Neutral Citation Number: [2025] EWCA Civ 480

Case No: CA-2025-000746

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (ChD), PATENTS COURT
Michael Tappin KC sitting as a Deputy High Court Judge
[2025] EWHC 748 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 16 April 2025

Before :

LORD JUSTICE COULSON
LORD JUSTICE ARNOLD
and
LORD JUSTICE WARBY

- -

Between :

(1) ASTRAZENECA AB **(2) ASTRAZENECA UK LIMITED**	**Claimants/ Appellants**
- and -	
GLENMARK PHARMACEUTICALS EUROPE LIMITED	**Defendant/ Respondent**

- -
- -

Geoffrey Pritchard KC and Thomas Lunt (instructed by **Freshfields LLP**) for the **Appellants**
James Abrahams KC (instructed by **Powell Gilbert LLP**) for the **Respondent**

Hearing date : 9 April 2025

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Approved Judgment

This judgment was handed down remotely at 10.30am on 16 April 2025 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Arnold:

Introduction

1. This is an appeal by the Claimants ("AstraZeneca") against an order of Michael Tappin KC sitting as a Deputy High Court Judge dated 28 March 2025 dismissing AstraZeneca's application for an interim injunction against the Defendant ("Glenmark") for the reasons given in the judge's judgment of the same date [2025] EWHC 748 (Pat). Although the judge's decision involved an exercise of discretion applying well-established principles, I nevertheless granted permission to appeal and expedited the appeal partly because those principles have recently been questioned, partly because the application is a rather unusual one and partly because the situation was (and remains) an evolving one. As explained in more detail below, the application was made on the eve of the trial of proceedings involving AstraZeneca, Glenmark and two other parties, and it sought an injunction until the form of order ("FOO") hearing following the judge's forthcoming judgment in those proceedings.

2. At the conclusion of the hearing the Court announced that the appeal would be allowed for reasons to be given in writing later. This judgment sets out my reasons for reaching that conclusion.

Dapagliflozin

3. The appeal concerns a prescription-only medicine called dapagliflozin. Dapagliflozin is an SGLT2 inhibitor. SGLT2 inhibitors work by targeting the sodium-glucose co-transporter 2 (SGLT2) protein in the kidneys. Normally, the kidneys filter blood and reabsorb glucose back into the bloodstream. SGLT2 inhibitors block the reabsorption of glucose in the kidneys, causing excess glucose to be excreted in the urine. This reduces the amount of glucose in the bloodstream, leading to lower blood sugar levels. This is beneficial for patients with Type 2 diabetes. SGLT2 inhibitors have also been shown to lower the risk of heart attacks, help people with heart failure and slow the progression of kidney disease. Other SGLT2 inhibitors include canagliflozin and empagliflozin.

4. As discussed in more detail below, the UK market for dapagliflozin is large, and has grown very substantially over the last three years. Dapagliflozin now has over 60% of the SGLT2 inhibitor market in the UK. Furthermore, heart and kidney disorders remain significantly underdiagnosed, and around 3.7 million people in the UK are currently eligible for, but not taking, SGLT2 inhibitors.

The revocation proceedings

5. The First Claimant was the proprietor of European Patent (UK) No. 1 506 211 ("the Patent"), which expired on 15 May 2023, and is the proprietor of United Kingdom Supplementary Protection Certificates Nos. SPC/GB13/021 ("the SPC"), which relates to dapagliflozin, and SPC/GB14/050, which relates to a combination of dapagliflozin and metformin ("the Combination SPC"). The SPC is due to expire on 13 May 2028 and the Combination SPC is due to expire on 14 May 2028. Both the SPC and the Combination SPC are based on the Patent.

6. The Second Claimant holds a UK marketing authorisation ("MA") in respect of a product known as Forxiga which contains dapagliflozin as the active ingredient, as well as MAs for products containing combinations of dapagliflozin with other active ingredients. Forxiga is indicated for the treatment of Type 2 diabetes, heart failure and chronic kidney disease.

7. On 6 October 2023 Generics (UK) Ltd trading as Viatris commenced proceedings for revocation of the SPC and the Combination SPC on the ground that the Patent was invalid. Similar proceedings were brought by Teva Pharmaceutical Industries Ltd and Teva UK Ltd ("Teva") on 24 November 2023 and by Glenmark on 21 December 2023.

8. On 26 January 2024 Meade J heard an application by all three claimants to list the trial. All three requested a trial in January 2025, but none of them advanced any commercial reasons for that request. Meade J refused that request, noting that there was no evidence of any planned launch in February or March 2025, and the claims were eventually listed for trial in March 2025.

9. The judge heard the trial, starting on 10 March 2025 and concluding on 20 March 2025, and reserved judgment. At the time of hearing the present application on 27 March 2025 the judge was unable to say when he would be in a position to hand down that judgment. The parties assumed that the FOO hearing would take place between one and three months after 17 March 2025, and the judge was content to proceed on that basis.

The application

10. Late on 20 February 2025 Glenmark notified AstraZeneca that it had obtained an MA for a dapagliflozin product and was prepared to launch that product "at risk" (i.e. to take the risk that AstraZeneca would bring proceedings for infringement of the SPC and the consequences which that might entail). Glenmark stated that it would not release the product to the market before 17 March 2025, but expected to be in a position to do so then. Glenmark's evidence is that its expectation as to the date on which it would be ready to launch its dapagliflozin product in the UK fluctuated over time, and it was only on 20 February 2025 that it became clear that it would be ready to launch as early as 17 March 2025.

11. Glenmark does not dispute that, if the SPC is valid, then its intended marketing of its dapagliflozin product will infringe the SPC.

12. On 28 February 2025 AstraZeneca notified Glenmark that they intended to commence infringement proceedings and to seek an interim injunction. AstraZeneca issued an application notice on 6 March 2025. At Glenmark's request, the application was made on a confidential basis and AstraZeneca did not at that stage issue a claim form. The parties asked the judge to hear the application on 17 March 2025, which was a non-sitting day during the trial, but he was unavailable. The first date on which it proved feasible for the judge to hear the application was 27 March 2025. Glenmark gave an undertaking not to market its product prior to the determination of the application in return for a cross-undertaking in damages from AstraZeneca. Having heard argument on the application, the judge reserved his judgment overnight and delivered it orally on 28 March 2025.

13. AstraZeneca requested permission to appeal from the judge, which he refused. Glenmark agreed to continue its undertaking until the conclusion of an oral application by AstraZeneca for permission to appeal before me which was hastily arranged for 31 March 2025. By that time Teva had become aware of AstraZeneca's application, and its solicitors had written to AstraZeneca's solicitors on 30 March 2025. I was provided with a copy of that letter and read it in preparation for the hearing.

14. Once I had granted permission to appeal and expedited the appeal, Glenmark extended its undertaking to the hearing of the appeal with the modification that in the meantime it would be permitted to distribute to wholesalers approximately 175,000 packs which it said it had loaded on lorries and ready to go, on terms that there would be no further sale or distribution by such wholesalers. That quantity represents around 17.5% of the current monthly total of dapagliflozin packs sold.

AstraZeneca's application to adduce further evidence

15. On 3 April 2025 AstraZeneca applied for permission to adduce further evidence on the appeal. This consists of a fourth witness statement of Christopher Stothers of their solicitors. In this statement Mr Stothers provides an update on communications between his firm and 10 other holders of MAs for dapagliflozin products since his previous witness statement made on 21 March 2025, which was before the judge, and in particular since the hearing before the judge. The update includes the letter from Teva's solicitors dated 30 March 2025 referred to above. Glenmark sensibly did not resist the admission of this evidence. I shall consider its significance below.

The applicable principles

16. The High Court has an inherent jurisdiction as a court of equity, which is confirmed by section 37(1) of the Senior Courts Act 1981, to grant an injunction, whether interim or final, in all cases where it is just and convenient to do so.

17. It was common ground before the judge that he should apply the guidelines laid down in the speech of Lord Diplock in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 at 407G-409D, which must rank as one of the most-cited passages in any English authority.

18. Lord Diplock's guidelines require the court to ask itself four questions:

    (1) Is there a serious question to be tried (or, in current terminology, does the claimant have a real prospect of success)? If not, no injunction should be granted.

    (2) Would damages be an adequate remedy for the claimant for the loss sustained pending trial as a result of the defendant continuing the acts complained of if the claimant were to succeed at trial in establishing its right to a permanent injunction? If they would, and the defendant would be in a financial position to pay those damages, then no injunction should normally be granted.

    (3) If not, would damages on the claimant's cross-undertaking be an adequate remedy for the defendant if the defendant were to succeed at trial in

establishing its right to do acts which had been enjoined? If they would, and the claimant would be in a financial position to pay those damages, then an injunction should normally be granted.

(4) Where there is doubt as to whether damages would be an adequate remedy for either side or both, where does the balance of convenience lie? This depends on all the circumstances of the case. Where other factors appear to be evenly balanced, it is a counsel of prudence to preserve the status quo. There may be special factors which need to be taken into account.

19. In *R v Secretary of State for Transport ex p. Factortame Ltd (No 2)* [1991] 1 AC 603 Lord Goff of Chieveley emphasised at 671F-H that Lord Diplock had laid down guidelines and that his speech was "not … intended to fetter the broad discretion conferred on the courts". Nevertheless Lord Goff reiterated at 672B that the availability to the claimant of an adequate remedy in damages "will normally preclude the grant to him of an interim injunction". He also reiterated that, if there was doubt as to the adequacy of the respective remedies in damages, then the court should proceed to consider the balance of convenience, which depended on the circumstances of the case.

20. In *National Commercial Bank of Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16, [2009] 1 WLR 1405 Lord Hoffmann, having referred to the second and third questions in *American Cyanamid*, observed at [17]:

> "In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. 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. This is an assessment in which, as Lord Diplock said in the *American Cyanamid* case [1975] AC 396, 408:
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> > '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.'"

21. In patent infringement claims, it is often the case that damages will be an adequate remedy for the claimant if it is successful at trial because a final injunction will restore the claimant's monopoly and the claimant can recover damages for its lost profits due to lost sales and/or price depression as a result of infringing acts in the intervening period. This is so even though the quantification of such damages may be heavily disputed. As Floyd LJ explained in *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2020] EWCA Civ 793, [2021] RPC 7 ("*Neurim I*") at [16]:

> "As the judge noted, when Lord Diplock spoke of damages being an 'adequate' remedy, he was not suggesting that damages must provide a perfect remedy. As the judge also observed, there comes a point where 'damages as a remedy falls so far short of the perfect, that the remedy can no longer be described as adequate'. I agree with this. The boundary between the adequate and the inadequate is not a precise one. It is a matter for judicial evaluation on the evidence in any given case whether or not the boundary is crossed. If it is not crossed in relation to the claimant's loss then, normally, an injunction will not be granted."

22. Over the last quarter of a century, a considerable number of interim injunctions have been granted in cases where a generic pharmaceutical company has launched a product at risk of patent infringement. This class of cases is distinguished by three factors in particular.

23. First, the entry of one generic company into a market which has hitherto been monopolised by the patentee is often (but not always) followed by the entry of one or more additional generic companies into that market. This is liable to lead to price-cutting by all the suppliers in order to build or maintain market share, and a resultant downward price spiral. The effect of this on the patentee is liable to be exacerbated, if it continues, by recategorisation of the product under the NHS Business Services Authority ("NHSBSA") Drug Tariff, which affects the reimbursement price of pharmaceuticals dispensed against prescriptions which do not specify a brand.

24. Secondly, the practical ability of the patentee to restore its previous price if successful at trial is generally constrained by NHS resistance to such price rises. Although in theory there is little to stop patentees raising their prices, at least in the absence of recategorisation, this would lead to a loss of goodwill which is generally regarded by patentees as unacceptable. So far as I am aware, there are very few, if any, cases in which a patentee, having cut its prices due to generic competition following the refusal of an interim injunction before trial, has successfully raised its prices back to where they were after having prevailed at trial. Counsel for Glenmark submitted that there were three such cases, but two do not correspond to the situation I have described. One is the apixaban case discussed in paragraph 69 below, where there is evidence of an unexplained price rise recently after a long period of price depression following the judgment of this Court (*Sandoz Ltd v Bristol-Myers Squibb Holdings Ireland* [2023] EWCA Civ 472, [2023] RPC 12). The other is *Cephalon Inc v Orchid Europe Ltd* [2010] EWHC 2945 (Pat), which concerned parallel imports. His best example is the *Neurim* case discussed in paragraphs 27 to 31 below, where there is evidence that product was returned to Category C and the reimbursement price returned to the original price after the defendant's substantive appeal was dismissed (*Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2022] EWCA Civ 699, [2022] RPC 19, "*Neurim III*"), but no further details. It appears, however, that there was only one generic company on the market during the intervening period.

25. The first two factors can lead to the conclusion that damages will not be an adequate remedy for the claimant because of the uncertainty involved. It is usually the case that damages will not be an adequate remedy for the defendant either, however, because it will have no track record of selling the product in question to enable its lost sales to

be quantified. Moreover, establishing the relevant counterfactual can be particularly difficult if it is either known or probable that other generic companies would have entered the market in the meantime, because then there will be uncertainty as to the extent to which the defendant would have benefitted from being the first generic entrant (e.g. by establishing relationships with customers for the product in question).

26. This leads to the third factor, which is that a generic company intending to launch a product at risk must first obtain an MA in order lawfully to be able to market its product and must have a source of supply of a product which has obtained all necessary regulatory approvals. This must be planned some time in advance. Furthermore, the generic company will usually be well aware of the risk of infringement. Typically, it will only launch at risk if it thinks it has a sufficiently strong case that the patent (or SPC) is invalid. In such circumstances the decision of this Court in *SmithKline Beech plc v Apotex Europe Ltd* [2003] EWCA Civ 132, [2003] FSR 31 establishes that it is proper for a court to take into account, when considering the balance of the risk of injustice and deciding to preserve the status quo, that the generic company could have "cleared the path" for its launch by bringing proceedings for revocation of the patent sufficiently far in advance.

27. Returning to the first of these factors, as Floyd LJ noted in *Neurim I* at [13], "whether a price spiral will occur in the period until trial in any given case is intensely fact specific". In *Neurim I* itself Marcus Smith J held that damages would be an adequate remedy for the claimants, and therefore refused to grant an interim injunction. This Court upheld his decision at least in part because the evidence fell a long way short of establishing that any generic company in addition to the defendant was likely to enter the market in the period up to trial and therefore a downward price spiral was unlikely: see Floyd LJ at [46] and [50].

28. There was a sequel to *Neurim I* after the trial. Marcus Smith J held that the patent was valid, granted a final injunction, refused permission to appeal and refused the defendant a stay of the injunction. This Court granted the defendant permission to appeal, expedited the appeal and granted the defendant a stay of the injunction pending the appeal: *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2022] EWCA Civ 370 ("*Neurim II*"). The three members of the Court gave slightly different reasons for reaching the last conclusion.

29. My reasoning was that there had been no relevant change of circumstances since *Neurim I*, and therefore it remained the case that damages would be an adequate remedy for the claimants: [26]-[31]. Even if the claimants would suffer damage which would be adequately compensated by an award of damages, the damage to the defendant would be more difficult to quantify and adequately compensate: [32]-[33]. Even if both sides were equally likely to suffer damage that could not be adequately compensated, it was prudent to preserve the status quo, which was that the defendant was on the market: [34].

30. Birss LJ said at [37]:

> "… I would hold that there is a material risk that damages will be an inadequate remedy for each party in the relevant circumstances (for Mylan if no stay is granted but Mylan win the appeal, and for Neurim/Flynn if a stay is granted and Mylan

> lose the appeal). This is clearly so for Mylan but I believe it is also true for Neurim/Flynn. If Neurim/Flynn win the appeal then there will be a damages enquiry relating to Mylan's patent infringement. The various features of this market and the complexities, actual and potential, are all matters which the Patents Court is familiar with and can handle. The court is well able to conduct a damages enquiry in the circumstances of this market and to arrive at a figure it finds to be just. However that does not mean that damages are an adequate remedy. The uncertainties in this case, relevant to either side, are very significant. In mathematical terms a numerical result can always be found but the error bars will be large. In my judgment the decisive factor here, given that the appeal has been expedited and will be resolved before the patent expires, is the preservation of the status quo. That status quo is that Mylan is on the market and has been since September 2020. The uncertainties do not justify disturbing that state of affairs."

31. Newey LJ said at [38]:

> " … Like Birss LJ, I take the view that damages will not necessarily be a fully adequate remedy for Neurim/Flynn should they succeed on the appeal, but it seems to me that the risk of uncompensatable loss to Mylan in the absence of a stay is greater and, perhaps more importantly, that preservation of the status quo favours the grant of a stay."

32. The importance of preserving the status quo is illustrated by the decision of HHJ Hacon sitting as a High Court Judge in a case which has some similarities with the present, *Bayer Intellectual Property GmbH v Aspire Pharma Ltd* [2024] EHWC 711 (Pat), [2024] FSR 23. The compound patent protecting rivaroxaban was due to expire on 1 April 2024, but Bayer had a patent ("EP 961") which protected tablets for once-daily administration. Six generic companies brought claims for revocation of EP 961. The claims were tried by HHJ Hacon and the trial concluded on 22 February 2024. Not having been informed of the significance of the date of 1 April 2024, HHJ Hacon told the parties that he planned to hand down judgment on 9 April 2024 with argument on the form of order on 11 or 12 April 2024. The defendants, and one other generic company, subsequently indicated an intention to launch generic rivaroxaban products for once-daily administration immediately after 1 April 2024. Bayer applied for an interim injunction to restrain them from doing so until the FOO hearing. HHJ Hacon heard the application on 25 March 2024. On 27 March 2024 he granted the injunction for the reasons given in his judgment of that date.

33. As HHJ Hacon explained, the short and crucial point about the application was that it was designed to preserve the status quo for a period of only 9-10 days. He doubted that either Bayer or the respondents would suffer a great deal of irreparable harm on the alternative hypotheses of an injunction being granted or not. He did not consider that Bayer was not at risk of any irreparable harm at all because there would be uncertainties, but they would be modest. The same applied to the respondents. The decisive consideration was the one he identified at [56]:

> "The Court of Appeal has emphasised the importance of maintaining the status quo in circumstances such as those of this application. It seems to me that it is all the more important where the period in question is so short. And as I have said, it would change the status quo in respect of any application there may be after judgment is handed down. That has the potential to give rise to significant irreparable harm to Bayer."

34. As the editors of *Terrell on the Law of Patents* (20th ed) point out at 21-228, there is presently a live question as to whether Lord Diplock's guidelines are to be applied sequentially, essentially considering each question in isolation from the others, or whether a more holistic approach should be adopted. The claimants in *Neurim I* applied to the Supreme Court for permission to appeal. The panel (Lords Kerr, Lloyd-Jones and Kitchin) refused permission for the following reasons:

> "The panel considered that there is a point of law of public importance touching on the question whether the four-stage test outlined by of Lord Diplock in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 should be applied in a rigid and strictly sequential manner or whether a more overarching and flexible approach to the issues adumbrated by Lord Diplock would be appropriate - cf. the observations of Lord Goff in *R v Secretary of State for Transport ex p. Factortame Ltd (No 2)* [1991] 1 AC 603.
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> The panel decided, however, that permission should not be given in this case. Prominent among the reasons for this decision was the imminence of the trial in the action. …"

35. Furthermore, the Supreme Court of Ireland has held that the preferable approach is to consider adequacy of damages as part of the balance of the risk of injustice: see *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd* [2019] IESC 65 at [35] (O'Donnell J).

36. This Court remains bound by *American Cyanamid*, but it seems to me that these recent developments serve to reinforce the wisdom of Lord Hoffmann's observation cited in paragraph 20 above. As the present case highlights, the court hearing an application for an interim injunction is often required to make its decision on the basis of limited information in a rapidly changing situation. That can mean that it is difficult to determine the adequacy of damages for either side. As Lord Diplock said, and Lord Hoffmann emphasised, when the court is in doubt as to the adequacy of the respective remedies in damages, then it should take into account all the other relevant factors in deciding what course is least likely to cause irremediable prejudice to the one party or other.

The judge's judgment

37. The judge's judgment may be summarised as follows. He set out the background to the application at [1]-[19]. In this context he explained that AstraZeneca relied in particular upon factual evidence from Dr Oonagh McGill (Unit Director of the Cardiovascular, Renal & Metabolic Business) and expert evidence from Richard

O'Toole, while Glenmark relied in particular upon factual evidence from Stuart Meanwell (Generics Business Unit Manager) and expert evidence from Andrew Farrant. He considered the applicable principles at [20]-[25].

38. At [26]-[33] he discussed the fact that the relief which AstraZeneca were seeking was an injunction until the conclusion of the FOO hearing. He expressed the view that it would be wrong for him to prejudge what might happen at that hearing in the event that he held that the SPC was valid, and noted that AstraZeneca had not decided whether to seek an injunction pending appeal if he held that the SPC was invalid. He concluded that he was only concerned with the damage that would be caused to either side due to events in the intervening period, whether that damage manifested itself in that period or later. He noted that this was the approach which AstraZeneca had urged upon him.

39. The judge then turned at [34]-[40] to consider the existing state of the market. AstraZeneca's evidence was that sales of Forxiga to the NHS had grown steadily from 2013 to £70 million in 2021, followed by a steeper increase to £235 million in 2023. (I interpolate that, as Dr McGill explained, this was due to a change in the relevant National Institute of Health and Care Excellence Guideline in June 2022.) Glenmark had produced data showing that sales had increased in 2024 on essentially the same trajectory as in 2022 and 2023. There was no reason to think that that trend would not continue until the FOO hearing in the absence of generic competition. The vast majority of prescriptions are written by GPs and dispensed by community pharmacies, with about 90% being for dapagliflozin (the international non-proprietary name or INN) and only about 10% for Forxiga (the brand name). Dapagliflozin is currently in Category C of the Drug Tariff with a reference price of £36.59 for a pack of 28 tablets, meaning that pharmacists are reimbursed at that price regardless of the price they pay wholesalers for the product. (I would add that, as Mr Farrant explained, the reference price for Category C is the originator's list price as approved by the NHSBSA.)

40. The judge considered Glenmark's plans at [41]-[42]. Glenmark had not revealed the price at which it intended to sell its product, but there was evidence that the first generic entrant to a market normally priced its product at a discount of 10-20% of the reference price, and the judge saw no reason to think that Glenmark would do otherwise in the absence of any other generic entrant. Nor had Glenmark revealed the proportion of the dapagliflozin market it expected to be able to capture in the period before the FOO hearing. AstraZeneca's evidence was that they did not expect Glenmark to have sufficient volume to supply the whole market initially, and the judge considered it appropriate to proceed on that basis.

41. The judge explained at [43] that there was a substantial dispute about whether any other generic companies would enter the market before the FOO hearing. Glenmark contended that it would be sole entrant, whereas AstraZeneca contended that others were likely to follow rapidly, quite possibly within a few weeks. There was no direct evidence, and the parties relied on inferences from the available material. Having discussed this, the judge concluded at [58]:

> "Overall, in my view, there is a real risk that one or more generic companies will enter the UK market following

> Glenmark and before the form of order hearing, though that entry may not be immediate."

42. The judge then considered at [59]-[70] whether, if other generic companies entered the market, there would be a price spiral. He first concluded at [62] that, on the information he had, it was impossible to estimate the likelihood of there being a drop in generic prices before the FOO hearing: that would depend on the number of entrants, the times of entry and the volume of products. He could not say that there was no real risk of generic price depression.

43. The judge then said:

> "63. More important though is how AZ will respond to that. Dr McGill did not say whether AZ would lower its price in response to a generic price spiral, let alone in response to a single generic entrant. Instead, she merely explained that if AZ chose not to reduce its price it would progressively lose market share as generics entered the market and, once they saturate the market, it would lose virtually all sales for prescriptions by INN, whereas if it did reduce its price it would reduce its profits on branded prescriptions and may see the reduced price impacting its prices in other markets, for instance through reference pricing.
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> 64. Mr Farrant said he did not expect AZ to reduce its list price over the period before the form of order hearing. He gave a number of reasons. First, AZ would have in mind that if the patent was held valid at trial, its market share may be completely restored. Secondly, in the case of a single generic entrant, there would be no price spiral to respond to. Thirdly, to the extent that the whole of the INN prescription market was not satisfied by the generic supply capacity, AZ would retain its profit margin on that segment of the INN market. Fourthly, AZ would retain its profit margin on the branded prescription share of the market. Fifthly, dropping its list price could affect its prices elsewhere through the reference pricing mechanism. Sixthly, because AZ was a member of the VPAG scheme, once the list price had been reduced it was unlikely to be possible to increase it again. While the second reason did not apply if there was a price spiral, all the other reasons did. He added that the apixaban case provided a good example of an originator maintaining its list price while generics entered the market pending a final decision on patent validity.
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> 65. Dr McGill did not respond to that evidence and neither did Mr O'Toole. For the reasons given by Mr Farrant, I think it is highly unlikely that AZ will decrease its list price over the period before the form of order hearing. That is the case whether other generics enter the market causing some degree of price reduction or not."

44. The judge acknowledged at [66] that, even if AstraZeneca did not change its list price, it could offer increased rebates to wholesalers. (I interpolate that, as Mr Farrant explained, it is usual for MA holders to offer wholesalers a modest discount from the list price, in the case of branded products, or the Drug Tariff reimbursement price, in the case of generics, in order to incentivise the wholesalers to stock and sell their products.) The judge considered, however, that many of Mr Farrant's reasons also applied to AstraZeneca's actual price to wholesalers. He continued:

> "67. Further, neither Dr McGill nor Mr O'Toole said that AZ would be likely to change its actual price to wholesalers. Nor did they give evidence that if AZ decided to do so, it would not be possible to reverse the position once generics were removed from the market. Mr Pritchard told me, on instructions, that if AZ wanted to remove a discount it had given to wholesalers, it would need to speak to the NHS first. It was not satisfactory for a point as significant as AZ's ability to change its actual price in the market in such circumstances to be dealt with on instructions during the hearing, but in any event what Mr Pritchard said does not establish that AZ could not remove a discount or that it would face any serious obstacles to doing so.
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> 68. Overall, there is no evidence that AZ would be likely to change its actual price to wholesalers in the period between now and the form of order hearing and no evidence that, if it did change its actual price, it would not be able to reverse that without obstacle."

45. At [69]-[70] the judge considered the possibility of dapagliflozin being recategorised, but concluded that there was no real prospect of that occurring before the FOO hearing.

46. The judge then turned to consider whether damages would be an adequate remedy for AstraZeneca at [71]-[79]. First, he considered the position if Glenmark were the sole generic entrant prior to the FOO hearing. In those circumstances, the quantity of products sold by Glenmark over that period would be known. Glenmark accepted that every sale by Glenmark would be a sale lost to AstraZeneca. AstraZeneca had an established profit margin per pack. *Prima facie*, the damages to AstraZeneca were the profit margin per pack multiplied by the number of packs sold by Glenmark. AstraZeneca would not reduce their list price, there was no evidence that they would increase the rebates offered, nor that they would not be able to reverse any such step without obstacle. Thus there was no basis for thinking that there would any continuing price reduction, and if AstraZeneca did increase rebates to wholesalers that additional loss could be quantified by multiplying the increase by the number of packs.

47. Secondly, he considered the position if there were other generic entrants before the FOO hearing and concluded that this would make no difference.

48. Thirdly, he considered two other sources of loss relied upon by AstraZeneca. The first was that it might be necessary to make adjustments to AstraZeneca's supply chain, which might be costly to reverse. The judge was not persuaded that this was likely before the FOO hearing. The second was that it might be necessary to scale back

AstraZeneca's investment in so-called Joint Workings, namely projects involving the pooling of skills, experience and resources between the NHS and the pharmaceutical industry with a view to improving patient outcomes. This would reduce patient access to dapagliflozin. Again, however, the judge was not persuaded that this was likely before the FOO hearing.

49. Accordingly, the judge concluded that damages would be an adequate remedy for AstraZeneca because they could be calculated with a reasonably high degree of accuracy. Although he did not say so in terms at [79], it is clear from what he went on to say later in the judgment that he considered that, subject to the point he considered next, this was determinative of the application.

50. At [80]-[85] the judge considered whether Glenmark would be able to pay damages due to AstraZeneca. This issue was resolved by means of an undertaking offered by Glenmark.

51. The judge then turned at [86]-[96] to consider, "[i]n case this matter goes further", whether damages on the cross-undertaking would be an adequate remedy for Glenmark. Glenmark argued that assessment of such damages was difficult because of the difficulty of constructing the counterfactual. The judge accepted that this could be difficult, but not that it would be difficult in every case. Nevertheless he considered that quantification of the damages due to Glenmark would be significantly more difficult than assessment of the damages due to AstraZeneca.

52. Even if Glenmark would have been the sole generic entrant, one could expect there to be a significant dispute as to how many sales Glenmark would have made and at what price. That difficulty was exacerbated by the possibility that other generic companies would have entered the market. Furthermore, if Glenmark was injuncted now, it was likely to lose a first-mover advantage, and that would be difficult to quantify. Finally, a further potential complication was that AstraZeneca had pending applications for second medical use patents for the use of dapagliflozin in the treatment of heart failure and chronic kidney disease. That give rise to the possibility of an infringement issue further down the line.

53. At [97]-[100] the judge considered the position of the NHS. The NHS had sought a cross-undertaking from AstraZeneca and AstraZeneca agreed to give one. The judge considered that the NHS would potentially have even more difficulty in establishing the counterfactual than Glenmark. Accordingly, damages would not be an adequate remedy for either Glenmark or the NHS.

54. Finally, the judge said this:

> "101. It will be apparent from what I have said that, had it been necessary to consider stage 4 of the American Cyanamid guidelines, I would have held that the balance of risk of injustice lay against the injunction sought.
>
> 102. Mr Pritchard emphasised the importance of maintaining the status quo and referred me to what Birss J said in *Neurim v Generics UK* [2022] EWCA Civ 370 at [37]. That was a case where Birss LJ regarded the uncertainties on either side as

> being very significant. Here the uncertainties involved in assessing damages under the cross-undertaking are in my view significantly greater than those involved in assessing damages to AZ. I acknowledge that status quo would favour the grant of an injunction had other factors been evenly balanced but, in my judgment, they are nowhere near being evenly balanced.
>
> 103. Mr Pritchard also contended that Glenmark had failed to clear the way in time to launch the product now. However, Glenmark did ask for a January 2025 trial back in January 2024. In my judgment this is not a case in which the fact that Glenmark is ready to launch shortly before the court has managed to produce a judgment on the validity trial is a factor of any significance in the balance of convenience."

AstraZeneca's grounds of appeal

55. AstraZeneca have four grounds of appeal, but ground 1 divides into two. Ground 1a is that the judge applied too high a threshold when considering whether damages would be adequate remedy for AstraZeneca, and failed to take into account the uncertainties involved in predicting the consequences of refusing the injunction and the importance of maintaining the status quo given Glenmark's failure to clear the path for its launch. Ground 1b is that the judge should have considered the adequacy of damages as part of the balance of the risk of injustice. Ground 2 is that the judge failed to take into account damage to AstraZeneca that would manifest itself after the FOO hearing despite correctly directing himself that he should do so. Ground 3 is that the judge incorrectly assessed the inadequacy of damages as a remedy for Glenmark. Ground 4 is that, in any event, aspects of the judge's assessment have been vitiated by subsequent developments revealed by the new evidence.

The new evidence and ground 4

56. It is convenient to begin by considering the new evidence. This shows as follows:

i) Teva's position as set out in its solicitors' letter dated 30 March 2025 is that it has had an MA since May 2024, and since December 2024 it has made "significant preparations including securing commitments with wholesalers in the UK for an immediate launch". The letter confirmed that Teva would not dispose of products containing dapagliflozin in the UK prior to the conclusion of the permission to appeal hearing on 31 March 2025. It made the point that, since Teva did not have sight of whether Glenmark was in fact ready to launch its product, Teva contended that it had "first mover advantage". Counsel for AstraZeneca informed us on instructions that Teva was negotiating an agreement not to launch its product prior to the conclusion of the hearing of Glenmark's appeal, in return for a cross-undertaking in damages from AstraZeneca, subject to the qualification that it be able to distribute 175,000 packs of its product to wholesalers in order to match Glenmark.

ii) Another generic company (referred to in argument as "Generic X" since its identity is claimed to be confidential, although it is not hard to work out who it is likely to be) has adopted the same position as Teva. Thus, as Mr Stothers

explains, Generic X has also demanded the right to be able to distribute 175,000 packs of its product to wholesalers.

iii) Three generic companies holding MAs for dapagliflozin products had still not replied at all to AstraZeneca's solicitors' letters by 3 April 2025, and one had not replied substantively.

57. Turning to ground 4, AstraZeneca do not go so far as to contend that the new evidence on its own justifies this Court in allowing the appeal. Rather, they rely upon the new evidence as bolstering grounds 1a, 2 and 3.

58. Glenmark contends that the new evidence makes no difference to the judge's assessments. I disagree with this. In my judgment the new evidence does put a different complexion on matters. First, it establishes that what appeared to the judge merely to be a real risk is in fact a certainty: namely, that if no injunction is granted against Glenmark, at least two other generic companies will enter the market prior to the FOO hearing. (I should perhaps explain that it is common ground that, if AstraZeneca do not obtain an injunction against Glenmark, then they will not be able to obtain an injunction against Teva, Generic X or any other generic entrants.) Secondly, it shows that this is likely to happen more quickly than the judge anticipated. Thirdly, it follows that it is inevitable that there will quickly be price competition between the three or more generic entrants leading to a downward price spiral.

The test on appeal

59. Although he wisely refrained from citing any of the well-known authorities on the point, counsel for Glenmark reminded us that this is an appeal against an exercise of discretion, and therefore this Court can only intervene on limited grounds. As I have explained, however, this Court has the advantage of evidence which was not before the judge and which puts a different complexion on matters. That inevitably tempers the degree of deference that we should give to the judge's assessments.

Ground 1a: adequacy of damages for AstraZeneca

60. It can be seen from the judge's reasoning that the primary ground on which he refused an injunction was that he considered that damages would be an adequate remedy for AstraZeneca. As counsel for Glenmark emphasised, that conclusion was based on a careful assessment of the evidence. AstraZeneca nevertheless contend that the judge's assessment was flawed, particularly given what is now known about Teva and Generic X. AstraZeneca contend that the judge should have concluded that there was real doubt as to whether damages would be an adequate remedy. This ground focuses on the damage which AstraZeneca will suffer in the period prior to the FOO hearing, whereas ground 2 focuses on the damage will suffer in the period after the FOO hearing.

61. AstraZeneca also contend that the judge should have recognised that it was important to maintain the status quo given the uncertainties involved, but this is analytically a distinct point which it is more convenient to consider after I have considered grounds 2 and 3.

62. AstraZeneca make two main criticisms of the judge's reasoning. The first is that, although the judge referred to the rapid recent growth in the market for dapagliflozin when discussing the current state of the market, he did not take this into account when considering whether damages would be an adequate remedy for AstraZeneca. AstraZeneca do not contend that this is sufficient on its own to undermine the judge's assessment of the adequacy of damages, but they rely upon it as adding weight to their second main criticism, because it means that there is a degree of uncertainty as to how much dapagliflozin would be sold at the current price pending the FOO hearing.

63. AstraZeneca's second main criticism concerns the judge's assessment of the effect of a downward price spiral on AstraZeneca. The judge accepted that there was a real risk of multiple generic entry leading to a real risk of a generic price spiral. The judge did not accept that AstraZeneca's evidence, and in particular the evidence of Dr McGill, showed that AstraZeneca would be likely to reduce their price in the period until the FOO hearing or that, if they did so, AstraZeneca would not be able to reverse such a price rise without obstacle if an injunction was granted then.

64. As AstraZeneca point out, Dr McGill's evidence must be viewed in context. At that stage, all she knew was that Glenmark intended to launch soon, but had not revealed at what price or in what quantities. She thought that, if Glenmark was permitted to launch, other generic companies would launch "rapidly, quite possibly within a matter of weeks". It was in that context that she said in paragraph 48 of her witness statement:

> "AstraZeneca will clearly be harmed in the event of early generic entry. The extent of that harm is difficult to quantify for two main reasons. First, as is typically the case whenever generics launch …, a price spiral is likely to occur. Once the NHS becomes accustomed to lower prices, AstraZeneca is unlikely to be able to restore its price even if the generics have to leave the market. I expect that the NHS will be especially resistant to price restoration of dapagliflozin because of the sheer size of the market and volume of prescriptions. This drug alone will account for a sizeable part of the NHS reimbursement budget. Second, and more unusually for a mature product, the demand for dapagliflozin is growing very rapidly and will do so for the foreseeable future as the impact of the 2022 changes to the NICE Guideline continues to flow through the system. This introduces additional uncertainty and will likely mask the true extent of AstraZeneca's harm. I address these and related points below."

65. The first part of this paragraph is clear evidence that (i) AstraZeneca would be likely to have to reduce its price for dapagliflozin in the event of a price spiral following multiple generic entry, and (ii) AstraZeneca would have difficulty in restoring its price even if the generic companies were subsequently excluded due to NHS resistance.

66. Dr McGill expanded on her first reason in paragraphs 49-56 of her statement. In that context she said:

> "52. Price erosion is … certain to occur in the event of [multiple] generic launch and it will happen rapidly. The only uncertainties are the speed and quantum of that erosion. …
>
> …
>
> 54. AstraZeneca will be put in a difficult position. If AstraZeneca chooses not to reduce the price of Forxiga, it will progressively lose market share as generics enter the market and once they saturate the market, AstraZeneca will lose virtually all sales for prescriptions by INN. However, if AstraZeneca does choose to reduce the price of Forxiga, it will reduce its profits from branded prescriptions and may see the reduced price impacting its prices in other markets (for instance through reference pricing).
>
> 55. Over time, having grown accustomed to lower prices, the NHS will be highly resistant to the budgetary impact of a return to the original price, even in circumstances where the competitors were subsequently found to be in breach of patent. This is particularly relevant in the circumstances of Forxiga …"

67. In paragraph 54 Dr McGill fairly acknowledged that AstraZeneca would not have to reduce their price, but explained what the consequences would be if they did not do so. She was clearly not intending to contradict her statement in paragraph 48 that it was likely that AstraZeneca would reduce their price, since she went on in paragraph 55 to repeat the point that the NHS would be highly resistant to a return to the original price. Dr McGill did not distinguish in this evidence between list price and actual price, and it covers reducing the actual price even if the list price is maintained.

68. As the judge noted, Mr Farrant's evidence which the judge summarised at [64] concerned the list price, not the actual price. Although counsel for Glenmark submitted to the judge that many of his reasons also applied to the actual price, that was not evidence given by Mr Farrant. Perhaps more importantly, the fifth reason can only apply to the list price, while the second and third reasons assume a single generic entrant and the fourth reason is of little weight given that the branded share of the market is only 10%.

69. As for the apixaban example referred to by the judge, that was not a precisely comparable situation, since it concerned the 13 month period between a first instance trial judgment finding the patent invalid and an appeal judgment confirming that decision with no injunction in the meantime. Furthermore, as Mr Farrant explained, relatively few generic companies entered the market during this period and there were stock issues with the generic supply. There was, as Mr Farrant put it, "limited price erosion suggesting a degree of caution from the generic companies". Even at the end of the period, the generic discount was only 15% off the branded list price. It is not surprising that, in those circumstances, the patentee did not change its list price and only offered a small discount. Nor is it surprising that, as a result, the patentee lost half its share of the market. There is no guarantee that multiple generic entry into the dapagliflozin market would have such limited impact on prices, and a real likelihood that it would have a much greater effect.

70. In any event, the judge's statement that Dr McGill had not said that AstraZeneca would be likely to change their actual price is incorrect on a fair reading of her evidence; and his statement that she had not said that, if AstraZeneca did so, it would not be possible to reverse that once generics were removed from the market without obstacle is incorrect on any reading of her evidence. Moreover, her evidence as to the difficulty of raising the price again is supported by Mr Farrant's sixth reason mentioned by the judge at [64], namely that AstraZeneca's membership of the VPAG scheme (a voluntary scheme under which members of the Association of the British Pharmaceutical Industry repay a percentage of their sales revenue on branded medicines to the Department of Health and Social Care) means that, as Mr Farrant put it, "it is very unlikely any future price increase will be accepted".

71. As for the judge's point that Dr McGill had not replied to Mr Farrant's evidence, it is difficult to see why it matters that she did not repeat what she had already said. (Although the judge did not mention it, counsel for Glenmark relied on the fact that AstraZeneca had filed reply evidence explaining why so-called "brand equalisation" deals were no longer used by companies in the position of AstraZeneca, but that evidence was in reply to some other evidence of Glenmark relying on what had happened in a case called *Napp v Sandoz*, and brand equalisation arrangements are more complex than simple discounts or rebates.)

72. For these reasons AstraZeneca contend that, even as matters stood at the date of the hearing, the judge applied too high a threshold to AstraZeneca's evidence and failed to make proper allowance for the uncertainties in the situation. Perhaps more importantly, AstraZeneca submit that, even if the judge's assessment was defensible as matters then stood, it has been undermined by the new evidence. Now that it is clear that multiple generic entry is both a certainty and will happen more quickly even than Dr McGill feared, the correct conclusion is that AstraZeneca would be likely to reduce their actual price prior to the FOO hearing and that, assuming they did so, they would have serious difficulty in raising them again.

73. I accept this submission. In my view it does not necessarily follow that damages would not be an adequate remedy for AstraZeneca, but it means that there is room for doubt about that even if attention is confined to the period prior to the FOO hearing because it is uncertain how long that period will be. In the very short term, it is unlikely that AstraZeneca would change their price. The longer the period turned out to be, however, the greater would be the pressure on AstraZeneca to reduce their price.

Ground 1b

74. The short answer to ground 1b is that it is not open to this Court to follow the Irish Supreme Court in *MSD v Clonmel* because we are bound by *American Cyanamid*. Given the view I take on the other grounds, this does not matter.

Ground 2: damage to AstraZeneca after the FOO hearing

75. The starting point here is that the judge directed himself at [31] that he should consider damage to AstraZeneca due to events in the period prior to the FOO hearing, whether that damage manifested itself during that period or later. It is common ground that he was correct to do so.

76. AstraZeneca contend that, despite directing himself that he needed to consider damage which manifested itself after the FOO hearing, the judge failed to do so. Specifically, the judge failed to take into account the fact that, if he refused to grant an injunction, it would mean that the status quo at the time of the FOO hearing would be that Glenmark, and possibly other generic entrants, would be on the market. That would inevitably prejudice AstraZeneca's ability to obtain an injunction pending appeal, if they needed to do so. That would in turn involve AstraZeneca being subject to generic price erosion for a longer period, making it even more likely that AstraZeneca would have to cut their price and even more difficult subsequently to restore it if AstraZeneca succeeded in obtaining a final injunction after the appeal. Moreover, in those circumstances it would be more likely that AstraZeneca would have to alter their supply chain and/or reduce their investment in Joint Workings in the intervening period.

77. As with ground 1a, AstraZeneca rely upon the new evidence as strengthening this ground since it is now certain that multiple generic entrants will be on the market by the FOO hearing if there is no injunction against Glenmark now.

78. This argument is closely related to AstraZeneca's argument with respect to preservation of the status quo, but nevertheless it is analytically distinct because it is directed to the prior question of adequacy of damages for AstraZeneca if no injunction is granted at this stage.

79. Glenmark objected that this was a new argument which had not been advanced before the judge. As AstraZeneca were able to demonstrate, however, this is incorrect. Although the point was made, even if not very clearly, in counsel for AstraZeneca's opening submissions, it is sufficient to refer to the peroration to counsel for AstraZeneca's submissions in reply. Having referred to the likelihood of multiple generic entry and a consequent price spiral, and submitted that preservation of the status quo was therefore important, he concluded:

> "The final point on the status quo is one has to look at one other point that arises is that once a party is on the market (that is the third point in paragraph 27 of [*Bayer v Aspire*]) it is all the more difficult to come back and ask for an interim injunction. That is an important movement in the status quo, potentially a very valuable one, if it turns out in fact there ought to have been an injunction in a month or two months' time."

80. The judge did not address this argument. There is a striking contrast in this respect between the judge's judgment and that of HHJ Hacon in *Bayer v Aspire* at [56] (see paragraph 33 above). In my view the judge fell into error in this respect.

81. When the potential damage to AstraZeneca arising after the FOO hearing due to Glenmark and the other generic entrants having come onto the market is considered together with the potential damage to AstraZeneca arising in the period before the FOO hearing, I conclude that there is real doubt as to the adequacy of damages as a remedy for AstraZeneca.

Ground 3: adequacy of damages for Glenmark

82. AstraZeneca contend that the new evidence is particularly important when it comes to ground 3. First, contrary to what the judge thought, it now appears that, viewed as at 27 March 2025, Glenmark had little first mover advantage. Although the evidence suggests that only Glenmark was prepared to launch at risk prior to judgment in the revocation proceedings, it appears that Teva and Generic X were in a position rapidly to follow suit.

83. Secondly, this Court now has more information than the judge did about the counterfactual if an injunction is granted. Although uncertainties remain, it now appears that Glenmark, Teva and Generic X were all in a position to launch in quick succession and in similar volumes. Although it remains possible that other generic companies would also enter the market before the FOO hearing if no injunction were granted, that seems improbable. Subject to the question of the potential impact of additional generic entrants after the FOO hearing, it follows that, if an injunction is granted now, but not following the FOO hearing, the resulting sales data would be likely to provide a reasonable guide as to what would have happened if no injunction had been granted now. The difference would be one of timing.

84. Furthermore, as this illustrates, the possibility of a future claim by AstraZeneca for infringement of a second medical use patent is neutral because it is unaffected by the timing of the injunction.

85. Counsel for AstraZeneca did not argue that damages would be a wholly adequate remedy for Glenmark. Rather, he argued that the disparity between the size of AstraZeneca's current market for dapagliflozin and the size of the market that Glenmark would be likely to be able to capture by the FOO hearing meant that the potential error was larger in absolute terms for AstraZeneca than for Glenmark.

86. I am not persuaded by this argument. It seems to me that the correct conclusion is that there is real doubt as to the adequacy of damages for both parties (and for the NHS), and it is not possible to form a reliable view as to which side is more at risk of receiving an inadequate remedy in damages.

Ground 1a: clearing the path and status quo

87. Given that it is not possible to form a reliable view as to which side is more at risk of receiving an inadequate remedy in damages, and given the shortness of the period in question, it is prudent to preserve the status quo until the conclusion of the FOO hearing. As AstraZeneca contend, this is reinforced by two related, but distinct, points.

88. First, I agree with AstraZeneca that the judge was wrong to discount Glenmark's failure to clear the path when considering whether to preserve the status quo. Clearing the path involves taking the steps necessary to obtain a judgment before launch. If proceedings are not commenced sufficiently far in advance to achieve that without a degree of expedition of the trial, then it is incumbent on the party seeking to clear the path to apply for that degree of expedition. That requires that party to give the court a good reason for expedition. Glenmark did not give Meade J any reason for seeking an

earlier trial. If the trial had been (slightly) expedited to January 2025, the situation which confronted the judge on this application would probably not have arisen.

89. Secondly, I agree with AstraZeneca that the judge was also wrong to discount the fact that Glenmark sought to launch its product in the middle of trial and without waiting for judgment when considering whether to preserve the status quo. There was never any suggestion that Glenmark might have to wait a long time for the judgment, as the agreed estimate of the likely period until the FOO hearing demonstrates. In those circumstances, it is relevant to take into account the fact that Glenmark was, to put it colloquially, jumping the gun. That would inevitably make it more difficult for the court to do justice to all the parties, including those not before the court on this application, at the FOO hearing once it is known whether the court has concluded that the SPC is valid or not, when considering any applications which might be made in the light of that conclusion, such as applications for permission to appeal and an injunction pending any appeal.

90. As judges both in the Patents Court and in this Court have observed in a number of cases, it is important that parties should behave in a manner which is conducive to an orderly resolution of disputes of this kind, and not attempt to gain a commercial advantage by disrupting such orderly resolution. The effect of Glenmark's conduct in this case has been to require a day of argument in the Patents Court and a day of argument in this Court to be devoted to, and very considerable costs to be expended on, the question of what is to happen during a period of one to three months. That is not a good use of the parties' resources, still less a good use of scarce court resources.

Conclusion

91. For the reasons given above, I conclude that the balance of the risk of injustice favours the grant of the injunction sought by AstraZeneca until the conclusion of the FOO hearing. For the avoidance of doubt, this does not dictate the outcome of any application that may be made by AstraZeneca for a further injunction at that stage. Any such application will need to be considered on its merits in the light of the relevant circumstances at that stage.

Lord Justice Warby:

92. I agree.

Lord Justice Coulson:

93. I also agree.