EIP

Court of Appeal overturns High Court's decision and grants interim injunction to AstraZeneca against Glenmark

AstraZeneca v Glenmark has seen the parties visiting the courts several times since the validity trial (heard in March of this year) over the past few weeks. This case relates to AstraZeneca's blockbuster drug Forxiga, used to treat type II diabetes and in which the active ingredient is known as dapagliflozin ("**dapag**").

On 27 March 2025 (judgment released on 28 March), the High Court heard and refused AstraZeneca's application for an interim injunction against Glenmark, preventing them from selling their dapag product in the UK, pending the Form of Order ("**FOO**") hearing in the validity proceedings. Of late, on the 9 April, the Court of Appeal overturned the High Court's decision and awarded AstraZeneca its interim injunction. It concluded that the balance of the risk of injustice favours the grant of the injunction sought by AstraZeneca until the conclusion of the FOO hearing. It has now provided its written reasons for reaching its conclusion.

This bumper newsflash looks at both the High Court and Court of Appeal judgments when coming to their decisions.

Background

AstraZeneca AB (the First Claimant) is the proprietor of the SPC relating to dapag (due to expire on 13 May 2028), as well as another SPC relating to a combination of dapag with another active ingredient. The UK entity of AstraZeneca (the Second Claimant) hold a UK marketing authorisation ("**MA**") for its product Forxiga which contains the active

ingredient dapag and further UK MAs for products containing combinations of dapag with other active ingredients. Glenmark commenced invalidity proceedings against the SPC and the combination SPC on 21 December 2023. Similar proceedings had already been issued by Generics (UK) on 6 October 2023 and by Teva on 24 November 2023.

The claimants of the various actions applied to have the trial listed ahead of the CMC and were looking for a January 2025 trial. On 26 January 2024, Meade J rejected this request and the claims were eventually listed for trial in March 2025. Meade J had not been provided any real reason as to why expedition was required. Michael Tappin KC, sitting as a Deputy Judge of the High Court, heard the trial between 10 March and 20 March 2025.

On 20 February 2025, ahead of trial, Glenmark notified AstraZeneca that it intended to launch a product containing dapag as the active ingredient in the UK on 17 March 2025. On 28 February, AstraZeneca notified Glenmark that it intended to seek an interim injunction to prevent Glenmark from selling its dapag product in the UK pending the FOO hearing following the validity trial. On 6 March, AstraZeneca issued and served its application for such an injunction.

AstraZeneca's application was not heard until after the validity trial on 27 March. By which time there had been a number of rounds of evidence exchanged between the parties, which the Judge went on to consider. In the meantime, Glenmark gave undertakings and AstraZeneca gave cross-undertakings pending judgment on this application.

The High Court's Decision on AstraZeneca's Application for an Interim Injunction

In coming to his decision as to whether it was just and convenient to grant an interim injunction, the Judge applied the well-known guidelines set out by Lord Diplock in American Cyanamid v Ethicon [1975] AC 396.

Would damages be an adequate remedy for AstraZeneca?

The Judge made clear that he was "concerned only with the damage that flows from events in the period between now and the form of order hearing, whether that damage manifests itself in that period or afterwards." The parties had no idea when such a hearing would take place but had estimated that this would be between one to three months from the original planned launch date of 17 March. The Judge indicated that he was in no position to inform the parties when a hand down of the validity judgment would be expected so adopted the parties' estimate.

In assessing the evidence before him, the Judge felt that the damages, if due to AstraZeneca as a result of refusing their application, could be easily calculated.

AstraZeneca suggested, through evidence of assessing Glenmark's filed accounts, that Glenmark would not be able to pay any damages that were due (if it came to that). The Judge understood AstraZeneca's position and believed them to be entitled to security for its potential damages if no injunction was to be granted. The Judge suggested that Glenmark should provide an undertaking to pay the amount identified by Glenmark's solicitors as the estimate of AstraZeneca's profit per pack of Forxiga into a separate bank account for each pack sold between now and the FOO hearing. This would allow for damages to be an adequate remedy for AstraZeneca.

Would damages on the cross-undertaking be an adequate remedy for Glenmark?

In contrast, the Judge felt that quantifying the damages to Glenmark on the cross-undertaking would not be as straight forward. And the fact, that there was a real risk of other generics entering the market in quick succession, would require the Court to tease out how many sales Glenmark would have made and at what price against the unknown level of competition from other generics at unknown prices. The Judge surmised that this sort of information would not be so easily attainable. The Judge also agreed with Glenmark's assertions that it would be difficult to assess the extent of any first-mover advantage that it would have obtained if it had not been injuncted.

Additionally, the NHS had written to the Judge regarding calculation of damages recoverable by the NHS on a cross-undertaking. The letter made clear that if NHS entities were included within any cross-undertaking in damages, the NHS were not in a strong position to enforce cross-undertakings, if needed, nor would it be easy to calculate the losses attributable to the delay in a generic entering the market.

With this information, the Judge decided that damages on the cross-undertaking would not be an adequate remedy for Glenmark nor for the NHS due to the varying uncontrollable factors.

If damages are not an adequate remedy for either side, where does the balance of convenience (or balance of risk of injustice) lie?

Given that the Judge had found that damages would be an adequate remedy for AstraZeneca, he did not go into this stage in any great detail. But added for completeness, that had he needed to consider stage 4 of the American Cyanamid guidelines, then he would have held that the balance of risk of injustice lay against the injunction sought.

The Judge went onto refuse AstraZeneca's application for an interim injunction pending the FOO in the validity proceedings.

Permission to Appeal Granted by the Court of Appeal

Following an application to the Court of Appeal, on 31 March 2025, Lord Justice Arnold heard the parties and granted AstraZeneca permission to appeal the High Court's decision.

Lord Justice Arnold also granted AstraZeneca an injunction pending a decision from the Court of Appeal. He permitted Glenmark to supply packs of its dapag containing product to its wholesalers but they were not allowed to release those packs for onward sale in the UK.

The Court of Appeal's Decision

On 9 April, the Court of Appeal overturned the High Court's decision at the end of the hearing and awarded an interim injunction. It has now provided its written reasons for reaching its conclusion.

AstraZeneca's Grounds of Appeal

AstraZeneca's grounds of appeal mainly focussed on the High Court's decision that damages would be an adequate remedy for AstraZeneca and looked to distinguish the periods leading up to the FOO hearing and after the FOO hearing and thus the damage that AstraZeneca would suffer within.

The Court of Appeal allowed AstraZeneca to run their four grounds of appeal. Ground 1 divided into two sub-parts with Ground 1a being that the High Court Judge applied too high a threshold when considering whether damages would be an adequate remedy for AstraZeneca (focussing on the period up to the FOO hearing), 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 was that the Judge should have considered the adequacy of damages as part of the balance of the risk of injustice.

p5

Ground 2 was that the Judge failed to take into account the damage that AstraZeneca would suffer after the FOO hearing despite the Judge noting that he should have done. Ground 3 was that the Judge incorrectly assessed the inadequacy of damages as a remedy for Glenmark. Ground 4 was that, in any event, aspects of the Judge's assessment would need to be reconsidered in light of subsequent developments shown in new evidence.

In coming to its conclusion the Court of Appeal found it convenient to consider the grounds out of sequential order. It also allowed new evidence from AstraZeneca into the appeal proceedings.

Ground 4 and the new evidence

Taking the lead on the judgment, Lord Justice Arnold, considered it convenient to review the new evidence that was put before the Court first. The new evidence was a number of communications with other generics, of which one, Teva, contended that they had "first mover advantage." Teva was even 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. Another generic (referred to as Generic X for confidentiality reasons) had also taken the same stance as Teva.

The Court of Appeal felt this new evidence was key and that it put a different complexion on matters which may have changed the First Instance Judge's mind had this evidence been before him.

Ground 1a: adequacy of damages for AstraZeneca

The Court of Appeal accepted AstraZeneca's submissions that at least the new evidence made it clear that multiple generic entry was now a certainty and would happen quicker than anticipated at the first instance hearing. Given the uncertainty of timing between the hand down of judgment and the FOO hearing, the Judge concluded that in the very short term, it was unlikely that AstraZeneca would change their price but that the longer the period turned out to be, there was a greater pressure on AstraZeneca to reduce their price, which they would likely have difficulty in raising again.

Ground 1b

The Court of Appeal dismissed this ground of appeal. The Court of Appeal was bound by American Cyanamid and thus not open for them to follow the Irish Supreme Court in MSD

v Clonmel.

p6

Ground 2: damage to AstraZeneca after the FOO hearing

The crux of this ground of appeal was that the High Court failed to consider the adequacy of damages for AstraZeneca, after the FOO hearing, if no injunction was granted at this stage.

The Court of Appeal concluded that 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 (as elaborated in Ground 1a), there was a real doubt as to the adequacy of damages as a remedy for AstraZeneca.

Ground 3: adequacy of damages for Glenmark

The new evidence suggested that Teva and Generic X were in a position to launch rapidly if Glenmark had launched at risk despite Glenmark's suggestions that it had first mover advantage.

The Court of Appeal came to the view that it would be difficult to assess which side would be more at risk of receiving an inadequate remedy in damages.

Ground 1a: clearing the path and status quo

The Court of Appeal made comments about Glenmark's behaviour in attempting to clear the way and the timing of the injunction application. The Court of Appeal agreed with AstraZeneca's submission that the High Court Judge was wrong to discount Glenmark's failure to clear the path when considering whether to preserve the status quo.

The onus should be on the party looking to clear the way and to seek expedition of trial, if necessary, with appropriate reasons. Glenmark provided no reason to Meade J at the listing hearing for seeking expedition of an earlier trial. Had they provided a modicum of information that they might be ready to launch in March 2025, then Meade J may have allowed a degree of expedition which may have avoided the situation the parties found themselves in.

On Glenmark's timing of its launch date, the Judge described it as "jumping the gun". There had been no suggestion that Glenmark would have to wait a long time for the judgment, given that the parties had estimated a one to three months wait between Glenmark's hypothesised launch date and the FOO hearing. The Court of Appeal felt that the High Court Judge was wrong to discount the fact that Glenmark sought to launch its product in the middle of trial without waiting for judgment when considering whether to

preserve the status quo.

p7 The Court of Appeal was also critical of Glenmark's behaviour. It surmised that it made it difficult for the courts to do justice to all the parties, including those not before the court on the application. It had required a day of argument in the Patents Court and a day of argument in the Court of Appeal to deal with the application, and with what was likely to be at a considerable cost covering a period of only one to three months. The Court of Appeal made it clear that this was not a good use of the parties' resources and still even less good use of scarce court resources.

On the whole, the Court of Appeal found that it was not possible to form a reliable view as to which side was more at risk of receiving an inadequate remedy in damages, and given the shortness of the period in question it was prudent to preserve the status quo until the conclusion of the FOO hearing. It concluded that the balance of the risk of injustice favoured the grant of the injunction sought by AstraZeneca until the conclusion of the FOO hearing.

Take Away Points

It is clear that the Court of Appeal does not want Court resources stretched unnecessarily. When looking to making an interim injunction application, as well as detailed evidence to support your application, it would be prudent to consider the timing of the application, the costs and court resources that may be needed in order to maximise your chances of success.

First instance judgment is available here.

Court of Appeal judgment is available here.