

EIP

Court of Appeal Maintain Status Quo in Neurim v Mylan By Refusing Injunctive Relief

In the latest flurry of judgments to arise from the Neurim v Mylan (now trading as Viatrix) battle over Neurim's insomnia patent and Mylan's presence on the market with its generic version, we report here on the developments regarding the "Provisional Judgment," which we previously reported on here.^[1] On 29 March 2022, in its judgment led by Lord Justice Arnold, the Court of Appeal (i) granted Mylan permission to appeal against an order made by Mr Justice Marcus Smith on 7 March 2022; (ii) expedited the hearing of the appeal to be fixed in the weeks commencing 16 or 23 May 2022; and (iii) granted Mylan a stay of the injunction contained in Marcus Smith J's order pending the determination of the appeal.

Background

As we reported previously, Marcus Smith J provisionally determined on the papers the validity of the divisional patent EP 3 103 443 ("the Divisional") of EP 1 441 702 (the "Parent" – the initial patent in which Neurim had brought an earlier claim against Mylan for infringement (the "First Claim")). In his judgment dated 10 February 2022, the Judge found, on the papers, that the Divisional was valid and infringed. He also refused permission to appeal. The Judge went on to invite the parties to appear before him if they wished to persuade him to take a different course.

Mylan took up the Judge's invitation leading to an additional judgment from Marcus Smith J dated 8 March 2022^[2] (the "March 2022 Judgment"). Mylan looked to rely on the

“lay-patient argument” which had been successful before the Board of Appeal at EPO. However, those submissions were rejected and the Provisional Judgment was affirmed with permission to appeal rejected. The Judge also went on to grant Neurim an injunction and refused Mylan’s application for a stay of the injunction pending the determination of an application to the Court of Appeal for permission to appeal.

Permission to Appeal

In the March 2022 Judgment, the Judge explained that the lay-patient argument failed due to the findings of fact he had made in his December 2020 judgment in the First Claim relating to the Parent. However, the Court of Appeal considered that Mylan’s grounds of appeal concerning the lay-patient argument had a real, as opposed to fanciful, prospect of success, and thus granted Mylan permission.

Expedition of the Appeal

Mylan also sought expedition of the appeal. The Court of Appeal noted that given the Divisional was due to expire 12 August 2022, expedition was clearly appropriate and permitted expedition.

Stay pending appeal

As the Court of Appeal had already granted permission to appeal and expedited the appeal, the issue was whether a stay of the injunction should be granted for a period of between two and three months.

In deciding Mylan’s application, the Court of Appeal considered the damage that Neurim and Mylan would suffer and whether it was quantifiable. In relation to Neurim, in the First Claim, the Court of Appeal dismissed Neurim’s appeal against the refusal of an interim injunction. Building on that decision, the Court of Appeal found that there had been no relevant change in circumstance given that Mylan had been on the market for nearly 18 months. One argument which Neurim tried to raise was that the grant of a stay would be a green light to other generic companies to enter the market, which would cause a downward price spiral and hence Neurim would suffer unquantifiable damage. Unfortunately for Neurim, this submission was not supported by the evidence before the Court of Appeal.

In relation to Mylan, the Court of Appeal felt their loss of their current first mover

advantage at the point of market entry by other generic suppliers upon expiry of the Divisional was their most compelling argument. And that the damage caused would be difficult to quantify.

Furthermore, it was concluded that even if the view was that both sides were equally likely to suffer damage that could not be adequately compensated, it would be prudent to preserve the status quo pending appeal. Lord Justice Birss and Lord Justice Newey, both in agreement with Lord Justice Arnold's judgment, also emphasised the importance of maintaining the status quo adding respectively "the uncertainties do not justify disturbing that state of affairs" and "preservation of the status quo favours the grant of a stay."

Take Away Points

This judgment exhibits one way in which the Court of Appeal will weigh up the damage that either party may suffer when considering an injunction application and that where the uncertainties are significant it will try to maintain the current circumstance.

Additionally, as an aside, it should be remembered that a submission made before the Court of Appeal that a party wishes to rely on needs to be based on evidence for the Court of Appeal to consider it seriously.

The judgment is available [here](#).

[1] Judgment available [here](#).

[2] Judgment available [here](#).