK, a point also emphasised by Birss J in his comments on the case at §§80–1 of *Pfizer*. Novartis' conduct, therefore, falls to be considered as part of the other factors relied upon by Teva.

Certainty for the NHS

44. Teva's second argument was that a declaration would provide clarity to the NHS that the subject-matter of the present claim is obvious. The problem with this argument, however, is that there is no evidence of confusion on the part of the NHS as to the status of Novartis' patent protection. On the contrary, the correspondence before me shows that Novartis informed Ms Mandy Matthews, the Medicine Lead Specialised Commissioning for NHS England, on 10 August 2022, of its intention to withdraw its infringement proceedings and not to validate the UK designation of EP 894.

45. At the end of September, Novartis then sent an e-mail to Ms Matthews confirming that, "The UK market for 0.5 mg fingolimod is open for generic competition and that Novartis does not seek to challenge any sales or other activities by generic competitors in relation to this dose."

46. In light of that correspondence, Bristows wrote to Pinsent Masons, among others, on 4 October 2022, saying:

> "We trust that our letter and the communication enclosed has resolved any remaining concerns that your clients held in relation to the alleged confusion in the fingolimod market. However, if that is not the case, please let us know by 4 pm on

> Friday 7 October 2022 so that the issue can be raised with the judge at the PTR hearing, which is listed to take place on Tuesday 11 October 2022."

47. There was no response to that letter, and by the time of the PTR hearing before me Teva had agreed to remove from the witness statement of Mr Sharp the passages that had suggested ongoing uncertainty on the part of the NHS.

48. I asked Dr Turner whether there was before me any other evidence that a declaration would make any difference to the NHS procurement policy or its understanding of the situation. Dr Turner confirmed that there was not any such evidence.

49. Novartis' conduct does not change that position. By contrast with the position in *Fujifilm*, where an important – and indeed crucial – plank of the assessment of Henry Carr J was that there was unchallenged evidence of commercial uncertainty that was perpetuated by AbbVie's conduct, there is no such evidence in the present case.

The undertakings offered by Novartis

50. Teva's submissions as to the adequacy or otherwise of the undertakings offered by Novartis suffer from the same problem: while Dr Turner's submission was that the undertakings were ambiguous and difficult to understand, that begs the question of who is confused. Teva did not suggest that it is, itself, unclear what its rights are in relation to the supply of fingolimod to the NHS. Nor is there any evidence before me suggesting ongoing confusion on the part of the NHS, as I have already noted.

51. Teva's main concern appeared to lie with the potential for confusion as to future rights arising from the fact that the undertakings originally offered by Novartis included the statement that:

> "For the avoidance of doubt, the effect of the said undertakings is that Novartis and its affiliates will not obtain or maintain in the UK patent claims (claiming a priority date of 27 June 2006 or later) whose technical contribution consists of fingolimod for use in the treatment of relapsing remitting multiple sclerosis at a daily dosage of 0.5mg p.o."

52. Dr Turner said that this implied that the undertaking related only to claims which only consisted of the objectionable integer and did not make clear what the position was for claims which consisted of that integer, among other integers.

53. Mr Waugh said that this was not the intention of Novartis and on the second day of the hearing, he handed up a revised set of undertakings with the relevant statement amended to read:

> "... for the avoidance of doubt, the effect of the said undertakings is that Novartis and its affiliates will not obtain or maintain in the UK patent claims (claiming a priority date of 27 June 2006 or later) <u>where the alleged inventive step or any part of the alleged step resides in the use of</u> ~~whose technical contribution costs of~~ fingolimod ~~for use~~ in the treatment of

> relapsing-remitting multiple sclerosis at a daily dosage of 0.5 mg p.o."

54. Dr Turner did not make any further objection to the clarity of that wording. I do not, therefore, consider that this is a case where the undertakings offered are ambiguous or lack clarity such as to create or perpetuate uncertainty on the market.

Effect of a declaration on the pending German proceedings

55. Teva's fourth reason was the potential utility of a UK judgment to the courts of other EPC Contracting States. Rather than putting forward evidence as to the position in every one of those States, as a matter of procedural economy, Teva has confined its evidence to Germany, on the basis that the German market is the largest in Europe. The position there is that while attempts to obtain interim injunctive relief against generic companies pending the grant of the EP 894 application have been unsuccessful, it is anticipated that now the patent has been granted, Novartis will renew its attempts to injunct Teva and others in the German courts. Novartis did not deny that in the hearing before me.

56. It was also common ground before me, on the evidence of Ms Wolters-Höhne and Professor Ann, that:

    i) In Germany, applications for injunctive relief of patent infringement are heard by an infringement court, which does not routinely examine the validity of a patent that is being enforced, since decisions on patent validity are heard by a separate court.

    ii) German courts considering patent infringement rarely consult independent experts.

    iii) A court considering patent infringement must, however, take into account the decisions of national courts of other EPC Contracting States, i.e. including the UK.

57. Teva's submission was therefore that a decision of this court granting a declaration would be taken into account by a German court in deciding whether to grant preliminary injunctive relief against Teva on the basis of the EP 894 patent.

58. While Novartis did not dispute that proposition, there was something of a difference of views in the evidence of the two experts as to the relative weight which a German court would give to a declaration of this court compared with other evidence, in circumstances where Novartis had not made any submissions on or advanced any evidence in relation to the technical case on obviousness.

59. I do not place great weight on the evidence of either of the experts on that point, which fell into the realms of speculation. Neither expert put forward any principle of German law or referred to any case-law as to the weight that would be given to a declaration of this court in a case where the defendant, while not submitting meekly to judgment, had not engaged with the technical issues. All that can be said, on the basis of the experts' evidence of German law and practice, is 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.

60. Indeed, the evidence of Ms Wolters-Höhne ultimately did not go beyond an assertion that a decision of the UK court in these circumstances would be "of interest" to the German court, and that the fact that Novartis has chosen not to cross-examine Teva's experts would not be a reason for the German court to disregard the decision. Professor Ann did not disagree with either of those statements.

61. More importantly, however, 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 a very compelling justification for doing so.

62. Teva's answer to that is to refer to its supply chain argument, to which I now turn.

Supply-chain

63. Teva says that the effect of the declaration will be felt in the UK because Teva's supply chain to the UK involves transit through Country A. If it is injuncted in that country, Teva says, it will be time-consuming and expensive to alter its supply chain. Teva will therefore seek to rely on any declaration of this court in resisting any injunction in Country A.

64. At the PTR Mr Waugh objected, for the first time, that Teva had not produced any evidence to establish that importation into Country A for onward shipment to the UK was an infringing act under the laws of that country. I do not accept that criticism. In the absence of evidence to the contrary, foreign law is presumed to be the same as English law, see the discussion of Lord Leggatt in *Brownlie v Cairo* [2021] 3 WLR 1011, §§108–112. There is no dispute that under English law, importation for the purposes of trans-shipment would be an infringing act.

65. If, therefore, Novartis wish to argue that transit through Country A would not infringe its patent in that country, Novartis should have adduced expert evidence on that point, which it has not done.

66. Novartis' second criticism was that Teva's evidence of supply chain disruption was very weak. Again, I do not accept that criticism. Teva's evidence was set out in two witness statements from Ms Kulla, whose responsibilities specifically involve overseeing the logistics for the supply of Teva's fingolimod product to the countries in which it is being launched. Her evidence set out the steps that she would need to take in order to change Teva's current supply chain through Country A. These include identifying an alternative licensed warehouse and distribution facility in Europe, organising staff resourcing, ensuring that the facility complies with regulatory standards for storage and distribution, agreeing processes for data-sharing and good manufacturing practices, organising transportation logistics, ensuring the safety of the product in transit and making any relevant amendments to Teva's marketing authorisations. Her evidence was that it would take a considerable amount of work to plan and implement such a change to the supply chain.

67. Mr Waugh questioned the reliability of that evidence on the basis that, in his submission, Teva should already have taken the steps to identify and plan for an alternative supply route in the event of an injunction being granted in Country A. He relied on Mr Denoon's evidence that this would be straightforward from a regulatory perspective.

68. That criticism, however, revealed itself to be rather hollow, since Mr Waugh was unable to identify any country through which, in his submission, Teva would have been able to plan an alternative supply route, safe in the knowledge that it would not be injuncted by Novartis there. The reality is that Novartis is taking steps to enforce EP 894 across the EPC Contracting States, and Novartis has not identified any alternative European country into which, on its case, Teva would be able to import its product for onward shipment to the UK without risk of infringement.

69. It is therefore entirely unsurprising that Teva has not already put in place an alternative supply route. If it is required to do so as a result of proceedings in Country A, the availability of any alternative route will depend on the status of proceedings in the other countries in which it might consider setting up an alternative distribution facility. It is self-evident that investigating and implementing such an alternative route is likely to put Teva to considerable time and expense, and Ms Kulla's evidence on that point is entirely credible.

70. I accept, therefore, Teva's submission that a declaration in this court may well have an impact on Teva's supply chain in so far as it is taken into account in Country A.

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.

72. As in *Pfizer*, that was, of course, not the case at the outset of these proceedings, when Novartis had a pending application for a patent designated in the UK. It is, however, the case now, in the light of Novartis' de-designation of the UK from its patent applications.

73. There is, in that regard, a key difference between this case and the *Fujifilm* case. In *Fujifilm*, as I have explained above, a central plank of the decision of Henry Carr J was the impact of the declaration in dispelling uncertainty on the UK market, given the conduct of AbbVie. In the present case, as I have already found, there is no evidence of such uncertainty. That was essentially the position in *Pfizer*, where Birss J refused to grant the declaration sought on the basis that its predominant purpose was to use in the Belgian courts.

74. Dr Turner sought to distinguish the facts of *Pfizer* on the basis that in that case Pfizer's product had not yet launched, and it appeared on the evidence that first instance proceedings in Belgium could be completed by the time that Pfizer wished to launch its product with a supply chain through that country.

75. It, is however, difficult to see what difference that makes. 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. I do not think that any meaningful distinction can be drawn based on the precise timing of those supplies.

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.

77. Dr Turner has not identified any other factors which justify the grant of an *Arrow* declaration, whose purpose is solely to use in the courts of Country A and other countries. The only other factor he floated at the hearing, other than the points I have already discussed, was the utility of a declaration in assisting settlement.

78. Novartis has served a CEA notice in respect of a statement by its Head of Intellectual Property, Innovative Medicines, Dr Galit Gonen-Cohen to the effect that the grant of declaratory relief in these proceedings would have no impact on Novartis' approach to settlement, but even if I were persuaded that, contrary to that statement, a declaration of this court would assist settlement, that would not be a sufficiently compelling reason to grant a declaration in this case and I note that Birss J reached the same conclusion in *Pfizer* at §121.

79. In conclusion, having regard to all of the considerations set out above, I do not consider it appropriate to grant an *Arrow* declaration in this case. I will hear submissions from counsel as to the form of the order and any consequential matters.

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