Kluwer Patent Blog

Clear The Way – Don't Jump the Gun: English Court of Appeal grants an Interim Injunction to AstraZeneca in Glenmark Dapagliflozin Case

Nischay Mall (Bristows) · Monday, April 28th, 2025

In the UK, as well as in many other countries, being the first to market with a generic or biosimilar to a leading branded medicine is a critical strategy that can offer a major advantage to a company in a highly competitive landscape. Being the first company to launch a generic product has several advantages. In particular the company can: (i) capture, and potentially maintain for a substantial period, a larger market share over the second or third generic to the market, and (ii) command a price premium before the inevitable generic price erosion commences. Given the comparatively reduced profit margins on which most generic companies operate, being first to market may represent a key factor for profitability. Therefore, it follows that the loss of this advantage may be substantial, and economically difficult to quantify. This first mover advantage provides a motive to generic companies to launch at risk, i.e., launch before they have cleared the way, or if the patentee has issued proceedings for patent infringement, before that claim has been decided. Importantly, in contrast to e.g. the US, a litigant which clears the way ahead of a launch in the UK obtains no period of exclusivity as against its competitors.

The difficulty in quantifying the loss of first mover advantage was one reason why Michael Tappin KC, sitting as a Deputy Judge of the High Court, on 28 March 2025, refused AstraZeneca's application for an interim injunction against Glenmark from launching generic dapagliflozin (**dapag**). However, AstraZeneca (**AZ**) appealed the decision (with the permission of the Court of Appeal) and, following a hearing on 9 April 2025, the Court of Appeal reversed the first instance judgment. The Court of Appeal subsequently handed down its written reasons on 16 April 2025. The ruling, delivered by Arnold LJ (with Warby and Coulson LJJ concurring), provides significant guidance to generic pharmaceutical companies considering launching at risk in the UK.

Background

Earlier in March 2025, Michael Tappin KC heard the trial on the merits between Glenmark, Teva and Generics (UK) on the one hand, and AZ on the other, concerning the validity of AZ's patent to dapag. Following a heavily contested trial with seven days in Court taken up largely with extensive oral evidence from expert witnesses from both sides, the Judge reserved judgment in accordance with conventional practice.

A few days before the trial, Glenmark informed AZ that it had obtained a marketing authorisation (**MA**) for its dapag medicine and was planning to launch it at risk. Consequently, on 6 March 2025,

AZ issued an application notice requesting the grant of an interim injunction against Glenmark. Given that the trial was scheduled to be heard from 10 to 20 March 2025, the application was heard after the trial, on 27 March 2025, with the judgment being handed down the next day on 28 March 2025.

As indicated above, Michael Tappin KC refused the interim injunction on the ground that any damages arising from the refusal of the interim injunction would be an adequate remedy for AZ because they could be calculated to a reasonably high degree of accuracy. By contrast, quantifying any damages payable under the cross-undertaking to Glenmark due to the loss of its first-mover advantage, and to the NHS (to which AZ agreed to give a cross-undertaking) would be significantly more difficult. Accordingly, damages would not be an adequate remedy for Glenmark or the NHS. AZ applied to Judge Tappin for permission to appeal but it was refused. AZ immediately sought, and obtained, permission to appeal from the Court of Appeal.

Court of Appeal's Reversal of the High Court's Judgment

Ahead of the appeal, AZ requested permission to introduce additional evidence which highlighted that two further generic companies (Teva and another unnamed entity, Generic X (although, as the Court observed "*it is not hard to work out who it is likely to be*")) were poised to enter the UK market with their generic dapag medicines imminently. Both these generic companies had secured MAs and were ready to distribute substantial volumes. The Court of Appeal acknowledged that this new evidence changed the situation significantly – putting "*a different complexion on matters*". It recognised the risk that if the injunction against Glenmark was not granted, at least these two companies might enter the market before the form of order hearing (**FOO hearing**) following the judgment in the main action which according to the Court rules should take place within 28 days of the date of handing down of the judgment – so potentially in May 2025. The Court found that, without an interim injunction against Glenmark, at least two other generics would enter the market prior to the FOO hearing. As such, the Court of Appeal held that what had been a "*real risk*" at the first instance had now become a "*certainty*". It therefore concluded that such widespread generic entry would likely result in a rapid and irreversible price spiral (generic price erosion).

The Court of Appeal agreed with AZ that if multiple generic entry happened as quickly as indicated by AZ's new evidence, AZ would be likely to reduce their price prior to the FOO hearing. Given the NHS reimbursement mechanism and the VPAG scheme, AZ would have serious difficulties raising the price again. Nonetheless, this did not imply that damages would not be an adequate remedy for AZ. It would ultimately be contingent on the gap before the FOO hearing – the longer the gap, the more AZ would feel compelled to lower its price.

The Court of Appeal also held that in considering the damage to AZ from a refusal of the interim injunction and Glenmark's market entry before the FOO hearing, the High Court should have considered the damage to AZ not just in the period before the FOO hearing but also afterwards – given that the refusal would inevitably prejudice AZ's ability to obtain an injunction against not only Glenmark but other generic entrants as well pending appeal (if AZ needed to do so). As a result, it was held that AZ might suffer generic price erosion for an extended duration, increasing the likelihood of needing to reduce its price. If AZ were to succeed in obtaining a final injunction following resolution of the merits, it would be far more difficult for them to raise the price again. Revisiting the *American Cyanamid* principles, particularly whether damages would be an adequate remedy for AZ, the Court of Appeal held that there was real doubt regarding the adequacy of

damages for AZ.

Whilst there was some uncertainty as to which side – AZ or Glenmark – was more likely to be inadequately compensated by damages, given that the period until the FOO hearing is rather short, the Court of Appeal held that it would be prudent to preserve the status quo and therefore injuncted Glenmark from entering the market.

Clearing the Path

The Court of Appeal criticised Glenmark's strategy of launching during the proceedings without awaiting judgment and remarked that Glenmark had not cleared the path and instead were "*jumping the gun*". Arnold LJ commented on the procedural inefficiencies caused by such tactics, which not only caused the parties to expend very considerable costs on the question of what is to happen during the period of about one to three months, but also, in his view, was not the best use of scarce court resources.

Key Takeaways

This judgment provides timely clarification on how the English courts will approach interim injunctions in the pharmaceutical sector. Like all interim injunction situations, the dapag saga depended on its facts. However some general principles can be taken away as follows:

- Preservation of the status quo remains a powerful factor, especially where market dynamics may shift rapidly and irreversibly before a final decision can be enforced.
- The first-mover advantage, while economically significant, does not automatically tip the balance of convenience if the generic has not cleared the path.
- The Court reiterated the importance of litigation conduct, with Glenmark's strategy of attempting to launch before the judgment on the merits had been handed down being viewed critically.

For patentees, the decision will be welcomed as reinforcement of their ability to seek interim relief even in the narrow window between trial and judgment. For generics, the message is clear: clear the way and don't jump the gun. The litigation strategy must be aligned not only with regulatory readiness but also with procedural propriety. The 'race to launch' should not come at the expense of legal prudence.

Also, by adjudicating AZ's application for an interim injunction and the subsequent appeal in a relatively short period, the High Court and the Court of Appeal have demonstrated remarkable speed and flexibility.

Postscript

At 2 pm on Monday 28 April, the High Court handed down its decision on the merits following the trial finding AZ's patent invalid on the basis that the patent did not disclose enough to make it plausible that dapag will have an in vivo effect on blood/plasma glucose (such that it could be used as an experimental tool) or will treat diabetes.

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Monday, April 28th, 2025 at 3:15 pm and is filed under Injunction, Litigation, Pharmaceutical patent, United Kingdom, Validity
You can follow any responses to this entry through the Comments (RSS) feed. You can leave a response, or trackback from your own site.