8 NEW SQUARE

INTELLECTUAL PROPERTY

# INTERIM INJUNCTIONS: FINDING THE BALANCE

*James Abrahams KC, 24 June 2025*

## Introduction

1. The impetus for this talk was the decision of the Court of Appeal in *AZ v Glenmark*.[1] Rebekka Thomas of the IPSoc committee asked me to talk to you this evening about the ramifications of the decision for those practising in life sciences litigation. Presumably Rebekka thought that the decision in *AZ v Glenmark* did not simply involve the application of well-established principles to a set of facts, but instead that it signalled, or at least solidified, an approach to interim injunction applications in pharmaceutical cases which is somewhat different to the approach adopted other interim injunction cases.

2. I think she's right about that, and this evening I'll try to explain why.

3. I am going to focus on the practical implications of *AZ v Glenmark* for practising lawyers. I will try to offer some suggestions as to how to approach an application for an interim injunction in a case of this sort, whether you are acting for the applicant or the respondent.

## What sort of case is *AZ v Glenmark* relevant to?

4. So what sort of case is *AZ v Glenmark* relevant to? It's relevant to the sort of case which frequently arises in the Patents Court:

   - The claimant is an originator pharmaceutical company (or at least the licensee or successor in title to the originator). It has a patent (or an SPC) which it says protects one of its products.

   - Usually the new pharmaceutical product is a prescription-only medicine. This is usually the case, because even over-the-counter (OTC) medicines usually start life as prescription-only medicines, and take years to be re-classified as OTC.

   - The claimant has enjoyed a stable monopoly for some time.

[1] *AstraZeneca v Glenmark* [2025] EWCA Civ 480.

- The defendant is a generic pharmaceutical company, which intends to launch a generic version of the pharmaceutical product.

- The defendant contends that its product does not infringe the patent and/or that the patent is invalid, but it has not yet obtained a final determination of that question. It wants to launch "at risk", i.e. before a final determination of that question. It is willing to run the risk that it will be found to have infringed a valid patent and have to pay damages for doing so.

5. In such a case, the claimant invariably applies for an interim injunction. That is because the structure of the market in these cases is that the claimant is making large profits while it maintains a 100% market share, and even if it has to compensate the defendant, under its cross-undertaking in damages, for being kept off the market, it can still make much larger profits than if it had to compete with the defendant.

6. The application for an interim injunction in these circumstances is governed by the well-known *American Cyanamid* case[2]. That involves 4 well-known questions which. In short, they are:

    1. Is there a serious question to be tried?

    2. Would damages be an adequate remedy for the claimant?

    3. Would damages be and adequate remedy for the defendant?

    4. Where does the balance of convenience lie?

7. The questions were framed with more precision by Arnold LJ in *AZ v Glenmark*.[3]

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

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2 *American Cyanamid v Ethicon* [1975] AC 396.

3 [2025] EWCA Civ 480, [18].

> 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.
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> (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.

8. I'd make two comments about those questions at this stage. First, the answer to the first question is invariably yes, because in pharmaceutical cases, the technical issues of invalidity and infringement are almost always unsuitable for resolution at an interim injunction hearing. Second, the status quo is the defendant not being on the market, provided the claimant acts swiftly.[4]

9. If you asked a lawyer who had no experience of pharmaceutical patent litigation, they would probably say that the *American Cyanamid* questions, ought to lead to an interim injunction being refused. And yet we all know that interim injunctions are almost always granted in these cases. The *AZ v Glenmark* case reaffirms, indeed it strengthens, that conventional approach. I will try to explain why that is.

How might *American Cyanamid* work in this type of case?

10. Let's start by considering the reasons why our hypothetical a lawyer, with no experience of pharmaceutical patent litigation, would expect an interim injunction to be withheld in this sort of case. They would say something like this.

11. First, they would not that the claimant has (usually) been on the market for some time. Their market share is 100%. Their volumes are stable, or at least fairly predictable. Their sale price is stable. And their profit margin per unit is well established.

12. That means that when the defendant comes on the market, it will cause the claimant to lose sales. But it is easy to calculate the damage caused by that. It is the number of units sold by the defendant, multiplied by the profit margin of the claimant before the defendant entered the market. Now the claimant may decide to lower their prices to try to maintain market share, and that will result in lower profits per sale. But again, it is easy to calculate the damage caused by

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4 *Garden Cottage Foods v Milk Marketing Board* [1984] 1 AC 130, 140D (Lord Diplock); *Allfiled UK v Eltis* [2015] EWHC 1300 (Ch), [153]-[155], Hildyard J.

that. It is: the number of units sold at the lower price, multiplied by the difference between the lower price and the price before the defendant's entry. So it is just a matter of mathematics. Provided that the defendant is good for the money, damages will be a perfectly adequate remedy for the claimant.

13. Claimants also argue that even if they succeed in obtaining a final injunction at trial, they will suffer continuing loss, because they will be unable to return their prices to previous levels. I am going to come back to this point. But our hypothetical lawyer would say that in terms of compensation for the claimant, this is also a simple matter of mathematics: it is not difficult to calculate the number of units that the claimant will sell during the remaining lifetime of the patent, and to multiply that by the difference in price.

14. Under the *American Cyanamid* approach, if damages would be an adequate remedy for the claimant, and the defendant is good for the money, no injunction should normally be granted.[5] So that should be the end of the application and there is no need to consider whether damages would be an adequate remedy for the defendant.

15. In fact it is well established that damages are not an adequate remedy for the defendant in such a case. It is impossible, or at least exceedingly difficult to work out how much profit the defendant would have made if allowed on to the market. There are too many unknowns:

    - It will never be known how much the profit the defendant have made, since it won't be known exactly how the originator will act to defend its market.

    - Further, the possibility of other generics entering the market is a further confounding factor. When there is only one generic on the market, they can usually keep their prices high and make large profits. But once other generics join the market, price competition becomes intense, prices fall, and profits are smaller. But it won't be known how many generics would have entered the market, at what volumes, and at what price.

    - Yet further, the first generic to enter a market tends to retain market share even after further generics enter the market. Wholesalers who have been buying from one generic but are approached by a second generic offering a different price, tend to give the original supplier the opportunity to reduce their price to retain the business. This is sometimes called the "incumbency effect". How do you put a number value on that?

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5 *American Cyanamid v Ethicon* [1975] AC 396, 408C (Lord Diplock); *R(Factortame) v Sec State for Transport* [1991] 1 AC 603, 672B & p672C (Lord Goff).

16. Furthermore, if we get to the balance of convenience, our hypothetical lawyer would point out that the balance appears to lies firmly in favour of withholding an interim injunction. That is because the uncertainties involved in assessing the damage suffered by the defendant would be significantly greater than the uncertainties involved in assessing the damage to the claimant.

17. At the time of the application, there are uncertainties on both sides:

    - We cannot know how much the damage the claimant will suffer if the defendant is allowed on to the market. It will depend on: (a) the defendant's price & volume of supply; (b) how much the claimant will lower its price to compete; (c) the actions & impact of other generics; (d) what volumes the defendant (and other generics) will take from the claimant in light of the foregoing; (e) whether and to what extent the claimant can restore its price if it wins at trial and the infringers are removed from the market.

    - We cannot know how much damage the defendant will suffer if it is not allowed onto the market pending trial. It will depend on: (a) the defendant's price & volume of supply; (b) how much the claimant would have lowered its price to compete; (c) the actions & impact of other generics; (d) what volumes the defendant would have taken from the claimant; (e) the value to the defendant of the incumbency effect.

18. However if an interim injunction is <u>not</u> granted, then by the time of the damages inquiry, if one is necessary, then the unknowns on the claimant's side will be known. At that stage it will be a simple matter of mathematics to calculate the claimant's loss. On the other hand, if an interim injunction <u>is</u> granted, on an inquiry under the cross-undertaking the uncertainties on the defendant's side will remain uncertain. The court will have to construct a counterfactual world in which the defendant had been allowed onto the market, to work out how much profit the defendant would have made in that world. But it will be exceedingly difficult to determine what that counter factual world would have looked like. And because of those difficulties and uncertainties, the risk that the defendant will be undercompensated is significantly greater than the risk of the claimant being undercompensated if an interim injunction is not granted.

19. I can give you two judicial illustrations of this last point:

    - The first time an Australian court had to determine the liability of a claimant to pay damages to a generic under a cross-undertaking was in a case called

*Sigma v Wyeth*.[6] The hearing took over a month and resulted in a 400+ page judgment. Jagot J concluded: [7]

> It is difficult to imagine that when Sundberg J and then I granted the interlocutory injunctions in 2009 we anticipated that if those injunctions turned out to be wrongly granted, the resulting exercise would bear any resemblance to this one. Hindsight makes one thing certain. Knowing what has occurred, it could never have been concluded, for example, that insofar as relevant to the balance of convenience it would be easier for the generics to prove their loss if the interlocutory injunctions were wrongly granted than for [the patentee] to prove its loss if the interlocutory injunctions were withheld and the method patent was valid.

This judgment has been influential in subsequent Australian cases in which an interim injunction has been refused for these reasons.[8]

- *Servier v Apotex*[9] is an English case, which provides an illustration of how uncertainties can lead to under-compensation and therefore injustice. Norris J held that there were two possible counterfactual scenarios that could have occurred if the defendant had not been injuncted: Scenario 1 in which the defendant's damage would have been £22.5 million, which was 67% likely to have occurred, and Scenario 2 in which defendant's damage would have been £7.9 million, which was 33% likely to have occurred. The result was that Apotex recovered £17.5 million (the judge rounded down). That approach was correct in law. But you can see that the final number was <u>probably</u> too low: there is a 67% chance that it was about £5 million too low.

<u>The decision in *AZ v Glenmark*</u>

20. *AZ v Glenmark* was a case of the type I have outlined.[10] It concerned the drug dapagliflozin. Several generic pharmaceutical companies (including Glenmark) had begun proceedings for revocation of AZ's patent: there had been a trial of the action in early March 2025, and judgment was awaited. But Glenmark wanted to launch its generic dapagliflozin product before the judge delivered

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6 [2018] FCA 1556.

7 [2018] FCA 1556, [1336].

8 *Sanofi-Aventis v Alphapharm* [2018] FCA 2060, [163] & [166] (Burley J), upheld on appeal: [2019] FCAFC 28; *Mylan v Sun Pharma* [2019] FCA 505, [137] (Yates J).

9 [2008] EWHC 2347 (Ch).

10 Paragraph 4 above.

that judgment, so as to become the first generic on the market. So AZ applied for an interim injunction to cover that period.

21. Michael Tappin KC, who was the trial judge, heard the application on 27 March and refused an interim injunction the next day, essentially for the reasons which I have outlined above.[11]

22. The Court of Appeal heard an appeal on 16 April, overturned the first instance decision and granted an interim injunction. Why did it do so? And is the effect of the Court of Appeal's reasoning an interim injunction ought to be granted in all these sorts of cases?

23. In the Court of Appeal, Arnold LJ gave the only judgment, with which Coulson and Warby LLJ agreed. He identified three factors which distinguish this class of case,[12] which essentially explain why interim injunctions are usually granted in this sort of case.

24. First, the entry of one generic company into a market which has hitherto been monopolised by the claimant is often followed by the entry of other generic companies. 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.

25. Second, the practical ability of the claimant 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 claimants raising their prices, this would lead to a loss of goodwill which is generally regarded by claimants as unacceptable. I am going to have more to say about this second point.

26. Arnold LJ said that first two factors can lead to the conclusion that damages will not be an adequate remedy for the claimant, because of the uncertainty involved. But he acknowledged that it is usually the case that damages will not be an adequate remedy for the defendant either, because of the difficulty in establishing the relevant counterfactual, including the uncertainty as to the extent to which the defendant would have benefitted from being the first generic entrant.

27. The third special factor is that a generic company intending to launch a product at risk will have had to do a lot of advance planning, and will usually be well aware of the risk of infringement. In those circumstances it is established that it is proper for a court to take into account, when considering the balance of convenience, that the generic company could have "cleared the path" for its

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11 [2025] EWHC 748 (Pat).

12 [2025] EWCA Civ 480, [23]-[26].

launch by bringing proceedings for revocation of the patent sufficiently far in advance.[13]

28. The crux of Arnold LJ's decision in *AZ v Glenmark* is at [86]-[87] (underlining added):

> 86. … 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.
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> …
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> 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...

29. This passage was interpreted in the following way by Judge Hacon at a later stage in the *AZ v Glenmark* litigation[14] (underlining added):

> 130. Each side is likely to suffer irreparable harm on the alternative hypotheses of an injunction being granted or not. The harm on either side is different, so there is no question of comparing like with like in assessing the comparative risk with any measure of accuracy. Uncertainties exist on both sides.
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> 131. In those circumstances, following a principle of law emphasised by the Court of Appeal in *Neurim Pharmaceuticals* and endorsed in the [the Court of Appeal's decision in *AZ v Glenmark*] I am persuaded that it is appropriate for me to maintain the status quo. … The status quo requires the grant of an injunction as sought.

30. I think that this fairly reflects Arnold LJ's reasoning in [86]-[87] of his judgment. Arnold LJ thinks so too, because he refused an application for permission to appeal against this judgment on the grounds that it had no prospect of success.

31. What is striking about these passages is that in every interim injunction case, the harm on either side will be different in nature. The damage caused to a claimant by a defendant doing something that the claimant objects to will always be of a different nature to the damage that will be caused to a defendant who is prevented from doing something that they want to do. What these

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13 *SmithKlineBeecham v Apotex* [2003] EWCA Civ 137, [2003] FSR 31,[38]-[40] (Aldous LJ).

14 [2025] EHWC 1339 (Pat). This judgment concerned an application for an interim injunction in the period of time between the first instance judgment on validity and the appeal on validity.

judgments appear to me to be saying is that in such a case the court does not even try to assess the comparative uncertainties and comparative risks of injustice. Instead, it says that there are uncertainties on either side, so I will maintain the status quo because the defendant did not clear the path.

32. And to be clear, clearing the path in this context means getting a final judgment after all appeals. We can see that, for example, from the second *AZ v Glenmark* judgment, which considered the period between the first instance judgment and the appeal to the Court of Appeal.[15]

Interim injunction applications after *AZ v Glenmark*

33. The upshot of all this, as I see it is as follows:

- Arnold LJ's first two factors mean that in any case like this, the claimant will be able to satisfy the court that damages would be an inadequate remedy for it. All the claimant has to do is provide evidence that if the defendant is allowed onto the market, it will have to or may have to lower its own prices to compete, and may not be able to restore them even if successful at trial. And that will be all the more so since multiple generics are likely to follow in the defendant's wake.

- The defendant will always be able to satisfy the court that damages would not be an adequate remedy for it. But that will not stop an interim injunction being granted.

- The court will proceed to the balance of convenience. And at that stage the correct analysis is, apparently, first: that there is "*no question*" [16] of trying to assess the comparative risks of injustice. Second: in those circumstances the right thing to do is to preserve the status quo, especially because the defendant did not clear the path. And that means granting an interim injunction.

34. So I do think that, for as long as the judgment of Arnold LJ in *AZ v Glenmark* remains authoritative, interim injunctions will invariably be granted in the sort of case that we are considering.

35. What hope then for defendants? There are five aspects of Arnold LJ's judgment which merit further comment, and which I would focus on if I were seeking to resist an interim injunction. It may be that, for at least some of these points, only the Supreme Court would be entitled to mandate a different approach to that approved by the Court of Appeal. But there is an appetite amongst the

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15 Paragraph 29 and footnote 14 above.

16 *AZ v Glenmark* [2025] EHWC 1339 (Pat), [130] (Judge Hacon) set out above.

generic pharmaceutical industry in this country for taking this whole question to the highest level.

36. First, Arnold LJ acknowledged[17] that whether a price spiral will occur is fact specific. The *Neurim* case[18] is a rare example of a case in which an injunction was refused at first instance and in the Court of Appeal. In *AZ v Glenmark*, Arnold LJ said that that was because the evidence failed to establish that any other generic company, apart from the defendant, was likely to enter the market in the period up to trial, and therefore a downward price spiral was unlikely.[19] So both sides on an interim injunction application should consider the question of multiple generic entry. But I doubt this will be much help to defendants, because: (a) it is usually easy to prove a high likelihood of multiple generic entry; and (b) even without multiple generic entry, the claimant can simply say that they will or may compete aggressively on price, thereby leading to depression of their price.

37. The second point is the validity of Arnold LJ's second factor. Is it really not possible for an originator pharmaceutical company to restore its prices, to previously levels, in circumstances where there has been generic entry, followed by a price spiral, and then the generics have then been removed from the market? This is of course a factual question. Arnold LJ's reasoning was that there is little to no evidence of a pharmaceutical company successfully returning its prices to previous levels in such a case.[20] However such cases very rarely arise. For this scenario to arise: (a) an interim injunction would have to be refused by the courts (which is very rare); and (b) the patent would have be found valid and infringed (which is fairly rare, not because pharmaceutical patents are usually bad, but because generic pharmaceutical companies do not challenge patents unless they are clearly vulnerable). So the necessary combination of those two occurrences is exceedingly rare. It may be that the only example of such a case is the *Neurim* litigation, and in that case, as Arnold LJ acknowledged,[21] the claimant was able to restore its price to the previous level.

38. I can also tell you that the Secretary of State for Health has taken an interest in this point, and his position is that there is no obstacle to originator

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17 [2025] EWCA Civ 480, [27].

18 *Neurim Pharmaceuticals v Generics* [2020] EWCA Civ 793, [2021] RPC 7,[46] & [50] (Flord LJ).

19 [2025] EWCA Civ 480, [27].

20 [2025] EWCA Civ 480, [24].

21 Ibid.

pharmaceutical companies restoring their prices in such circumstances. The Secretary of State has filed evidence in the *AZ v Glenmark* case, which will be considered when the Court of Appeal decides whether there should be an injunction pending an appeal on the substantive validity issue from that court to the Supreme Court.

39. The third point on Arnold LJ's judgment is the proposition that permanent price depression cannot be adequately compensated by way of damages. Arnold LJ did not examine that proposition in detail. On one view, calculating the relevant loss would be easy: you simply take the difference between (a) the price at which the claimant was selling before the defendant entered the market, and (b) the new, lower price; and then you multiply that by the number of units sold at the lower price. If the patent has expired by the time of the damages inquiry, then these figures will be known, and it should be simple mathematics. Even if the patent has some years left to run, it should be possible to forecast the number of units that will be sold during the remaining life of the patent (during which the claimant will enjoy a 100% market share).

40. The fourth aspect of Arnold LJ's judgment that merits comment relates to the difficulty of comparing the relative uncertainties and relative risks of injustice. The point of the "balance of convenience" is to try to find the course which carries with it the least risk of injustice. In *National Commercial Bank of Jamaica v Olint,*[22] Lord Hoffman said this (underlining added):

> 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.

41. That passage is often quoted interim injunction cases – indeed, Arnold LJ quoted it himself.[23] But I do think that there is force in the suggestion that he did not engage in the process described there by Lord Hoffman. The passages from the judgments in *AZ v Glenmark* which I have quoted[24] appear to direct the court to go straight to the preservation of the status quo, without trying to

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22 *National Commercial Bank of Jamaica v Olint* [2009] UKPC 16, [2009] 1 WLR 1405, [17].

23 [2025] EWCA Civ 480, [20].

24 Paragraphs 28-29above.

predict whether granting or withholding an injunction was more or less likely to cause irremediable prejudice, and to what extent.

42. Finally, importance of "clearing the path" remains a matter of debate. It is settled as a relevant factor at the Court of Appeal level but may be a topic fit for a Supreme Court appeal. A countervailing argument by the generic companies is that there is a significant public benefit in generic companies challenging bad patents; but they will be disincentives from doing so if they cannot reap the full benefits of doing so by launching at risk as the first mover (or one of the first). This argument was raised by before Judge Hacon in the later *AZ v Glenmark* hearing but not given any weight by the Judge.[25]

Conclusion

43. I hope these thoughts will be helpful the next time you are confronted with one of these cases. If you would like to discuss strategies further, then my clerk's e-mail address is always open.

[25] [2025] EWHC 1339 (Pat), [50]-[52].