Claim No: HP-2020-000005

Neutral Citation Number: [2022] EWHC 2366 (Pat)

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

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Friday, 19th September 2022

Before:
MR. JUSTICE MEADE

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Between:

(1) TEVA UK LIMITED **(2) TEVA PHARMACEUTICAL INDUSTRIES LIMITED**	**Claimants**
- and -	
NOVARTIS AG	**Defendant ("The Teva Action)**

And Between:

Claim 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 (UK) 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 (The "Novartis Action")**

MR. JUSTINE TURNER KC and MS. KATHERINE MOGGRIDGE (instructed by **Pinsent Masons LLP**) for the **Claimants**
MR. ANDREW WAUGH KC and MR. GEOFFREY PRITCHARD (instructed by **Bristows LLP)** for the **Defendants**

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Approved Judgment

Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd.,
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MR. JUSTICE MEADE:

1. This is an application by Teva in these proceedings in which there are two actions, which I will call "the Teva action" and "the Novartis action", to amend its pleadings. The trial of the claims is floating from 3rd October 2022. The reduced issues, as I will describe, which Teva now wishes to raise will, it is clear, occupy much less time than the full issues originally destined for trial and what was under discussion at the hearing today was the possibility of dealing with those new issues at the back end of the current trial window, whose last two days are the 17th and 18th October. Although no definite decision has been arrived at, it does seem to me that if I allow the proposed amendment, the trial of them will take about two days, plus some pre-reading.

2. The Novartis action is in respect of a European patent application, whose date of grant has changed over time, but as I understand it, it is currently due to grant in about early/mid-October. I think I have been referred to a date of 12th October. It is a dosing regimen patent and an unusual feature of this litigation is that Novartis sought interim injunctive relief prior to the grant of the patent and Roth J, having heard the application in March, gave judgment in April in which he found that there was jurisdiction to grant relief prior to the grant of the patent, but he declined to do so on the balance of convenience and permission to appeal his decision was refused, finally, at a hearing before Birss LJ, in due course.

3. Teva's claim has from the outset included *Arrow* declaratory relief. Part of the reason for that was the fact that the patent had not yet granted; there is also *Arrow* declaratory relief sought in the counterclaim in Novartis's claim

4. Matters were thereafter progressing towards trial and there are parallel proceedings in a number of courts of Europe against Teva and other defendants, as I will touch on in due course, but so far as the UK is concerned, matters changed significantly when, on 10th August, Novartis announced that it was going to withdraw the UK designation so that the patent ("EP 894"), will not grant in the UK. Novartis has declined to state the reasons for that decision on the basis of confidentiality and privilege and it has said that the reasons are specific to the UK. It is unnecessary to dig into the detail of that, but one point that does appear to be specific to the UK is that following the refusal of injunctive relief, the UK supply of the drug in question, fingolimod, for treating relapsing remitting multiple sclerosis, in the dose claimed has become a generic market.

5. Teva wants to carry on its claim for *Arrow* declaratory relief in October and that presented it with a problem, because whilst the patent was on course for grant and while there was the likelihood, indeed, the intention that there would be a contested fight over validity, that claim needed no great support and based on the judgment of Birss J, as he then was in *Pfizer* (as I will touch on again shortly and will give the citation), it was more or less inevitable that if Teva won on validity, it would get the *Arrow* declaratory relief or, at the very least, the question of discretion to grant the relief would be an easy one for Teva to succeed on. That all changed with Novartis's withdrawal of the UK designation.

6. It is said by Mr. Waugh, King's Counsel, who appears for Novartis today, that Teva could have supported the *Arrow* claim on the bases which it now relies on at any time. In a theoretical sense that is true, but for reasons I have just gone into, there was simply no reason for Teva to even think about that until the events of August.

7. A timetable of recent events is given in Teva's skeleton at paragraph 13 as follows:

> • 25 February 2022: Teva commenced proceedings in the Teva action.
> • 2 March 2022: Novartis commenced proceedings in the Novartis action.
> • 17-18 March Novartis' application for a PI heard by Roth J.
> • 26 April 2022: Roth J gave his reasoned judgment refusing a PI.
> • 25 May 2022: Court of Appeal refused Novartis' application for permission to appeal.
> • 6 July 2022: Dr Lublin witness statement first served by Novartis.
> • 20 July 2022: replacement compliant with PD57AC Dr Lublin witness statement served.
> • 9 August 2022: further amended Dr Lublin witness statement served.
> • 10 August 2022: Novartis informs Teva and the EPO that it is de-designating the UK from EP894.
> • 11 August 2022: Novartis serve its application to discontinue its infringement claim in the Novartis action. The Application was noted as being for a Master and to be determined on the papers.
> • 17 August 2022: Teva and the other active defendants serve technical expert evidence from Professor Muraro and Dr Schmith. Novartis in a letter of the same date informed Teva and the other active defendants that they would not be serving expert reports from their named experts.
> • 25 August 2022: Teva issued and served its application for directions.
> • 2 September 2022: Novartis issued its application under CPR 3.1(2)(e) and(m) for determination that the declaratory relief sought by Teva serves no useful purpose.
> • 6 September 2022: Teva issued and served its application for permission to amend its pleadings."

8. There is no controversy about that and it covers events from 10th August onwards. Teva has served its technical evidence. Novartis has not, and said that it will not do so. On 25th August, Teva issued an application for directions for the conduct of the October trial in the changed landscape confronting it. On 2nd September, Novartis made an application under CPR Part 3 to determine that the declaratory relief sought by Teva served no useful purpose, and therefore that the *Arrow* claim had to be struck out. On 6th September, Teva sought to amend its pleadings to raise a different basis for *Arrow* relief, as I will shortly discuss, and then the matter came before me last week, when -- given that I was sitting in the applications court at the time and given the speed with which things had moved -- there was no time to deal with it substantively. I adjourned the matter until this week with a direction to Teva that it must put in a full pleading of the matters which it wished to raise and must put in the evidence that it would seek to rely on at trial, if permitted to amend, which it has now done in the shape of a fifth witness statement of Mr. Sharp, of Teva's solicitors, and an expert report of Dr. Anna Wolters-Höhne, a German-law expert who has also provided a very short supplementary expert report yesterday in response to some criticisms of her earlier evidence made by Novartis.

9. The effect of the amendments, to which I will turn in due course, is to completely replace the basis for *Arrow* relief. There is no real doubt about that. The more or less

unanswerable case on discretion which was present when there was the likelihood of a UK right has been replaced with something very different which I set out as follows:

23A. The declaratory relief sought will serve a useful purpose and there are special reasons why it should be granted. Hereunder the Claimant relies upon the following matters.

(a) On 9 August 2022 Novartis served the witness statement of Dr Fred Lublin as evidence of fact in support of its case of inventive step (the admissibility of which was disputed). On 10 August 2022, in a letter from Bristows, Novartis indicated that it would not validate EP894 in the UK and that it intended to discontinue its infringement claim HP-2022-00006. It chose not to serve expert evidence to defend the validity of EP894. In a further letter of 22 August 2022 Bristows, on behalf of Novartis, stated that the reasons for not validating EP894 are "confidential and privileged and include commercial considerations relating specifically to the UK". The context of this statement is that Gilenya, Novartis's product which is protected by EP894, is Novartis UK's second best-selling product with sales of £46.5 million in 2021. During the course of a 2 day hearing on 17-18 March 2022 before Roth J Novartis sought interim injunctive relief against a number of defendants, including Teva, citing the commercial importance of patent protection given by EP894 in the UK.

(b) There have been no events of which Teva is aware (such as the discovery of new prior art or a change in market conditions) to explain why Novartis is not pursuing the UK designation of EP894 or infringement proceedings to obtain an injunction and/or damages. Teva contends that the reason Novartis is abandoning these proceedings is that it intends to shield the validity of EP894 from scrutiny by the UK courts and that this is the commercial consideration for its actions.

(c) Novartis has refused to submit to judgment on this claim or on the counterclaim in HP-2022-00006. In the premises it is inferred that Novartis is of the view that submitting will serve a useful purpose which is detrimental to Novartis' interests and which will impact its commercial position. This refusal is of itself evidence that the declarations will serve a useful purpose.

(d) Novartis has an extensive patent estate relating to fingolimod including, *inter alia*, EP3453387, EP3677260 and EP3831371. Teva cannot know all the patent applications which have been and will be applied for and granted in the future. The grant of a declaration that the proposed acts in relation to fingolimod in accordance with the SmPC would have been obvious at 27 June 2006 affords Teva protection against future patent infringement proceedings. Although various undertakings have been offered by Novartis they do not offer the same protection as the declaration sought will provide.

(e) Further the declaratory relief sought will enable third parties to know that the proposed acts are obvious and will thus provide reassurance that Teva fingolimod will not be subject to patent infringement proceedings.

(f) Teva also places reliance upon the special reason that Novartis has aggressively pursued patent infringement proceedings against Teva and other defendants in respect of EP894 across a number of contracting states of the EPC including *inter alia* in Denmark, Germany, Finland, the Netherlands, Portugal, Spain, Austria, Switzerland, Sweden, Greece, France and Italy. Novartis is pursuing an EPC wide strategy of impeding the sale of generic fingolimod, initially relying on EP894 as an application. It is expected that Novartis will be pursuing litigation even more aggressively against Teva in EPC contracting states once EP894 is granted, including Germany, and that it will be making applications for interim injunctive relief. In jurisdictions where the merits of the validity of EP894 may not ordinarily be taken into account Novartis will obtain a tactical advantage in shielding the validity of EP894 from scrutiny in the UK. Having commenced infringement proceedings in the UK in claim HP-2022-00006 in relation to EP894 and having sought, and for a limited time obtained, interim injunctive relief, it is submitted that Novartis should not be permitted to avoid declaratory relief and obtain a procedural advantage in this way.

(g) Teva relies upon the following principles of German law:

i. Nullity and infringement proceedings are heard by separate courts in Germany.

ii. A nullity action cannot be commenced in the German Courts when a patent grants due to the pending nine-month EPO opposition period (and likely opposition thereafter).

iii. A German infringement court does not determine the validity of a patent but can order a stay of infringement proceedings or can refuse a preliminary injunction if it forms the view that there is a high likelihood that the patent in suit is invalid. A German infringement court does not hear technical evidence relating to validity but in determining whether there is a high likelihood a patent is invalid it will consider the prior art, relevant decisions of the EPO and relevant decisions of the courts of a contracting state.

iv. In determining whether there is a high likelihood that a patent in suit is invalid, the German infringement court is required to take into account decisions of the courts an EPC contracting state, relating to an essentially similar issue, including decisions which determine whether the prior art renders the subject matter of a patent obvious. The reasoning in decisions of the courts of contracting states are of interest to the German court but are not binding on the German court.

v. In deciding whether to grant a preliminary injunction or stay infringement proceedings the German infringement court will have regard to a reasoned decision of a UK Court which has considered whether the subject matter of the patent in suit is obvious in the light of the prior art. If, after considering the prior art and the reasoning of the UK court, it concludes that there is a

high likelihood the claims of the patent in suit are obvious it will decline to grant a preliminary injunction.

(h) Further, Novartis's strategy of enforcing EP894 in a number of EPC contracting states has the potential to impact supply chains for the sale of Teva's generic fingolimod product in the UK, which is supplied in the following way:

i. Teva's generic fingolimod product is supplied from its site of manufacture outside of the EU, from a country which is not a contracting state of the EPC, into Country A, which is a contracting state of the EPC in which EP894 is currently designated. Country A is not the UK.

ii. There is onward distribution from Country A into other EPC contracting states, including the UK. Details regarding Country A are provided in Confidential Annex 1 to this statement of case.

(i) The granting of the declaratory relief may promote settlement of the dispute in relation to the entitlement of Teva to sell fingolimod across contracting states to the EPC.

10. Novartis maintains its opposition to the amendment and I therefore have to decide whether I should permit it or not and, if I do, how to carry matters forwards to trial. It is clear that this is, in form and in substance, an application by Teva to amend its pleadings and part of the picture, but only part of the picture, is therefore whether the pleading raises an arguable case. I also have to consider very carefully whether to allow an amendment of this kind so close to trial.

11. This application engages a number of strands of authority. In my view, what I first and foremost must consider is that this is an application to amend close to trial and I have been directed to the following authorities on that question, primarily by Novartis, but I do not understand Teva really to disagree with them. First of all, in *Pearce v East and North Hertfordshire NHS Trust* [2020] EWHC 1504 (QB) Lambert J stated:

> "The legal framework is not in dispute and can be stated succinctly here. The starting point is CPR 17.3 which confers on the Court a broad discretionary power to grant permission to amend. The case-law is replete with guidance as to how that discretionary power should be exercised in different contexts. I need cite only two cases which taken together provide a helpful list of factors to be borne in mind when considering an application such as this: *CIP Properties (AIPT) Ltd v Galliford Try Infrastructure Ltd* [2015] EWHC 1345 (TCC) and *Quah Su-Ling v Goldman Sachs International* [2015] EWHC 759 (Comm). From those cases, I draw together the following points.

a) In exercising the discretion under CPR 17.3, the overriding objective is of central importance. Applications always involve the court striking a balance between injustice to the applicant if the amendment is refused, and injustice to the opposing party and other litigants in general, if the amendment is permitted.

b) A strict view must be taken to non-compliance with the CPR and directions of the Court. The Court must take into account the fair and efficient distribution of resources, not just between the parties but amongst litigants as a group. It follows that parties can no longer expect indulgence if they fail to comply with their procedural obligations: those obligations serve the purpose of ensuring that litigation is conducted proportionately as between the parties and that the wider public interest of ensuring that other litigants can obtain justice efficiently and proportionately is satisfied.

c) The timing of the application should be considered and weighed in the balance. An amendment can be regarded as 'very late' if permission to amend threatens the trial date, even if the application is made some months before the trial is due to start. Parties have a legitimate expectation that trial dates will be met and not adjourned without good reason. Where a very late application to amend is made the correct approach is not that the amendments ought, in general, to be allowed so that the real dispute between the parties can be adjudicated upon. A heavy burden lies on a party seeking a very late amendment to show the strength of the new case and why justice to him, his opponent and other court users requires him to be able to pursue it. The timing of the amendment, its history and an explanation for its lateness, is a matter for the amending party and is an important factor in the necessary balancing exercise: There must be a good reason for the delay.

d) The prejudice to the resisting parties if the amendments are allowed will incorporate, at one end of the spectrum, the simple fact of being 'mucked around' to the disruption of and additional pressure on their lawyers in the run-up to trial and the duplication of cost and effort at the other. The risk to a trial date may mean that the lateness of the application to amend will of itself cause the balance to be loaded heavily against the grant of permission. If allowing the amendments would necessitate the adjournment of the trial, this may be an overwhelming reason to refuse the amendments.

e) Prejudice to the amending party if the amendments are not allowed will, obviously, include its inability to advance its amended case, but that is just one factor to be considered. Moreover, if that prejudice has come about by the amending

> party's own conduct, then it is a much less important element of the balancing exercise."

12. Secondly, *Scott v Singh* 2020 EWHC, 1714, (Comm) where Judge Eyre said this:

> "18. First, the proposed amendment must be properly formulated in the sense of being comprehensible and setting out clearly the case which the other party is to meet. The proposed amendment must satisfy the requirements of the CPR in terms of the proper particularisation and pleading of any cause of action asserted in the amended pleading. This is particularly so in the case of a late amendment (see per Lloyd LJ in *Swain-Mason v Mills & Reeve* [2011] EWCA Civ 14, [2011] 1 WLR 2735 at [73]). It is not open to a party seeking to make a late amendment to say that any deficiencies in the proposed pleading can be remedied in due course by further particularisation.
>
> 19. The new case set out in the proposed pleading must have a real prospect of success (see the commentary in the White Book at 17.3.16 and Mrs. Justice Carr's summary of the position in *Quah Su-Ling v Goldman Sachs* [2015] EWHC 759 (Comm) at [36]). The approach to be taken is to consider those prospects in the same way as for summary judgment namely whether there is a real as opposed to a fanciful prospect of the claim or defence being raised succeeding. It would clearly be pointless to allow an amendment if the claim or defence being raised would be defeated by a summary judgment application. However, at the stage of considering a proposed amendment that test imposes a comparatively low burden and the question is whether it is clear that the new claim or defence has no prospect of success. The court is not to engage in a mini-trial when considering a summary judgment application and even less is it to do so when considering whether or not to permit an amendment. Mr. Bergin says that this requirement only applies when the amendment in question is raising a new claim or defence. He contended that it did not apply if the amendment was in reality further particularisation or amplification of an existing claim. Mr. Pipe did not concede this but in my judgement Mr. Bergin is right. The requirement that the claim or defence proposed by way of amendment has a real prospect of success arises from the need to avoid the futility of allowing a claim or defence to be made by way amendment which is liable to be struck out or to be defeated by a summary judgment application. The same consideration does not apply if the line of claim or defence is in the original pleading and will remain in issue even if the amendment is not allowed. In practice in this case the Defendant said that the proposed amendments made new allegations while the Claimants said that they were no more than a fuller particularisation of the existing claim.

> 20. If the amendment is very late in the sense of being an amendment which will cause the vacation of an existing trial date then other considerations come into play. In such cases particular regard is to be had to the strength or otherwise of the new case and there is a heavy burden on a party seeking to make such an amendment to show that justice requires him or her to be allowed to do so (see *Swain-Mason v Mills & Reeve; Quah Su-Ling v Goldman Sachs*; and *Nesbit Law Group v Acasta Europe Insurance Company* [2018] EWCA Civ 268).
>
> 21. In the context of the current case those principles mean that I am to consider each limb of the proposed amendment. I must consider the amended pleading in relation to the original Particulars of Claim and assess whether a new claim is being made or whether the amendment is in reality no more than fuller particularisation of the existing claim. I am to consider whether the amended pleading satisfies the requirements of the Rules and is adequately pleaded. Where a new claim is being made regard must be had to whether it is a claim with a real prospect of success. I must then consider whether the inclusion of the new material will necessitate the loss of the trial date and if it would whether the Claimants have satisfied the heavy burden of showing that justice requires that they should nonetheless be permitted to advance the amended claim.
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> 22. Having applied that approach to the limbs of the amended pleading separately I must then stand back and consider the combined effect of such parts of the proposed pleading as pass that scrutiny to see if that combined effect leads to a different result."

13. Novartis relies, drawing those threads together on the following propositions.

14. First, that it is not the law that amendment should in general be allowed purely in order to resolve a dispute between the parties, but rather there is a heavy burden on a party seeking a very late amendment to show the strength of the case and why justice requires them to be able to pursue it.

15. Secondly, that a proposed amendment must be properly formulated, coherent and clearly set out the case which the other party is to meet, especially in the case of a late amendment. Novartis go on to say that it is not open to a party seeking to make a late amendment to say the deficiencies in the proposed pleading can be remedied in due course by further particularisation -- a point to which I will return.

16. Third, that the new case set out in the proposed pleading must have a real, as opposed to a fanciful, prospect of the claim being raised succeeding. Although it is a shorthand, I am going to call that "the strike out standard".

17. Fourth, that a proposed amendment has to be supported by evidence that establishes a factual basis.

18. I was also referred, by Novartis, to the CPR, and what it says in the notes to Part 17 about late amendments, and in particular to the note at 17.3.8 referring to:

> "... *CIP Properties v Galliford Try Infrastructure* [2015] EWHC 1345 (TCC) where Coulson J (as he then was) described ... lateness as a relative concept but an amendment is always in principle late if it could have been advanced earlier. Therefore, the question of when an amendment might have been sought should not be eclipsed by the potential complexity or importance of the arguments advanced by the amendment."

Clearly, and the note makes this clear, an amendment is regarded as being very late if its introduction being permitted will necessitate vacating and re-listing the trial.

19. When I directed Teva to put its case in by way of pleading and evidence last week, I did so under a very tight timetable and I gave Teva what I thought was an appropriate warning, and it is against that background that I will assess the criticisms of the pleading and evidence made by Novartis. However, this is not a one-way street. The time pressure has arisen because Novartis pulled the UK designation in August, something which it has failed to explain. Indeed, it has consciously chosen not to explain. I am of the view that it is quite likely that Novartis could have made that decision earlier. I do not say they did do this, but it is even possible that they did in fact make that decision earlier and made a further calculated decision about when to notify it to Teva. In any event, it is Novartis's very unusual conduct in asserting a patent, seeking and even for a brief period obtaining interlocutory relief, and then pulling it, all the while maintaining it in other proceedings in EPC States that has caused the shortness of time.

20. That, in my view, would not be anywhere near enough to lead me to let through an amendment if there could not be a fair trial, but it forms the background against which to consider the criticisms of Teva's evidence and pleadings to which I have referred.

21. Later in this judgment, I will touch on a few of the key decisions in relation to *Arrow* declarations. Those are a couple of judgments in the *Fujifilm* litigation and the decision of Birss J (as he then was), in *Pfizer v Hoffman-La Roche* [2019] EWHC 1520 (Pat). I think caution is required in considering that those litigations represent what is typical to *Arrow* declarations or that they represent, in some way, the minimum complexity or effort that is needed. The *Fujifilm* litigation was truly a saga, returning to court many times with many different courses of conduct by the patentee to seek to preserve its position, with a number of reported judgments with a very long and complicated trial at the end of the day.

22. The *Pfizer* case, whilst it only took three days in court, packed a lot in because it involved detailed consideration of the prosecution history of the patent families in question and cross-examination on deeply disputed aspects of foreign law, in that case Belgian law, where there was a real and significant issue between the parties.

23. I do not consider that I should fall into the trap of considering either of those as a metric for what would be involved in a trial of what Teva's pleading raises. Teva's pleading is much more self-contained and as I have said already, I agree with the assessment that two days of court time ought to be enough and the issues raised are basically fact

evidence about the litigation landscape, fact evidence about other litigations in Europe, some fact evidence about how the declarations sought would help Teva or might help Teva and then expert evidence of German law where, I can see already from the comments that have been passed by Novartis on Teva's expert evidence, any areas of dispute are likely to be extremely limited.

24. I approach the question of whether a trial at the back end of the current window is possible with, I hope, a realistic assessment of what is truly involved in this case.

25. Novartis says that it cannot be ready and that a fair trial which gives it an opportunity to make its case and understand and meet the case against it is not possible in the time available and it also criticises the particularity of the pleading put forward by Teva. These points all go together to some extent, but I have to break them down somehow or other, so the way that I am going to seek to do that is by looking at the points where Novartis has said that it will be in difficulty meeting the timetable or meeting any timetable for a trial in October.

26. The first point that Novartis put forward in its skeleton was that it does not currently have a German-law independent expert on whose evidence it can rely. I am unimpressed by this. The dispute on German law, if indeed there is one at all, is extremely narrow and Novartis is an enormous organisation which is clearly willing to throw tremendous resources at this case and I am sure that it will be able to find a German-law expert if it feels that it is essential. I have to say that I think putting that forward as its first reason why there was a problem meeting the trial date is somewhat symptomatic of an approach by Novartis that it simply is not willing to try all that hard to meet the timetable.

27. Secondly, it is said that there are matters which might require disclosure or matters where Teva's case is not yet clear. For example, Novartis says, that paragraph 23A(d) of the draft pleading, asserting that some undertakings have been offered by Novartis are not such as to offer the same protection as the declaration sought, is unclear and may require evidence which cannot be obtained in time.

28. I agree that that subparagraph of the pleading lacks some particularity and Dr. Turner KC, appearing for Teva, agrees that Teva will spell out the ways in which the undertakings leave gaps, as Teva would say, but that is a really small point. It is primarily a point of argument and not of fact, and although, as I said earlier, Novartis says that in the case of a very late amendment, the party seeking to amend should not be allowed to fix problems of this kind, I do not consider for a moment that that can be an immutable rule and, under the time pressure imposed on it in circumstances which I have described, I think Teva's omission in that respect is not unreasonable and pretty much as soon as it has been raised by Novartis, Teva has addressed it. The substantive question of whether the undertakings match the protection given by a declaration is not a difficult one to argue or one that is very fact-sensitive at all.

29. Second, it is said that Teva has pleaded a vague case about whether the declaratory relief sought will enable parties to know that the proposed acts are obvious. Novartis says that the pleading should spell out who those third parties are. I agree, and this is another respect in which there is a problem with Teva's pleading, but for reasons

touched on already, I think it is curable and in the course of oral submissions, Dr. Turner, on behalf of Teva, clarified that the third parties in question are the NHS.

30. On a practical level, and jumping across to the question of evidence, there was a lack of clarity about Teva's intentions in relation to this and Mr. Sharp, Teva's solicitor, had cross-referred in his evidence to some witness statements used in interlocutory stages of this litigation, namely from a Ms. Paddy and a Ms. Britton. It has been clarified that those are not relied on and Teva does not intend, as one would expect, to try to call evidence from people who are actually confused and, therefore, this boils down to a dispute, really, about whether the undertakings and/or the declarations are clear and comprehensible and whether either of them is better than the other and I do not consider that requires much, if any, factual investigation. Novartis has said that it might want to call evidence from the NHS and/or from its internal people, explaining that the matters are entirely clear to the NHS and it can do that, but I do not regard this as a particularly heavy issue to be tried in mid-October.

31. Next, and more significantly, in my view, Novartis has focused on Teva's pleading at paragraph 23A(h), that Novartis's strategy has the potential to impact supply chains for the sale of Teva's generic product. Novartis has made a number of responses to this. One response that it has made is that a question will arise which might require cross-examination and/or disclosure over whether it would be burdensome for Teva, if it cannot carry on activities in the manner in which it has described, to switch to doing the same things or substitute things in a different jurisdiction.

32. This issue has given me considerable pause because I do not think it is unreasonable for Novartis to raise this question and, furthermore, Teva's position on this has evolved during the course of the hearing before me. Initially, Dr. Turner's position was that Teva was not going to say anything one way or another about the burden of changing its supply chain but, later on in the hearing, he said that Teva might want to give some evidence and that it would do so by next Wednesday.

33. This is related to a further criticism of the evidence of Mr. Sharp, because in paragraphs 7.12 and 7.13, he speaks on information and belief from a Dr. McBride of Teva as to the position with supply chains and a point is made that that is not a proper form of evidence with regard, in particular, to PD57AC. Dr. Turner sought to meet that particular procedural objection by saying that Teva would provide a witness from within the company to verify what is said, which is that the product is shipped from a non-EPC Contracting State jurisdiction to what is designated as Country A, which is designated by the patent-in-suit and that there would be disruption if Teva had to change that, but he does not speak to the burden of that or alternative options available to Teva.

34. I agree that this part of Mr. Sharp's evidence is not in compliance with PD57AC and unlike other objections where he simply, for example, summarises foreign proceedings and the question of whether he is speaking from personal knowledge is one that just does not matter. There is a genuine point here to be taken. However, having thought about it carefully, I think that this is unlikely to be a point of grave importance at any trial, if the pleading otherwise raises an arguable case, and I very strongly suspect that if Teva puts in the evidence it seeks next week, it will be at a rather general level, saying that moving supply chains from one country to another is disruptive and expensive. I am dubious in the extreme that that can either realistically be contradicted

or that there is any merit in going into the nitty-gritty of how much it will cost or why or how long it will take or anything like that. Whilst I agree, therefore, there was a deficiency in the procedural route adopted by Teva and being cautious to allow it off the hook with an amendment which is so close to trial, I think this is in the end a minor point and curable in the sense that I have indicated.

35. If I turn out to be wrong and it proves, when Teva provides that evidence next week, that there is a genuine dispute, then the matter may have to be revisited and it may come about that Teva even has to choose between running the point and keeping the trial date, but for the moment, in my view, in the unusual circumstances of this case, I am justified in allowing Teva the opportunity to improve its position.

36. Mr. Sharp's evidence in relation to Ms. Paddy and Ms. Britton will require surgery to remove references to that hearsay; that is the certainty for the NHS point I have touched on already. The last objection taken is that Mr. Sharp has given evidence which contravenes PD57AC when he says in paragraph 7.19 that a reasoned decision and declaration from the Patents Court could assist the parties to reach settlement. I do not think Mr. Sharp has any personal basis for saying that and I think it is, with no disrespect, vague and useless and any litigator, including a former litigator such as a judge, could reach a conclusion on that without the assistance of Mr. Sharp. I note that Novartis has already responded to this by giving, at least at this interim stage, evidence on information and belief from a named individual within Novartis who says that of course there could be a settlement, but this additional UK decision will not make any difference. I have to say, without expressing any concluded view, that very much has the ring of truth about it but, in any event, promotion of settlement, in my view, is a very small part of the picture.

37. All that being so, I consider that with appropriate directions, which I will deal with in the event that I conclude that the case is at least arguable, this is not an amendment which threatens the trial date and having regard to the overriding objective of devoting an appropriate amount of the court's resources to a case and deciding the real issues, I think that if the pleaded case is arguable, it would not be an objection to it that there is a practical problem with having a trial.

38. I should also say, although I think this is probably better organised under the analysis of whether the claim is arguable, that Mr. Waugh criticised the German-law expert evidence put in by Teva on the basis that it does not address itself specifically to the question of whether a UK decision would have additional value in a German court, over and above the other litigation taking place across Europe. To my mind, that is not a question about the feasibility of a trial in October, but an issue on the merits.

39. I turn to consider whether the pleaded case crosses the strike out threshold. On that, I have been referred by Teva to the decision of Lord Browne-Wilkinson in *Barrett v L B Islington* [1999] 3 Weekly Law Reports 83, referred to in a number of later cases which I have been shown, that in an area of law which is uncertain and developing, it would not normally be appropriate to strike out and that development of the law should be on the basis of actual facts and not on the basis of hypothetical facts. There is no dispute as far as I can tell before me today about that being a principle which I have to bear in mind.

40. I have been referred, against that background, to the following parts of *Fujifilm* in the Court of Appeal by one side or another as follows:

> "60. In *Financial Services Authority v Rourke* Neuberger J (as he then was) proposed the following, with which we respectfully agree:
>
> > '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 whether there are any other special reasons why or why not the court should grant the declaration.'"

41. Paragraph 73(vi) records an argument of Mr. Hobbs KC and gives context to some of the later part of the judgment:

> "(vi) To allow declarations in the Arrow form 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. If the Arrow declaration does not raise issues of validity, then it would be a way of undermining the system of allocation of jurisdiction under the recast Brussels Regulation in ways which the courts have striven to prevent: See e.g. *Gesellschaft für Antriebstechnik MBH & Co KG v Lamellen und Kupplungsbau Beteilungs KG* Case C-4/03 [2006] FSR 45 ("*GAT v LUK") and Anan Kasei Co. Ltd and another v Molycorp Chemicals & Oxides (Europe) Ltd* [2016] EWHC 1722 (Pat) (Arnold J)."

42. Paragraph 95, rejecting a floodgates argument that was made states as follows:

> "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. Mr Hobbs' example of a business problem in Romania would be unlikely to justify the grant of a declaration by the English court."

43. Paragraph 99, which is under the heading of discretion, and records, as Floyd LJ said:

> "Given that a discretionary power exists, it is for the Patents Court to develop the principles for its exercise in more detail. It will be apparent from the above, however, that we consider an important factor to be borne in mind in the exercise of the discretion is the existence of the statutory proceedings for revocation, which should be regarded as the normal vehicle for obtaining any desired findings of invalidity."

44. That last point about the statutory proceedings for revocation of course has to be read against the qualification that in the present case the patent has not yet granted, although it probably will have done very shortly before the end of the current window.

45. I was referred next to the decision of Henry Carr J in the trial in *Fujifilm*, which is [2017] EWHC 395 (Pat), where he referred to spin-off judgment at paragraph 374 and following:

> "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.
>
> 375. This is illustrated by the judgment of the Court of Appeal in *Dow Jones v Jameel* [2005] EWCA Civ 75. The on-line version of the Wall Street Journal had published an article linking the Claimant to the funding of al Qaeda. The Claimant brought libel proceedings in the United Kingdom even though very few United Kingdom residents had seen the article. One of his objects was to seek a judgment which would vindicate him in respect of the global publication. When considering the question of vindication, the Court of Appeal at [65] referred to the judgment of Lord Hoffman in the *Berezovsky v Michaels* [2001] 1 WLR 1004:
>
> > 'The plaintiffs are forum shoppers in the most literal sense. They have weighed up the advantages to them of the various jurisdictions that might be available and decided that England is the best place in which to vindicate their international reputations. They want English law, English judicial integrity and the international publicity which would attend success in an English libel action.
> >
> > ...
> >
> > My Lords, I would not deny that in some respects an English court would be admirably suitable for this purpose. But that does not mean that we should always put ourselves forward as the most appropriate forum in which any foreign publisher who has distributed copies in this country, or whose publications have been downloaded here from the Internet, can be required to

> answer the complaint of any public figure with an international reputation, however little the dispute has to do with England. In *Airbus Industrie G.I.E. v Patel* [1991] 1 AC 119 your Lordships' House declined the role of 'international policeman' in adjudicating upon jurisdictional disputes between foreign countries. Likewise in this case, the judge was in my view entitled to decide that the English court should not be an international libel tribunal for a dispute between foreigners which had no connection with this country.'

376. The Court of Appeal in *Jameel* concluded at [66]:

> 'So far as concerns the issue currently under consideration there is no conflict between the view of Lord Hoffmann and the view of the majority. This action falls to be considered as relating exclusively to an independent tort, or series of torts, in this country. It is thus not legitimate for the claimant to seek to justify the pursuit of these proceedings by praying in aid the effect that they may have in vindicating him in relation to the wide publication.'

377. This (amongst other authorities relied on by AbbVie) shows that, when considering whether to grant the declaration in the present case, I am concerned with whether it will serve a useful purpose in the United Kingdom. A declaration which is sought solely for the benefit of foreign courts will rarely be justified, as was emphasised by Floyd LJ in the FKB Appeal Judgment.

> '95 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. Mr Hobbs' example of a business problem in Romania would be unlikely to justify the grant of a declaration by the English court.'"

46. Then Carr J said in his assessment:

> "386. I do not accept AbbVie's submissions, and I accept the Claimants' case on this issue, to the extent set out below. If, as AbbVie submits, the declarations have no useful purpose, and the steps that they have taken have the same effect in achieving commercial certainty, there is no coherent explanation as to why it refuses to submit to judgment, or alternatively to give an acknowledgement in the same form as the declarations. The suggestion that AbbVie resists the declarations because it does

not accept that the relevant dosing regimens were anticipated or obvious does not withstand examination, and has not been put forward in evidence. If that were the case, AbbVie would not have abandoned its UK patent protection. Had it maintained that protection, and won the trial, it would have been able to stop the launch of the Claimants' biosimilars.

387. In my judgment, AbbVie would not have invested the considerable resources that this trial has required unless there was a good commercial reason to resist the declarations. In the absence of any alternative explanation in evidence, I believe that the declarations will be more damaging to AbbVie's strategy in relation to its Humira patent portfolio than the complex set of undertakings and abandonment of UK patent protection that it has chosen to provide.

...

394. I consider that the grant of a declaration would serve a useful purpose, for the following reasons. First, commercial certainty. Mr Inman and Dr Gilbert suggested in their evidence that the reason why AbbVie had abandoned its UK patents was to shield them from the scrutiny of the UK Courts. They claimed that AbbVie continued to resist the declarations precisely because they would serve a useful purpose, namely to provide the Claimants with adequate certainty as regards the intended launch of their biosimilar adalimumab products; see for example Gilbert (3) [33].

...

397. I have also found that AbbVie has made threats that it will enforce its patents against biosimilar competition anywhere in the world. The declarations will serve a useful purpose of dispelling commercial uncertainty in the UK (and European) market, which those threats have created.

...

401. I also consider that the declaration would serve a useful purpose in protecting the Claimants' supply chain for the UK market. At [2.8(a) – (b)] of his eleventh Statement, Mr Inman expressed concern as to the 'chilling effect' in the market, in the absence of a declaration, in that manufacturers of products are likely to find it more difficult to enter into an agreement with a prospective EU marketing partner, when despite the UK being patent free, the rest of the EU remained subject to the threat of potential patent litigation. He explained that, as a practical matter, due to the international nature of the industry, most biosimilar manufacturers will be unable to confine their

> manufacture and supply chain to within the UK, so the UK market may not be able to be exploited without being at risk of AbbVie's patents in other jurisdictions.'
>
> ...
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> 404. Dr Gilbert explained in her fourth statement at [7]–[9] that if AbbVie were to commence proceedings for infringement of those patents which it has de-designated for the UK in other European jurisdictions, then it is foreseeable that this will have an effect on the supply of SB/Biogen's biosimilar to the UK market. She stated that once manufactured or imported into the EU, a pharmaceutical product may be transferred to other countries for QA release in accordance with EMA requirements, and may be transferred elsewhere for filling into vials, packaging and labelling before being stored at a central distribution hub. An injunction obtained at any of these locations could disrupt the European supply chain, including supply to the UK market. Dr Gilbert has been informed that SB/Biogen's plans for launching SB5 in the UK will involve such a European supply chain.
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> 405. This evidence goes beyond spin-off value to assist the Claimants' products to be launched in other jurisdictions. It explains how the grant of a declaration will make injunctive relief in other jurisdictions less likely, and why this will be of direct benefit to the UK market.
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> ...
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> 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 (see Gilbert (4) [7]- [9])."

47. Henry Carr J accepted that the spin-off value of a judgment in a Contracting State can be valuable, but that he would not take that into account other than to the extent that would impact on the UK market, which was a reference to supply chains.

48. Finally 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."

49. Henry Carr J said that he found relevance in the unusual facts of the case to do with AbbVie's conduct of threatening infringement whilst abandoning proceedings at the last moment. I do not accept that there is any direct parallel between AbbVie's conduct and that of Novartis in this case. I have made clear in the course of argument that I do not think it is appropriate to conduct my decision-making on this application by comparing facts, but it does seem to me that paragraph 416 justifies the proposition that the conduct of the patentee is a relevant factor to put into the mix and can have weight. Whilst, as I say, Novartis's conduct is very different in many ways from that of AbbVie, it is unusual and I would go so far as to say surprising.

50. Finally, on this, I was referred to the decision of Birss J in *Pfizer*, to which I have referred already. That is [2019] EWHC 1520 (Pat). Birss J (as he then was), identified the high-level points, the key principles at paragraph 64 as follows:

> "64. However, there the agreement between the parties about principles ends. The parties do not agree on how these principles are to be applied in this case. In summary 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.
>
> ...
>
> 67. I believe the most important case on the modern approach to declarations is *Messier-Dowty v Sabena* [2000] 1 WLR 2040. There the Court of Appeal held that when determining the question of whether to grant a negative declaration the Court should decide 'whether the declaration would serve a useful purpose'. The court went on to hold that:
>
> 'The approach is pragmatic. It is not a matter of jurisdiction. It is a matter of discretion.' [P2050 G-H]"

51. He said that the most important case on the modern approach is *Messier-Dowty* and that the key touchstone there was useful purpose; that the approach is pragmatic and not a matter of jurisdiction, but a matter of discretion.

52. I have also found important and helpful paragraphs 85-88, where Birss J concluded that he would not grant the declarations sought, basically because he concluded that it was an exercise in forum shopping and that the foreign court -- in that case the Belgian court -- would be able to reach its own decision about what to do and would not be assisted by a decision of the English court.

53. Finally at paragraph 118, Birss J said had there been pending UK applications there would be a plain case for an *Arrow* declaration. That is what I referred to at the beginning of this judgment. At paragraph 122, in a wrap-up, he said, reiterating what I have touched on already, that the true purpose of an *Arrow* declaration in the case before him was for its use in foreign courts and that that was not enough.

54. Novartis says that the proposed amended pleading is no more than what was before Birss J in *Pfizer* and, furthermore, that given the other disputes in other European territories, details of which are given in the evidence and which I think it is unnecessary to pick through, the German court will not get any additional benefit from a UK decision and, furthermore, even if there were not any other cases going on in Europe, an uncontested decision in the UK will not be of assistance there.

55. The two key points for me are that this is an uncertain and developing area and that I am hearing not a trial or a mini-trial, but a strike-out application. I say this is an uncertain and developing area because there are few decisions. It is developing. My recollection is that it was for commercial reasons, but certainly it is true to say that the *Pfizer* case did not go to the Court of Appeal. So whilst it is a decision of a respected patents judge, it cannot be taken as a firm decision to the effect that spin-off value is of such very limited use and only relevant in such limited circumstances. In my view, it is not impossible that, at trial, with a full understanding of the German law position and of the other proceedings around Europe, and of the other factors which make this situation unique, in particular Novartis's conduct, it is not impossible that the court exercising a discretion would make an *Arrow* declaration. I am confident that it is the better, fairer route to find the facts against the backdrop of my decision that that can fairly be done, rather than to decide this as a matter of law, which just simply, to my mind, opens up the possibility that my decision to strike out the claim or to not allow it because it does not pass the strike out standard, will itself go to the Court of Appeal and delay things.

56. I am bolstered in that conclusion, although it is not necessary to the ultimate result, that proceeding in this way uses court time that is already set aside for these litigants and offers the possibility, I put it no more highly than that, that if the trial judge is minded to grant a declaration, it will be done in a timeframe which is useful to Teva.

57. My conclusion is that I will allow the amendment, subject to the further particularisation of the pleading and subject to the changes to Teva's evidence that I have indicated and I will allow Teva until next Wednesday to amplify that evidence, but apart from that, I think the pleading should be allowed.

58. I want to make it clear that, in that conclusion, I am by no means saying that Teva has an easy ride to come. It could easily be the conclusion of the trial judge in due course that an uncontested decision of a UK court, when there are many other decisions to broadly similar effect just is not worth it, but that is for another day and for trial. My decision today is that, in the sense that I have indicated and with the limitations indicated, permission to amend, and I will now consider directions.

59. Post script: when giving judgment orally I intended to say, but inadvertently omitted to, that that the 2-day trial I have directed is on the discretionary issues only. It does not include dealing with the technical issues in the event that Teva succeeds on discretion. In the event that Teva succeeds on discretion it will be for the trial judge also to decide when and how to assess the technical issues. In that scenario Teva will of course be free to argue that decision on the technical issues is needed, and can be done, quickly.

60. My reasons for this conclusion are that there is already time and resource pressure on the trial, that Teva has not sought to argue that the apparent strength of the patent is a factor on discretion, that in the event that Teva does not succeed on discretion the technical issues should arguably not be considered at all (see *Pfizer*), and the fact (already mentioned) that if Teva succeeds, a quick decision on the technical issues can be argued for.

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