Neutral Citation [2020] EWHC 1362 (Pat)

Claim No: HP-2020-000005

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (Pat)
PATENTS COURT

Royal Courts of Justice
Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 3 June 2020

Before:

THE HONOURABLE MR JUSTICE MARCUS SMITH

BETWEEN:

(1) NEURIM PHARMACEUTICALS (1991) LIMITED
(a company incorporated under the laws of Israel)
(2) FLYNN PHARMA LIMITED
(a company incorporated under the laws of the Republic of Ireland)

Claimants

(1) GENERICS UK LIMITED (trading as MYLAN)
(2) MYLAN UK HEALTHCARE LIMITED

Defendants

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Mr Andrew Waugh, QC and **Ms Katherine Moggridge** (instructed by **Gowling WLG (UK) LLP**) for the First Claimant

Mr Andrew Waugh, QC and **Ms Katherine Moggridge** (instructed by **Pinsent Masons LLP**) for the Second Claimant

Mr Mark Vanhegan, QC and **Mr Adam Gamsa** (instructed by **Taylor Wessing LLP**) for the Defendants

Hearing dates: 20 May and 3 June 2020

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

Mr Justice Marcus Smith:

A. THE CLAIMANTS AND THE PATENT

1. The First Claimant – Neurim Pharmaceuticals (1991) Limited (**Neurim**[1]) – is the registered proprietor of a patent, EP(UK) 1,441,702 B1 (the **Patent**). The Second Claimant – Flynn Pharma Limited (**Flynn**) – is the registered exclusive licensee under the Patent in the UK.

2. The Patent[2] claims prolonged release pharmaceutical formulations concerning the active ingredient melatonin to improve the restorative quality of sleep in a patient suffering from primary insomnia characterised by non-restorative sleep.

3. The pharmaceutical formulation claimed by the Patent is sold under the brand name **Circadin**. More recently, Neurim has developed a paediatric version of prolonged release melatonin, **Slenyto**.

4. The Patent was filed on 12 August 2002 and claims priority from 14 August 2001. The Patent is a "second medical use" patent. If not revoked sooner, the Patent will expire on 12 August 2022, i.e. in some two years and three months' time.

5. Pharmaceuticals like Circadin receive protection from competition in the shape of a monopoly derived from the patent under which they are produced. This serves as a form of negative protection against competitors. However, in order actually to sell such a pharmaceutical (at least in the UK), regulatory approval is also required. In very general terms:

   (1) Regulatory approval to sell a pharmaceutical will typically require considerable (and expensive) testing in order to be assured that the pharmaceutical provides clinical benefits with an acceptable level of side effects.

   (2) If approval is granted, the pharmaceutical's **label** will indicate its intended use. Normally, this use is closely tied to the claims in the patent. However, at least in this jurisdiction, it is possible for there to be an **off-label** use for which the pharmaceutical may be sold and used. As the term implies, off-label refers to a use that is not described in the label.

6. There are often, therefore, two markets for pharmaceuticals: the on-label market, which is generally closely tied to the claims in the patent (if there is a patent in relation to the pharmaceutical); and an off-label market, which involves prescribing or selling for uses that are not specified in the label. It will be necessary to consider the on-label and off-label uses of Circadin in the course of this judgment. For the present, it is simply worth noting that Circadin's label indicates a use for the short-term treatment of primary insomnia in patients aged 55 or over, which is a narrower use than the claims in the Patent (which have no age limitations as to use). There is, therefore, unsurprisingly an off-label

[1] Annex 1 hereto lists the terms and abbreviations used in this judgment.

[2] Specifically, independent claims 1 and 4 of the Patent, which are set out in paragraph 59 below.

market for Circadin for insomnia in patients under the age of 55. There are also off-label uses for Circadin in relation to treatments for non-insomnia symptoms.

7. Slenyto received regulatory approval in October 2018. Slenyto is for insomnia in children. There is obviously going to be competition between Circadin and Slenyto, with the latter taking sales away from the former, as well as bringing in new sales in those cases where Circadin would not previously have been prescribed.

8. The Patent was granted by the European Patent Office (the **EPO**) on 10 May 2017. It was subject to opposition by – amongst others – the First Defendant, Generics UK Limited. I shall refer to the First Defendant and to the Second Defendant, Mylan UK Healthcare Limited, collectively as **Mylan**. At an oral hearing on 20 November 2019, the Patent was revoked by the EPO Opposition Division. It was held to be invalid as having been anticipated by certain prior art that I need not describe. The EPO Opposition Division published its written decision on 2 January 2020. That decision has been appealed, but it is unlikely that a final decision on the appeal will be made before 2022 at the earliest. It is perfectly possible that there will be no decision until the Patent has expired which, as I have said, will be on 12 August 2022.

B. MYLAN

9. Mylan propose to release a "generic" rival to Circadin. Mylan's precise launch plans are confidential, and I am going to proceed on the basis that that launch is "fairly imminent", without being any more specific than that. I have confidential evidence before me providing some greater specificity on this point: but I do not consider this to be material to this judgment. I shall refer to this rival pharmaceutical as the **Generic Product**.

10. Mylan obtained a marketing authorisation for their Generic Product in about December 2019. This marketing authorisation "piggy backs" on Neurim's own marketing authorisation for Circadin. Unless restrained by this court, Mylan proposes to sell the Generic Product in the UK as soon as it can.

C. THESE PROCEEDINGS

11. In these proceedings – commenced by Neurim and Flynn – Neurim and Flynn contend that Mylan intends to infringe the Patent. They seek a declaration of infringement and injunctive and other relief. Mylan counterclaims for revocation of the Patent on grounds of anticipation, obviousness and insufficiency.

12. "Interim" interim protection has been obtained by Neurim and Flynn in the form of an undertaking from Mylan that "holds the ring" until 20 May 2020, the date of the hearing before me. This was the date of Neurim and Flynn's application for an interim injunction until trial. Because the hearing before me overran, and argument continued until the early evening,[3] that undertaking was, helpfully, extended by Mylan to 3 June 2020, when this judgment is formally to be handed down.

[3] That is no criticism of any of the counsel. The hearing, which was conducted remotely, was affected by many interruptions in the connection. Although I am satisfied that all points were properly laid out before me, there was a distinct lack of flow, and it seemed to me important to re-visit the transcript before giving judgment.

13. For the purpose of this judgment, the question before me is, therefore, whether interim injunctive relief should be provided until after final judgment in these proceedings or further order.

14. An expedited trial had been ordered, which is due to take place in a 5-day window floating from 26 October 2020.

D. THE LAW AS STATED IN *AMERICAN CYANAMID*

15. The relevant law – or at least the starting point for considering the relevant law – remains the speech of Lord Diplock in *American Cyanamid Co v. Ethicon Ltd*.[4] Given the arguments that were put before me, it is appropriate – despite the well-known nature of the test propounded by Lord Diplock – to set out the reasoning in some detail.

16. In general terms, the object of interlocutory relief is as follows:[5]

> "The object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial; but the plaintiff's need for protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated under the plaintiff's undertaking in damages if the uncertainty were resolved in the defendant's favour at the trial. The court must weigh one need against another and determine where "the balance of convenience" lies."

17. Ascertaining the balance of convenience involves a number of steps:

(1) ***Stage 1: A serious issue to be tried?*** The applicant for interim relief, the claimant, must show that there is a "serious issue to be tried":[6]

> "The court no doubt must be satisfied that the claim is not frivolous or vexatious; in other words, that there is a serious issue to be tried...So unless the material available to the court at the hearing of the application for an interlocutory injunction fails to disclose that the plaintiff has any real prospect of succeeding in his claim for a permanent injunction at the trial, the court should go on to consider whether the balance of convenience lies in favour of granting or refusing the interlocutory relief that is sought…".

The whole point of this test is to avoid conducting a "trial within a trial". If it were possible to correctly anticipate the outcome of a trial at an interlocutory stage, trials would become redundant and matters would be resolved finally (subject to any appeal) at what would no doubt no longer be known as an "interlocutory" hearing. Lord Diplock's point – which has as much force today as it had in 1975 – was that trials served an essential purpose, and that because there was inevitably a time-lag between the joining of issue on a legal dispute and the resolution of that issue at trial, interim protection between joinder of issue and trial needed to be based on criteria very different to those operating at the trial itself:[7]

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[4] [1975] AC 396.

[5] *American Cyanamid* at 406.

[6] *American Cyanamid* at 407-408.

[7] *American Cyanamid* at 407.

> "It is no part of the court's function at this stage of the litigation to try to resolve conflicts of evidence on affidavit as to facts on which the claims of either party may ultimately depend nor to decide difficult questions of law which call for detailed agreement and mature consideration…"

Thus, the requirement that there be a serious issue to be tried is no more than a roughly-meshed filter, intended to remove from the court's consideration the obviously unsustainable.

(2) ***Stage 2: Are damages an adequate remedy to the claimant?*** Lord Diplock's position was that provided damages were an adequate remedy, a claimant should not obtain an interim injunction, even if the claim was very strong:[8]

> "If damages in the measure recoverable at common law would be an adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however strong the plaintiff's claim appeared to be at that stage…"

Significantly, Lord Diplock did not merely focus on the theoretical adequacy of damages as a remedy, but on the practical aspects as well. Thus, if a defendant were not in a financial position to pay damages – even if, theoretically speaking, damages would be adequate, if only the defendant had money to pay – that would militate in favour of granting interim relief. Although not mentioned by Lord Diplock, it seems to me that other practical aspects – for example, the length of time it might take for a claimant to obtain an order for damages, and the procedural difficulties that might bedevil the route to damages – are relevant factors to take into account in the particular case.

In assessing whether damages are going to be an adequate remedy, it is essential that the court identify those aspects in which damages will not be an adequate remedy. Matters are rarely black and white, and it is implicit in Lord Diplock's use of the word "adequate" that an injunction may nevertheless be refused if damages are not a "perfect" remedy; but that there comes a point when damages as a remedy falls so far short of the perfect, that the remedy of damages can no longer be described as adequate.

(3) ***Stage 3: If damages are not an adequate remedy to the claimant, consider the adequacy of the undertaking in damages to the defendant?*** If damages are an adequate remedy to the claimant, then the inquiry stops at Stage 2. However, the converse does not hold good. An injunction will not lie automatically, even if damages are an inadequate remedy to the claimant and the requirements of Stage 2 are satisfied:[9]

> "If, on the other hand, damages would not provide an adequate remedy for the plaintiff…, the court should then consider whether, on the contrary hypothesis that the defendant were to succeed at the trial…he would be adequately compensated under the plaintiff's undertaking as to damages for the loss he would have sustained by being prevented from doing so between the time of the application and the time of the trial. If damages in the measure recoverable under such an undertaking would be an adequate remedy and the

[8] *American Cyanamid* at 408.

[9] *American Cyanamid* at 408.

plaintiff would be in a financial position to pay them, there would be no reason upon this ground to refuse an interlocutory injunction…"

It is trite that an injunction will not normally be granted unless the claimant offers to hold the defendant harmless against any losses sustained by the defendant in being enjoined by the injunction in the event that the outcome at trial proves that the interim injunction should not have been granted (because the claims that would justify the making of a final injunction fail). It will be necessary to consider the ambit of this undertaking later on in this judgment, but (for the present) it is enough to note that if the undertaking in damages will adequately[10] protect the defendant an interim injunction will, in the ordinary course, be granted.

(4) ***Stage 4: no adequate remedy for either side.*** Of course, a court must consider all relevant factors when granting a discretionary remedy like an interim injunction. But it is where both parties can plausibly contend that damages (whether granted as a remedy at law or through the cross-undertaking) will not be adequate that a balancing exercise as to whether or not to grant relief arises for careful consideration:[11]

"It is where there is doubt as to the adequacy of the respective remedies in damages available to either party or to both, that the question of balance of convenience arises. It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them. These will vary from case to case…"

As Lord Diplock noted, it is not possible to enumerate the factors that a court should take into account at this stage. However, Lord Diplock did identify two factors which might be taken into account:

(a) The first of these was the significance of the *status quo*:[12]

"Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the *status quo*…"

(b) The second was a residual role for the merits of the claim. Lord Diplock put the matter thus:[13]

"If the extent of the uncompensatable disadvantage to each party would not differ widely, it may not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence adduced on the hearing of the application. This however should be done only where it is apparent upon the facts disclosed by evidence as to which there is no credible dispute that the strength of one party's case is disproportionate to that of the other party…"

It is important to be aware of the limits that apply when taking into account the merits. Not only does the appropriateness of a merits analysis arise at a very late stage in the *American Cyanamid* assessment process; it is also the case that the court should not be sucked into a merits analysis unless the facts are so clear that "there is no credible dispute" in relation to them.

[10] All that was said about "adequacy" in paragraph 17(3) above is equally true here.

[11] *American Cyanamid* at 408.

[12] *American Cyanamid* at 408.

[13] *American Cyanamid* at 409 (emphasis added).

E. "TRIALS WITHIN TRIALS" ON INTERLOCUTORY MATTERS

18. Hard fought and financially significant applications for interim relief will often involve hotly contested matters of fact that will not, or at least not in that form, be the subject of resolution at trial. In this case, there was (quite rightly and entirely unsurprisingly) considerable debate about the question of "adequacy" of damages at both Stages 2 and 3 of the process described above. By way of example, both parties adduced some evidence as to what would happen to the market for Circadin (and Slenyto, although the market for this pharmaceutical is less well developed) were an interim injunction not to be granted. Neurim and Flynn contended:

(1) That Mylan's Generic Product would enter the market at a price significantly lower than the prices that Neurim and Flynn could otherwise charge for Circadin (and Slenyto).

(2) That the market price for Circadin and Slenyto would materially fall for that reason, and that Neurim and Flynn would either have to follow the market price down (in an attempt to maintain market share) or else lose a significant amount of market share whilst maintaining pre-existing prices. Either way, their revenue would fall, and would fall materially.[14]

(3) That the fall in market price would not be capable of being recovered by Neurim and Flynn. Thus, supposing an imminent entry into the market by Mylan, and assuming victory at trial in October by Neurim and Flynn, these 6 months between the beginning of June and the end of November (which is when I shall assume judgment would be handed down) would be sufficient to suppress the price of Circadin and Slenyto irretrievably for the remaining duration of the Patent when compared to pre-June 2020 levels.

19. Thus, according to Neurim and Flynn, if an interim injunction were not granted, their losses would fall to be categorised under two broad heads, which I shall call **Period 1** and **Period 2**:

(1) ***Losses in Period 1.*** Neurim and Flynn's losses in Period 1 would arise because of direct competition between Circadin/Slenyto and Mylan's Generic Product. That direct competition would – according to Neurim and Flynn – result in lower revenues as a result of a combination of lower volume of sales at lower prices.

(2) ***Losses in Period 2.*** The outcome of the trial in October is, of course, unknown. However, assuming Neurim and Flynn were to be successful at trial, it is likely (as it seems to me) that Neurim and Flynn would successfully be able to argue that (even if no injunction had been granted at the interlocutory stage) they should, having won on the merits, obtain a permanent injunction on the handing down of judgment in their favour. Neurim and Flynn contended that even if this occurred, and Mylan's Generic Product was excluded from the market at that point, their losses would still continue. Neurim and Flynn would not simply be able to increase their prices to the levels they were at before the commencement of Period 1. Instead

[14] The extent to which there would or might be a fall in price – and in respect of which markets (the on-label market, the off-label market or both) – was itself contested. Indeed, even the scope of these markets was not agreed. Neurim and Flynn, to be clear, contended that there would be a "dramatic" fall in the price. The use of the more neutral word "material" is mine.

> – throughout Period 2, which I shall take to be from the imposing of a final injunction at the conclusion of the trial, to the expiry of the Patent in August 2022 – Neurim and Flynn would continue to suffer loss, even whilst doing their utmost to rebuild the market for Circadin and Slenyto.

20. These points were contested by Mylan. In particular, it was suggested that the market would recover if Neurim and Flynn succeeded at trial and obtained a permanent injunction.

21. It is impossible to reach a conclusion "on the merits" as to what would happen to the market for Circadin and Slenyto if an interim injunction were not granted. Although I have read the evidence adduced by both parties with great care, there has been no disclosure; no expert evidence; and no oral evidence. None of this is a criticism of the parties. To conduct a trial in order to establish whether Stages 2, 3 and 4 of Lord Diplock's process are met or not met would be entirely to subvert the purpose of Stage 1, which enjoins a trial on the merits on the matters due to be heard at trial in favour of a "balance of convenience" approach.

22. Accordingly, when considering contentious questions of fact such as these, I have taken the view that *American Cyanamid* provides an order in which material factors going to my discretion should be considered. In short, I have a structured discretion, within which certain factually contentious factors arise. These are matters on which I cannot reach a finally concluded view: I can only weigh them in the manner suggested by Lord Diplock at Stage 1 – namely, is there a "serious issue" to be tried? As *Gee* notes, the process for the grant of an interim injunction is essentially a discretionary one, and not a fact-finding one:[15]

> "The discretion whether to grant or refuse an interim injunction is that of the first instance judge, and will not be interfered with by an appellate court, unless the judge took into account something he should not have taken into account, failed to take into account something which he should have taken into account, was wrong in law, misunderstood the evidence, or was plainly wrong, or if there has been further evidence which shows that the judge proceeded on a mistaken view of the facts, or there has been, since the decision at first instance, a material change of circumstances."

F. THE DIRECTIVE ON THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

23. Mylan referred me to article 3 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (the **IP Enforcement Directive**).[16] Article 3 provides:

> "(1) Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

[15] Gee, *Commercial Injunctions*, 6th ed (2016) at [2-29].

[16] Paragraph 12 of Mylan's written submissions.

(2) Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."

24. I am grateful to Mylan for reminding me of this provision. It seems to me that the *American Cyanamid* regime that I have described seeks to achieve the ends described in article 3 of the IP Enforcement Directive.

G. APPROACH

25. I propose to consider Neurim and Flynn's application for an interim injunction essentially in accordance with the schema laid down by Lord Diplock. Thus, Sections H to K engage with Stages 1 to 4 as I have described them in Section D above.

H. STAGE 1: A SERIOUS ISSUE TO BE TRIED

(1) The merits (again)

26. The *American Cyanamid* test is extremely clear as to the role of the merits. There is a threshold test of a "serious issue to be tried"; and the possibility of taking the merits into account at Stage 4, provided the facts are unequivocal – and that is it.

27. Nevertheless, there have been attempts to allow the merits to intrude more, notably by Laddie J in *Series 5 Software Ltd v. Philip Clarke*.[17] In *Re Brickvest Ltd*,[18] I was invited to take this course in relation to the merits of the case:

"9. Mr Hornett did seek to tempt me into applying a different test to the "serious question to be tried" in *American Cyanamid*. In *Series 5 Software Ltd v. Philip Clarke*, [1996] FSR 273 at 286, Laddie J suggested that it was possible to shortcut the later stages of *American Cyanamid* by focussing on the merits. The approach of Laddie J was that, in a clear-cut case, one could grant an injunction independently of the *American Cyanamid* criteria. I must say I have my doubts. As is well-known, in *American Cyanamid*, Lord Diplock sought to avoid the difficulties of conducting a "trial within a trial" at an interlocutory stage by articulating the "serious question to be tried" test.

10. It seems to me that Laddie J's approach is one that is redolent with danger, in that it seeks to re-incorporate into the test for the granting of an interlocutory injunction precisely those elements that Lord Diplock was at pains to remove. Apart from the case where the court can conclude that it appropriate to order summary judgment in favour of the applicant for an injunction, it seems to me that the test to be applied – when considering the merits – is whether there is a serious issue to be tried."

There is always a temptation to try to achieve at an earlier stage than trial the certainty that a trial is intended to achieve. But there is a reason we have trials: it is because many questions cannot be determined without consideration of all the evidence in light of the material available at trial. Whilst the appeals process from trials shows that the certainty of outcome at the conclusion of a trial may be fractured on a successful appeal, that

[17] [1996] FSR 273 at 286. Mylan sought to suggest that there were other indicators of a more aggressive role for the merits in *National Commercial Bank Jamaica v. Olint*, [2009] UKPC 16 at [17] and *Warner-Lambert v. Actavis*, [2015] EWHC 72 (Pat) at [90]. Looking at these passages, it seems to me that Lord Hoffmann and Arnold J, respectively, were doing no more than articulate the *American Cyanamid* principles.

[18] [2019] EWHC 2662 (Ch).

merely underlines how dangerous it is to anticipate the outcome of a trial. There is good reason why Lord Diplock expressed the hurdle as lowly as he did – "serious issue to be tried". Whilst I have no doubt that there are means, apart from a successful application for summary judgment, for showing that there is no serious issue to be tried, I equally have no doubt that they are limited and that they do not permit very much scope for a "merits" approach. Unless and until the Supreme Court articulates a different test, it is Lord Diplock's approach that governs.[19]

(2) Serious issue to be tried

28. Looking simply at the issues in the proceedings, it is difficult to see how it could be said that there was no serious issue to be tried as to the validity of the Patent. In his oral submissions before me, Mr Vanhegan, QC, for Mylan, accepted that there was a serious issue to be tried.[20] He was correct to make that concession in light of the evidence before me, and it follows that there is no need for me to consider further the issues of validity that will trouble this court at the trial of these proceedings.

(3) The proceedings before the EPO

29. Mylan did seek to rely on the fact that the Patent had been revoked by the EPO Opposition Division in support of its contention that there was no serious issue to be tried.[21] I was also referred to certain decisions in other jurisdictions: in particular, I was referred to the refusal by the Patent and Market Court of Stockholm to grant an interim injunction in favour of the Patent against Orifarm in Sweden.[22]

30. It being conceded that there is – on the face of these proceedings – a serious issue to be tried, neither of these points can, in my judgment, alter that conclusion. In some cases, the decisions of courts of foreign jurisdictions are entitled to great weight. This is not one of those cases. I have no idea what evidence was adduced before the Swedish (and other) courts; more to the point, I have no idea what test for the granting of interim relief these courts applied.

31. In these circumstances, the fact that an interim injunction was refused in these other jurisdictions is a matter of no moment. It might be that, if an exhaustive comparative analysis were carried out, embracing both the legal test applied by such courts and the evidence adduced before them, some light might be cast on the question of serious issue to be tried. But the benefit is so marginal, and cost in legal expense and court time so great, that such a course cannot be encouraged. The question of serious issue to be tried must be considered through the prism of the proceedings being tried in this jurisdiction.

32. The same goes for the proceedings before the EPO. If it were the case that the conclusion of the EPO Opposition Division were binding on this court, then the question of whether there was a serious issue to be tried would not even arise: the merits of the matter would

[19] *Cephalon v. Orchid*, [2010] EWHC 2945 (Pat) at [43] to [45], where Floyd J articulated precisely the approach I have described.

[20] Transcript/p.94 (submissions of Mr Vanhegan, QC).

[21] Mylan's written submissions at paragraphs 31 and 32.

[22] Mylan's written submissions at paragraph 32.

already have been determined. But that is not the status of an EPO Opposition Division decision.

33. In *Buehler AG v. Chronos Richardson Ltd*,[23] the Court of Appeal held that under article 138 of the European Patent Convention 1973, the validity of a patent was a matter to be determined in revocation proceedings in the national courts. The Convention was given effect by the Patents Act 1977 and the power to revoke a patent on specified grounds was given to courts and the Comptroller under section 72. The jurisdiction under section 72 extended further than that exercised by the Opposition Division under article 100 of the Convention and the grounds for revocation under section 72 were different to the grounds for opposition. Accordingly, a party who had unsuccessfully opposed the grant of a patent before the EPO was not precluded from advancing substantially the same point in the English courts. A decision of the Opposition Division was not a final judicial decision as to the validity of a patent and therefore was no bar to revocation proceedings under section 72.

34. *Terrell*, citing *Buehler*, says this:[24]

> "An opponent who unsuccessfully opposes the grant of a European patent in the EPO is not estopped from alleging invalidity by way of a defence to a subsequent allegation of infringement in proceedings on the European patent (UK) in this country. There is no cause of action estoppel because the causes of action are not identical and, more fundamentally, the decision of the Opposition Division is not a final and conclusive judicial decision to the validity of the patent, validity being finally decided in revocation proceedings by the courts of the contracting states. Similarly, there can be no issue estoppel in the absence of a final decision."

35. *Buehler* and *Terrell* are, of course, considering the case where an attack on a patent in the EPO fails, and the same (or similar) attack is mounted again in the English courts. The present case is the exact converse: the EPO Opposition Division has found the Patent to be invalid: Neurim and Flynn have nevertheless commenced proceedings for infringement in this jurisdiction, on the basis that the Patent is valid (which is being contested by Mylan). Neurim and Flynn are perfectly entitled to take this course. It seems to me that either the decision of the EPO is binding on the English courts – in which case, there is no serious issue to be tried and all that needs to be considered is whether an injunction should lie pending the appeal from the EPO's decision – or the decision of the EPO is not binding, in which case I am at a loss to understand why the EPO's decision should have any more or less weight than that of a court of any other foreign jurisdiction.

36. Since it is clear that the EPO's decision is not binding on the English courts, I repeat the point made in paragraph 31 above: the question of serious issue to be tried must be considered through the prism of the proceedings being tried in this jurisdiction.

37. Both parties adduced evidence before me as to whether the EPO Opposition Division's decision would or might be overturned on appeal. Since I find the decision of the EPO Opposition Division to be, essentially, irrelevant to the question of serious issue to be tried, it follows that what might happen on an appeal, and why the EPO Opposition Division decided the matter in the way that it did, are also essentially irrelevant questions.

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[23] [1998] RPC 609 at 616.

[24] Birss *et al, Terrell on the Law of Patents*, 18th ed (2016) (***Terrell***) at [19-188].

I. STAGE 2: ARE DAMAGES AN ADEQUATE REMEDY TO NEURIM AND FLYNN?

(1) Mylan's financial position

38. I do not understand it to be disputed that Mylan have the assets to pay damages of any amount that Neurim and Flynn may recover. Nor is it suggested that there would be any enforcement issues, were an order for payment of damages to be made.

39. Thus, the question before me boils down to the adequacy of a remedy (damages) that can clearly be provided by Mylan if ordered by the court.

(2) The harm anticipated

(a) General nature and likely duration

40. It is best to begin with the harm that Neurim and Flynn anticipate. That harm is as I described it in paragraphs 18 and 19 above. My starting point must be that unless enjoined, Mylan will do what they are threatening, and cause the Generic Product to enter the market. It seems to me inconceivable that Mylan would not cause the Generic Product to be priced at a level substantially lower than the price for Circadin and Slenyto. Whilst, of course, it is possible that there is such brand loyalty to Circadin, or such inelasticity in the system,[25] such that Neurim and Flynn could maintain their market at the prices they currently sell, I consider this to be highly unlikely. The whole point about generic pharmaceuticals is that they do what the patented product says it does on the box, only without the name of the patented product. It seems to me that the mere fact that Mylan are contemplating an entry into the market is sufficient to provide a strong indicator that Neurim and Flynn will suffer a combination of loss of sales and lower sales prices for Circadin and Slenyto.

41. The likely duration of this harm is a matter that I must consider. As I have noted, there are two aspects to this. First, assuming no interim injunction is granted by me on this application, for how long will Neurim and Flynn be faced with competition from the Generic Product? Secondly, even if, at some point before the Patent's expiry, Neurim and Flynn succeed in excluding Mylan's product from the market – for example, by establishing at trial or on appeal that the Patent is, indeed, infringed – whether Neurim and Flynn will succeed in re-establishing the *status quo ante*? I have referred to these two aspects as Period 1 and Period 2.[26]

(b) Duration of competition between Circadin/Slenyto and the Generic Product: Period 1

42. Turning to the first of these questions, assuming no interim injunction were to be granted on this application, Mylan would be free to compete until at least judgment in the proceedings was handed down. If Neurim and Flynn were successful at trial, and the trial judge found that the Patent was valid and infringed, then I consider that there would be a relatively high chance of an injunction being imposed by the trial judge: Neurim and Flynn would, after all, have established infringement of their Patent rather than simply a

[25] For instance, in the databases to pharmacies and general practitioners, in terms of the available drugs. It is possible that such systems are so unresponsive to new pharmaceuticals that pharmaceuticals in the system are effectively immune from competition.

[26] See paragraph 19 above.

serious issue to be tried as to the question of infringement. Even if there was an appeal by Mylan, it seems to me quite likely that a permanent injunction would be granted.

43. If, on the other hand, Neurim and Flynn were unsuccessful at trial, it seems to me unlikely that an interim injunction would be imposed pending their appeal to the Court of Appeal. Obviously, this question would be considered in light of all the material facts prevailing at the time, and on the basis of the test that applies for interim relief pending an appeal from a trial on the merits.[27] But it seems to me unlikely that an interim injunction would be granted at this stage given: *(i)* that it was not granted before trial (that is the assumption I am making); and *(ii)* that Neurim and Flynn would have been unsuccessful at trial. On this basis, therefore, there would be no injunction at all unless, at the end of the process, Neurim and Flynn succeeded on appeal.

44. Considering matters in the round, it seems to me that I must proceed on the assumption that, were I to grant the interim injunction sought by Neurim and Flynn, that decision would ultimately be justified by the outcome of the trial of these proceedings. In other words, I must assume that (in hindsight) the correct decision would be for me to grant the interim injunction. On this basis, were I not to grant the injunction, harm that ought not to have occurred to Neurim and Flynn will have occurred by reason of my failure to grant the interim injunction. *Per contra*, assuming that Neurim and Flynn fail at trial only underlines the fact that they will have obtained an interim remedy that – with hindsight – they ought not to have obtained. Proceeding on this basis, it is clear that were I not to grant the interim injunction sought, the period in which Neurim and Flynn would be exposed to competition from the Generic Product would be until judgment at first instance was handed down in these proceedings. That period (Period 1) begins imminently – when, exactly, would depend on when Mylan could begin selling the Generic Product – and would end with the handing down of judgment in, say, late November 2020, a period of around 6 months.

(c) Effects after cessation of direct competition: Period 2

45. Assuming, then, that the period of direct competition between Circadin/Slenyto and the Generic Product would be limited to a period of no more than 6 months, can it safely be said that if – in November 2020, Neurim and Flynn having been successful in the proceedings and having obtained a final injunction against Mylan – competition between Circadin/Slenyto and the Generic Product ceases, Neurim and Flynn would be able to resume their *status quo ante* in terms of price level and volumes of Circadin and Slenyto sold?

46. The evidence before me, unsurprisingly, went both ways, with Mylan contending that the *status quo ante* could easily be restored, and with Neurim and Flynn contending that it would simply not be possible to restore prices to their previous levels. Their point was that, once fractured, the effects of the monopoly deriving from the Patent simply could not be restored without more.

47. In order to reach a concluded view on such a point, a great deal of evidence would be required from independent market experts and economists. Whilst I accept that each side

[27] *Novartis v. Hospira*, [2013] EWCA Civ 583 at [41].

had a degree of expertise in this market, all persons giving evidence on this point were *parti pris* and I found their evidence on this point substantially valueless.

48. One might say that removing a competitor from the market would enable the market situation pertaining under the earlier monopoly to revive without more. I cannot accept that that would seamlessly be the case. I do not see how Neurim and Flynn could hope – in a single jump – to restore monopoly prices without alienating substantial parts of their market. I consider that, in the 6 months of price reduction due to competition in Period 1, purchasers of Circadin and Slenyto would re-evaluate the values and benefits of the product in light of the new price, and factor in that new price into their budgets and calculations. They would be very hostile to a dramatic attempt to restore the *status quo* in terms of price.

49. Whilst I do not say that Neurim and Flynn could not, over time, claw their way back to the present position, it would require careful consideration by them of the market circumstances in Period 2, and certainly that object could not be achieved at once. I consider that, in the limited time remaining to the Patent in Period 2 (some 20 months), during much of that period Neurim and Flynn would suffer a combination of lower sales of Circadin and Slenyto, and lower prices for those sales, than exists at present. In short, there would be losses to Neurim and Flynn during most, if not all, of Period 2.

(3) Damages an adequate remedy?

(a) Points taken by Mylan

50. Mylan contended that – even if, as I have found for the purposes of this application, the harm to Neurim and Flynn would extend beyond the period of competition between Circadin/Slenyto and the Generic Product in Period 1 – damages would nevertheless be an adequate remedy.

51. This, to my mind, is the critical question, which I consider below. However, Mylan took a number of other points which must be considered in advance of this critical question, because they affect its parameters. These points are as follows:

(1) Whether Flynn has standing to bring this claim?

(2) Whether all of the damages anticipated by Neurim and Flynn can be attributed to an infringement of the Patent?

52. It is necessary to consider these points in turn, before considering the question of the adequacy of damages.

(b) Flynn's standing

53. Section 67 of the Patents Act 1977 provides as follows:

> "(1) Subject to the provisions of this section, the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence; and references to the proprietor of the patent in the provisions of this Act relating to infringement shall be construed accordingly.

(2) In awarding damages or granting any other relief in any such proceedings the court or the comptroller shall take into consideration any loss suffered or likely to be suffered by the exclusive licensee as such as a result of the infringement, or, as the case may be, the profits derived from the infringement, so far as it constitutes an infringement of the rights of the exclusive licensee as such.

(3) In any proceedings taken by an exclusive licensee by virtue of this section the proprietor of the patent shall be made a party to the proceedings, but if made a defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings."

54. Thus, only the holder of the patent and an exclusive licensee of the holder have standing to bring an action for the infringement of that patent.

55. Mr Vanhegan, QC's submissions raised a number of interesting points as to the nature of an "exclusive" licence, and the manner in which the rights under a patent may be sliced and divided between different licensees, each of whom is or may be (within its sphere) exclusive. Neurim and Flynn did themselves no favours in relation to this point by disclosing only an aggressively redacted licence agreement, which was then varied at the last minute. It seems to me – for much the same reasons as were stated in *Promontoria (Oak) Ltd v. Emanuel*[28] – that where what is at issue in proceedings is the nature and effect of a written instrument, the whole of that instrument must be disclosed. Of course, I appreciate that such documents may be highly confidential, but there are procedures whereby the whole of the document can be produced whilst maintaining confidentiality. The fact is that contracts and other instruments are construed as a whole; and redactions such as those which occurred in the present case cannot possibly be justified on the grounds of irrelevance.

56. Nevertheless, it seems to me that to decide that Flynn is not an exclusive licensee in the absence of an application to strike Flynn out of the proceedings would be to do precisely what *American Cyanamid* enjoins me not to do, which is to conduct a "trial within a trial". The question of whether Flynn is an exclusive licensee is by no means straightforward, and by no means purely and simply a question of law. The agreement between Neurim and Flynn needs to be construed in light of the entire factual matrix – which is not before me – and it seems to me that the questions of legal construction that will arise are going to be coloured by such questions of fact.

57. More to the point, even if Flynn were to be treated by me as a non-exclusive licensee – and so without standing in these proceedings – it seems to me clear that Neurim (whose standing is rightly unchallenged) would itself nevertheless suffer loss through the competition between Flynn and Mylan in the United Kingdom. The notion that I should, on an application for interim relief, seek to ascertain what the loss to Neurim alone would be, assuming Flynn had no standing to claim damages, seems to me to stretch the interlocutory process too far. I cannot possibly reach any kind of determination of this point save to say that it is clear that if Flynn's sales of Circadin and Slenyto suffer, in terms of either quantity or price, the royalties payable to Neurim would fall as a result. That is so, whether Flynn is a party to these proceedings or not.

[28] [2020] EWHC 104 (Ch).

58. In short, I find that on this application the question of Flynn's status as exclusive licensee is an irrelevant factor.

(c) The damages flowing from the infringement

59. The two relevant claims in the Patent are:

(1) ***Claim 1.*** Claim 1 provides:

> "Use of a prolonged release fomulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10mg of melatonin, in the manufacture of a medicament for improving the restorative quality of sleep in a patient suffering from primary insomnia characterised by non-restorative sleep, wherein the medicament comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier."

(2) ***Claim 4.*** Claim 4 provides:

> "A medicament for use in improving the restorative quality of sleep in a patient suffering from primary insomnia characterised by non-restorative sleep, which comprises a prolonged release formulation comprising melatonin in unit dosage form, each unit dosage comprising 0.025 to 10mg of melatonin, and at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier."

60. It is to be noted that patented medical use concerns improving the restorative quality of sleep in a patient suffering from primary insomnia characterised by non-restorative sleep without reference to the age of the patient.

61. The label for Circadin specifies the following therapeutic indications for Circadin:[29]

> "Circadin is indicated as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over."

The scope of the label is thus narrower than the patented medical use.

62. In terms of the actual use of Circadin, data in the period 2017 to 2019 shows a number of prescribed uses of Circadin that are both off-label and outwith the claims of the Patent. Thus, for instance, in excess of 2.5 million units were prescribed for prescription code F840, which is for "childhood autism". Mylan contended that sales of Circadin for its patented use accounted for only about 2% of all prescriptions.[30]

63. This data was disputed by Neurim and Flynn, but even Neurim and Flynn accepted that there were three classes of medical use for Circadin, which I shall refer to as **Medical Use 1**, **Medical Use 2** and **Medical Use 3**:

(1) ***Medical Use 1: Use within the label and within the Patent.*** This would be for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.

[29] See the Summary of Product Characteristics for Circadin. Emphasis added.

[30] See paragraph 52 of Mylan's written submissions.

(2) ***Medical Use 2: Use outside the label but within the Patent.*** This would be for use in improving the restorative quality of sleep in a patient suffering from primary insomnia characterised by non-restorative sleep, where the patient's age is below 55.

(3) ***Medical Use 3: Use outside the label and outside the Patent.*** The range of use outside the label and outside the Patent would include – for example – prescriptions for childhood autism.

64. Neurim and Flynn accepted the principle, but contended that Mylan's data as to quantities of use falling into each category was unreliable:[31]

> "While I agree with Ms Britton's comment in paragraph 3.4 that a significant part of the Circadin market comprises unlicensed use, and that this use is complex and growing, I disagree with the statement that growth in the market for Circadin is "not due to the patented indication but from off-label use". It seems that Ms Britton is eliding two different points – unlicensed use (i.e. use outside the scope of the marketing authorisation and approved label) on the one hand and use outside of the scope of the claims of the patent in the other. The first is relatively easy to discern from prescribing data given that any use in patients under the age of 55 is unlicensed (albeit within the scope of the Patent). The second is not straightforward, and relies on consideration of the disease state. Reliable data in relation to this point are hard to find as it relies on prescribers including details of the proposed use of Circadin in individual patients. I deal with the data Ms Britton has put forward below."

65. Again, it seems to me that I cannot possibly resolve, on an interim application, the quantity of sales falling within each of these three classes. Whilst the evidence would appear to suggest that possibly quite substantial sales of Circadin fall within Medical Uses 2 and 3, the critical question is whether this should affect the view I take as to the loss that Neurim and Flynn will suffer if an interim injunction were not to be granted. It was Mylan's contention that Neurim and Flynn could only properly recover damages for losses in relation to Use 1; and that this was a relatively stable market, that would be unaffected by the introduction of the Generic Product. Not granting an injunction would, therefore, not result in any great loss to Neurim or Flynn at all.

66. Leaving on one side the rather considerable number of questions that this assertion on the part of Mylan begs – I consider that there was no sufficient evidence before me to reach any such conclusion safely – the point seems to me an essentially bad one, at least on an application such as this:

(1) The damages that are recoverable by the owner of a patent or an exclusive licensee are essentially assessed according to the ordinary rules. In *Gerber Garments Technology Inc v. Lectra Systems*,[32] Staughton LJ stated:

> "Infringement of a patent is a statutory tort; and in the ordinary way one would expect the damages recoverable to be governed by the same rules as with many or most other torts. We were referred to Halsbury's Laws of England (4th ed.),Vol.12, para. 1128 and following, to establish the elementary rules (i) that the overriding principle is that the victim should be restored to the position he would have been in if no wrong had been done, and (2) that the victim can recover loss which was (i) foreseeable, (ii) caused by the wrong,

[31] Second statement of Dr Fakes at paragraph 15.

[32] [1997] RPC 443 at 452.

and (iii) not excluded from recovery by public or social policy. The requirement of causation is sometimes confused with foreseeability, which is remoteness. The two are different—see Halsbury, para.1141:

> "1141. *Causation in tort* Subject to foreseeability and the principles of public policy it is prima facie necessary and sufficient for a plaintiff to prove that a defendant's wrongdoing was a cause and not necessarily the sole or dominant cause of his injuries, as a matter of physical consequences or common sense, but subsidiary principles associating foreseeability and causation have been evolved in certain categories of concurrent or intervening causes."

It is not enough that the loss would not have occurred but for the tort; the tort must (for present purposes at any rate) be, as a matter of common sense, a cause of the loss.

There is no dispute about foreseeability or causation in the present case. It is conceded that both requirements (if there are two) are satisfied. What is said is that either the general rules in Halsbury do not apply to the Patents Act, or else there is now a fourth limitation which must be satisfied. That fourth limit is to be derived from the speech of Lord Hoffmann in *South Australia Asset Management Corp v. York Montague Ltd*, [1996] 3 WLR 87 (aka the *Banque Bruxelles* case) at pp.92–l94:

> "…"

My answer would be, at first impression, that the Patents Act is aimed at protecting patentees from commercial loss resulting from the wrongful infringement of their rights. That is only a slight gloss upon the wording of the statute itself. In my judgment, again as a matter of first impression, it does not distinguish between profit on the sale of patented articles and profit on the sale of convoyed goods. So I must look to see whether any such distinction emerges from the case law…"

This statement of the law was endorsed by the Court of Appeal in *SmithKline Beecham plc v. Apotex Europe Ltd*.[33]

(2) The question, therefore, is whether Neurim and/or Flynn could properly claim damages for loss of sales falling within Medical Use 3 (to take the clearest case[34]). It seems to me that this, too, is a matter that I cannot decide conclusively one way or the other. Whether losses under Medical Use 3 can properly be recovered or whether they fall outside the scope of recoverable damages is obviously a matter for trial. But, given the relationship between the Patent and the label for Circadin (and Slenyto), and the fact that Mylan copies the label for Ciradin as a means of avoiding the cost of obtaining its own label, the point is clearly an arguable one. The point was explored in the course of Mr Vanhegan, QC's submissions:[35]

Mr Vanhegan, QC	My Lord, in effect, there is a regulatory hurdle to get a product into the UK market. The regulatory hurdle is the marketing authorisation. In a normal patent, a pharmaceutical case, the marketing authorisation indicates what the product is going to be used for, and in the normal case that product is prescribed for that use, in the vast majority of cases, 90%/95%. There may be a little bit of off-label prescribing. Therefore, normally, if

[33] [2003] EWCA Civ 137 at [8] and [9].

[34] The position in relation to Medical Use 2 is *a fortiori*.

[35] Transcript/pp.117*ff* (submissions of Mr Vanhegan, QC).

you have a patent for that pharmaceutical, your relief is coterminous, if you like, with the market. This is not that case. This is in fact the complete inverse of this case.

Here the claimants knew, or they have a marketing authorisation, which they have had since 2007, the core market for the protection is a tiny percentage of the market. What they have done is use that marketing authorisation and know that it is going to be prescribed off-label for a variety of other conditions. As you have seen, what seems to be growing are the conditions, certainly recently, are the childhood autism and ADHD-type illnesses. They know that, and as a result they are making a lot of sales on the back of that. No-one is criticising them for doing that, but when it comes to patent infringement, what their patent protects is only a very, very small sub-set of the actual market for which this product is being prescribed in the UK.

Marcus Smith J All that I understand. But let us be clear. Your clients are well-informed players in this market. What I am trying to tease out is the extent to which there is a nexus between the patent and the off-label use. In a sense, as you say, in most cases this will not be an issue, in that if your on-label use is broadly speaking coterminous with the scope of the patent, then you have to infringe in order to sell.

Here you say, in most cases, where the market is valuable, you do not infringe in order to sell, but you have the problem that the label you have adopted from Mr Waugh, QC's clients [Neurim and Flynn] includes the patent protected market as well. My question is simply this: if there was such a fragile nexus between the marketing authorisation and the patent, why do you no just say, yes, they obviously have a label that embraces the patented market, for obvious reasons, because it is their patent. You should have a label that is quite clear that it does not apply to the patented market, and then we do not have to be here at all, on your case.

Mr Vanhegan, QC My Lord, you are absolutely right, and we would not be; but we are. The practical reality is, the reason that this happens is that it is much faster for any further entrant into the marketplace to adopt an existing, if you like, marketing label or marketing authorisation, than to go through the whole process of establishing a new marketing authorisation, even though it is common practice in the field that 90% odd of the prescriptions are for that other field. You would have to demonstrate all the tests for safety and so forth in relation to those other prescriptions. That is a practical reality. So there is a regulatory hurdle, which would take some time for someone, like my clients, to overcome. However, that is not coterminous with, and it is wrong to consider it to be, the same as the patented protection.

One can also stand back and just think about it. The marketing authorisation was granted, as I recall, to Neurim, I think about 2007. The claims of the Patent had not even been properly formulated then. It was going up and down through the European Patent Office. The Patent was not granted until 2017.

> So the marketing authorisation has no nexus with the patent *per se*. It is almost happenchance, this is evergreening. This I, I think, their third patent…They are trying to use the Patent to seek to stop people coming into the marketplace altogether. On the facts of this case, there is no legal nexus between the actual market, in 98% of prescriptions, and the patent which they now have still outstanding some validity, because they have appealed from the European Patent Office.
>
> **Marcus Smith J** I see. What you are saying, and I am trying to frame the question, rather than frame the answer to the question, but what you are saying is, actually, the claimants are treating the marketing authorisation as the intellectual property right?
>
> **Mr Vanhegan, QC** Absolutely. They are saying, exactly, you are infringing because that is effectively our patent. That is what my learned friend is saying, that is absolutely right, and that is the wrong way to look at it.
>
> **Marcus Smith J** Even though they have devoted a great deal of time to obtaining the authorisation, and you are effectively piggy-backing on that, because, as you said a moment ago…
>
> **Mr Vanhegan, QC** …Absolutely. There is no wrong in piggy-backing on someone's authorisation.
>
> **Marcus Smith J** I am not in any way seeking to identify the rights and wrongs, I am trying to understand the intellectual argument. What you are saying is, we may very well be piggy-backing on the marketing authorisation, indeed, we are, you just said that.
>
> **Mr Vanhegan, QC** True.
>
> **Marcus Smith J** But that is a perfectly efficient way of…getting to the marketplace quicker, and avoiding the expense of getting your own label, but the price that you pay is that you have a label which enables someone properly to sell the product to someone whose need falls within the scope of the patent?
>
> **Mr Vanhegan, QC** Absolutely right, my Lord. You are absolutely right.
>
> **Marcus Smith J** And you cannot stop that, because to do so would be to go right back to the beginning and to rewrite the label.
>
> **Mr Vanhegan, QC** Absolutely right.
>
> **Marcus Smith J** I have been a little slow.

(3) This is a very interesting point, not without its difficulties on either side of the argument. It is, however, not a point for this application. It is precisely the sort of difficult point of law which, as well as being enormously dependent on the facts, calls for detailed argument and mature consideration at trial.[36] For the present, I need only say that I consider that Neurim and Flynn can contend (as a serious issue to be tried) that the losses flowing from Mylan's (likely to be limited) infringements

[36] See paragraph 17(1) above.

in the case of Medical Uses 1 and 2 can arguably include lost sales where the medical use was Medical Use 3.[37]

(d) Adequacy of damages

(i) The general position

67. Mylan's attempts to suggest that Neurim and/or Flynn would not suffer loss, or not losses of the sort contended for by Neurim and Flynn, were an interim injunction not to be granted thus fail. There is, in my judgment, a clear argument that significant losses will be sustained by Neurim and/or Flynn if Mylan's Generic Product is permitted to compete, even during the limited period between now and the determination (at first instance) of these proceedings.

68. These losses will be two-fold:

(1) First, there will be the losses arising out of direct competition between Circadin and Slenyto and the Generic Product. This will be in the form of diminished volume of sales at a diminished price. These will occur in the period between now and the end of November (Period 1).

(2) Secondly, recovery by Neurim and Flynn in the period after November 2020 (Period 2). In my judgment, whilst there will be a recovery of some price and some volume, it cannot be said that Neurim and Flynn will recover their former position either at once or at all.

69. Generally speaking, damages are an adequate remedy for a tort, including an infringement of a patent. *Terrell* says this:

> "19-227 Many patent cases are not appropriate ones for the grant of an interim injunction because damages would be an adequate remedy for the patentee. Where the infringement causes the patentee to lose sales, provided the defendant keeps proper records of the sales they have made, the court can award damages based upon its assessment of the proportion of the defendant's sales that the patentee would have made and the patentee's usual profit margin.
>
> 19-228 However, there is a well-established line of patent cases in which interim injunctions are commonly granted. These all concern the launch of a generic pharmaceutical product. 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. The argument goes that entry of the generic product(s) will result in a downwards spiral in the price of the product and that even if the patentee were to be successful at trial and remove the generic products from the market, they will not be able to put the price back to previous levels. Examples of cases where this argument has been accepted are listed in the footnote. An exception to this general principle was *Cephalon v. Orchid*.

[37] Another potentially interesting question that might have arisen in this case was whether the interim injunction sought by Neurim and Flynn should be limited to sales actually infringing the Patent – that is, sales by Mylan relating to Medical Use 1 and Medical Use 2. Given my conclusion on Stage 2 of *American Cyanamid* below, that is not a matter I have had to consider, and I should be clear that this question has not formed a part of my reasoning in this judgment. Had I concluded that damages was not an adequate remedy to Neurim and Flynn, then I accept difficult questions regarding the scope of the interim relief would have arisen. These were considered by Birss J in [51]*ff* of *Novartis Pharmaceuticals Ltd v. Dr Reddy's Laboratories (UK) Ltd*, [2019] EWHC 92 (Pat).

> However, that was a case where the infringement claim only just passed the serious issue hurdle, the invalidity arguments looked strong and, most importantly, there was evidence that the patentee had been able to raise the price of the product after temporarily lowering it to compete with competition from parallel imports. Another case in which a patentee's argument of unquantifiable loss by reason of a permanent price depression was rejected was *Actavis v. Icos*. In that case, an injunction pending an appeal to the Supreme Court was sought after the patent was found invalid by the Court of Appeal. There were several aspects of the case that were different from other cases. First, if the appeal to the Supreme Court was successful, the patent would only have a short period before it expired. There would therefore be only a very short period in which the price could be raised. Secondly, the patentee's price was fixed. The court would therefore know on a damages inquiry the price at which it would have sold any product during the next few years. Thirdly, the market for the product in question was flat and not growing in terms of either volume of packs sold or price. Finally, the defendants accepted that every sale made by them would be a sale lost to the patentee."

70. Unsurprisingly, Neurim and Flynn contended that this was a case falling within the "norm" discussed in [19-228] of *Terrell* – where an interim injunction ought to be granted – whereas Mylan contended that this was a case like *Cephalon v. Orchid* – where an interim injunction was inappropriate. I am not attracted to a course whereby I seek to categorise this case into either camp by comparing and contrasting its facts with the facts of other cases. It seems to me that the legal principles are clear, and that – as *Terrell* says – each case turns on its own facts. In short, recognising that this is an area where interim injunctions have in the past been granted, I must consider whether, on the facts of this case, a similar conclusion should pertain.

71. In this case, it seems to me that damages will prove to be an adequate remedy to both Neurim and Flynn. I have reached this conclusion for the following reasons:

(1) The general measure of damages in a patent infringement case is clearly stated. It is the standard tortious measure, the calculation of which was articulated in *Livingstone v. The Rawyards Coal Company*:[38]

> "…where any injury is to be compensated by damages, in settling the sum of money to be given for reparation of damages you should as nearly as possible get at that sum of money which will put the party who has been injured, or who has suffered, in the same position as he would have been in if he had not sustained the wrong for which he is now getting his compensation or reparation…"

(2) In the present case, I can see no reason why Neurim and/or Flynn's losses during both Period 1 and Period 2 cannot properly be calculated, whether it is necessary to calculate lost revenues by reference to all three Medical Uses or individually by reference to each particular Medical Use.[39] Clearly, Neurim and Flynn will have records of their sales to date of Circadin and Slenyto, and they will continue to keep such records. Equally, there is no difficulty in Mylan maintaining and (for the purposes of trial) providing to Neurim and Flynn records of its sales of the Generic Product, differentiating as far as can be done between Medical Use, and providing information as to the price at which the Generic Product sold. (It should be clear

[38] (1880) 5 App Cas 25 at 39. See also, Buckley LJ in *Catnic Components v. Stressline*, [1976] FSR 157 at 162.

[39] That process will depend on the answer to the question that I framed – but did not resolve – in paragraph 66 above.

that, to the extent necessary, I am minded to set out in the order consequential on this application the sort of information that Mylan must keep.)

(3) Thus, in Period 1, Neurim and Flynn will have sales figures (including as to price) for the sale of Circadin and Slenyto as at the beginning of Period 1 and will be able to show how those figures vary over the course of Period 1. *Prima facie*, as it seems to me, Neurim and Flynn's loss will be calculated by reference to the difference between volume of sales and sales prices at the beginning of Period 1 and the lower volumes of sales, at lower prices, during the course of Period 1.

(4) It may be that during Period 1, but for the intervention into the market of Mylan, Neurim and Flynn were anticipating an increase in the volume of sales and/or an increase in the price of individual units sold. I can see no reason why evidence on such points cannot be adduced, and why such increases cannot inform the losses that Neurim and Flynn claim.

(5) All of these losses can – in my judgment – be calculated by reference to information that is or will be in the hands of Neurim and Flynn. But, as I say, it would be appropriate to ensure that proper figures were maintained and disclosed by Mylan for the purposes of the trial of these proceedings.

(6) I turn, then, to the adequacy of damages for any losses sustained by Neurim and Flynn during the course of Period 2. As *Terrell* notes, there have been a number of cases, superficially at least similar to the present, where an interim injunction has been granted in order to prevent unquantifiable damage to holder of the patent. For that reason, I have devoted particular thought as to whether Neurim and Flynn's losses during the course of Period 2 are such that damages would not be an adequate remedy. As to this:

(a) I am proceeding on the basis that the effect of Mylan's entry into the market during Period 1 has consequences that are not reversible by Neurim or Flynn – or, at least, not immediately so.

(b) That being the case, Neurim and Flynn's losses, commencing in Period 1, will continue into (and quite possibly throughout) Period 2. In short, I am prepared to accept that the damage done to Neurim and Flynn's market may be irretrievable.

(c) If, therefore, the avoidance of irretrievable harm to the market position of a patent-holder was the test for an interim injunction, this would be an appropriate case for the granting of such an injunction.

(d) But that is not the test. The question is whether that irretrievable harm to market position cannot be compensated for in damages. I can see no reason why the process of quantification of loss for Period 2 will not be very similar to that for Period 1. Indeed, the process of quantification of loss for Period 2 will be an extension of or extrapolation from the process undertaken in relation to Period 1.

(e) As I have noted, Neurim and Flynn will have an absolutely clear idea of their present market position. It may well be that they have views as to how

that market will develop between now and August 2022. Obviously, such projections will have to be proved on a loss of chance basis, but I see no reason why Neurim and Flynn cannot recover the difference between these projections and what they in fact make in the period between the end of November 2020 and August 2022 (Period 2). Period 2 is actually very limited in duration – Periods 1 and 2 together amount to just over two years – and, as I have noted, there will be considerable market data in the hands of Neurim, Flynn and Mylan to enable the losses in Periods 1 and 2 to be quantified.

72. In short, assuming (as I do) that Neurim and Flynn will be unable to recover their former market position, even if Mylan is injuncted from the end of November 2020, I consider that Neurim and Flynn's losses can adequately be compensated for in damages.

(ii) Two special cases

73. There are two further points which I must consider in this regard:

(1) Mylan is unlikely to be the only producer of generic pharmaceuticals entering the market for Circadin and Slenyto. Mylan is likely to be the "first mover", but not the only "mover". Although the period between now and the end of November 2020 is a short period of time, it seems to me that I must consider whether the entry of a yet further competitor to Neurim and Flynn, in addition to Mylan, would make a difference to the conclusion as to the adequacy of damages that I have reached.

(2) In paragraph 68 of their written submissions, Neurim and Flynn set out a number of "compelling" reasons as to why damages would not be an adequate remedy. Although a number of these have been considered in the course of my analysis so far, it is necessary for me to ensure that all of the adverse consequences to Neurim and Flynn that have been articulated by them are taken into account.

(iii) The first special case: entry of other competitors

74. As I have stated, I proceed on the basis that Neurim and Flynn will succeed at trial, and that they will obtain from the trial judge a permanent injunction against Mylan, even if they fail to obtain an interim injunction from me on this application. That gives Mylan a "first mover" advantage from the date of this judgment, and other generic manufacturers only a limited time period within which to follow Mylan into the market. As I have noted, Period 1 is a period of only six months.

75. Nevertheless, it seems to me that I ought to proceed on the basis that, whilst Mylan is the first mover, the rest of the generic herd is not going to be far behind, and that one effect or consequence of not granting an interim injunction against Mylan will be to open the door to competitors in addition to Mylan.

76. I was provided with some evidence on this. There was some debate as to whether another manufacturer of generic pharmaceuticals – Teva – could enter this market and compete with both Mylan and Flynn. The debate centred on whether a settlement agreement between Neurim and Teva precluded Teva's entry.

77. Once again, it seems to me that the parties were seeking to tempt me down a path of making specific findings of fact when *(i)* the material before me was entirely insufficient for the purpose of making such findings and *(ii)* where the process itself was in any event unsuited to making findings of fact.

78. It seems to me that Mylan's interest in the Circadin/Slenyto market is one that is likely to be replicated in other manufacturers of generic drugs, and that I should not presume that Mylan's "first mover" advantage is so great as to preclude the entry into the market of yet another competitor.

79. Were another competitor to enter the market in Period 1, then I anticipate that whilst Neurim/Flynn's volume of sales and sales prices would diminish to a similar extent as if there were only a single competitor (i.e., Mylan), the cause of Neurim/Flynn's losses would not (in this case) necessarily be attributable only to Mylan. Mylan might very well be able to argue that it was the actions of another competitor that caused loss to Neurim and Flynn. I say nothing about the merits of such an argument, but I can certainly see causation of loss in Period 1 as being an issue that may (depending on the facts) cause Neurim and/or Flynn additional difficulties in terms of the recovery of their losses. It goes without saying that the extent of these losses will be heavily fact dependant; and this is one reason why Mylan's own sales figures during Period 1 may be of importance.

80. Period 2, as it seems to me, gives rise to rather different questions. Clearly, if Mylan is injuncted at the end of November 2020, so too will any other entrant onto the market. In Period 2, Neurim and Flynn will, once again, be alone in the Circadin/Slenyto market, but that market will – as I have described – have been damaged by Mylan's first entry into that market in Period 1. It seems to me that, as a matter of causation, the damage to Neurim and Flynn's market in Period 2 will be entirely attributable to Mylan.

81. In these circumstances, whilst I recognise that the entry of competitors additional to Mylan into the market will cause additional complications to the damages claim of Neurim and Flynn, these additional complications are not sufficient to persuade me that damages are not an adequate remedy.

(iv) The second special case: "consequential effects"

82. Paragraph 68 of Neurim and Flynn's written submissions states:

> "There are compelling reasons why damages would not be an adequate remedy for the Claimants, including the following:
>
> (1) the inevitable and rapid price depression;
>
> (2) the need for Flynn Pharma to cut its prices to meet that competition;
>
> (3) the fact that prices are easy to cut but far harder to restore (impossible in practice);
>
> (4) the green light which Mylan's activities would give to other generics which would then compound (1), (2) and (3); and
>
> (5) the numerous consequential effects of (1) – (4) including:
>
> (a) the impact on the Claimants' investment in research and development largely funded by Circadin;

(b) the impact on the market development Slenyto;

(c) the effect on Flynn's other fledgling products and co-market products;

(d) the impact on Neurim's manufacturing and distribution networks;

(e) the potential loss of or reduction in medical educational programs that both Neurim and Flynn support;

(f) the risk to ongoing and planned clinical trials on several products; and

(g) the prospect of redundancies in both Neurim and Flynn, which are debilitating to small companies and their futures."

83. I have considered points (1) to (4) already: points (1) to (3) were considered in paragraphs 67-73 above; and point (4) was considered in paragraphs 74-81 above. For the reasons I have given in those paragraphs, I consider that damages are an adequate remedy, and that Stage 2 of the *American Cyanamid* process has not been met.

84. Point (5) – the "consequential effects" – has not (yet) been considered by me. But for the fact that Neurim is obviously a company of some substance (albeit of at least an order of magnitude less in size than Mylan) and well able to fund these matters in the interim, these points might have been relevant. But the fact is that Neurim sits on cash of a significant amount and can – in the six months of Period 1 that we are speaking of – fund these activities.[40]

85. I also bear in mind that these consequential losses were always going to arise in the relatively near future, on the expiry of the Patent in August 2022. All that my failure to grant an interim injunction does is to cause these consequences to vest early and (assuming the Patent is indeed infringed) for the limited period of Period 1. Such consequential losses as are inflicted on Neurim and on Flynn will be recoverable by them as damages and all I am considering is Neurim and Flynn's ability to fund these losses pending an assessment of damages. Since Neurim and Flynn are able to do so, my conclusion that damages are an adequate remedy is unaffected.

86. It follows that Neurim and Flynn's application for an interim injunction fails at Stage 2 of the *American Cyanamid* process. Mylan additionally contended that, under Stage 3 of this analysis, the undertaking in damages that Neurim and Flynn would be obliged to give as the "price" for the injunction would not adequately compensate them. Out of deference to the arguments that I heard, I propose briefly to address this point.

J. STAGE 3: ARE DAMAGES (PURSUANT TO THE UNDERTAKING) AN ADEQUATE REMEDY TO MYLAN?

87. I do not understand there to be any issue but that Neurim and Flynn are prepared to offer the undertaking in damages; and that Neurim and Flynn are in a financial position to make good on that undertaking if called upon to do so.

[40] This material was confidential to Neurim and therefore I do not specifically reference it in this judgment.

88. The question, therefore, as was the case with Neurim and Flynn's losses at Stage 2, is whether Mylan's loss, in being deprived of the opportunity of competing in the market for Circadin and Slenyto, is capable of being adequately compensated for in damages.

89. At first sight, just as in the case of Neurim and Flynn, this appears to be simply a case where damages can adequately be assessed. Instead of calculating what Neurim and Flynn lose by reason of Mylan's competition, it is necessary in Mylan's case to calculate what Mylan has failed to gain in being deprived of this opportunity. That said, there are a number of factors that render this assessment of damages more difficult:

(1) Neurim and Flynn know the market in which they are selling. If Mylan compete with Neurim and Flynn through the Generic Product, and Neurim's and Flynn's volume of sales and unit price falls, the inference that this has been caused by the new entrant to the market will be an obvious one.

(2) Whilst no doubt Mylan have plans as to how to enter the market, and have made forecasts as to what sales revenues they might hope to generate from the sale of the Generic Product, these will be projections of an altogether more uncertain nature compared to the assessment of Neurim's and Flynn's losses in Period 1.

(3) More to the point, if enjoined, Mylan will lose the advantage of the "first mover". As I have noted, Mylan's interest in the Circadin/Slenyto market is one that is likely to be replicated in other manufacturers of generic drugs. The effect of an interim injunction would be to remove or diminish Mylan's "first mover" advantage. Thus, were an interim injunction to be granted, but the Patent to be invalidated at trial, Mylan would lose its advantage and start on an equal footing with its rivals. The "first mover" advantage, Mylan contended, was impossible to quantify in damages. Although I do not accept that damages would be "impossible" to quantify, I have some sympathy with this submission.

90. My conclusion is that it would be materially harder to assess Mylan's loss than that of Neurim or Flynn. I do not say that it could not be done, but the uncertainties inherent in the process would be formidable, and considerably more difficult in my judgment than would be the case with the losses sustained by Neurim and Flynn were the interim injunction not to be granted.

K. STAGE 4: THE BALANCE OF CONVENIENCE

91. Given the conclusions that I have reached, it is again strictly unnecessary to consider this stage. Again, however, because these factors were addressed in submissions, I should briefly set out my views:

(1) ***No adequate remedy on either side.*** I have concluded that damages would be an adequate remedy for Neurim and Flynn, and a less adequate remedy for Mylan. I would hesitate to conclude that an award of damages for Mylan would be inadequate. I would merely go so far as to say that any award of damages to Mylan would be materially more uncertain than calculating Neurim and Flynn's loss.

(2) ***David against Goliath.*** On behalf of Neurim and Flynn, Mr Waugh, QC pointed out that Mylan is at least an order of magnitude larger and more powerful than Neurim and Flynn, who are much smaller players in the pharmaceutical market.

Mr Waugh also made the point that Circadin and Slenyto, as products, are far more important to Neurim and Flynn than the Generic Product is to Mylan. In other words, the Generic Product is just another pharmaceutical in a vast range of pharmaceuticals being sold and developed by Mylan, whereas Circadin and Slenyto are "flagship" products for both Neurim and Flynn. To an extent, I have taken this into account. More particularly:

(a) It seems to me that a difference in economic size *per se* is irrelevant. The fact that a claimant is economically huge and defendant economically insignificant (or *vice versa*) is not a matter that a court should take into account when such parties come before a court, unless this mismatch in economic power can be shown to be relevant to some factor that the court should take into account.

(b) Thus, were it the case (which is not the case here) that Neurim and Flynn would not be able to continue their business, through lack of funds, were I not to grant the injunction, then that would militate strongly in favour of granting the injunction. That, obviously, is a factor that goes to the adequacy of damages. To take an entirely hypothetical example, it would obviously be material to the granting of an injunction were a failure to do so to drive the party seeking interlocutory relief out of business. This is not a factor that is in play in this case.

(3) ***Clearing the way.*** In *SmithKline Beecham plc v. Apotex Europe Ltd*,[41] Aldous LJ considered whether the manufacturer of generic drugs ought to "clear the way" to market by commencing proceedings to achieve clarity as regards any patents that might operate as a barrier to selling a particular generic product in that market:[42]

> "Apotex rightly submitted that there was no obligation on a potential defendant to start proceedings. However this was a case where Apotex intended to come on to the market with their product and they must have realised, back in November 2001, that SB would be likely to seek an interlocutory injunction if there was an arguable case of infringement. It was Apotex who knew the process that was to be used and when they intended to launch their product, but they refrained from telling SB until the late autumn of 2002. If they had wanted to they could have had the issue of infringement and validity decided before launch. They chose not to do so with the result that there was potential injustice whichever way the court decides."

As to this:

(a) In my judgment, "clearing the way" is a relevant factor to take into account when considering whether the party opposing the grant of an interim injunction would adequately be compensated for in damages awarded pursuant to the undertaking in damages.

(b) If, by failing to take steps that could sensibly have been taken, a party has put itself into a position where damages are going to be inadequate or less

[41] [2003] EWCA Civ 137 at [8] and [9].

[42] At [39].

adequate than they otherwise would be, then that is a factor that must be taken into account.

(c) In the present case, the Patent was granted on 10 May 2017, but that grant was opposed by Mylan and – in November 2019 – it became clear that the opposition would be successful (albeit that the written decision of the EPO Opposition Division was not published until 2 January 2020). It is certainly true that Mylan could have commenced proceedings in this jurisdiction for a declaration that the Patent was invalid; and Mylan did not do so. I do not consider Mylan's point that a grant of a patent by the EPO spans all of the jurisdictions of the EU and that it would be a waste of resource to challenge the Patent in each of those jurisdictions. Obviously, the "clearing the way" point applies to those jurisdictions where the generic manufacturer intends to market, and it is clear (given the size of the UK market) that Mylan intended to launch its Generic Product in the UK in particular.

(d) Given that Mylan has been assiduous in obtaining a marketing authorisation, it seems to me that there is no proper reason why Mylan could not have taken the initiative in relation to the Patent's validity. That Mylan did not do so is, as it seems to me, a factor that I should take into account when considering the extent to which damages are an inadequate remedy.

In short, I consider that this point narrows the difference between Neurim and Flynn on the one hand, and Mylan on the other, in terms of how adequate damages would be as a remedy. However, since I have concluded that damages would be an adequate remedy for Neurim and Flynn, this point makes no difference to my decision.

(4) ***Status quo.*** I accept that the *status quo* points towards the granting of an injunction: but this is not, in this case, a particularly strong factor and in any event cannot affect my conclusions as to the adequacy of damages.

(5) ***Third party interests.*** Shortly before the hearing, I received a communication from solicitors for the Secretary of State for Health, writing on behalf of the National Health Service in England. That communication referred to the application being made by Neurim and Flynn and stated:

> "If the injunction is granted and/or continued on an interim basis, but later discharged, the NHS may well suffer substantial losses as a consequence of the delayed generic entry (since in those circumstances, but for the interim injunction, generic entry would be achieved sooner and the prices for Circadin would likewise decrease sooner).
>
> It is for this reason that the Court of Appeal has accepted that it is current practice in the Patents Court when an application for an interim injunction in respect of a pharmaceutical is sought to require the patentee to give notice to the Department of Health of the application in case it too wishes to seek a cross-undertaking in damages in addition to the usual cross-undertaking provided in favour of the respondent (see *SmithKline Beecham plc and others v. Apotex Europe Ltd and others*, [2006] EWCA Civ 658 at [77] *per* Jacob LJ). The same rationale is applicable in relation to the NHS in Wales, Scotland, and Northern Ireland. It is also for that reason that section 10 of the Patents Court Guide requires the applicant to provide notice to the Department of Health.

> The position of third parties, such as the NHS, is one that the Court can properly take account of in exercising its discretion when deciding whether or not to grant the injunction (see *SmithKline Beecham* above, [27]). The unique position of the NHS in such matters, recognised by the courts, is such that it is just and convenient for it to benefit from a cross-undertaking in damages, should the Court grant the Claimants' application.
>
> Accordingly, if the injunction is granted and/or continued at the hearing tomorrow, our clients respectfully request that the following cross-undertaking is provided…"

The precise terms of the cross-undertaking sought are not important. Mr Waugh, QC, on behalf of Neurim and Flynn indicated to me that his clients would have no difficulty in principle in providing such an undertaking. As it is, for the reasons that I have given, the question of a cross-undertaking does not arise. However, it does seem to me that the interests of participants in a market where the market price is likely to be materially affected by the entry of a generic product are interests that ought to be considered by the court not merely when framing a cross-undertaking in damages where an interim injunction is going to be granted, but also when considering whether the injunction ought to be granted at all:

(a) In *SmithKline Beecham plc v. Apotex Europe Ltd*, Jacobs LJ noted that "the position of third parties or the public who may be affected by the injunction is a matter which the court can take into account in exercising its discretion".[43]

(b) Here, the granting of an interim injunction would have had the effect of protecting not merely the sales price of Circadin for its patented purpose, but also the price in those cases where Circadin was sold for other medical uses (i.e. Medical Use 3).

(c) Had I been minded to grant an interim injunction, I would have wanted to have heard further submissions on whether, in these circumstances, the granting of an injunction would be appropriate.

L. DISPOSITION

92. For the reasons that I have given, I decline to make an interim injunction in this case.

[43] [2006] EWCA Civ 658 at [77].

ANNEX 1

(footnote 1)

LIST OF TERMS AND ABBREVIATIONS USED IN THE JUDGMENT

TERM/ABBREVIATION	FIRST USE IN THE JUDGMENT
Circadin	Paragraph 3
EPO	Paragraph 8
Flynn	Paragraph 1
Generic Product	Paragraph 9
IP Enforcement Directive	Paragraph 23
label	Paragraph 5(2)
Medical Use 1	Paragraph 63
Medical Use 2	Paragraph 63
Medical Use 3	Paragraph 63
Mylan	Paragraph 8
Neurim	Paragraph 1
off-label	Paragraph 5(2)
Patent	Paragraph 1
Period 1	Paragraph 19
Period 2	Paragraph 19
Slenyto	Paragraph 3
Terrell	Paragraph 34 footnote 23