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A wake-up call for patentees?

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The English Patents Court has often been regarded as a relatively favourable jurisdiction for patentees seeking interim relief in the life sciences arena. This is for various reasons, including the fact that the English Court follows the approach adopted by the House of Lords in the **American Cyanamid** case, in which an assessment of the merits of the case is a low first hurdle to be crossed. Also, the Court has generally been willing to accept that in the pharmaceutical field premature generic entry may lead to unquantifiable and irreparable harm to the patent holder which outweighs that to the potential infringer.

Nevertheless, in a judgment dated 3 June 2020, Marcus Smith J refused to grant an interim injunction to Neurim against the leading generics company Mylan. It remains to be seen if this decision will mark the start of a new direction from the English Patents Court or whether, like certain earlier cases such as **Cephalon v Orchid** [2010], this decision will come to be regarded as one where based on all the evidence before the Court, the Judge felt unable to impose an interim injunction to maintain the status quo until trial. In any event, the decision contains some interesting, and perhaps in some respects unconventional, observations.

The basic facts of the case are relatively straight forward. Neurim – of course the same Neurim as the patentee in the famous second medical use SPC case – is the holder of a patent to prolonged release formulation of melatonin to improve the restorative quality of sleep in patients suffering from primary insomnia. Neurim markets the pharmaceutical formulation of the patent under the brand name Circardin® and had developed a paediatric version of the medicine called Slenyto®. The patent is due to expire in August 2022 and was held invalid by the Opposition Division of the EPO in November 2019. An appeal to the TBA is pending but may well not be heard until after patent expiry. The patent is licensed to Flynn Pharmaceuticals. Both Neurim and Flynn were represented by the same advocate and in this commentary when we refer to “Neurim” we mean Neurim and Flynn unless the context otherwise demands.

In the UK, an expedited trial is scheduled to be heard from 26 October 2020. Mylan wished to sell its generic version of Circadin® as soon as possible and, although it agreed to refrain from selling its product until the interim injunction application was determined, Mylan was not prepared to wait until the outcome of the trial on the merits. The hearing was conducted remotely on 20 May 2020.

Marcus Smith J’s analysis began with a condensed summary of **American Cyanamid**, noting that each of the stages is a gate to be passed through and that should the applicant fail at any stage, an injunction should be refused. This appeared to be a settled approach and is in line with the

approach taken by Henry Carr J in **Evalve v Edwards Lifesciences** [2019]. The Judge then turned to each of the **American Cyanamid** stages as applied to the facts of the case:

Stage One – Serious Issue to be Tried

Although noting the temptation to analyse the merits of the case at an early stage and also the attempt by Laddie J to move in this direction in **Series 5 Software** [1996], Marcus Smith J adhered to the approach of Lord Diplock in **American Cyanamid** that the merits hurdle is a low one. He also noted that Mylan had sensibly accepted that there was a serious issue to be tried. Nevertheless, the Judge went on to confirm the established law in the UK that EPO rulings are not binding on the English Court (following the **Buehler** decision from the Court of Appeal, and unless the patent is finally revoked by the EPO) and that the refusal of the Swedish court to grant an interim injunction was irrelevant to his analysis.

Interestingly, the Judge also stated that there are means other than an application for summary judgment for showing that there is no serious issue to be tried. It is unclear whether the Judge is referring here to procedural means, or is comparing the test for summary judgment (whether there is no real prospect of success) with the serious issue to be tried test. If the latter, then this may be contrasted with the approach taken by Pumfrey J in **Abbott v Ranbaxy** [2004] where he stated that had he not granted summary judgment on validity grounds, he would have granted a preliminary injunction.

Stage Two – Are Damages an Adequate Remedy to Neurim?

For this part of the analysis, the Judge split his assessment into two periods, Period 1 – the time up to the handing down of the first instance decision on the merits (assessed to be around the end of November 2020) and Period 2, the period from the end of Period 1 until patent expiry in summer 2022.

It was Neurim's position that if Mylan were allowed to enter the market at the present time, it would sustain irreparable and unquantifiable harm in both periods, even if it were successful at trial and Mylan were ordered to withdraw after the decision on the merits was handed down. As would be expected, Mylan contended that even if the harm to Neurim extended beyond Period 1, damages would be an adequate remedy. However, Mylan also ran two other points. The first related to the standing of Flynn as an exclusive licensee. In short, Mylan argued that the licence between Neurim and Flynn was not such to render the latter an exclusive licensee with a right to instigate proceedings pursuant to Section 67 of the UK Patents Act. The Judge found the point interesting, but was not prepared to engage with it fully on an interim injunction application. He noted that even if Mylan were correct, Neurim would suffer loss through Flynn's lost sales. This is in itself an interesting point which may perhaps be contrasted with the observations of Floyd LJ in **FujiFilm v Abbvie** [2017] at paragraphs 113-116 that the absence of an exclusive licence to an entity which exploited the invention in the UK might place difficulties in the way of obtaining an interim injunction.

The other point run by Mylan was that not all of the damages anticipated by Neurim could actually be attributed to patent infringement. The arguments from both sides were original and some might even say courageous. The relevant claims of the Patent were to prolonged release formulations of melatonin at certain doses in unit dose form to improve the restorative quality of sleep in a patient suffering from primary insomnia. The label for Circadin was narrower than the claims of the

patent, being restricted to short-term treatment of primary insomnia by poor quality of sleep in patients aged 55 or over. However, there was evidence that Circadin was also used extensively off-label for conditions such as childhood autism. In fact, Mylan contended that sales of Circadin for the patented use accounted for only about 2% of all prescriptions. Nevertheless, Neurim argued that in addition to damages for patented (on label and off label) uses it was in principle able to recover damages for non-patented (and also therefore off label) uses. This was on the basis that but for the launch of a product within the scope of the patent, Mylan would not have been able to access the off-label market. Marcus Smith J categorised the issue as *"a very interesting point, not without its difficulties on either side of the argument"* and one which was best left over to the trial. The authors also consider that further interesting questions arise about whether Mylan could ever take any steps to discourage the patented use, given that to do so would effectively be to promote unauthorised uses (this is not a case where carve-outs are available as there is only one indication). Also, the extent to which Mylan can accurately monitor the uses to which its generic product is put.

Having dealt with these two preliminary points, the Judge looked at the adequacy of damages to Neurim. He accepted that if the interim injunction were not granted, there would be damage in both Period 1 and Period 2, including that it would not be possible for Neurim to restore price and market share. The Judge quoted from the leading practitioner textbook Terrell on Patents which comments that in generic pharmaceutical cases, interim injunctions are commonly granted and that: *"although each case turns on its own facts, the court has shown itself to be ready to accept an argument that the launch of a generic pharmaceutical product will cause substantial and unquantifiable loss to the patentee because it will permanently depress the patentee's price."* However, he refused to accept that the present case was within the norm or analogous to one of the exceptions, preferring instead to consider the facts before him on their own. In the circumstances, the Judge considered that damages would provide an adequate remedy to Neurim. He was of the view that it would be possible to restore Neurim to the position it would have been in for the unlawful act even in Period 2, and notwithstanding his acceptance that it would not be possible to restore the market to the same position as it was before Mylan's entry.

Finally, the Judge considered what he described as *"two special cases"*, the first being the position of other generic entrants and the second, a list of compelling reasons from Neurim why damages would not be an adequate remedy. As to the first point, Neurim argued that Mylan's entry as first mover would open the door to other generic entrants. Overall, the Judge considered that in Period 1, losses caused by additional entrants might cause difficulties to the calculation of damages but in Period 2, assuming any would be entrants were injuncted, any damage to Neurim would be entirely attributable to Mylan and that overall, this was not enough to persuade him that damages were not an adequate remedy. In relation to the second point, which in large part went to the wider impact of a decision not to grant an interim injunction on Neurim, the Judge considered that Neurim had sufficient resources to ride out the storm and that such consequential damages were going to occur anyway upon expiry of the patent in 2022. The authors note that whilst this analysis may in itself be correct for a single medicine viewed in isolation, it could have significant implications for patentees who at any point in time may in fact be trying to defend their position in relation to multiple medicines.

Because the **American Cyanamid** is a staged approach, and the special cases did not affect the analysis, the finding that Neurim could be adequately compensated in damages was fatal to the application for an injunction. However, out of deference to the arguments made, the Judge went on to consider the further grounds. In relation to whether damages would be an adequate remedy for

Mylan, the Judge considered that it would be more difficult to calculate the losses to them than Neurim, especially the damage caused by the loss of first-mover advantage.

In relation to the balance of convenience, the Judge considered in particular the failure of Mylan to attempt to clear the way by seeking to revoke the patent in the English Court. Somewhat oddly, at least in the authors' opinion and contrary to the commentary from Henry Carr J at 47 – 60 of **Evalve v Edwards Lifesciences** [2019], the Judge opined that clearing the way is a *"relevant factor to take into account when considering whether the party opposing the grant of an interim injunction would be adequately compensated for in damages awarded pursuant to the undertaking in damages."* However since the Judge had already concluded that damages would be an adequate remedy, he considered that this point made no difference to his decision.

Finally, the judge made reference to a communication from the Secretary of Health, writing on behalf of the NHS, to ask to be joined to any cross-undertaking given by the Court if the interim injunction were granted. Marcus Smith J considered that it was appropriate to take into account the interests of the NHS not only when framing the cross-undertaking but *"also when considering whether the injunction ought to be granted **at all**."* (Emphasis in the original). He noted that had he been minded to grant the interim injunction, he would have wanted to have heard further submissions on the appropriateness of the injunction.

There is much food for thought in this decision. In particular:

• If the Judge intended to suggest that there is a difference in the threshold for summary judgment (no real prospect of success) and *"serious issue to be tried"*, what are these differences?
• Is failure to clear the way to be considered as part of the assessment of adequacy of damages?
• Is the impact on the NHS to be taken into consideration when deciding whether to grant the injunction at all and not just when framing the cross-undertaking?
• To what extent may damages be recoverable for sales of medicines outside the scope of the patent (as well as outside the scope of the authorisation)?

It remains to be seen if this case will mark the start of trend away from the comparative willingness of the English Patents Court to grant interim injunctions in the pharma v generic arena. The authors suspect that this will not be the case and that the circumstances before the Court in this case were somewhat unusual. Whilst it was not said to be relevant, the authors wonder whether the finding of invalidity by the opposition division, combined with the fact that there is to be an expedited trial in only a few months time (after a failure to clear the way) and the fact that any injunction would be difficult to formulate and could result in restricting significant non-patented (although also non-authorised) uses, gave the Judge comfort in coming to his decision. Time alone will tell whether patentees need to wake up to a new approach, or whether this was just a bad dream.

Postscript: On 8 June 2020, the Judge handed down his judgment on costs. He held that costs should not be reserved to the trial judge, and instead determined them himself on an issues based approach. He concluded that, whilst Mylan was the overall winner, it should recover no more than 65% of its costs once deductions had been made, for example for the fact that it lost on the issue of whether there was a *"serious issue to be tried"*.

A copy of the preliminary injunction judgment can be found here and the costs judgment can be found here.

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