EIP

High Court refuses Neurim and Flynn interim injunction against Teva in third instalment of melatonin product dispute

In the third chapter of Neurim and Flynn's dispute with generic companies, Mr Justice Mellor refused the Claimants' application for an interim injunction against generic giant, Teva, on the basis that Teva would not be adequately compensated by damages if their melatonin product was taken off the market.

Background of the dispute

The First Claimant (Neurim) is the registered proprietor of the EP443 patent; a divisional patent for a prolonged release formulation for the use of melatonin in the manufacture of a medicament for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterised by non-restorative sleep. The Second Claimant (Flynn) is the exclusive licensee, which markets and sells the melatonin product Circadin in the UK. EP443 will expire shortly, on 12 August 2022. This action against Teva was commenced in November 2021 and follows two actions by the Claimants against Mylan over the EP702 parent patent, since revoked by the EPO, and EP443. Mylan's melatonin product launched in the UK in September 2020 and Teva's product launched in October 2021.

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Application ofAmerican Cyanamid test

In his determination the Judge applied the American Cyanamid test, comprising a five-stage analysis:

1.Is there a serious issue to be tried?

2.Are damages an adequate remedy for the Claimants?

3.If not, are damages under a cross-undertaking, an adequate remedy for Teva?

4.If damages are not adequate for either, where does the balance of the risk of injustice lie?

5.Where other factors appear to be evenly balanced, the status quo should be preserved.

In particular the Judge considered whether the refusal of an interim injunction against Teva would lead to a downward price spiral, which usually occurs where the presence of two or more generics on the market drives down the price of products. A summary of his assessment is below.

Stage 1: The general principle is that the court should not attempt to resolve critical disputed questions of fact or difficult points of law. On this occasion, however, both parties agreed there was a serious issue to be tried, for both infringement and validity. In particular, the Judge noted that Teva raised different validity attacks to those ruled upon by Marcus Smith J in the Mylan actions.

Stage 2: As to whether damages would be an adequate remedy for the Claimants, the key principle is that the more uncertain the quantification, the more likely damages would be deemed inadequate. The Judge approached this question looking at two periods of time, damage that would be suffered pre-patent expiry and post-patent expiry.

The Judge held that the loss suffered by the Claimants pre-patent expiry would be capable of being ascertained with a reasonably high degree of accuracy. He also considered that this would not be affected by any downward price spiral, which would also be reasonably quantifiable. He noted the unusual circumstances of the case that Mylan currently awaited an expedited hearing of its Appeal and, as such, would not likely want to engage in or precipitate a downward price spiral, especially having benefited from its first mover advantage, giving it a duopoly with the Claimants.

On the other hand, the Claimants' potential losses post-expiry were "subject to a much greater degree of uncertainty". The Claimants would likely contend that, had generic companies not entered the market pre-patent expiry, they would have sustained higher prices for longer, whereas Mylan and Teva would likely argue that the price would have rapidly reduced. Due to the lack of certainty, the Judge found that damages would not be an adequate remedy for the Claimants in the post-expiry period.

Stage 3: Teva argued that damages under a cross-undertaking would not be an adequate remedy, asserting that sales of its melatonin product had fluctuated along with its share of the generic market, so that it would not be possible to predict the volume and prices of the sales which it would otherwise have made during the remaining life of the patent. Teva also argued that an injunction would deprive it of the foothold it had already established in the generic market, ahead of additional generics entering, making it harder for Teva to regain its market share after patent expiry. The Judge agreed and concluded that damages would not be an adequate remedy for Teva. Further, the Judge found that there would be "much greater uncertainties applying to Teva's position than that of the Claimants" in the post-expiry period.

Stage 4: The Judge now had to determine where the balance of convenience lay, the basic principle of which is that the Court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other. Although the Claimants argued that Teva should have cleared the way to market instead of launching at risk, the judge found that EP443 was granted so close to expiry as to effectively exclude the possibility of Teva invalidating it before expiry and clearing the way. As such the Judge concluded that "since damages would be considerably less adequate for Teva, I consider the balance comes down in Teva's favour".

Stage 5: Finally, following Frank Industries v Nike, assessing the status quo is to be at the point immediately before the issue of proceedings, or the application notice if substantially later. In considering this, the Judge noted the Claimant's delay in bringing their application. Teva had informed the Claimants as early as October 2021 that they had launched that same month. Despite this, the Claimants did not consider that Teva was on the market "in any material way as at 11 March 2022" a few days before making their application. The Judge considered that Teva had made their intentions clear to the Claimants who had sufficient evidence of a threat to launch to justify seeking to restrain Teva from entering the market. Instead the Claimants made it clear that they did not intend to seek injunctive relief against Teva until they had secured an injunction against Mylan. In a volte-face, however, despite not having an injunction yet against Mylan, the Claimants made their application against Teva. The Judge found that "in not seeking any interim relief against Teva before or just after [Teva's] launch, thereafter the Claimants were running the risk that Teva would make sales and build up a presence on the UK

market. This is exactly what has happened. Thus I find that the Claimants delayed significantly in seeking interim relief against Teva". Although the delay was not said to be such that it disentitled the Claimants to relief, the status quo was assessed as being mid-March 2022, the date of the Claimants' application, by which time Teva had been on the market for 4 months and so the Judge found that the status quo was to allow Teva to remain on the market.

Commentary

The Claimants' delay in seeking an interim injunction in this action was a factor that went against them, reinforcing the need for such applications to be made as quickly as possible. Further, the Judge added as a postscript note that "difficulties have been caused by the Court not having both Mylan and Teva before it at the same time", suggesting that future consideration should be given to achieving that. Accordingly, where similar applications are before the Court against multiple defendants in separate actions, it may be beneficial for case management steps to be taken to ensure the Court has all arguments before it.

Written by Lydia Birch.