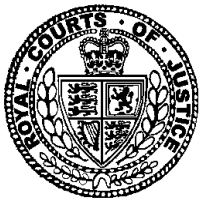

Neutral Citation Number: [2022] EWHC 959 (Ch)

Case No: HP-2022-00006

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: 26/04/2022

Before:

THE HONOURABLE MR JUSTICE ROTH

- -

Between:

(1) NOVARTIS AG
(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 **Defendants**

- -
- -

MS CHARLOTTE MAY Q.C., MS. LINDSAY LANE Q.C. and MR. HENRY EDWARDS (instructed by **Bristows LLP**) for the **Claimants**

MR. THOMAS HINCHLIFFE Q.C. and **MR. ADAM GAMSA** (instructed by **Pinsent Masons LLP**) for the (**1st Defendant)**
MR. CHRISTOPHER HALL (instructed by **Lambert Hornby**) for the (**2nd Defendant)**

MR. TOM MITCHESON Q.C. (instructed by **Taylor Wessing LLP**) for the (**3rd Defendant)**

MR. WILLIAM DUNCAN (instructed by **Mishcon de Reya LLP**) for the (**5th Defendant)**

The 4th and 6th Defendants did not attend and were not represented

Hearing dates: 17-18 March 2022

- -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

THE HONOURABLE MR JUSTICE ROTH

Mr Justice Roth:

INTRODUCTION

1. The First Claimant is the parent company of a well-known pharmaceutical group based in Switzerland and the Second Claimant is its wholly owned English subsidiary which distributes the group's products in the UK. I shall refer to them together as "Novartis".

2. These proceedings were commenced on 2 March 2022 and Novartis applied for an interim injunction as a matter of urgency, for reasons which I explain below.

3. There are six defendants named on the claim form but the Sixth Defendant has not been served and no relief is sought against it. The five defendants against whom relief is sought are all manufacturers or suppliers of generic drugs and I shall refer to them together, except where it is necessary to distinguish between them, as "the generic Defendants" or simply "the generics". Novartis and the Fourth Defendant have agreed that the application as against the Fourth Defendant will stand or fall with the application against the other four active defendants, and on that basis that Fourth Defendant took no part in the hearing of the application.

4. The application came on for hearing just over two weeks after it was issued. Following the hearing, some further information was received from the parties in writing, and I then informed them that the application for interim relief is refused for reasons to follow. This judgment sets out my reasons.

BACKGROUND

5. The application concerns a prescription-only pharmaceutical drug called fingolimod. It is used very beneficially as a disease modifying treatment ("DMT") for relapse remitting multiple sclerosis ("RRMS"), which is one of the three main types of MS. It is supplied in the UK by Novartis under the brand name "Gilenya".

6. Gilenya was launched in the UK in 2011. The regulatory and market exclusivity for Gilenya expired on 22 March 2022, i.e. five days after the application was heard.

7. The generic Defendants have all received marketing authorisation for their generic version of fingolimod in 2020 or 2021, and it appears that some if not all of them are in a position to seek to enter the market. By this application, Novartis seeks an injunction to prevent that from happening.

8. The reason the application was not made earlier is the somewhat unusual situation regarding the patent on which Novartis seeks to rely. In summary, the relevant patent application is EP 2 959 894 ("EP894"). That is an application for a divisional patent which was filed before the European Patent Office ("EPO") on 16 July 2015 and published on 30 December 2015. It claims a priority date from 27 July 2006. On 29 June 2016, the application was amended to introduce a claim at a once daily dosage of 0.5 mg.

9. In early November 2019, the EPO examiner raised an objection to the application in response to which Novartis filed an amended claim, relying on a single main request, incorporating the 0.5 mg dosage. That is the form which was ultimately approved.

10. An oral hearing before the Examining Division of the EPO was scheduled to take place on 29 May 2020. However, due to the Covid-19 pandemic, it became clear that the hearing could only take place virtually. Novartis considered that an in-person hearing would be preferable and therefore sought postponement of the hearing; it was rearranged for 2 November 2020. In the event, since the pandemic had not subsided, Novartis then accepted that this would have to be an on-line hearing. The Examining Division refused to grant the patent for lack of novelty and issued its formal decision on 19 November 2020.

11. Novartis immediately appealed to the Technical Board of Appeal ("the TBA") and sought expedition for the hearing of the appeal.

12. The appeal in fact was not heard until 8 February 2022, also as a virtual hearing. Although objectors to an application are not heard on such an appeal, they can put in observations. A significant number of observations were submitted, including observations which placed reliance on the prior art on which the generic Defendants now rely in contending that EP894 would be invalid for lack of novelty.

13. In its appeal, due to concern about the delay, Novartis requested the TBA to consider also the other requirements for patentability under the European Patent Convention ("EPC") that had not been addressed by the Examining Division, to avoid remittal of the case to the Examining Division in the event that the appeal was otherwise successful. The TBA acceded to that request and the hearing of the appeal therefore covered also sufficiency and inventive step. At the end of the hearing, the TBA announced its decision that the patent should be granted and its order to that effect was issued on 11 February 2022.

14. However, the process of issuing the patent involves, first, the production by the TBA of its full written decision, and then remission to the Examining Division, where various formal procedures have to be gone through. As a result, the estimate of Mr Marshall, an experienced patent attorney who assisted Novartis in its appeal to the TBA, is that Patent EP894 will be formally granted only around mid-June 2022.

15. Mr Marshall's view is not challenged by any of the generic Defendants. It is common ground that Patent EP894 will now be granted. At that point, the generic Defendants may invoke the EPO opposition procedure and also seek to challenge the validity of the patent before the Patents Court here. However, the consequence of all this is that the present application for an interim injunction is made by a prospective patentee, in circumstances where it does not yet hold an actual patent.

JURISDICTION

16. Once the patent is granted, Novartis can clearly bring proceedings to restrain threatened or alleged infringements: s. 61(1)(a) of the Patents Act 1977 ("PA"); and indeed if a generic Defendant should now enter the market, following grant Novartis can claim damages for any act which would have infringed the patent if it had by now been granted: see s. 69 PA. But the question arises whether the Court has jurisdiction prior to grant of the patent to issue an interim injunction to restrain such acts. None of the experienced counsel appearing on this application could point to any authority which addresses that question.

17. However, only the Second Defendant ("Dr Reddy's") and the Fifth Defendant ("Zentiva") contended strongly that the Court has no such jurisdiction. The other generic Defendants adopted a neutral position.

18. The submissions for Novartis on this aspect of the application were made by Ms May QC. She relied on s. 37 of the Senior Courts Act 1981 ("SCA"), which provides:

> (1) The High Court may by order (whether interlocutory or final) grant an injunction or appoint a receiver in all cases in which it appears to the court to be just and convenient to do so
>
> (2) Any such order may be made either unconditionally or on such terms and conditions as the court thinks just."

19. Ms May pointed out that it has been recognised that this provision constitutes a statutory enactment of the court's inherent jurisdiction to grant injunctive relief, and referred to the enunciation of the breadth and flexibility of this jurisdiction by the majority of the Judicial Committee of the Privy Council in the recent landmark judgment, *Convoy Collateral Ltd v Broad Idea International Ltd* [2021] UKPC 24 ("*Convoy*").

20. Ms May helpfully set out four principles which she submitted can be derived from the judgment of Lord Leggatt (with whom Lords Briggs, Sales and Hamblen agreed) in *Convoy*. Adapting them slightly, I consider those principles can be stated as follows:

i) No cause of action is needed to seek an injunction under s. 37 SCA: *Convoy* at [52] and [53]-[56];

ii) The court's power to grant an injunction under s. 37 SCA is unlimited, subject to any statutory restriction: *Convoy* at [57]-[58] and [78];

iii) The courts exercise that power in accordance with established practice but have the flexibility to modify existing practice where to do so accords with principle and is necessary to provide an effective remedy: *Convoy* at [59];

iv) The power should be exercised to protect an interest of the claimant which merits protection on the basis of legal or equitable principles: *Convoy* at [52].

21. As I understood it, none of the generic Defendants contested this analysis of the jurisdiction under s. 37 SCA.

22. Does the PA impose a statutory restriction on this otherwise broad and flexible jurisdiction, that is applicable in the present circumstances? The scheme of remedies for patent infringement is set out in s. 61 PA, and s. 61(1) states:

> "**61 Proceedings for infringement of patent**
>
> (1) Subject to the following provisions of this Part of this Act, civil proceedings may be brought in the court by the proprietor of a patent in respect of any act alleged to infringe the patent and (without prejudice to any other jurisdiction of the court) in those proceedings a claim may be made—

> (a) for an injunction or interdict restraining the defendant or defender from any apprehended act of infringement;
>
> (b) for an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
>
> (c) for damages in respect of the infringement;
>
> (d) for an account of the profits derived by him from the infringement;
>
> (e) for a declaration or declarator that the patent is valid and has been infringed by him."

23. The critical question is the implication and effect of s. 69 PA. This states:

> "**69 Infringement of rights conferred by publication of application**.
>
> (1) Where an application for a patent for an invention is published, then, subject to subsections (2) and (3) below, the applicant shall have, as from the publication and until the grant of the patent, the same right as he would have had, if the patent had been granted on the date of the publication of the application, to bring proceedings in the court or before the comptroller for damages in respect of any act which would have infringed the patent; and (subject to subsections (2) and (3) below) references in sections 60 to 62 and 66 to 68 above to a patent and the proprietor of a patent shall be respectively construed as including references to any such application and the applicant, and references to a patent being in force, being granted, being valid or existing shall be construed accordingly.
>
> (2) The applicant shall be entitled to bring proceedings by virtue of this section in respect of any act only—
>
> (a) after the patent has been granted; and
>
> (b) if the act would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent, but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.
>
> (3) Section 62(2) and (3) above shall not apply to an infringement of the rights conferred by this section, but in

> considering the amount of any damages for such an infringement, the court … shall consider whether or not it would have been reasonable to expect, from a consideration of the application as published under section 16 above, that a patent would be granted conferring on the proprietor of the patent protection from an act of the same description as that found to infringe those rights, and if the court … finds that it would not have been reasonable, it … shall reduce the damages to such an amount as it … thinks just."

24. Mr Duncan, who made the submissions contesting jurisdiction, contended that the law is therefore clear that pre-grant, the applicant has rights only in respect of damages for infringement, and that it may not sue to recover those damages until after grant. His written submissions stated boldly:

> "It cannot be that where a patentee explicitly only has rights in damages pre-grant under the Act, and even then can only sue after grant, a Patentee could nonetheless sue pre-grant, and seek an immediate injunction. This is explicitly contrary to the wording of the Act."

25. However, a remedy in damages, which is of course final, is very different from relief by way of interim injunction, which by its nature is temporary and provisional, and supported by a cross-undertaking in damages to protect the defendant. Injunctive relief is not explicitly referred to in s. 69 PA. Moreover, I see no inconsistency as a matter of principle in the court having power, when appropriate, to prevent a defendant from doing something which, if it were done, might subsequently give the victim of those acts the right to claim damages for the resulting loss, just because there is a bar on seeking those damages until a later stage.

26. It has been recognised that the PA does not set out an exhaustive code of the circumstances in which relief may be available, at least where a patent has not been granted. That is demonstrated by the courts' recognition of the jurisdiction to award a so-called *Arrow* declaration, i.e. a declaration that a given product was obvious at a certain date, with the consequence that any subsequent patent for it would be invalid. The circumstances in which the validity of a patent may be put in issue are prescribed by PA s. 74, and s. 74(2) states specifically:

> "The validity of a patent may not be put in issue in any other proceedings and, in particular, no proceedings may be instituted (whether under this Act or otherwise) seeking only a declaration as to the validity or invalidity of a patent"

27. In *Fujifilm Kyowa Kirin Biologics Co, Ltd v Abbvie Biotechnology Ltd* [2017] EWCA Civ 1, the Court of Appeal considered whether s. 74 PA therefore excluded the grant of an *Arrow* declaration. The contention to that effect was summarised by Floyd LJ at [90]:

> "At its most straightforward, the argument is that it is the Act which grants the patent rights enjoyed by the patentee, and which provides for the manner in which their validity is to be examined.

> It is not for the courts in those circumstances to find other ways of making findings of invalidity which are not contemplated in the statute. The statute provides the exclusive remedy."

Rejecting that argument, the Court held that the PA provides a complete statutory code for challenging the validity of a *granted* patent, but an *Arrow* declaration does not declare such a patent to be invalid. Floyd LJ's judgment continued, at [92]:

> "… it is one thing to say that the statute should be understood to be providing an exclusive statutory remedy in relation to granted patents (which it does). It is going much further to say that it is providing an exclusive remedy in relation to patents which have not and may never be granted. We do not think that it can have been the intention of Parliament to preclude the grant of declarations, however strongly justified, in circumstances where the statutory remedy is simply not available."

28. Furthermore, there is nothing in the PA equivalent to s. 74(2) as regards the granting of injunctions and s. 69 refers only to proceedings for damages. However, in *Spring Form Inc v Toy Brokers Ltd* [2002] FSR 17, Pumfrey J (as he then was) held that s. 69(1) PA enables not only a claim for damages to be brought in respect of the period pre-grant but also a claim for an account of profits. As the judge observed, it is difficult to see any rational distinction between those two remedies in view of the evident purpose of s. 69(1). Pumfrey J reached that result by interpreting s. 69(1) as importing all the remedies under s. 61(1) by reason of the cross-references in the second part of the sub-section. He referred (at [15]) to the argument of counsel for the patentee that:

> "the provisions in respect of sections 60-62 and 66-68 are entirely general and confer a right on the patentee to claim an account of profits in respect of the period during which he was an applicant merely."

29. Pumfrey J effectively accepted that argument and proceeded to state, at [16]:

> "In my judgment, it would be clear that an account is available in respect of infringements committed during the pre-grant period were it not for subsection 69(3). It can be argued with justice that if it is irrational to exclude accounts of profits, so also is it irrational not to provide this defence, when it is available to a claim for damages. However, the contention loses some of its force when one considers that although subsection 62(3)does not on its face apply to an account of profits, it may well be that an account of profits, an equitable remedy, should not be awarded in respect of infringement of a patent framed without good faith or the exercise of reasonable skill and knowledge. Mr Silverleaf submits that the award of an account can be refused on equitable grounds, and that such grounds as the unforeseeability of relevant protection must be relevant. On the whole, I consider that I should give greatest weight to the words of the section which apply sections 60–62 with the necessary amendments to the position before grant, and hold that in principle an account of

> profits is available in respect of infringing activities before grant."

30. In the light of that interpretation, Mr Duncan submitted that s. 69(1) covered a claim for an injunction: see s. 61(1)(a). Accordingly, he argued that s. 69(2) bars proceedings for an injunction being brought pre-grant, and therefore precludes jurisdiction in this court to grant the present application.

31. With the greatest respect to Pumfrey J, his construction of s. 69(1) seems to me a strained reading of the statutory language that effectively emasculates the words "for damages" in the first part of the provision. The tail end of s. 69(1) appears to me no more than the necessary adaptation of the language in the sections identified so that they can be applied to such "proceedings … for damages" in the period before grant. In my view, the same and desirable result of allowing a claim for an account of profits to be brought for the pre-grant period could be arrived at by construing the word "damages" as meaning reasonable compensation, and thus including also an account of profits, by reason of s. 130(7) PA and art. 32(1) of the Community Patent Convention and in view of art. 67(2) of the EPC. This would also provide a straightforward answer to the issue concerning s. 69(3) to which Pumfrey J referred.

32. If that is the correct construction of s. 69(1), a claim for an injunction would not be within the scope of s. 69(1) at all and the prohibition in s. 69(2)(a) would have no application. However, this point was not argued, and I would in any event be reluctant at first instance to reach a different conclusion on the interpretation of the PA from that of a very experienced patent judge.

33. Ms May advanced a very different submission that s. 69(2) is only a procedural bar to a claim for final relief. For that she relied on the decision of the House of Lords in *Sevcon Ltd v Lucas CAV Ltd* [1986] RPC 609. That was a decision under the Patents Act 1949 ("the 1949 Act"), where the issue arose in the context of a limitation argument. For that purpose, it was necessary to establish when the cause of action for infringement accrued. The claim there was for infringement of the patent, but the acts of infringement relied on all occurred after publication of the specification but before grant. Section 13(4) of the 1949 Act stated as follows:

> "After the date of the publication of a complete specification and until the sealing of a patent in respect thereof, the applicant shall have the like privileges and rights as if a patent for the invention had been sealed on the date of the publication of the complete specification:
>
> Provided that an applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed."

34. In his speech, with which all the other members of the Judicial Committee agreed, Lord Mackay said (at 619):

> "I conclude … that section 13(4) does provide rights to an applicant for letters patent immediately after the publication of the complete specification and that if he is in a position to allege that acts have been committed by a defendant which constitute

> infringement of any claim of the complete specification as published, he has a cause of action from the date of these acts although he may subsequently lose that cause of action by failing to obtain a patent or by the complete specification being amended with retrospective effect in such a way that these acts no longer constitute infringement of any of its claims."

35. However, it is notable that Lord Mackay went on to say:

> "If he were to institute proceedings for infringement before the patent for the invention was sealed, the procedural requirement of the proviso would not be satisfied but a statement of claim could not be struck out as disclosing no cause of action although it might be liable to be struck out as an abuse of the process of the court."

36. As I have observed above, under the law as restated in *Convoy*, a claimant seeking an injunction does not need to have an accrued cause of action. So the existence of a cause of action does not for present purposes seem relevant. In any event, although he held that s. 13(4) was "merely procedural", Lord Mackay added that a claim seeking relief falling within its scope "might be liable" to be struck out as an abuse of process.

37. I accept Ms May's submission that although directed at the proviso in s. 17(4) of the 1949 Act, the reasoning of *Sevcon v Lucas* applies equally to s. 69(2) PA. It is well-established that abuse of process is a broad, merits-based test, taking account of all the facts of the case: see the well-known statement of Lord Bingham of Cornhill in *Johnson v Gore Wood & Co* [2002] 2 AC 1 at [31]. Here, where Novartis and the generic Defendants all know that a patent will be granted and the scope of that patent, where the reason that it was not granted immediately following the decision of the TBA in February 2022 is only because of the administrative procedures which apply in the EPO, and where once it has been granted Novartis will then be entitled to claim damages for loss suffered over the period between present introduction of generic product and the date of grant, in my judgment it cannot be regarded as an abuse of process for Novartis to seek interim relief to restrain the acts which would otherwise give rise to that loss.

38. Accordingly, I consider that s. 69 PA is not to be interpreted as a statutory bar on the jurisdiction of the court to grant interim relief under s. 37 SCA.

39. Mr Duncan further submitted that so to find will open the floodgates to claims for interim injunctions pre-grant. I do not accept that. The circumstances of the present case are exceptional as regards the certainty both that a patent will be granted and as to its scope. I consider that the Patents Court will be wary of an attempt to seek interim relief prior to grant of a patent on the basis that such a grant is very likely. The Court can be expected to take account of the legislative policy underlying s. 69 PA that a remedy should not be given until the scope of the claimant's patent has been determined. Floodgates arguments are often raised by parties seeking to resist a legal development, but once the argument is rejected the predicted flood generally fails to materialise. I note that a similar floodgates argument was rejected by the Court of Appeal in the challenge to the jurisdiction to grant *Arrow* declarations: *Fujifilm* at [95].

INTERIM INJUNCTION

40. It is common ground that the test for the grant of interim relief is that set out in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396. That is generally regarded as involving four successive steps or stages:

    i) Is there a serious issue to be tried?

    ii) Are damages an adequate remedy for the loss which the claimant will suffer if no injunction is granted?

    iii) If not, are the damages payable under the claimant's cross-undertaking an adequate remedy for the loss which the defendant will suffer if an injunction is granted but the claimant then fails on its claim at trial?

    iv) If damages are not adequate for either side, where does the balance of convenience lie?

41. As regards step (iv), it is appropriate to recall the words of Lord Diplock in his seminal judgment in that case, at 408-409:

> "It is where there is doubt as to the adequacy of the respective remedies in damages available to either party or to both, that the question of balance of convenience arises. It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them. These will vary from case to case.
>
> Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the *status quo.* If the defendant is enjoined temporarily from doing something that he has not done before, the only effect of the interlocutory injunction in the event of his succeeding at the trial is to postpone the date at which he is able to embark upon a course of action which he has not previously found it necessary to undertake ; whereas to interrupt him in the conduct of an established enterprise would cause much greater inconvenience to him since he would have to start again to establish it in the event of his succeeding at the trial.
>
> Save in the simplest cases, the decision to grant or to refuse an interlocutory injunction will cause to whichever party is unsuccessful on the application some disadvantages which his ultimate success at the trial may show he ought to have been spared and the disadvantages may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's undertaking would not be sufficient to compensate him fully for all of them. The extent to which the disadvantages to each party would be incapable of being compensated in damages in the event of his

> succeeding at the trial is always a significant factor in assessing where the balance of convenience lies; and if the extent of the uncompensatable disadvantage to each party would not differ widely, it may not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence adduced on the hearing of the application. This, however, should be done only where it is apparent upon the facts disclosed by evidence as to which there is no credible dispute that the strength of one party's case is disproportionate to that of the other party. The court is not justified in embarking upon anything resembling a trial of the action upon conflicting affidavits in order to evaluate the strength of either party's case"

And Lord Diplock added:

> "I would reiterate that, in addition to those to which I have referred, there may be many other special factors to be taken into consideration In the particular circumstances of individual cases."

42. More recently, in *National Commercial Bank Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16, Lord Hoffmann summarised the position at [17]:

> "The basic principle is that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other."

(i) Is there a serious question to be tried?

43. It is accepted by the generic Defendants that this threshold is crossed, notwithstanding their contention that EP894 is a very weak patent which will be annulled. They are clearly right to make this concession in light of the decision of the TBA.

(ii) Are damages an adequate remedy for Novartis?

44. Before addressing damages, whether for Novartis if an injunction is refused or, conversely, for the generic Defendants if an injunction is granted, it is necessary to describe briefly the way fingolimod is supplied and administered in the UK. Notably, it is prescribed only in secondary care, not by GPs. Unlike most other prescription medicines, the price is therefore not determined by the NHS drug tariff. At present, where Novartis is the only supplier, supply is under contracts concluded with NHS trusts and hospitals. Ms Bride, the Second Claimant's Director for Market Access, explains that fingolimod is provided under NHS specialised services, involving specialised commissioning which applies where services are provided that require specially trained staff with appropriate expertise, and states that those services are offered in "relatively few hospitals."

45. However, in the expectation of the drug 'going generic', this is changing to an overall tender process. The NHS is not monolithic and different arrangements are being

introduced in the different 'nations'. The current position was clarified following the hearing and, as I understand it, is as follows:

> *NHS England*: the invitation to tender was published on 17 March 2022 and closed on 22 April 2022. The supply period is from mid-July 2022 until 2023 or 2024. Three contracts will be awarded, each of three for a different region of the country.
>
> *NHS Scotland*: the deadline for tender submissions was 8 March 2022. The start date of the 16 months framework agreement for supply is 1 May 2022. Since the hearing of this application, it has been announced that four bidders have been successful, including the First and Second Defendants. It is understood that under the terms of the Scottish framework agreement, a hospital can purchase fingolimod from any of the appointed suppliers.
>
> *NHS Wales*: although the period for submission of tenders closed on 31 January 2022 (for supply for two years from 1 July 2022), because of these proceedings it has been decided not to award a contract on the existing tenders but to re-issue the invitation to tender at the earliest opportunity following the decision regarding Novartis' interim injunction application.
>
> *NHS Northern Ireland*: it is intended to launch a tender process later this year.

46. Fingolimod is administered as a once daily oral dosage which can be taken by patients at home. However, patients must take their first dose under extended professional observation ("FDO") and then they are monitored over the first year of treatment. This therefore requires a patient support programme ("PSP"). Novartis provides such a dedicated PSP, called "GilenyaConnect", at no additional charge to the NHS. This is explained by Ms Bride in her evidence as follows:

> "Novartis delivers GilenyaConnect through specialist third parties, which provide specially trained MS nurses or cardiac technicians to manage the pre-initiation, FDO and first year monitoring of patients, as well as providing direct telephone support when required. GilenyaConnect patients benefit from having a dedicated GilenyaConnect nurse who can collect blood samples from patients, requiring the ongoing monitoring, and return these samples to NHS hospitals. Where possible, GilenyaConnect support is provided to patients in their own homes. This helps patients to feel at ease, alleviates the pressure on bed space in NHS hospitals and minimises the risks that immunocompromised patients have to face when travelling to hospitals or treatment centres for appointments. Novartis also funds the specialist equipment needed to conduct the pre-initiation checks and FDO … in addition to the general equipment required for taking samples and reporting results."

47. For Novartis, Ms Lane QC relied on two different aspects of damage: direct financial damage and damage to reputation.

Financial damage

48. Financial damage in turn has to be considered for two distinct periods:

    a) the interim period, from now until final judgment.[1] I directed a speedy trial of the infringement and expected annulment claims, to be heard in October 2022, so judgment can be expected in November-December 2022. This period therefore comprises some 7-8 months.

    b) the period post-judgment to the end of patent life in June 2027.

49. The interim period encompasses both the pre-tender supplies and then supplies pursuant to the tenders. Much the greatest volume of supply (c. 85%) is in England, and accordingly there will be under 3 months of pre-tender sales followed by 4-5 months' supplies under tender. In Scotland, accounting for the second highest proportion of supply, given the start date of supply pursuant to the framework agreement on 1 May, the pre-tender sales are insignificant.

50. I recognise and accept that with a number of generics entering the market, there may well be a marked depression in the price of fingolimod in pre-tender sales. But I do not consider that the overall effect is likely to be the kind of significant price-spiral often referred to in pharmaceutical interim injunction cases. As Floyd LJ observed, giving the judgment of the Court of Appeal, in *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2020] EWCA Civ 793 at [13], whether a price spiral will occur in the period until trial is an intensely fact sensitive question. Here, the pre-tender period is very short and, significantly, supplies are pursuant to a limited number of contracts (which I understand usually involve also other drugs), and not spot sales to pharmacies (either directly or through wholesalers). The distribution arrangements for fingolimod, as described above, are very different from those which apply for most prescription medicines. The generics can be expected to keep records of the volumes sold and prices achieved over this short period, and since if Novartis succeeds at trial those sales would instead have been of Gilenya, in my view there is no significant difficulty in calculating Novartis' estimated loss. Moreover, as the Court of Appeal held in *Neurim*, the damages do not have to be a perfect remedy: they have to be adequate.

51. The majority of supplies in the interim period will be pursuant to the tenders. For those, the estimation of damages should be relatively straightforward. The identity of the successful tenderers and the prices of supply will be known and fixed throughout the period. There was conflicting evidence as to how much below the current Gilenya price the tender price is likely to be, but in my view that does not matter. There will be a clear basis on which to determine Novartis' estimated loss. It may be that the generics would seek to argue that if fingolimod had only been available at Novartis' patent price, some NHS purchasers would have switched to other DMT drugs for RRMS, but it would be for them to sustain any such contention and, in any event, the maximum amount of Novartis' damages should be clear.

[1] The generic Defendants undertook not to make generic supplies (other than to participate in the ongoing tender processes) pending delivery of this judgment.

52. Post-judgment, if Novartis sustains its patent protection, it is necessary to consider whether it will suffer any financial loss. There will obviously be no price spiral during the tender period, comprising the months leading up to judgment. Novartis owns a generic, Sandoz, so if it wishes to compete for the tenders to supply fingolimod at a lower price, it can be expected to do so through Sandoz: there is no rational, commercial incentive for Novartis itself to reduce the price of Gilenya. Therefore, if successful in upholding the patent, Novartis would doubtless wish to resume supply of Gilenya at the same price.

53. Ms Bride states that if Novartis' patent was upheld and generic supplies were halted, the NHS "would be extremely reluctant to pay the higher price for Gilenya". Although the Court must be cautious about rejecting evidence at an interim hearing, it does not have to accept uncritically any assertion in a witness statement. That is all the more so when the evidence concerns not past fact but prediction as to the future; and to be fair, Ms Bride does not say that this is certain but only that in her view it is likely. However, the circumstances here, for all the reasons set out above, are very different from those typically arising when drugs are purchased by pharmacies that are reimbursed pursuant to the NHS drug tariff. Here, the purchasers are the NHS commissioning bodies directly, and they are of course very sophisticated purchasers well familiar with the patent system. If it were to be established that fingolimod is protected by a valid patent (as Novartis has of course contended all along), so that the NHS has to revert to purchasing Gilenya, I do not accept that it should be assumed that the NHS will nonetheless refuse to pay the monopoly patent price at which Gilenya has previously been sold.

54. I appreciate that the contention that the patentee would not be able to resume sales at the monopoly price following generic intervention is a familiar argument, and counsel for Novartis referred to the decision of the Court of Appeal in *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 583. But the argument has to be assessed on the evidence in the particular case. There, the Court held that an "immediate downward price spiral" was highly likely "if not inevitable": see at [63]. For the reasons set out above, I consider that such a spiral here is unlikely.

55. Ms Bride considers that instead of paying the high Gilenya price, it is likely that patients would be switched to other medicines where possible. The only reasons given by Ms Bride to support her prediction are that the reputation of Gilenya would be "tarnished" in the period of generic fingolimod availability and that other DMTs "although they may be more expensive, might be viewed as providing better value for money when viewed though a different lens post generic fingolimod entry."

56. I address the question of reputational damage below. However, as regards alternative DMT drugs, the evidence shows that there are indeed a number of alternatives currently on the market or anticipated to enter it in the foreseeable future. I have no doubt that the NHS commissioning bodies, which are always alert to the need for effective medicines management, will evaluate the price-value of Gilenya as against alternative treatments. But in my view that is a continuing process which would apply irrespective of generic entry. To suggest that the NHS will not otherwise consider, over the period 2023-2027, whether alternative DMT drugs are substitutable for fingolimod and give better value, seems to me wholly unrealistic. Moreover, there is a distinction between switching a patient who is stable on treatment with a DMT and initiating a new patient onto DMT treatment. As the NHS *Treatment Algorithm for Multiple Sclerosis:*

Disease-Modifying Therapies (2019) makes clear, the general principles for switching such patients are based on drug intolerance or disease activity (i.e. efficacy). Patients treated with fingolimod are by definition suffering an extremely serious disease, and I regard it as close to fanciful to suggest that the specialist clinical teams[2] caring for such patients would switch their drug for purely financial reasons. The *Treatment Algorithm* also states, significantly:

> "Every region should make all licensed MS drugs available to all people with MS in that region."

57. Ms Bride also suggests that physicians evaluating patients on fingolimod "may well consider and prescribe alternative medicines when generic fingolimod is removed from the market." She acknowledges that the extent to which this might happen cannot be predicted. However, it is axiomatic that physicians are required to make prescribing decisions according to the best interests of the patient. As Ms Bride notes in her evidence, a large number of new DMTs to treat MS have recently been introduced and continue to be introduced. As she states:

> "The introduction of a large number of new DMTs to treat MS in quick succession has presented, and will continue to present, physicians with a greater range of options as to how to treat patients."

58. In that regard, she highlights four new medicines: Mayzent (launched in September 2020), Kesimpta (launched in May 2021), Ponvory (launched in February 2022) and Vumerity (which is expected to be launched in May 2022). She says that these may be expected to achieve greater market share in future "given the clinical benefits that they offer patients". I have no doubt that this expectation is reasonable, but it results from the clinical benefits of these newer formulations, compared to Gilenya, which was launched for adults in 2011. That is a process which will take place in any event, as Ms Bride recognises in her second witness statement. Moreover, on Novartis' own evidence, Mayzent is a treatment for secondary progressive MS ("SPMS"), a different form of the disease from RRMS. Altogether, I see no justification for the suggestion that the degree to which patients will be prescribed other DMT treatments will somehow be affected by whether or not fingolimod is available in generic form for the next 7-8 months. It is notable that none of these four drugs is available in generic form so they are all likely to be significantly more expensive than generic fingolimod.

59. Ms Bride also suggests that the entry of generic fingolimod onto the market will lead to downward price pressure on DMTs as a whole, which would cause the prices for all these newer products to be reduced, which in turn would make it harder for Novartis to sustain the existing price for Gilenya. Not only is this pure speculation, but I regard it as inherently improbable that suppliers of new, patented medicines, which claim to offer enhanced clinical benefits, would reduce the price of those products in reaction to the availability, for a limited period of 7-8 months, of generic supply of a considerably older medicine. Indeed, both Mayzent and Kesimpta are Novartis products, and the

[2] The *Algorithm* explains that the "minimum team" for any prescribing service is a MS specialist consultant neurologist and a MS specialist nurse, working with support from a specialist MS centre and its multi-disciplinary team.

extract from Novartis' Annual Report 2021 placed in evidence shows the promotional effort being made by Novartis as regards Kesimpta and that it regards Kesimpta as one of the newer drugs offsetting the decline in sales experienced for Gilenya that have nothing to do with generic pricing.

60. Moreover, as I have just noted, Gilenya's market share is declining in any event. Ms Bride records that the UK market for DMTs for RRMS is growing, as each year more people are diagnosed with RRMS. She says that the number of MS patients receiving DMTs increased by 12% between 2020 and 2021. The evidence filed on behalf of Dr Reddy's shows that while the number of patients on Gilenya increased by 10% from 2018 to 2019, thereafter it remained fairly stable (and indeed declined by almost 5% between 2020 and 2021). That is consistent with Novartis's statement in its 2021 Annual Report that, worldwide, Gilenya sales declined in value by 7% "due to increased competition."

61. If all that Novartis is seeking to say is that the level of sales of Gilenya from late 2022 onwards cannot accurately be predicted, then I agree, for the reasons briefly set out above. The evidence suggests that it seems unlikely to increase to any significant extent and may gradually decline. However, I do not see any sound basis to find that the future sales of Gilenya would be materially affected by the temporary introduction of fingolimod in generic form for a period of months and then a return to supply in branded form only. Since the pecuniary effect of that brief generic presence would be the loss for which Novartis would be entitled to recover damages, in my judgment on the evidence, it is not made out and is extremely unlikely.

Reputational damage

62. Novartis states that it is a leading developer of MS drugs and that it has a high reputation in the field. The assertion that this reputation would be damaged is also put two ways: first, as regards patients; and secondly, as regards doctors and healthcare professionals.

63. As regards patients, Ms Bride states that they tend to have "an emotional connection" to their treatments and to be very informed regarding their options and treatment decisions. She says that they are likely to blame Novartis if they are moved from the GilenyaConnect PSP to another programme and then back again. Further, she contends that at least for most generics the PSP which they could offer will be inferior to that of Novartis because of the lower margin they will enjoy as a result of competition driving down the price.

64. However, as regards GilenyaConnect, while I do not belittle the quality of that service, I note that it is provided not by Novartis itself but delivered through specialist third party providers. I have no reason to suppose that there are not third party providers of equal quality who could be engaged to provide patient support (and possibly even the same providers could continue, contracting with a different party). Moreover, the generics point out that in each of the three existing invitations to tender they have not been asked to supply a PSP, and that the savings in the cost of fingolimod achieved by the NHS through generic supply should more than cover the cost to the NHS of arranging for a replacement PSP. The NHS currently spends over £46 million p.a. on Gilenya whereas the cost to Novartis of operating GilenyaConnect and its homecare delivery service was only £2 million last year. There is of course no clinical difference whatever between generic fingolimod and Gilenya, and if patients are well informed

they should, at least for the most part, appreciate that the switch to another PSP has been made because it results in significant savings for the NHS while maintaining their treatment with the identical medicine.

65. I should add that much the most patient-intensive aspect of the PSP appears to be the FDO when the patient is initiated on fingolimod. On the evidence, between 4000 and 5000 patients in the UK are being treated with Gilenya and the average length of treatment is 3.5-4.7 years. There is no evidence as to the number *initiated* on Gilenya in a year, but clearly it is a minor proportion of the total number being treated. Therefore over the period of 7-8 months until judgment after trial, a relatively small number will have to be initiated and receive FDO in any event.

66. Furthermore, as Dr Reddy's point out, it appears that only a minority of patients treated with Gilenya are receiving PSP services under the GilenyaConnect programme. The position is not altogether clear, but Ms Bride's evidence states that, in the last six months, 91 NHS trusts had active patients on Gilenya using homecare services,[3] but only 17 NHS trusts received PSP services via GilenyaConnect.

67. For healthcare professionals, Novartis asserts that "it would present a very large administrative burden" to deregister patients from GilenyaConnect and register them with a new provider, and then reverse the process once Novartis succeeds at trial. A similar point is made as regards Novartis' homecare delivery service. Ms Bride also says that removal of GilenyaConnect would place a strain on the cardiology departments in hospitals which would have to carry out the cardiac FDO.

68. I accept that there would be some administrative burden, but if the NHS, or (pre-tender) individual hospitals, decided to switch to generic supply they can be expected to take account of the resulting cost as against the savings they make through the lower drug price. Similarly, they are well able to assess the impact on cardiology departments and are free to decide to use specialist third party suppliers of FDO. If the NHS (or a hospital) subsequently finds that it struggles to maintain an adequate PSP, I do not see how that would harm Novartis' reputation.

69. Novartis also operates a homecare dispensing and delivery service, apparently provided through multiple third party providers which enable the NHS trusts to use their preferred supplier. As I understand it, unlike GilenyaConnect this is provided for all patients on Gilenya. There is no reason to suppose that the NHS itself or a generic supplier could not similarly arrange for such a service and I do not see why patients should feel "messed around", as Ms Bride asserts, if their delivery service is changed or, even if they do, why that should affect the reputation of Novartis.

70. Accordingly, I reject as unconvincing and inherently unlikely the contention that refusal of the injunction and generic entry for the period between now and judgment after trial would damage Novartis' reputation.

71. It follows that on the *Cyanamid* stepped approach, I find that damages would be an adequate remedy to Novartis and no interim relief should therefore be granted. But in

[3] See para 69 below.

case that is wrong, I turn to the question whether damages under the cross-undertaking would be an adequate remedy to the generic Defendants if an injunction were granted.

(iii) Are damages an adequate remedy for the generic Defendants?

72. The loss for which the generic Defendants would claim primarily reflects the sales they would have made if they had been able to enter the market between now and final judgment. Given that there are several Defendants, this requires consideration of (a) the volume of sales which each individual Defendant would have made; and (b) the prices they would have charged.

73. In my view, although the two factors are doubtless related, both are extremely uncertain. Novartis realistically accepts that, as regards pre-tender sales, it may be difficult to quantify the generic Defendants' loss. As regards the tenders, if an injunction were granted, presumably they would not proceed and it would therefore be necessary to consider who would have been likely to have won each tender. Under the Scottish tender, where it appears that the intention is to select several approved suppliers between whom Scottish hospitals could then choose, there would be the further hypothetical question of the level of sales which each of those putative successful tenderers would have made.

74. In my view, these matters would be very difficult to estimate as regards the counter-factual world of generic competition that never took place. I therefore find that damages for the generic Defendants, considered individually or even collectively, would be hard to quantify on an adequate basis.

(iv) The balance of convenience

75. Given my conclusions on the respective adequacy of damages, I do not reach the stage of the balance of convenience. But as it was addressed by several of the parties, I add some brief comments.

76. I was urged by several of the generic Defendants to take account of the strength of their underlying case on the patent. They submitted that it is a very weak patent, since it is a dosage patent and is obvious over the prior art. I was referred in that regard to the Supreme Court judgment in *Actavis Group PTC EHF v ICOS Corp* [2019] UKSC 15. I will not rehearse the competing arguments but say only that I do not regard the position as sufficiently clear and consider that at this interim stage it would be wrong to reach even a preliminary view either way.

77. Reliance was placed by the generic Defendants on the tactics adopted by Novartis regarding divisionals. The position is that Novartis filed the parent application with the EPO (EP 2 037 906) on 25 June 2007. On 27 September 2013, Novartis made its first divisional application (EP 2 698 154). On 24 March 2015, the parent application was withdrawn and on 16 July 2015 Novartis filed its second divisional (the EP894). On 25 May 2016, the first divisional was deemed to be withdrawn. As noted above, on 29 June 2016, the application for EP894 was amended to include the 0.5 mg dosage claim. It was as a result of this process that it was only in May 2020 that the hearing concerning the application for the EP894 patent was due to take place before the Examining Division.

78. Mr Hall, who made submissions on this point for the generic Defendants, readily acknowledged that there was nothing unlawful in what Novartis had done. He recognised that such conduct was not altogether unusual among innovator drug companies. But it had the effect of delaying the potential grant of the patent until close to the time when regulatory exclusivity came to an end. That meant that any generic who then wished to enter the market would not have the opportunity first to challenge the validity of the patent: if it wished to enter, it would have to do so 'at risk'.

79. Novartis is of course highly experienced when it comes to pharmaceutical patents and the operation of the EPO. Although pursuit of the strategy which it adopted here is not a cause for recrimination, it effectively precluded the potential for a generic to seek to 'clear the way' by seeking to revoke the patent (or obtain a declaration of non-infringement) before it could commence supply. It is now established that the failure by a generic to clear the way counts in favour of the grant of an interim injunction to restrain alleged infringement: see *Terrell on the Law of Patents* (19th edn, 2020) at para 19-245 and the cases cited in fns 385-386. Similarly, it seems to me that conduct by a patentee by way of repeated divisional filings and amendments to prolong the patenting process with the consequence that generics cannot effectively seek to clear the way is relevant as a factor against the grant of interim relief.

80. Dr Reddy's also submitted, as a further consideration against the grant of equitable relief, that Novartis was responsible for material non-disclosure to the EPO. This concerned Novartis' assertions that the 0.5 mg dosage was not obvious. However, I consider that the fact that Novartis' own scientists thought that this dosage might be effective does not mean that it was obvious in the relevant sense: clearly, Novartis would not be making the claim unless its own researchers considered that it would be effective. I reject as misconceived the contention that Novartis was involved in material non-disclosure.

CONCLUSION

81. For the reasons set out above, I conclude that:

(a) the Court has jurisdiction to grant an interim injunction although the patent has not yet been granted to Novartis; but

(b) in all the circumstances, Novartis' application for interim relief is refused.

82. I should add that I would have reached the same conclusion as regards (b) if, instead of adopting a step-by-step approach on the basis of *American Cyanamid*, I had considered the overall question of whether the least risk of irremediable prejudice results from the grant or refusal of interim relief.