Kluwer Patent Blog

A snooze reminder?

Rachel Mumby (Bristows) · Thursday, June 25th, 2020

The tendency of English people to be understated in their use of language (other than on Twitter…) is often joked about with continental friends and colleagues. For example, when an English person expresses a slight disagreement, their continental counterpart might have felt more able to be blunt and say that something is just plain wrong. Similarly, English Judgments are generally written in a very respectful, and understated manner, using stronger language on occasion for effect. This careful use of language is definitely on display in the recent judgment of the Court of Appeal in Neurim v Mylan[1] where the Court of Appeal has dismissed Neurim's appeal against the rejection of its application for a preliminary injunction, but at the same time politely picked apart significant sections of the reasoning of Marcus Smith J at first instance.

As many readers will be aware, Neurim had applied for a preliminary injunction to stop Mylan launching its generic version of Neurim's prolonged release melatonin medicine (which is used to improve the restorative quality of sleep in patients suffering from insomnia) prior to a trial on the merits. Marcus Smith J had held on 3 June 2020 (see here) that damages would be an adequate remedy for Neurim and had therefore rejected the application. As discussed here this judgment raised quite a few eyebrows amongst the English patent community, not necessarily because of the outcome, but more because of the way the American Cyanamid test had been applied and the potential implications of some of the analysis.

Floyd LJ's judgment (with which Arnold LJ and Males LJ agreed) starts, as would be expected, with a summary of the background and timetable. Even at this early stage, the use of occasional strong words (by English standards) provides a hint as to the ultimate outcome. It is noted that "very significantly" an expedited trial of the substantive proceedings had been ordered and fixed for only four months' time. This wording was apt. As discussed further below, Floyd LJ ultimately agreed that damages would be an adequate remedy, based mainly on his conclusion that there would be little impact on Neurim's market in this short period of time.

It was accepted on appeal that there was a serious issue to be tried, so the Court of Appeal next considered whether damages were an adequate remedy for Neurim. Floyd LJ agreed with Marcus Smith J that "adequate" should not be equated with "perfect". He also acknowledged that the boundary between what is adequate and what is

inadequate is not precise. However, he rejected the suggestion from Neurim that the Court should normally accept that damages are not an adequate remedy for either party and instead just move on to consider the balance of convenience.

A key part of the basis for arguing that damages will not be an adequate remedy in any pharmaceutical case is often the price spiral that will occur if multiple generics launch. Floyd LJ noted that whether this will in fact occur is "intensely" fact specific, and on the facts of this case, the expedited trial brings the issue of a price spiral into "sharp focus" (more strong words…). Given that the judge did not attempt to decide this point, Floyd LJ did so himself. On the number of generics, he held that the evidence did not establish that it was likely that a second generic would launch before trial, let alone a third or fourth. Another factor which influences the price spiral is the irreparable changes to the Drug Tariff. However, there was evidence that there could be a significant delay to the list price of Circadin (at least in the context of the four months to trial). He also noted that in fact, 53% of prescriptions are written for Circadin (i.e. the brand name, rather than INN), and Mylan's product could not be dispensed to a patient with such a prescription. None of this pointed towards a price spiral.

Floyd LJ also dismissed Neurim's arguments about consequential losses – he held that it was not realistic to suppose that the lost revenues would be on such a scale that would necessitate the steps referred to by Neurim such as loss of investment in Circadin or other new medicines. He effectively appeared to suggest that if Neurim backed itself to win at trial, it should continue to support these endeavours, on the basis that if it is worthwhile to invest for the remaining two years' of the patent's life, it is still worth it if the period of exclusivity is reduced by 4 months. Some patentees will likely feel aggrieved at the suggestion that they should be forced to allocate resources in this way, but again the short time period is likely to be influential to the analysis.
When coming to a conclusion on whether damages would be an adequate remedy, Floyd LJ acknowledged (as Marcus Smith J had done) that in many pharmaceutical patent cases the courts have treated the patentee's losses as being unquantifiable. However, in this case, having rejected the idea of a price spiral or other consequential losses, he viewed the court's task as relatively straightforward (he even later suggested that the judge may have over-estimated the complications of the assessment of damages). This was on the basis that Neurim had provided detailed forecasts of their expected sales revenues, and the fact that the Court would have both side's sales figures and prices for the period to trial, and could make an extrapolation for the period after that, when the monopoly is restored.

Whilst Floyd LJ describes this analysis as straightforward, one of the points identified by Marcus Smith J as being tricky had been the impact of there being three different markets for Circadin (i.e. the fact that the marketing authorisation was narrower than the patent claims, and also that there were further off-label uses which fell outside the scope of the patent). There was no mention of this in Floyd LJ's analysis (although he does note the different markets in the background section). Given that as a judge, Floyd LJ does not tend to leave any point on the "too difficult" pile, this seems surprising, especially in light of indications from both sides that analysing the market for these three categories of uses was not simple. Presumably this is because the issue

goes not to adequacy of damages but to quantum.

In any event, having come to the conclusion that damages would be an adequate remedy for Neurim, there was no need for Floyd LJ to consider the subsequent stages in the American Cyanamid test.

A large concern for many patent lawyers following the first instance judgment was the approach that had been taken to the evidence. Marcus Smith J had essentially dismissed much of the evidence as partisan and of no weight given that the witnesses had not been tested under cross-examination. This had left many wondering how either party could ever reasonably put forward acceptable evidence in the time available to prepare for a preliminary injunction application. Floyd LJ implicitly disagrees with this approach when he notes that "the court must do the best it can on the available written evidence." He accepts that it may not be possible to form a view on certain issues, but the Court "should not abandon the task at the outset". Unfortunately for Neurim, Floyd LJ also makes it clear that the evidence should still be examined with a critical eye. In this regard, he notes "one difficulty" for Neurim is the fact that its principal evidence had been prepared before the expedited trial had been fixed. This meant that the evidence from Neurim was all about the impact of losing 1-2 years of exclusivity before trial, not just four months. He accepted that "such a period would indeed deprive Neurim and Flynn of a large part of the remaining monopoly under the patent… but that it cannot be assumed that a short period of generic competition followed by a final injunction would have the same effect." This analysis of the longer time frame will have provided some comfort to patentees, but at the same time highlights the significance of the expedited trial.

All in all, the judgment appears to be an attempt to settle nerves for patentees by dealing in a very English way with some unconventional analysis from the judge, by highlighting the "extremely unusual facts" and reiterating that he had not "decided any principle of general application. On this initial analysis, the case doesn't seem to indicate future nightmares for patentees, or even necessarily a wake-up call, but maybe a snooze reminder about the importance of the facts of each specific case and the potentially highly significant impact of securing an expedited trial.

A copy of the appeal judgment can be found here.

[1] We use the Neurim to refer to Neurim and its exclusive licensee, Flynn, unless otherwise stated.

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