Neutral Citation Number: [2022] EWHC 954 (Pat)

Case No: HP-2021-000040

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

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

Date: 26th April 2022

Before :

THE HON MR JUSTICE MELLOR

- -

Between :

(1) NEURIM PHARMACEUTICALS (1991) LIMITED **(2) FLYNN PHARMA LIMITED**	**Claimants**
- and -	
TEVA UK LIMITED	**Defendant**

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- -

Mr Andrew Waugh QC (instructed by **Gowling WLG)** for the First Claimant (and by **Pinsent Masons LLP)** for the Second Claimant
Miss Charlotte May QC and **Edward Cronan** (instructed by **Bird & Bird LLP**) for the **Defendant**

Hearing date: 12th April 2022, Confidential Judgment provided in draft 20th April.

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Non-Confidential 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.

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THE HON MR JUSTICE MELLOR

Mr Justice Mellor:

Introduction

1. By application notices dated 14th March 2022, the Claimants applied first for expedition and second for interim injunctive relief against the Defendant (Teva). The First Claimant (Neurim) is the registered proprietor of the patent in suit and the Second Claimant (Flynn) is the exclusive licensee. Roth J granted expedition on the papers, enabling the Claimants to secure a hearing which was listed before me on 12th April 2022. At this hearing, the injunction which the Claimants seek is, in summary, an Order to restrain Teva (howsoever acting) until judgment in this action or further Order in the meantime from disposing, offering for sale or disposal, selling or supplying:

> any generic version of the Claimants' Circadin product to which the Defendant's Marketing Authorisation (PL 00289/2202) relates, including under any other name or marketing authorisation, or any other product that falls within any claims of EP (UK) 3,103,443 ("the Patent") or that has been manufactured by any process that falls within any claim of the Patent.

2. The Patent expires on 12 August 2022. Circadin is the brand name for the drug melatonin. Melatonin is a naturally occurring hormone. The Patent (EP443) in its amended claim 1 claims, in a prolonged release formulation, the use of melatonin 'in the manufacture of a medicament for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterised by non-restorative sleep'.

3. Currently, there are three melatonin products on the market in the UK: Circadin, Melatonin Mylan and Teva Melatonin, although there is hot dispute as to the position of Teva Melatonin.

4. In most cases, an application for an interim injunction is issued at or around the same time as the claim form. However, in this case the claim form was issued on 5th November 2021 and the first warning shot to Teva was fired on 25th June 2021. These dates indicate that there is an unusual history to this application, a topic I will have to explain further below because of its impact on the status quo. The history feeds into the other principal issue: whether the refusal of this interim injunction against Teva will lead to a downward price spiral.

Applicable legal principles

5. There was no real dispute as to the applicable principles. Both sides chose to characterise the *American Cyanamid* approach as comprising the first four stages set out below. I have slightly restated the fourth. Teva drew attention to the paragraph in Lord Diplock's judgment in which he explained the fifth stage, which I have added here, not least because I have always understood it to be part of the correct approach and sometimes the crucial part:

    i) Is there a serious issue to be tried?

ii) Are damages an adequate remedy for the claimant?

iii) If not, are damages under the cross-undertaking an adequate remedy for the defendant?

iv) If damages are not adequate for either side, where does the balance of the risk of injustice lie?

v) 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.

6. Beyond the basic test, each side sought to emphasise certain further general points, some of them having arisen in particular in patent cases. Again, none of these additional points were disputed and I can combine the points from each side as follows:

i) Serious issue to be tried:

> 'The general principle is now well established that, on an application for an interim injunction, the court should not attempt to resolve critical disputed questions of fact or difficult points of law on which the claim of either party may ultimately depend, particularly where the point of law turns on fine questions of fact which are in dispute or are presently obscure': *Sukhoruchkin v Van Bekestein* [2014] EWCA Civ 399 at [32].

ii) Adequacy of damages: the more uncertain their quantification, the more likely that damages will not be deemed to be adequate: *Leo Pharma A/S* v *Sandoz Ltd* [2008] EWCA Civ 850 [23]-[25].

iii) The issue of adequacy of damages is a matter for judicial evaluation in each case, but the boundary between adequate and inadequate is not a precise one: *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2020] EWCA Civ 793 ('*Neurim CA Int Injn Jmt'*) at [16] per Floyd LJ:

> '16. As the judge noted, when Lord Diplock spoke of damages being an "adequate" remedy, he was not suggesting that damages must provide a perfect remedy. As the judge also observed, there comes a point where "damages as a remedy falls so far short of the perfect, that the remedy can no longer be described as adequate". I agree with this. The boundary between the adequate and the inadequate is not a precise one. It is a matter for judicial evaluation on the evidence in any given case whether or not the boundary is crossed. If it is not crossed in relation to the claimant's loss then, normally, an injunction will not be granted.'

iv) As Teva pointed out, the adequacy of damages to the Claimants in the First Mylan action (i.e. at stage 2 of the *American Cynamid* approach) was considered in relation to two periods: "period 1" being the period in which the injunction will take effect pending trial, and "period 2" being the period between trial and expiry of the patent in suit. As Floyd LJ explained at [51]-[52], from the point

of view of the patentee it is more likely to be period 2 that provides the basis for unquantifiable loss (although it did not in that case):

> '51. It is true that in some, indeed many, pharmaceutical patent cases the courts have treated the patentee's lost sales and loss due to price depression as giving rise to unquantifiable loss for the purpose of stage 2. Comparisons with other cases for this purpose usually reveal differences on the facts which render them unhelpful. A number of features of the present case, in my judgment, make the court's task in assessing the loss to Neurim and Flynn relatively straightforward. First, and most importantly, Neurim and Flynn have, and have provided to the court, reasonably detailed forecasts of their expected sales revenues in Periods 1 and 2. These can form the basis of the court's calculation of the position which Neurim and Flynn ought to have been in, but for Mylan's infringement, for both Periods. The object of the inquiry as to damages will be to restore their revenues to those levels. Secondly, in respect of Period 1, the court will have Flynn's and Mylan's actual sales figures and the prices at which they have sold. This can form the basis for the lost sales and price depression claim for Period 1, and I see no reason to suppose that this will be inadequate.
>
> 52. At the start of Period 2 the price for Circadin may have been depressed by the period of generic competition in Period 1. The court will, however, know what this price is. During this period Circadin will not be exposed to generic competition, and to that extent the monopoly will be restored, albeit that it will no longer be possible to charge the monopoly price, because the court is likely to accept the evidence that it will not be possible to raise the Circadin price to its former levels without loss of customer goodwill. I agree with the judge that the calculation for Period 2 will require an extrapolation to determine Flynn's likely sales and prices in Period 2, and to that extent it will be marginally less robust. Damages are, however, to be "assessed liberally" without going so far as to punish the infringer: see Pneumatic Tyre Co Ltd v Puncture Proof Pneumatic Tyre Co Ltd (1899) 16 R.P.C. 209 at 215. I therefore agree with the judge that damages will provide an adequate remedy for the loss in Period 2 as well.'

v) The extent and nature of the price depression which Floyd LJ referred to in [51] above may depend on the number of generic entrants in the market. As Floyd LJ observed in *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 583 (where the CA were concerned with the grant of an interim injunction pending appeal where the patentee had lost at the first instance trial) at [23]:

> 'The arguments [before the first instance judge, Birss J] were the familiar ones in the pharmaceutical patent field. On Novartis' side it was maintained that Novartis would suffer harm from the effect of Hospira and other generic companies undercutting its monopoly price. It would have to reduce its prices or lose market share. It would be difficult to raise its prices again if successful on appeal. If it did

> so, it would face damage to its reputation. On Hospira's side, Hospira would or might lose the advantage of being the first to market, the so-called 'first mover advantage'. The first mover advantage is the advantage that the first generic to market enjoys when it enters the market at a price near the monopoly price in the absence of other generic competition. In such circumstances it can reap far greater rewards than second and subsequent companies who would be likely to cause an uncontrolled downward price spiral.'

vi) Whether the price depression manifests itself in a downward spiral in price is 'intensely fact sensitive': see Floyd LJ in *Neurim CA Int Injn* at [13]:

> 'Whilst it is recognised that the entry of a first generic competitor may be at a price not far below that of the branded product, much fiercer price competition can be contemplated where two or more generic manufacturers are competing with each other on price. The price will accordingly be driven down faster and further. Whether a price spiral will occur in the period until trial in any given case is intensely fact sensitive.'

vii) The same point was made by Arnold LJ in his recent judgment on Mylan's renewed application to stay the injunction granted by Marcus Smith J following the trial on EP443: *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd* [2022] EWCA Civ 370 ('*Neurim CA Stay Jmt'*) at [30]:

> '…. the presence of two or more generic suppliers commonly leads to a price war between the suppliers, and hence a downward spiral in the price which is apt to cause the patentee damage which is difficult to quantify even if the patent monopoly is subsequently restored by an injunction.'

viii) More generally but as is clearly recognised in the citations above, once the monopoly price previously charged by the patentee has been depressed (whether a price spiral occurs or not), it is often difficult if not impractical to restore the price to previous levels: see e.g. *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 583, per Floyd LJ at [63]:-

> "The unquantifiable damage to the claimant seems to me to outweigh that to the defendant. From the evidence, an immediate downward price spiral, even in the period between now and the hearing of the appeal, seems highly likely if not inevitable. The fact that the claimant can divert sales to Sandoz does not vitiate this conclusion. They will still be faced with the fact that the market will have become accustomed to lower prices, and restoring their monopoly position will, if possible at all, be accompanied by harm of other kinds."

ix) Balance of convenience:

> 'The balance of convenience is simply 'the basic principle…that the court should take whichever course seems likely to cause the least

> irremediable prejudice to one party or the other': *National Commercial Bank Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16, per Lord Hoffmann at [17].

x) Status quo: finally, as regards the status quo, in *Frank Industries v Nike* [2018] EWCA Civ 497 Lewison LJ explained (Kitchin LJ agreeing) at [19]:

> '19. The status quo to which Lord Diplock referred is as he clarified in the later case of *Garden Cottage Foods Limited v The Milk Marketing Board* [1984] AC 130, the status quo immediately before the issue of proceedings, or the application notice if substantially later, rather than the status quo when the conduct complained of began.'

7. For the Claimants, Mr Waugh QC also relied on this passage from the latest edition of Terrell (19th Edition) at 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 [fn364]. An exception to this general principle was *Cephalon v Orchid*. 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.'

8. Although this passage elevates the price spiral argument to a 'general principle', the two exceptions mentioned illustrate the point made in the citation above by Floyd LJ that whether a price spiral will occur in the period until trial in any given case is intensely fact sensitive.

9. Mr Waugh QC for Neurim made an additional point in these terms:

> 'Damage for this purpose includes harm that is not normally recoverable in damages – see Terrell 19th ed'n at 14-175 - 14-178 citing *SmithKline Beecham* v *Apotex Europe Ltd* [2003] EWCA Civ 137 per Aldous LJ at [18].'

10. This needs a bit of unpacking. Carnwarth LJ (as he then was) at [43] made the same point as Aldous LJ in [18] and, to my mind, in clearer terms (see the passage I have underlined below):

> 'Aldous LJ has also quoted from Lord Diplock's classic statement in American Cyanamid Co v Ethicon Ltd [1975] A.C. 396, 406, where he said:
>
> > 'The object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he would not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial …'
>
> The purpose of an interlocutory injunction therefore is protection, not just against 'loss which would sound in damages', but against violation of any right where damages would not be adequate compensation. An obvious example of the need for that wider formulation is the case of trespass to land. A landowner whose title is not disputed is normally entitled to an injunction to restrain trespass on his land, even if the trespass does not harm him (see Patel v WH Smith (Eziot) Ltd [1987] 1W.L.R. 853, 858F).'

11. In the present case, the Claimants complain of the violation of their patent monopoly. Claim 1 of EP443 is relatively narrow and not every sale by Teva of melatonin will constitute or entail a use within claim 1. The Claimants' point is that without their marketing authorisation (which refers, effectively, to the use covered by claim 1), Teva would not be on the market at all. Hence, the Claimants suffer damage caused by Teva's sales outside the claim, for which the Claimants may not be able to recover damages.

12. I have kept all these principles in mind in my analysis below.

13. Before leaving the caselaw, I should also mention some passages from the recent *Neurim CA Stay Jmt*, recognising that, for the purposes of this judgment, these passages represent a mixture of principles of law and conclusions on the facts then before the Court. I quoted above from part of [30] in the judgment of Arnold LJ in the *Neurim CA Stay Jmt*. I will set out here the full terms of his [30]:

> 'Dr Fakes also explained that the Claimants had commenced proceedings against Teva. We were informed by counsel for the Claimants that they had recently applied for an interim injunction in those proceedings, but the Claimants had failed to place the evidence relied upon before this Court and so we do not know what the basis for that application is. Counsel for the Claimants nevertheless submitted that, if this Court granted Mylan a stay, that would adversely affect the Claimants' prospects of obtaining an interim injunction against Teva. I do not accept that that is necessarily so. The status quo is that there is only one generic supplier in the market place. In that situation it is generally not in the interests of the generic supplier to engage in a price war (as opposed to undercutting the patentee by a certain percentage), and there is no suggestion that Mylan have done so. By contrast, the presence of two or more generic suppliers commonly leads to a price war between the suppliers, and hence a downward spiral in the price which is apt to cause the patentee damage which is difficult to quantify even if the patent monopoly is subsequently restored by an injunction. Just as preservation of the status quo favours a stay of the injunction against Mylan, it favours the grant of an interim injunction against Teva. In saying that, I am not intending to pre-judge the outcome of that application. As I have explained, we have not seen the Claimants' evidence in support of it, let alone any evidence filed by Teva resisting it. There may be good reasons for concluding that, in the particular circumstances of that case, an interim injunction against Teva should be refused. The point is that the outcome is not dictated by the grant of a stay in this case.'

14. Amongst the points I must consider below are (a) whether the status quo is that there is only one generic supplier in the market place and (b) whether the facts support the Claimants' 'downward spiral' argument.

15. Both Birss and Newey LJJ agreed with Arnold LJ's conclusions, but, it seems, differed slightly as to where the line between the adequacy or not of damages for the Claimants lay. This point again emphasises that the evaluation is not only fact sensitive but that reasonable minds may differ on the evaluation itself.

The relevant factual background

16. It helps to understand the complex background to know that it involves three UK actions and two sets of EPO proceedings.

17. Melatonin Mylan was launched by Mylan in the UK in September 2020, by which time Mylan was already being sued for infringement in what I will call the First Mylan action under the parent patent owned by Neurim, EP(UK) 1,441,702 (EP702), which contained essentially the same principal claim as in EP443. An expedited trial was ordered in the First Mylan action, a principal reason why the Claimants failed to secure an interim injunction against Melatonin Mylan either from Marcus Smith J or the Court of Appeal.

18. Shortly after Marcus Smith J handed down his judgment from the trial of the First Mylan action (in which he found EP702 valid and infringed), EP702 was revoked when

Neurim withdrew its appeal at the EPO against the Opposition Division's decision that the patent was invalid.

19. EP443 (a divisional of EP702) was conveniently still in prosecution. Neurim secured the grant of EP443 on 30 June 2021 and commenced the Second Mylan action on the same day. EP443 has been opposed by various entities, including Mylan and Teva, but there is no prospect of those oppositions being decided before expiry of the Patent.

20. The third action is this one, commenced against Teva as I have indicated on 5 November 2021.

21. Within the structure of the First Mylan action and the Opposition to EP702, the following chronology of events summarises the relevant background:

> 10 May 2017: EP702 granted.
>
> 9 February 2018: Mylan filed a Notice of Opposition. Oppositions also filed by Teva and Aspire Pharma.
>
> 20 November 2019: the Opposition Division at the EPO finds that EP702 lacked novelty. Neurim appealed to the TBA, which suspended the revocation of the Parent Patent pending the outcome of that appeal, in the usual way.
>
> Early 2020: Mylan obtains a marketing authorisation for generic melatonin and refuses to provide notice of any launch of their product.
>
> 14 February 2020: Claim form in the EP702 action issued.
>
> 17 February 2020: Neurim serve proceedings on Mylan for infringement of EP702. Mylan denies infringement and counterclaims that EP702 is invalid by a Defence and Counterclaim served 1 April 2020.
>
> 2 March 2020: Neurim applies for a preliminary injunction (PI) pending trial in the light of Mylan's refusal to give any undertaking not to launch.
>
> 6 March 2020: Mylan applies for expedition of EP702 trial, to which Neurim agrees on 13 March 2020. On 19 March 2020, Nugee J ordered an expedited trial.
>
> 20 May 2020: Marcus Smith J hears the PI application, and in a judgment of 3 June 2020 refuses it [2020] EWHC 1362 (Pat). His refusal was upheld by the Court of Appeal in a judgment of 24 June 2020: [2020] EWCA Civ 793. The reasoning of both Courts was based partly on the fact that the trial had been expedited and there was limited time for damage to accumulate. The Supreme Court, despite considering that there was a point of law of public general importance, refused to give permission chiefly because of the imminence of trial.

September 2020: Mylan launched its generic melatonin product.

29 October – 5 November 2020: the EP702 trial was heard by Marcus Smith J, who in a judgment of 4 December 2020 found EP702 valid and infringed [2020] EWHC 3270 (Pat). Mylan admitted infringement if EP702 was valid.

16 December 2020: form of order hearing where Marcus Smith J made a number of oral orders, and refused Mylan's application for permission to appeal his validity findings. Certain other matters were left to be agreed in the light of the TBA hearing which was to take place on 17-18 December 2020.

18 December 2020: the TBA gave an oral opinion that EP702 was invalid for insufficiency, in the light of which Neurim withdrew its appeal. The suspensive effect of the Opposition Division's decision ceased and EP702 was revoked.

30 December 2020: Marcus Smith J revoked his oral order of 16 December 2020, the terms of the order not having been settled in writing. The Judge made no order on Mylan's counterclaim and recorded a declaration that EP702 had been revoked *ab initio,* a point he also stated in his judgment on the consequential issues.

12 March 2021: Marcus Smith J made a further consequential Order in the EP702 action. See also his judgment on the consequential issues [2021] EWHC 530 (Pat).

22. At this point, it will cause less confusion if I relate the steps taken in the Second Mylan action and the second EPO Opposition, separately from events directly relating to Teva. The relevant chronology is as follows:

28 January 2021 and 17 March 2021: Since the opposition procedure operates post-grant, Mylan filed third party observations at the EPO bringing the insufficiency argument raised before the TBA to the attention of the examiner of what became EP443.

14 April 2021: the Examining Division issued its Notice of Intention to Grant EP443, stating that Mylan's third party observations had been examined but found not to be relevant.

19 April 2021: Mylan filed a complaint that the Examining Division had not properly considered its third party observations. On 4 May 2021, the EPO replied confirming that Mylan's third party observations had been debated, that a reasoned decision had been taken internally about how to consider them, and that the point relating to sufficiency had been thoroughly discussed.

4 June 2021: the Examining Division issued its Decision to Grant.

30 July 2021: On the Claimants' application for an expedited trial of preliminary issues in the Second Mylan action, I grant the application, embodied in my Order sealed on 12 August 2021.

15-17 December 2021: Trial of the Preliminary Issues in the Second Mylan action before Meade J.

24 January 2022: Judgment of Meade J on preliminary issues, referring matters to Marcus Smith J.

10 February 2022: Provisional judgment of Marcus Smith J (on the papers) confirming his previous judgment regarding EP702 stands in respect of EP443.

4 March 2022: Hearing before Marcus Smith J in relation to his provisional judgment.

7 March 2022: Order of Marcus Smith J granting a final injunction against Mylan Melatonin to take effect from 10 March 2022.

8 March 2022: Further Judgment of Marcus Smith J in respect of 'lay patient' argument. Refuses stay of injunction.

10 March 2022: Order of Arnold LJ granting a stay of the injunction against Mylan until later of the determination of Mylan's application for permission to appeal or 16 March 2022.

16 March 2022: Court of Appeal hearing at which Mylan is granted permission to appeal against the Order of Marcus Smith J dated 7 March 2022 and a stay of the injunction pending judgment on the appeal.

29 March 2022: Court of Appeal judgments: [2022] EWCA Civ 370, re PTA and Stay; [2022] EWCA Civ 359 on the Claimants' appeal on the exclusive license issue.

16 (or 19) May 2022: Prospective date for the expedited hearing of Mylan's appeal.

12 August 2022: EP443 expires.

23. Against that background, I turn to consider the Claimants' application

The evidence on this application

24. There were five rounds of evidence served for this application. This reflected the changing nature of the Claimants' case as regards Teva's position on the UK market for melatonin. Although I will have to delve into parts of the evidence in more detail, in summary, the evidence evolved as follows.

25. In October 2021, the Claimants were told via solicitors that Teva had launched its product in October 2021. The Claimants also saw the announcement on Teva's website because this triggered the letter before claim. Dr Fakes' evidence is that he and his

Commercial Director, Ms Lesley Jarvis, tried on numerous occasions to purchase or obtain samples of Teva Melatonin, and Dr Fakes exhibits copies of the relevant entries from Ms Jarvis' notebook. All these attempts were unsuccessful down to 11 March 2022.

26. However, Dr Fakes relates that late in the afternoon on 8 March 2022, Ms Jarvis told him that she had received a phone call from one of her contacts at a large independent wholesaler that a representative of Teva had offered them Teva Melatonin at competitive prices lower than Flynn's and that Teva were offering to indemnify the supplier who purchased. Dr Fakes says this was the first indication he received '*that Teva is taking active steps to materially enter the market in the UK'*.

27. On 10 March 2022, having provided signed confidentiality undertakings, Dr Fakes was shown the confidential Bird & Bird letter containing the sales volumes of Teva Melatonin since October 2021. Despite these figures, Dr Fakes (as he states in his evidence) took the view that the alleged sales were '*not material'* and that the Teva product had not been supplied to patients through retail pharmacies. His conclusion was that '*Teva was not on the market in any material way as at 11 March 2022'*. This (or the view that Teva were not on the market) is a view which he must have formed before seeing the letter, because he says in terms '*Bird & Bird's letter does not change my view that there is no evidence that Teva were materially on the market*.'

28. Dr Fakes' evidence is carefully worded. It is clear it was so worded to provide the Claimants with the argument that the status quo position was that Teva was not (really) on the market.

29. The hearing of Mylan's renewed application for a stay of the final injunction granted by Marcus Smith J took place on 16 March 2022. It is clear that Arnold LJ was given the impression from the Claimants that Teva was not on the market. I was shown the transcript of that hearing. Counsel for the Claimants evidently felt constrained as to what she was able to submit to the Court of Appeal. What she did say was as follows (at pp47-48):

> However, my
> Lords, I feel it is my duty to bring the following to your
> attention. I apologise to the court that I do not have
> evidence in this regard but this is something that only
> happened in the last day or two, which is that we have
> indications -- my Lords, I regret I have to give this to you
> on instructions -- my clients have indications in the market
> that Teva are manoeuvring to enter fairly forcefully and as
> a consequence we took the liberty of issuing a preliminary
> injunction application against them at court either yesterday
> or the previous day. Again, I apologise that given the timing
> with everything else that has been going on, I do not have any
> evidence to support that. However, that is the position and,
> of course, my Lords, if the injunction here is stayed then
> plainly as a matter of common sense the chances of my client
> succeeding on that preliminary injunction against Teva will be
> slim to the extreme and, in my submission, that will be
> a clear green light for Teva to stop, as we would say, waiting

> 1 in the wings to firmly enter and jump into the middle of the
> 2 stage.

30. This prompted further exchanges between Counsel and Arnold LJ in which he acknowledged (as I do) that a lot of work had been undertaken on the Claimants' side in a very short space of time.

31. With the benefit of 20:20 hindsight, it would have been better if the Claimants had asked permission of Teva to show the confidential Bird & Bird letter of 9 March 2022 to the Court of Appeal and had done so. Mr Waugh submitted it would have been in the Claimants' interests to have done so and there is some force in that. However, the clock cannot be turned back and I have to deal with the situation which now presents itself.

32. Returning to the way in which the evidence on this application developed, Root 1 was served, to which Dr Fakes responded in his second witness statement. In that statement he did not develop his view that Teva's sales were not material but he continued to cast doubt on Teva's stated position – he made an observation that if Teva had been on the market since October 2021, he would have expected the Drug Tariff price to have been recategorized to Category A or M before now. He mentioned that the first sample of Teva Melatonin he had been able to obtain was sourced 'last week' through a customer of AAH and reached him on 28 March 2022.

33. The Claimants appear to have changed tack once Teva served their evidence in answer in Reynolds 1 and Bleasby 1 (dated 5th April). In their evidence, they strongly refuted Dr Fakes' view. Ms Bleasby also provided sales figures for March 2022, which were a very considerable increase over the average monthly sales for October 2021-February 2022. Ms Bleasby explains the variations in those monthly figures and also gives her view why the sales volumes jumped so radically in March 2022. In part, her explanations were that sales volumes in December were higher because Teva's customers wanted to meet rebate targets by the end of the calendar year and higher in March because of targets connected with agreement year-end dates at the end of March and because Teva had some aging stock which it wished to dispose of (this latter explanation being one on which Mr Waugh poured scorn).

34. Ms Bleasby also explained in detail how the NHS Drug Tariff works and the mechanism by which a drug may be re-categorised from category C to A or M. The Drug Tariff price is the sum reimbursed to the dispensing pharmacy. It represents a ceiling within which the pharmacy, wholesaler and manufacturer take their profit. In general, the system encourages pharmacies to obtain their drugs from wholesalers at the cheapest price possible, so as to maximise the pharmacy's profit. This places pressure on the supply chain and encourages wholesalers and manufacturers to offer competitive pricing. However, the prices of drugs are influenced by generic availability. Depending on the level of generic competition in the market, drugs are allocated to a particular category C, A or M.

35. In summary, Category C products are not generally available as a generic. To be in Category A or M, the medicine must be available as a generic. Decisions as to whether or not to move a product from Category C to Category A or M are taken by the Secretary of State, after consultation with the Pharmaceutical Services Negotiating Committee

(PSNC) (the point here is that the decision is nothing to do with Teva, as Dr Fakes insinuated might have been the case).

36. The reimbursement price for Category A products is an average price listed in the Drug Tariff, weighted by the following 4 manufacturers and suppliers: AAH, Alliance Healthcare, Teva and Accord Healthcare. To be considered for Category A, the product has to score 4 in the weighted formula. To be in Category M, a drug must be available as a generic. The guideline criteria for Category M are that the drug must be available from more than one manufacturer and the drug fulfils minimum spend and/or volume requirements. Category M prices are calculated based on quarterly information provided by all manufacturers and suppliers, which they are obliged to provide pursuant to the Health Service Products (Provision and Disclosure of Information) Regulations 2018.

37. Each quarter, the Department of Health and Social Care (DHSC) sends out a proforma with the list of the products for which data is required. In general terms, the data has to be supplied in the month following the end of the quarter and any price adjustment takes effect from the start of the month two months after that.

38. Ms Bleasby said that the 2mg prolonged release melatonin product has just changed to Category M from April 2022 and the Tariff price has been reduced from £15.39 (Cat C) to £10.38 (Cat M). As she says, this is consistent with the DHSC having had data from Teva for one quarter and data from Mylan for two quarters with suitable spend/volume requirements being met in accordance with the Cat M guideline criteria. The DHSC will receive Teva and Mylan data for Q1 2022 in April 2022 which will be considered after 29 April 2022, with any price adjustment taking effect from July 2022. Similarly, the review of Q2 2022 data will only take place after 29 July 2022. Any decision to recategorise based on the Q2 data could only take effect from October 2022 (i.e. after expiry of EP443). Her point was that even if Teva was taken off the market now, it would be unlikely that the recategorisation of melatonin could happen before the market becomes patent free on 12 August 2022.

39. From her evidence, I was satisfied that the observation made by Dr Fakes (see paragraph 32 above) does not cast any doubt on the evidence from Teva that it did launch in mid-October 2021 (see further below).

40. In his reply statement (Fakes 3), Dr Fakes says that Flynn were not able to obtain a sample of Teva Melatonin until 24 March 2022. He also relates that Ms Jarvis and her notebook record a call on 8 March 2022 from Lexon which reported that Teva had approached them and offered to supply [ ] packs the following week. Ms Jarvis also told Dr Fakes that Lexon told her that Teva had never offered the product previously.

41. More pertinently, in Fakes 3, Dr Fakes essentially accused Teva of dumping large volumes of stock onto the market. He did not accept Ms Bleasby's explanation for the very large jump in volumes in March. He said that unless restrained, he fears that Teva will continue to dump stock, precipitating a downward price spiral. To support that view, he also related information he received from Ms Jarvis that in a telephone call on 4 April with an unidentified person she was told that Teva sales representatives had been recently offering generic prolonged release melatonin at [ ] per pack and informing suppliers they can have as much as they want at that price.

42. Not surprisingly, Teva responded to this new evidence in Bleasby II. She exhibits the sales data from the Teva SAP system as at 7 April 2022. This, together with the confidential exhibits to her first statement, show the selling price of Teva Melatonin to every customer. As she says, Teva has never sold Teva Melatonin at or in the region of [ ] per pack and she says Teva has never offered the product at or in the region of that price. She says, again, that Teva have no desire or intention to cause a price spiral and that it is not in Teva's interests to cause a price spiral.

43. Naturally (but save as aforesaid), I am not in a position on this application to decide any of these disputes of fact. However, what I must do is to form a view as to what is likely to happen in the event that no injunction is granted and conversely, if an injunction is granted. In order to do so, I must first consider (a) whether the Claimants have delayed bringing this application, as Teva submits and (b) the status of Teva Melatonin on the UK market.

44. Teva draw attention to the following events:

> 7 September 2018: Teva obtains a marketing authorisation.
>
> Teva's evidence was that, following the revocation of EP702 (on 18 December 2020) they put in train plans to launch what became Teva Melatonin.
>
> 25 June 2021: The Claimants write to Teva noting that Teva are making preparations for launch. That letter also acknowledged that the Claimants had seen, from the MHRA website, that the package leaflet for the Teva product had been updated and new artwork had been registered in late May 2021 and was now approved.
>
> 30 June 2021: EP443 granted. Claim form issued in the Second Mylan action.
>
> 2 July 2021: Teva's solicitors respond to the 25 June letter:
>
> > "…Teva is not prepared to restrain any of its commercial activities relating to its melatonin product in the UK. Accordingly, if your client intends to take any legal action against Teva in the UK, it should do so at once."
>
> 8 July 2021: further letter from Teva's solicitors:
>
> > [Teva] "does not intend to restrain its commercial activities in relation to its melatonin product in the UK whilst the Patent is in force."
>
> September 2021: the Claimants failed to obtain a preliminary injunction to prevent sales of the Teva Melatonin product in the UK through the court in Israel under a settlement agreement relating to a different patent.
>
> 28 September 2021: Teva Melatonin product details were provided to the TevaOne Wholesalers.

6 October 2021: Teva Melatonin added to the pharmacy ordering systems.

7 October 2021: Teva Melatonin added to Teva's website. It is apparent from the Claimants' initial disclosure that they printed off a copy of the relevant webpage on 12 October 2021.

11 October 2021: TevaOne customers were emailed to inform them of the intended launch.

13 October 2021: the listing for Teva Melatonin went live on the Dictionary of Medicines and Devices (DM+D), the dictionary of descriptions and codes in use across the NHS. The evidence was that this listing is required to launch a product onto the UK market, and that the Claimants have access to the DM+D.

15 October 2021: Letter before claim sent to Teva noting infringement of EP443. The Claimants' solicitors made it clear that they did not intend to seek injunctive relief against Teva until they had secured an injunction against Mylan.

29 October 2021: Teva respond confirming that it has launched Teva Melatonin and refusing to withdraw product from UK market.

5 November 2021: Claim form in this action issued and served on Teva.

23 November 2021: Particulars of Claim and Particulars of Infringement served on Teva, the latter relying on Teva's offer for sale of Teva Melatonin on its website before the letter before claim dated 15 October 2021.

The parties agreed that the deadline for service of the Defence and Counterclaim should be extended until 14 days after the first instance judgment in the Second Mylan action. Accordingly, the Defence and Counterclaim and Grounds of Invalidity were served on 28 March 2022.

7 March 2022: following the *ex tempore* judgment of Marcus Smith J at the hearing on 4 March 2022 in the Second Mylan action, the Claimants' solicitors wrote drawing attention to the Judge's decision and suggested that, in light of the final injunction he had ordered against Mylan, it was highly likely that they would also obtain interim injunctive relief against Teva.

8 March 2022: Claimants threaten ex parte injunction hearing against Teva on 9 March 2022 on the basis that they had been informed that day by Lexon (a wholesaler) that it had been offered Teva Melatonin at a price below the price of Melatonin Mylan. The letter claimed that this was the first time that the Claimants had become aware of any indication that Teva was actively attempting to sell on the UK market.

9 March 2022: Teva refuse to give undertakings but provide confidential sales data to the Claimants' solicitors in Bird & Bird's letter of that date. Claimants' threat of *ex parte* relief withdrawn.

14 March 2022: Claimants issue application notices seeking interim injunction against Teva plus expedition of the hearing, supported by the witness statement of Paul Inman (which repeated the point '*It has always been clear to the Claimants that attempting to seek a preliminary injunction against Teva was not likely to succeed when another generic (Mylan) was on the market.')* and the first witness statement of Dr Fakes of the Second Claimant.

24 March 2022: Witness statement of Eleanor Root of Teva's solicitors, opposing expedition of this hearing.

28 March 2022: Roth J grants expedition of this hearing.

30 March 2022: Second witness statement of Dr Fakes, in support of the Claimants' application and in response to Root.

5 April 2022: Witness Statements of Laura Reynolds and Abigail Bleasby for Teva.

7 April 2022: Third witness statement of Dr Fakes, responding to Reynolds and Bleasby 1.

8 April 2022: Second witness statement of Abigail Bleasby, responding to two key points in Fakes 3. Skeleton arguments exchanged and filed for this hearing.

12 April 2022: Hearing of Claimants' application for interim injunctive relief.

12 August 2022: EP443 expires.

45. Against that chronology of events, Ms May QC for Teva, appearing with Mr Cronan, posed the natural rhetorical question: what more was Teva supposed to have done to make their intentions clear? Mr Waugh QC for the Claimants responded with two points: first, he criticised Teva for not 'clearing the way' and second, he drew my attention to the transcript of the hearing before Meade J on 17 December 2021. The Judge was considering the best way forward and in that context, he had asked the previous day about Teva's activities. Mr Waugh QC answered his question by stating '*as far as the claimants are aware, they have not yet put a product on the market'.* Mr Waugh's point to me was that a representative of Teva was observing the proceedings (remotely) but no attempt was made to correct the position. Frankly, I am not surprised.

46. As for 'clearing the way', I was told by Ms May that Teva were precluded from clearing the way in relation to EP702. In relation to EP443, even with an expedited trial (of which there was no guarantee), an attempt to 'clear the way' would have left very little time before expiry of the patent.

47. In my view, Teva did make their intentions clear to the Claimants. Indeed, via their solicitors, Teva's position was very clearly stated: no undertakings would be given and the product had launched on 13 October 2021 (as the Claimants were well aware). Even before the launch, the Claimants had sufficient evidence of a threat to launch to bring an application for an interim injunction to restrain any launch by Teva onto the market. At that point in time, the Claimants had made it clear that they did not intend to seek injunctive relief against Teva until they had secured an injunction against Mylan. I do not need to form any view as to whether that position was right or sensible because the fact remains they did not seek any interim relief against Teva until the present Application Notice was issued on 14 March 2022.

48. Mr Waugh pointed to the confidential Bird & Bird letter dated 9 March 2022. He said that was the first *corroboration* which supported what Bird & Bird had said in previous correspondence. However, in my view, the Claimants did not need corroboration to be able to launch an application for an interim injunction against Teva. The previous correspondence (and the website) provided sufficient evidence of a threat. Even if the Claimants suspected that Teva had made a 'soft' launch, that would not have provided a convincing answer against an application for interim relief.

49. It remains the case at this hearing that the Claimants still have not secured an injunction against Mylan, yet the Claimants make the price spiral argument. Even though the Claimants would not have had the March sales figures or the evidence related from Ms Jarvis, from July 2021 onwards, in my view, they could still have made many of the arguments they have made at this hearing i.e. with no injunction against Teva (the second generic on the market), there is a risk/certainty of a downward price spiral and it would signal a green light to other generics to enter the market etc.

50. In not seeking any interim relief against Teva before or just after their launch, thereafter the Claimants were running the risk that Teva would make sales and build up a presence on the UK market – as Teva thought fit. This is exactly what has happened. Dr Fakes' protestations that he and his staff were unable to obtain samples of Teva Melatonin until 24 or 28 March 2022 is nothing to the point, and does not change the position. The same is true of Dr Fakes' view that the sales disclosed in the 9th March letter from October 2021 to February 2022 were not 'material'.

51. Thus I find that the Claimants delayed significantly in seeking interim relief against Teva. However, the delay is not such as to disentitle the Claimants to relief on laches grounds.

52. In any event, Ms Bleasby presented some important market data in her confidential exhibit AB-6, based on IQVIA MIDAS data. These data show the following:

    i) The overall UK market for melatonin has [ ] (at a rate of about [ ] per annum over 2020 and 2021).

    ii) The generic share of the market reflects Mylan's entry in September 2020, with October 2020 showing a market share of [ ], rising to [ ] by September 2021.

    iii) Teva's entry in mid-October 2021 established a market share in October 2021 of [ ], but [ ] of the generic market, but with around [ ]

market share in November & December 2021 and February 2022, and over [ ] of the generic market in those months. The figures for January 2022 are much lower, for the reasons explained by Ms Bleasby.

iv) The monthly figures for the total market in March and December in each year are elevated above the months around them, consistent with Ms Bleasby's explanations.

53. It is true that Teva's sales in March 2022 were probably around [ ] of the total market, but that behaviour was Teva acting in its commercial interests, as it had made plain it would do unless restrained. In my view, the sales made by Teva from October 2021-February 2022 (as disclosed in the 9th March 2022 letter) cannot be brushed aside as 'not material'.

54. Ms Bleasby also provided, in further confidential exhibits:

i) The number of packs of Teva Melatonin and ASP (actual selling price) sold to each wholesaler each month since launch.

ii) For the period from launch to March 2022, the customer, order quantity, order date, net price, total value and delivery date of every sale made, and similar data for the sales made 1-7th April 2022.

55. In stark contrast, the Claimants' evidence presented very scant market and sales data. The only specifics which Dr Fakes put forward was the ASP range in the absence of generic competition; that the volumes in the market as at June 2021 were on average 250,000 units a month, a figure consistent with the data presented in AB-6; a total UK market size, consistent with his monthly average; the Drug Tariff prices when melatonin was a Category C drug (£15.39) and the new price of £10.38 which took effect on 1st April following its recategorization to Category M; and the split in prescribing between branded and generic scripts (53:47).

56. In this regard, I consider I must take judicial notice of the information which the Claimants put before the Court when they sought an interim injunction against Mylan back in September 2021. As Floyd LJ held at [51]:

> 'A number of features of the present case, in my judgment, make the court's task in assessing the loss to Neurim and Flynn relatively straightforward. First, and most importantly, Neurim and Flynn have, and have provided to the court, reasonably detailed forecasts of their expected sales revenues in Periods 1 and 2. These can form the basis of the court's calculation of the position which Neurim and Flynn ought to have been in, but for Mylan's infringement, for both Periods. The object of the inquiry as to damages will be to restore their revenues to those levels. Secondly, in respect of Period 1, the court will have Flynn's and Mylan's actual sales figures and the prices at which they have sold. This can form the basis for the lost sales and price depression claim for Period 1, and I see no reason to suppose that this will be inadequate.'

57. As I indicated above, Period 1 was the period in which the injunction would take effect pending trial, and Period 2 was the period between trial and expiry of the patent in suit. In this case, there is no period 2.

The *American Cyanamid* analysis

58. Both sides accepted there was a serious issue to be tried – in other words, both as to infringement and validity. So far as validity is concerned, I note that Teva have different validity attacks to those ruled upon by Marcus Smith in the Mylan actions, relying on different prior art.

59. So far as adequacy of damages are concerned for each side I must consider first, the position in the four months between now and expiry, and second, the position post-expiry.

Will damages be an adequate remedy for the Claimants, if no injunction is granted?

60. Considering the first period, in the circumstances, it is reasonable for me to infer that the Claimants have 'reasonably detailed forecasts of their expected sales revenues' from September 2021 down to expiry of the Patent, on the assumption that no generic product was on the market over that period.

61. In any event, by the time any inquiry as to damages comes around, in fact there will be market data showing the number of packs of melatonin sold each month down to expiry of EP443. In the absence of generic competition, it can be assumed that Flynn would have made all of these sales [ ]. Furthermore, although Dr Fakes indicates a degree of variation in the price Flynn charged in the absence of generic competition, the Court will be in a position to make a determination of the price which would have been charged by Flynn.

62. The Court will also have the data as to the sales volumes and prices charged from each of the Claimants, Mylan and Teva (and any other generic which entered the market).

63. It seems to me that the loss suffered by the Claimants over this period will be capable of being ascertained with a reasonably high degree of accuracy. I acknowledge that the attribution of that loss between the generics (exclusively or principally Mylan and Teva) may be the subject of fierce argument between them, but that should not detract from the fact that the Claimants will (on this hypothesis) be able to recover and be compensated more than adequately for their loss.

64. There are two points to notice. First, that this analysis assumes the Claimants' point based on each of the generics' marketing authorisations piggy-backing on the Claimants'. In the event that the generics successfully argue that the Claimants should not be compensated for sales which fall outside EP443, I acknowledge that in the determination of the volumes which fall in and outside the Patent it may be difficult to find exact figures, but the Court will make a determination. The uncertainty inherent in this exercise works both ways, so its effect is neutral.

65. The second point to notice is that this analysis is unaffected by whether a downward price spiral occurs between now and trial or not. If the downward spiral happens then the Claimants' loss will be greater (and the profit made by the generics will be less),

but it does not alter the fact that the Claimants' losses will be capable of being calculated with a reasonably high degree of accuracy. If a downward price spiral occurs between now and expiry, where it will have an impact is on the position post-expiry. Before turning to consider that second period, in case this matter goes further, I will state my view on the likelihood of a downward price spiral occurring between now and expiry.

A downward price spiral between now and expiry?

66. I start with the evidence in Dr Fakes' Third Witness statement that Teva representatives had recently (on or around 4 April) been offering generic prolonged release melatonin 2mg at [ ] per pack and informing suppliers that they can have as much product as they want at that price. He suggests that Teva can only be reducing their price in this way to compete with Mylan and that Mylan will respond by lowering its prices in order to compete with Teva.

67. However, given the history of the Claimants' unsuccessful attempts to get hold of the Teva product or to find out what was happening, it seems unlikely that if these [ ] offers were being made they started on or around 4 April. Even if they had, one would expect to see that price reflected in Teva's sales data immediately. Yet exhibit AB-8 contains the sales made down to the date of Ms Bleasby's second witness statement (8 April), with sales (albeit in small quantities) being made on the 1st, 5th and 7th April, all at prices higher than the lowest price charged in March and well above [ ] per pack. The sales data is not consistent with the picture painted in Dr Fakes' evidence.

68. I acknowledge entirely the received wisdom that a downward price spiral occurs once there are two or more generics on the market, but the current situation is unusual. Mylan are waiting (for about a month) until the expedited hearing of their Appeal. I have no evidence from Mylan as to their intentions over this short period, but it seems unlikely that Mylan would want to engage in or precipitate a downward price spiral. Mylan has been establishing its position in the market as the first mover and benefiting from the duopoly with the Claimants which has meant that prices have remained reasonably high. If Mylan loses its Appeal, it will come off the market until after expiry but if it wins its Appeal, it will retain some of its first mover advantage into the future.

69. Of course, matters are not entirely in Mylan's hands but, on the very incomplete picture I have, I consider that Mylan will only engage in a downward price spiral if forced to do so by Teva. In that regard, Teva's deponents assure me that Teva have no intention or desire to engage in a price spiral, and that is a logical position to take in the current unusual circumstances. If no injunction is granted against Teva but Mylan lose their Appeal, Teva will then have a decision to make: do they continue selling or come off the market until after expiry? If they continue selling, they can engage in a duopoly with the Claimants until expiry and with that in prospect, it would not make sense to precipitate or engage in a downward price spiral in the month before Mylan's Appeal is heard. It may also make commercial sense for Teva to continue selling on the basis that most of the damage to the Claimants has already been caused and because in the last three months of the life of the patent the Claimants will not be able to raise their prices back to monopoly levels. By contrast, if Teva come off the market, they will have to re-launch on expiry along with all the other generics. On balance, the evidence points to Teva continuing on the market (unless restrained) with no wish to engage in a downward price spiral.

70. The remaining point is the Claimants' argument that if Teva is not injuncted, that will be a 'green light' to other generics to enter the market and before expiry. Where the evidence came out was that one other generic has obtained a marketing authorisation and it has provided an undertaking to the Claimants not to sell pending patent expiry. Whilst other generics may be seeking a marketing authorisation, I consider it is unlikely that they will enter the market until either EP443 is revoked or it has expired. It seems more likely to me that the smaller generics are more risk averse than either Mylan or Teva.

71. Standing back, I am not inclined to place much weight on the 'evidence' related by Dr Fakes concerning the [ ] offer. Not only is it multiple hearsay from unidentified persons, it does not fit with other more concrete evidence which indicates that a downward price spiral is unlikely to occur between now and the point at which EP443 has either expired or been revoked, if earlier.

The period post-expiry

72. So far as the period post-expiry is concerned, I acknowledge that the position is subject to a much greater degree of uncertainty. If the generics had not entered the market pre-expiry, the Claimants would have been able to sustain their prices for a certain time following expiry. Again, I consider it is reasonable to assume that the Claimants have already modelled this scenario.

73. Of course, on any inquiry, there will be a fierce dispute on this issue. The Claimants will contend they could have sustained higher prices for longer, whereas the generics will argue that the price would have rapidly reduced. Again, there will be uncertainties in the determination, but, once again, these uncertainties are certainly capable of working both ways. I apprehend that the effect of them on the Claimants can be and will be reduced by the application of the principle mentioned by Floyd LJ in [52], quoted above, namely that:

> 'Damages are, however, to be "assessed liberally" without going so far as to punish the infringer: see *Pneumatic Tyre Co Ltd v Puncture Proof Pneumatic Tyre Co Ltd* (1899) 16 R.P.C. 209 at 215.'

74. So, although there will be uncertainties, I confess I was initially attracted to the view that it will be possible for the Claimants to be *adequately* compensated for their post-expiry losses on that basis that, although the calculation will not be by any means perfect, the uncertainty works both ways – the generics can hardly complain if they have to pay slightly more in damages than would have been the case in a perfect world. However, on reflection and taking account of the fact that I may be wrong and a downward price spiral occurs before expiry, there is so little certainty in the post-expiry situation that I must conclude that damages will not be an adequate remedy for the Claimants in the post-expiry period.

75. There is no question that Mylan and Teva will be good for the damages. However, I proceed on the basis that damages will not be an adequate remedy for the Claimants for the post-expiry period.

Will damages be an adequate remedy for Teva, if an injunction is granted, yet the Patent is revoked?

76. Teva put forward five reasons why they say damages would not be an adequate remedy if an injunction is granted but it is later found to have been wrongly granted.

77. First, it is clear from the sales data that Teva have put before the Court that their sales of Teva Melatonin have fluctuated. There has also been some fluctuation in the prices achieved e.g. depending on the volume sold to a particular customer. It is on this basis that Teva submit that it will not be possible to predict the volume and prices of the sales which Teva would otherwise have made during the remaining life of the Patent.

78. Second, Teva say that Confidential Exhibit AB-6 shows that Teva's relative share of the generic market is not stable, even if, as appears, the generic share of the overall market is [ ], as is the overall size of the market for melatonin. So, Teva say, one cannot predict what proportion of the generic market Teva would have secured going forward.

79. Third, if Teva is injuncted now, that will cause unquantifiable damage to its reputation in the marketplace as a reliable supplier and its customer relationships. Teva point out this could have a knock-on effect in respect of Teva's wider portfolio.

80. Fourth, an injunction would deprive Teva of the foothold it has already established in the generic market, ahead of additional generic competition such that it will be much harder for Teva to regain a commensurate market share after expiry of the patent. Teva complain that this would be particularly unfair if Mylan remain on the market and thereby effectively retain a first mover advantage by default.

81. Teva's fifth reason was an afterthought. They now contend that there is no evidence that the Claimants would have sufficient financial resources to meet their liability under the cross-undertaking.

82. I accept the first and second reasons, even though they are really the same point. I am less impressed by the third reason since I expect that the wholesalers buying Teva Melatonin are aware that the status of the patent protection remains uncertain. I accept the fourth reason but not the complaint that it would be unfair if Mylan retain a first mover advantage. Mylan were not only the first mover, they (on this hypothesis) will be responsible for establishing the invalidity of EP443. I am also not impressed by the fifth reason – the Claimants will be able to pay damages under the cross-undertaking even if their planned expenditure in other parts of their busines may have to be curtailed in the short term. Overall, however, I have concluded that damages would not be an adequate remedy for Teva largely because the uncertainties in trying to ascertain their damages would be considerable.

83. Considering the post-expiry period, I consider that it is going to be more difficult to compensate Teva adequately (on the assumption that they are injuncted but should not have been) than the Claimants (on the assumption that no injunction is granted but the Claimants are ultimately successful). There will be much greater uncertainties applying to Teva's position than that of the Claimants.

Balance of the risk of injustice and status quo

84. The Claimants put forward the following factors which they say should be weighed in the balance:

    i) First, that Teva did not clear the way and launched at risk.

    ii) Second, that Teva have refused to give any undertaking at least until determination of Mylan's appeal.

    iii) Third, because Teva is a massive company and in its very large portfolio, Teva Melatonin is commercially insignificant, whereas for the Claimants, Circadin is a fundamentally important product, being (until 2018) the First Claimant's only product.

85. In respect of the status quo, Mr Waugh made a variety of submissions as to what constituted the relevant *status quo ante bellum* – e.g. when Teva started the activity complained of, when Teva was first on notice that they would be subject to an injunction if the Claimants were to succeed against Mylan and so on. He submitted that the status quo should not include any of the sales in March, otherwise '*Teva could shift the status quo whilst they are on notice...'*

86. I have some sympathy for the Claimants because they are relatively small entities facing two powerful generic companies. Having said that, I found all these submissions unconvincing. They were, in various ways, attempts to excuse the Claimants' delay in bringing this application and to put the blame at Teva's door. They also assume the Claimants will ultimately be successful. On that first point, it was entirely in the Claimants' hands when to bring their application for interim relief and they and their legal advisers must have known or be taken to have known the risks of delaying applying for interim relief to stop Teva selling Teva Melatonin. On the second point, I am not supposed to nor am I in any position to judge whether the Claimants will ultimately succeed or not. That is the whole point of the *American Cyanamid* approach.

87. As for the failure to clear the way submission, that submission would have greater force if EP443 had been granted in sufficient time before expiry to make it feasible and worthwhile for a generic to seek to invalidate it and secure a market position before it would otherwise have expired. As events transpired, EP443 was granted so close to expiry as to effectively exclude the possibility of Teva invalidating it before expiry. Thus, the Claimants' manoeuvring at the EPO and their bringing forward this divisional was, in my view, the principal cause of no 'clearing the way' action by Teva. Accordingly, this point is at best neutral.

88. If damages had been an inadequate remedy to an equal extent on each side, the balance would have been neutral. However, since damages would be considerably less adequate for Teva, I consider the balance comes down in Teva's favour.

89. In any event, though, applying *Frank Industries v Nike,* the relevant status quo is that which existed at the date the Application Notice was served on Teva, which was late in the evening on 14 March 2022. At that point, Teva had been on the market in the UK with Teva Melatonin for 4 full months and, in those first two weeks of March, Teva had taken orders to supply a very considerable number of packs of Teva Melatonin –

just under [ ] packs. I am not deterred from taking this date as the point at which to assess the status quo by the Claimants' accusation that, in March 2022, Teva was dumping large quantities of product onto the market. Even if that is the correct characterisation, that was the risk which the Claimants were running – as Mr Waugh pointed out, Teva have dumped product before.

90. Accordingly, I refuse the Claimants the relief they seek on this Application. To summarise the position:

    i) Damages will be an adequate remedy for the Claimants pre-expiry, but not post-expiry.

    ii) Damages will not be an adequate remedy for Teva, either pre- or post-expiry.

    iii) The balance of the risk of injustice comes down in favour of Teva. As I indicated above, calculating the Claimants' damages post-expiry is subject to fewer uncertainties than for Teva.

    iv) In any event, maintaining the status quo leaves Teva on the market.

91. There are three further points to mention, by way of postscript.

92. First, at various points in his submissions, Mr Waugh QC floated the idea of an injunction limiting Teva as to the volumes and prices at which it could sell Teva Melatonin from now until expiry e.g. by reference to the February 2022 monthly volume and not below the average sales price of its sales in February 2022. Even though the idea was raised in recent correspondence, the precise wording of such alternative relief was not before me nor were any of the difficulties it would entail discussed in evidence. As Ms May QC submitted, that type of relief might give rise to competition concerns. Furthermore, it is not difficult to envisage severe difficulties resulting if one market participant cannot go below a certain price, but any other market participants can do so. For all these reasons, I saw no requirement to consider this any further.

93. Second, I realise that the Claimants have had to try to cope with a developing situation involving these two large generic companies in separate actions. It is evident that difficulties have been caused by the Court not having both Mylan and Teva before it at the same time. Although achieving that state of affairs in this case might have been procedurally challenging (and might have increased costs), in the future consideration should be given to achieving that.

94. Third, I provided a draft of this Judgment to the parties containing various pieces of confidential information and invited them to agree appropriate redactions so that a non-confidential version could be made public. This they did. Thus the parties have a Confidential Approved version of this judgment and the non-confidential version is public.