EIP

Neurim presses on with UK action over insomnia patent despite parallel EPO proceedings

Neurim has been allowed to continue its case in the UK, in which it is seeking an injunction against Defendant Mylan for selling its generic melatonin product, which Neurim says infringes its divisional patent for a method for treating primary insomnia. Neurim managed to successfully fend off an attempt by the generics pharma giant to stay the case. Ian Karet, sitting as Deputy Judge, ruled that the balance of justice in all the relevant circumstances lay on the side of allowing Neurim to continue with the UK proceedings. This, the judge said, would provide the parties with more commercial certainty and open the possibility for Neurim to secure an injunction before the divisional patent's expiry in August 2022.

Background of the case

This is the second action between the parties concerning Neurim's patent family for a method of treating primary insomnia. Mylan had launched their 2mg prolonged release melatonin product for improving the restorative quality of sleep, at risk in the UK in September 2020. Despite refusing Neurim's application for a preliminary injunction that summer, in December Marcus Smith J found Neurim's parent patent valid and infringed. A twist in the tale, however, arose when, only weeks after the UK court's finding, the EPO Board of Appeal revoked Neurim's parent patent, finding it invalid for insufficiency. Neurim responded by reviving a divisional patent application that had previously been deemed withdrawn. Once granted this became the subject of the current dispute, with EPO proceedings once again running in parallel.

In seeking to rely on the finding of the initial UK judgment for the parent patent, Neurim argued before Mellor J, in late July, that the parties had already litigated all the issues of infringement and validity that would apply to the divisional patent, and that Mylan should be estopped from asserting otherwise. Neurim sought expedition of the trial addressing the estoppel arguments by way of a preliminary issue. Mellor J agreed and ordered the expedited trial to be heard in December 2021, with the aim of judgment being handed down before patent expiry in August 2022, thereby giving Neurim the opportunity to secure injunctive relief before the patent ran out.

In the hearing that followed, the judge addressed Mylan's application to stay the UK proceedings, pending final determination of the validity of the divisional patent in the EPO opposition proceedings. An intervening event between the two hearings, which was an additional factor that the judge needed to consider, was third-party generic company Teva coming onto the UK market with a similar product. A satellite contractual dispute as to whether Teva is allowed to enter the UK market under the terms of a settlement agreement with Neurim is also on foot before the Israeli court.

Application of theIPCom v HTC Court of Appeal criteria

To assess whether the UK court should award a stay of UK proceedings, pending an EPO opposition, the judge turned to the approach taken in IPCom v HTC [2013] EWCA Civ 1496, assessing the 13 factors considered in that case by the Court of Appeal. Such factors included noting that the UK Court should exercise its discretion to achieve a balance of justice between the parties, having regard to all the relevant circumstances in the case, and that the possibility of concurrent proceedings (at the EPO and national court level) contesting the validity of a patent is inherent in the system established by the EPC. As the party resisting the stay, it was for Neurim to justify why a stay should not be granted, which would otherwise be the default position.

In particular, the seventh factor involved considering the extent to which refusal of a stay would irrevocably deprive Mylan of any part of the benefit which the concurrent jurisdiction of the EPO and the national court was intended to confer. During the course of the hearing itself, Neurim offered a last-minute undertaking to repay any damages or profits which might be ordered in respect of infringement of the patent if it was finally revoked. Notwithstanding the delay in providing this undertaking, the judge was satisfied that it dealt with a significant element of Mylan's argument that it would suffer

irrevocable loss if a stay was not ordered. The judge also rejected Mylan's proposal that the undertaking should make good all of the defendant's losses in the event that any final injunction was later discharged following revocation of the patent by the EPO. In line with Adaptive Spectrum v BT [2014] EWCA Civ 1513, the judge held that there was no reason for a patentee to pay for the harm during the period when an injunction was rightly granted.

Consideration of the eighth IPCom factor was also significant, noting that a stay may be refused where "some" commercial certainty would be achieved at a considerably earlier date in the UK proceedings than in the EPO. In other words, "some certainty sooner rather than later, and somewhere, rather than nowhere, is, in general preferable". Mylan argued that the trial, in only dealing with discrete and novel estoppel issues, rather than the infringement and validity of the patent, would not provide any such certainty – the only certainty being that any outcome would be appealed. Although this was a reason to find that the proceedings would not benefit the public interest (under factor 11), the judge did consider that a stay would deprive Neurim of the chance to obtain a final injunction before the patent expired. As such, allowing the UK claim to proceed did in fact "offer a chance of increased certainty at an earlier stage", taking into account the possibility that Neurim may also separately be able to secure an injunction against Teva in the early part of 2022. The judge also found that any risk of wasted costs in refusing the stay (under factor 12) was "relatively small" in the "overall context of the dispute". Finally, the judge was keen to observe factor 13, that a hearing to determine whether a stay should be granted should not manifest as a mini-trial and accordingly approached matters with a "relatively high level of generality".

Commentary

The case features a particular set of facts which has at its core the interplay between national court and EPO Opposition proceedings running in parallel. This is an interesting case applying the IPCom approach when parties, in that situation, may seek to hibernate UK proceedings in favour of the concurrent EPO proceedings.

Ultimately, the UK court was mindful of the race to patent expiry and the need to preserve the patentee's chances of obtaining an injunction during the life of the patent – a particular concern in the life science industry where an underlying product stands to be extremely valuable. With large amounts of money and market positioning at stake, it is not surprising that pharmaceutical companies will almost always want to run races in both the EPO and UK courts where possible, meaning that life alongside concurrent opposition proceedings is likely to be here to stay and ripe for considering in your

strategic arsenal.

p4 [2021] EWHC 2897 (Pat)

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