Interim Injunctions: AstraZeneca v Glenmark

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Court of Appeal (Lords Justices Coulson, Arnold and Warby) *AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Ltd* [2025] EWCA Civ 480 (16 April 2025)

This was an appeal against Michael Tappin KC's refusal in *AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Ltd (Re Interim Injunction Application)* [2025] EWHC 748 (Pat) (28 March 2025) to grant AstraZeneca AB and AstraZeneca UK Ltd. an interim injunction to restrain Gelnmark Pharmaceuticals Europe Ltd. from selling a product containing dapagliflozin pending a hearing on the form of order following a trial to determine the validity of the first claimant's supplemental protection certificates for dapagliflozin and a combination of dapagliflozin and metformin. The appeal was heard by Lords Justices Coulson, Arnold and Warby on 9 April 2025. At the end of the hearing, the Lords Justices announced that they would allow AstraZeneca's appeal. Lord Justice Arnold handed down the Court's reasons in *AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Ltd* [2025] EWCA Civ 480 on 16 April 2025.

The SPC Revocation Proceedings

AstraZeneca AB holds United Kingdom Supplementary Protection Certificate No. SPC/GB13/021, which relates to dapagliflozin, and United Kingdom Supplementary Protection Certificate SPC/GB14/050, which relates to a combination of dapagliflozin and metformin. On 6 Oct 2023, Generics (UK) Ltd. commenced proceedings for the revocation of the SPCs on the ground that European patent (UK) 1506211 B1 had been invalid. Similar proceedings were brought by Teva Pharmaceutical Industries Ltd and Teva UK Ltd ("Teva") on 24 Nov 2023 and Glenmark Pharmaceuticals Europe Ltd. ("Glenmark") on 21 Dec 2023. The action was tried between 10 and 20 March 2025. Judgment was reserved, and the trial judge has been unable to say when he can deliver judgment.

Glenmark's Product Launch

On 20 Feb 2025, Glenmark told AstraZeneca AB and its British subsidiary AstraZeneca UK Ltd ("AstraZeneca") that it had obtained a marketing authorisation for a product containing dapagliflozin and that it proposed to launch it on or after 17 March 2025. There was no doubt that Glenmark's product would infringe AstraZeneca's SPCs if they were valid.

AstraZeneca's Application

AstraZeneca applied for an interim injunction on 6 March 2025. Mr Tappin heard the application on 27 March 2025. Glenmark delayed its product launch until the day of the hearing upon a cross-undertaking of damages from AstraZeneca. The deputy judge delivered his judgment the next day.

Mr Tappin's Judgment

At para [20] of his judgment, Mr Tappin directed himself that the court has power to grant an interim injunction where it is just and convenient to do so, but it is not an unfettered discretion. It has to be exercised according to settled principles in accordance with Lord Diplock's speech in *American Cyanamid v Ethicon* [1975] 2 WLR 316, [1977] FSR 593, [1975] AC 396, [1975] UKHL 1, [1975] 1 All ER 504:

"(1) Is there a serious question to be tried?
(2) Are damages an adequate remedy for the claimant? If they are and the defendant would be in a position to pay those damages, then no injunction should normally be granted.
(3) If not, are damages on the cross-undertaking an adequate remedy for the defendant? If they are and the claimant would be in a position to pay those damages, then the injunction should normally be granted.
(4) If damages are not an adequate remedy for either side, where does the balance of convenience (or the balance of risk of injustice) lie? Where the facts appear evenly balanced, it is a counsel of prudence to preserve the status quo."

As Glenmark had conceded that the sale of its dapag product would infringe the SPCs, both parties accepted that there was a serious question to be tried on validity. At para [71] the deputy judge turned to stage 2 of the *American Cyanamid* guidelines, namely whether damages would be an adequate remedy to AstraZeneca. At [79] he concluded that the damages due to AstraZeneca as a result of refusal of an interim injunction pending the form of order hearing were calculable to a reasonably high degree of accuracy and that damages would be an adequate remedy for the claimants subject to Glenmark's ability to pay. Having satisfied himself that Glenmak would be good for any damages that might be awarded against it and upon Glenmark's undertaking to pay its profits into a special bank account in case AstraZeneca elected an account of profits, Mr Tappin decided that damages would be an adequate remedy for AstraZeneca.

In case the matter went any further, the deputy judge decided to address stage 3 of the *American Cyanamid* guidelines. That stage required him to consider whether damages on the cross-undertaking would be an adequate remedy for Glenmark. He decided at para [100] that damages on the cross-undertaking would not be an adequate remedy for Glenmark because of the difficulty in establishing a counterfactual with any degree of accuracy. Finally, were it necessary to consider the balance of convenience, he would have held that the balance of risk of injustice lay against the injunction sought.

Mr Tappin refused permission to appeal.

The Appeal

AstraZeneca applied to the Court of Appeal for permission to appeal on the following grounds, which Lord Justice Arnold summarized at para [55] of his judgment in *AstraZeneca AB and another v Glenmark Pharmaceuticals Europe Ltd* [2025] EWCA Civ 480:

"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 letters "FOO" in this passage stand for "form of order",

The learned Lord Justice granted AstraZeneca permission to appeal and expedited the hearing of the appeal for the reasons that he set out in para [1] of his judgment:

"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."

His lordship described the situation as evolving because he had evidence that Teva and several other generic manufacturers were about to launch products containing dapagliflozin. Lord Justice Arnold said at para [58]:

"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."

Ground 1a: Adequacy of Damages for AstraZeneca

AstraZeneca contended that, even as matters stood at the date of the hearing before Mr Tappin, the deputy judge applied too high a threshold to AstraZeneca's evidence and failed to make proper allowance for the uncertainties in the situation. However, even if the deputy judge's assessment was right when he heard the case, his assessment had been undermined by the new evidence. As it was clear that multiple generic entry was both a certainty and would happen very quickly, the correct conclusion was that AstraZeneca would be likely to reduce their actual prices before the form of order hearing. If they did so, they would have serious difficulty in raising them again. Although it did not necessarily follow that damages would not be an adequate remedy for AstraZeneca, it did mean that there was room for doubt about the adequacy of the damages.

Ground 1 b: Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd.

AstraZeneca contended that the Court of Appeal should consider the adequacy of damages as part of the balance of convenience, as urged by Mr Justice O'Connor of the Irish Supreme Court's at para [35] of his judgment in *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd*. *[2020] 2 IR 1, [2019] IESC 65*. Lord Justice Arnold rejected that contention on the ground that the Court of Appeal was bound by *American Cyanamid* and not by *Clonmel.*

Ground 2: Adequacy of Damages for AstraZeneca after the Point of Order Hearing

Even though Mr Tappin directed himself at [31] that he should consider damage to AstraZeneca arising from events in the period before the hearing, whether that damage manifested itself during that period or later, AstraZeneca complained that he failed to do so. In particular, he failed to take into account the fact that, if he refused an injunction, it would mean that the status quo at the time of the form of order hearing would be that Glenmark, and possibly other generics, would be in the market. That would inevitably diminish AstraZeneca's ability to obtain an injunction pending appeal, if they needed one. It would also expose AstraZeneca to generic price erosion for a longer period, making it even more likely that AstraZeneca would have to cut their prices and even more difficult for AstraZeneca to restore them even if completely successful. The deputy judge did not appear to have considered these points.

That argument was fortified by the new evidence mentioned above.

After taking all the above factors into consideration, Lord Justice Arnold concluded that there was real doubt as to the adequacy of damages as a remedy for AstraZeneca.

Ground 3: Adequacy of Damages for Glenmark

Although AstraZeneca argued that it would be easier to assess Glenmark's damages in the light of the new evidence mentioned above, Lord Justice Arnold disagreed. In his view, there was real doubt as to the adequacy of damages for both sides. It was not possible to form a reliable view as to which was more at risk of an inadequate remedy in damages.

Ground 4: The Status Quo

Lord Justice Arnold criticized Glenmark for launching its product before the validity of the SPCs had been determined. Had it wanted to expedite the revocation proceedings, it had an opportunity to do so at a hearing before Mr Justice Meade, but Glenmark did not give his lordship a sufficient reason for bringing the trial forward. It timed its product launch for the middle of the trial. A lot of time and money had been wasted on obtaining an order which could only apply for a few months. The balance of the risk of injustice law in allowing the appeal and granting the interim injunction.

Comment

A fascinating case on the application of the *Cyanamid* principles half a century after their inception. Despite such challenges as *Series 5 Software v Clark*e [1996] FSR 27 an*d Clonmel*, they remain intact. Anyone wishing to discuss this case may call me on 020 7404 5252 or send me a message through my contact form.