EIP

Another day, another interim injunction granted by the UK High Court: Boehringer Ingelheim find success against Dr Reddy

Michael Tappin KC (sitting as a Deputy Judge of the High Court) has granted the interim injunction sought by Boehringer Ingelheim Internation GmbH ("BI DE") against Dr Reddy's (UK) Limited ("DR"). The injunction will remain in place until the form of order hearing following judgment after the revocation trial brought by DR, which is scheduled for October 2026. This decision reflects the Court's continuing approach that maintaining the status quo is currently best achieved by granting injunctions.

Background

BI DE is the holder of the UK marketing authorisations for Jardiance. A medication for the treatment of type 2 diabetes, which is based on empagliflozin (a SGLT2 inhibitor). BI DE is the proprietor of a number of patents relating to empagliflozin.

DR began corresponding with BI DE in March 2024 regarding the invalidity of two patents (and the related SPC) covering empagliflozin. In October 2024, DR issued a revocation action against BI DE. However, the claim form and accompanying pleadings were not served until February 2025. DR obtained a marketing authorisation for empagliflozin following the expiry of marketing exclusivity in May 2025. At the July 2025 CMC, a trial was fixed for October 2026 with DR indicating that its launch plans were still under discussion.

On 18 September 2025, DR gave 28 days' notice of its intention to commence sales of its empagliflozin products in the UK. This was the trigger point for BI DE to apply for an interim injunction against DR. The proposed interim injunction was expected to last at least 14-15 months, which, in turn, would have been the amount of time that DR could be on the market ahead of trial, if the injunction had not been granted.

American Cyanamid Guidelines

As is usual with injunction applications of this kind, the facts of each case are very specific and taken into consideration when the Court looks to apply the guidelines set out in American Cyanamid v Ethicon when assessing whether an injunction should be granted or not.

1. Is there a serious issue to be tried?

It was common ground that there was a serious question to be tried on the validity and infringement issues at play.

2. Would damages be an adequate remedy for BI?

Based on the evidence (of which there was a lot), the Deputy Judge surmised that damages were not an adequate remedy for BI. His main reasoning centred on the real risk that additional companies may launch empagliflozin before trial judgment leading to an uncertainty on how the market would change. BI DE's expert economist stated that such launches would lead to a price spiral forcing BI to discount its prices to maintain market share. Furthermore, if the drug were recategorized in the Drug Tariff, there was a significant risk that BI would be unable to restore prices to current levels.

3. Would damages be an adequate remedy for DR?

Again, based on the evidence, the Deputy Judge concluded that damages under the cross-undertaking provided by BI DE would not be an adequate remedy for DR if it turned out that the injunction sought should not have been granted. The Deputy Judge felt that given the varying scope of the patents, there was the uncertainty that if one was found valid (e.g. the method of use one) and the other invalid (e.g. the crystalline form one), then there would be an issue that an injunction preventing DR from selling any generic empagliflozin was too broad given the scope of protection in the method of use patent. Additionally, if any other generics were to enter the market, then DR would have lost first mover advantage in the generic empagliflozin

market and thus lost an opportunity which would be difficult to assess in terms of value.

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4. If damages are not an adequate remedy for either BI or DR, where does the balance of convenience lie?

The Deputy Judge found that given the facts specific to the case, the evidence and particularly DR's failure to take effective steps to clear the way, that the status quo favoured the grant of BI's interim injunction.

The evidence before the Deputy Judge included evidence from commercial managers of the parties, pharmacists, clinicians and expert evidence from economists and ran to approximately 300 pages (excluding exhibits). But yet, despite the length, there was very little evidence to explain DR's conduct in the litigation. DR explained that its decision to launch its empagliflozin product so quickly was tied to the dapagliflozin litigation (another SGLT2 inhibitor), following the invalidation of AstraZeneca's compound patent for dapaglifloxin and then the Supreme Court's refusal of AstraZeneca's permission to appeal on 31 July 2025. The Deputy Judge noted that DR's failure to prepare for the dapagliflozin market becoming generic and adapting its litigation strategy accordingly was a contributing factor to his decision, citing Lord Justice Arnold's reasoning in his Court of Appeal judgment in Astrazeneca v Glenmark [2025] EWCA Civ 480.

As an aside, the Deputy Judge granted permission to the Secretary of State for Health and Social Care to intervene, serve evidence and make submissions. The statements were served by the head of the Medicines Framework and Reimbursement team from within the Medicines Directorate in the Department of Health and Social Care (the "DHSC"). The Deputy Judge made it clear that he found the evidence an extremely valuable account of the pricing and reimbursement system operated by the DHSC and that any court hearing an application for an interim injunction in a pharmaceutical patent case would benefit greatly from reading it.

Take away points

Two points to note from this judgment is that, first, the current case law makes it clear that a generic will need to take effective steps to clear the way, and, where necessary, anticipate any changes to their relevant market if that may suddenly become a factor as to changing their launch plans.

Second, the volume of evidence before the court may soon become standard practice, particularly with the increasing use of expert economic evidence. This may be another

factor to keep in mind when developing a strategy for this type of application.

p4 The judgment is available here.