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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

Rolls Building,
Fetter Lane, London, EC4A 1NL

Date: 29th June 2022

Before :

THE HON MR JUSTICE MELLOR

- -

Between :

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

- -

Mr Douglas Campbell QC (instructed by **Gowling WLG)** for the First Claimant (and by **Pinsent Masons LLP)** for the Second Claimant
Miss Charlotte May QC and **Mr Henry Ward** (instructed by **Bird & Bird LLP**) for the **Defendant**

Hearing date: 23rd June 2022, Confidential Judgment provided in draft 27th June 2022

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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.

This judgment was handed down remotely by circulation to the parties' representatives by email. This non-confidential version will also be released for publication on the National Archives website. The date and time for hand-down is deemed to be Wednesday 29th June 2022 at 10.30am.

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THE HON MR JUSTICE MELLOR

Mr Justice Mellor:

Introduction

1. This is the second application by the Claimants (Neurim/Flynn) seeking interim injunctive relief against the Defendant (Teva). The first application was brought by notice dated 12th March 2022 which I heard on 14th April 2022 and rejected in my judgment handed down on 26th April 2022, the neutral citation of which is [2022] EWHC 954 (Pat) ('my First Judgment'). On this second application, there is now a period of just over 7 weeks until expiry of the Patent, which will occur on 12th August 2022.

2. This second judgment proceeds on the basis of my First Judgment and must be read in conjunction with it. Everything I said in my First Judgment continues to apply save where the context indicates otherwise and except where I say otherwise in this judgment. All references to numbered paragraphs in square brackets are references to my First Judgment.

3. Since my First Judgment the main events have been as follows:

   i) On 19th May 2022, the Court of Appeal heard Mylan's appeal against the Order of Marcus Smith J in which he found the Patent valid and infringed.

   ii) The Court of Appeal handed down their judgment on that appeal on 27th May 2022, rejecting Mylan's Appeal: [2022] EWCA Civ 699. As a result, as from 30th May 2022, Mylan was injuncted from selling Melatonin Mylan and ordered to take certain steps to retrieve infringing product from their customers, being obliged to contact customers by 6th June 2022 and to ensure by 28th June 2022 that all infringing product has been withdrawn from channels of distribution and put into escrow.

   iii) On 7th June 2022, Neurim/Flynn issued the application notice now before me. It was served on Teva's solicitors just after 10pm, so deemed served on 8th June 2022. Neurim/Flynn sought expedition of this hearing, which I granted after a short hearing on 13th June 2022, at which I gave permission for expert evidence and directions for this hearing. The part of the application which remains live seeks an interim injunction until judgment in this action or further order in the meantime and orders requiring Teva to retrieve product from customers (in similar terms as the Court of Appeal granted against Mylan (by way of final order)). Since there is no chance whatever of judgment in this action being given before 12th August 2022, the date of expiry of the Patent, in reality the injunction sought can only be until expiry of the Patent on 12th August 2022.

4. Neurim/Flynn served with its application notice two witness statements, one from Dr Fakes (Fakes IV) and one from its solicitor (Inman II) and a first expert report of Richard Williams (Williams I). In accordance with my directions, Teva served its evidence on 17th June 2022, being the second witness statement of Laura Reynolds (Teva's Associate General Counsel), and the expert report of William Potter. Neurim/Flynn's evidence in reply was served on 20th June 2022, being Inman III and Williams II, leaving a day to prepare/complete Skeleton Arguments which were filed on the morning before this hearing.

The additional witness statements

5. Much, if not all, of the evidence was an update on the position I considered in my First Judgment. However, the evidence now available to me has provided more information and greater detail in certain areas, so, subject to one point which I consider below, it is appropriate for me to revisit certain findings. In any event, I am now dealing with a different period of time and I assess the situation from the date of this hearing looking forward in the light of the evidence now available.

6. As before, Neurim/Flynn have not put in evidence any details of their individual sales or prices at which individual sales have been made – see [55] – nor any information as to their blended or weighted average price in their brand equalisation programme. As I mentioned in my First Judgment at [54], previously Teva put in evidence details of the volume and selling price of every sale of Teva Melatonin from launch in October 2021 down to 7th April 2022. Ms Reynolds updated those schedules. Thus in Highly Confidential LR-5, I have details of every sale made by Teva from launch down to 15th June 2022. Ms Reynolds also exhibited an updated version of what was Confidential exhibit AB-6, now Confidential LR-6. Each of those exhibits provides an analysis by month (from January 2020 to April 2022) of various sectors of the prescription-bound market for Melatonin, including figures for branded and generic product and Teva's shares of both (a) the overall market for melatonin and (b) the generic market. LR-6 contains two extra months – March and April 2022 - on top of the analysis of January 2020 to February 2022 in AB-6. These extra months require me to revisit the findings I made in [52] because the additional data alter the picture somewhat:

   i) [52i)] remains true and [……] of the overall market seems to have continued.

   ii) The generic share of the market has continued to increase gradually.

   iii) Teva's shares of (a) the overall market for melatonin and (b) the generic market for melatonin have [……..].

7. The LR-5 data establish the following points:

   i) First, the findings I made at [77] continue to hold. In particular, the volumes sold by Teva each month have continued to fluctuate significantly. With some exceptions, the sales in April, May and to 15th June 2022 have been at three main prices and the lowest price in March, April, May and to 15th June has remained the same. Often this lowest price is for the larger volume consignments, but not exclusively. I infer that a customer may secure this lowest price for reasons other than volume of Teva Melatonin, perhaps because that customer also orders significant volumes of other Teva products.

   ii) Second, that there has been no downward price spiral. It is true that Teva's average price each month (i.e. by taking the total value of all sales in a month and dividing by the total volume) since October 2021 has been [……. ……. ……]. The June data [……] and it is unclear […….].

8. In his evidence on this second application Dr Fakes repeats a number of assertions which I dealt with previously. It is not necessary to address them all. The first I will address is his repeat of the assertion that if Teva is not injuncted, other generics are likely to enter the market before expiry of the Patent. I do not agree and a very rough calculation shows why. The total market is approximately 250k packs a month. Let me assume there are two months of sales until expiry. Taking account of Dr Fakes' evidence as to the proportions of retail:hospital/tender sales and branded:generic, these supposed market entrants would be competing (with the existing market incumbents) for a maximum quantity of around [……] packs. Let me make the generous assumption that one of them manages to capture 10%, i.e. around […….] packs. Even at Teva's current lowest price (which a new entrant would probably have to go below to capture any sales at all), it seems to me that the profit a new entrant might be able to make would be likely to be dwarfed by the legal costs which they would inevitably incur when sued by Neurim/Flynn and joined into an inquiry as to damages (on this hypothesis the Patent is later found to be valid and infringed). In my view, it is far more likely that any other generic with a marketing authorisation will only enter the market on expiry.

9. In submissions, Mr Campbell suggested that it would be in the interests of the other generics with marketing authorisations to enter the market in the days before expiry in order to establish some market share. This is even more unlikely than the notion of other generics entering the market shortly after refusal of this application (if that is the result), for the reasons just explained.

10. The second assertion I address is Dr Fakes repeat of the notion that there will be a downward price spiral between now and expiry, if no injunction is granted. I reject this. In my view, a downward price spiral between now and expiry is even more unlikely than on the first application (a) because of my finding that other generics will not enter the market before expiry and (b) it is certainly not in the interests of the duopolists now in the market (Neurim/Flynn and Teva) to engage in any price spiral.

11. There are other disputes on the evidence which are best addressed in the context in which they arise and to the extent necessary.

The Expert Evidence

12. It is not necessary for me to discuss all the ins and outs of the arguments presented by each expert. Suffice to say that each of them was qualified to give evidence in this case and I am grateful to both of them for their assistance. I will identify the three scenarios they considered here:

    i) Scenario 1A: Teva injuncted, Patent ultimately held to be valid and infringed. It is probably not necessary to consider this any further.

    ii) Scenario 1B: Teva injuncted, Patent ultimately held invalid (This was also referred to in argument as 'Injunction wrongly granted', even if that label is not entirely apposite.)

    iii) Scenario 2: No injunction, Patent ultimately held to be valid and infringed. (Again, in argument this was also referred to as 'Injunction wrongly refused')

13. As Ms May submitted, it is important to be clear at all times as to: (i) the position of which party is under consideration; (ii) in which Scenario; and (iii) whether one is considering the factual or the counterfactual.

14. In his submissions, Mr Campbell made a number of points to the effect that if argument A applied to Teva's position, then the same must also apply to Neurim/Flynn. Mr Williams made some similar points in his evidence. I did not find this helpful because Teva and Neurim/Flynn have different positions and, in my view, it is necessary to examine each argument as to damage suffered by reference to their individual positions.

15. In general, I am inclined to place somewhat greater weight on the views of Mr Potter than of Mr Williams, for three main reasons:

    i) First, I was somewhat surprised that in Williams I, he was invited to make observations only on the position of Neurim/Flynn and not Teva. Neurim/Flynn suggest that the justification for this was because Teva had yet to serve its fact evidence. It is true of course that Teva had yet to update its fact evidence, but its position was tolerably clear from the evidence served on the first application. The consequence was that Mr Potter in his report dealt with the positions of both Neurim/Flynn and Teva. Williams II therefore responded on the position of Teva, to which Mr Potter did not have an opportunity to respond. However, I do not believe that Teva was disadvantaged by this, not least because it has had ample opportunity to respond in its Skeleton Argument. Furthermore, this point is not really a criticism of Mr Williams but of what he was invited to do.

    ii) Second, but more importantly, in Williams II, his response to some of Mr Potter's points I found to be rather argumentative. I can give two examples.

    iii) First, in paragraphs 19-20 of Williams II, he said this:

> '19. In the post 12 August period under Potter Scenario 1B, again Mr Potter concludes that Teva's loss cannot be accurately calculated. In concluding that there would be any loss to Teva post 12 August, I assume from paragraph 5.6 of Potter 1 that he believes that this arises from Teva's loss of its 'early mover advantage'. This means that a supplier (Teva) is denied the benefit of being on the market, at agreed volumes and price points on 12 August, before the so-called 'free for all' occurs.
>
> 20. If this is indeed the case, then surely it equally applies to Flynn's post 12 August losses since Flynn will also be on the market, at agreed volumes and price points on 12 August, before the free-for-all occurs. Flynn's established market share and ASP will be fundamentally different under my two Scenarios. Under Scenario 1 (injunction) it will have 100% of the market and it is not unreasonable to assume that the drug tariff concessionary price will be at £15.39, and Flynn's ASP's will be at its NHS List Price of £15.39 less normal wholesaler and distribution discounts. Under Scenario 2 (no injunction) on 12 August it will have both uncertain market share and uncertain ASPs.'

iv) Thus, in paragraph 19 Mr Williams related the substance of Mr Potter's evidence regarding an aspect of Scenario 1B. Instead of saying clearly whether he agreed or disagreed, I found the start of paragraph 20 argumentative.

v) Similarly, in paragraph 22.1.3 of Williams II, when discussing one of four 'unquantifiable elements in the assessment' of Flynn's losses post-12th August (namely the point in italics in the first sentence), he said this:

> '22.1.3 *The rate at which generic competition drives prices down.* Mr Potter concludes this will be rapid ("within days of patent expiry"). If he is of that view, it seems to fly in the face of the claimed value of the "first mover advantage" that Teva would have if not injuncted (and consequent post 12 August losses it would suffer if the first mover advantage is removed as a result of an injunction). If Mr Potter is of the view that the market in the first few days post 12 August will reset rapidly, having no regard to the participants' market positions on 12 August, then surely he must also conclude that Teva's losses under his Scenario 1B are similarly not significant.'

vi) In each case, in my view, it would have been more straightforward if Mr Williams had stated clearly the extent of any agreement or disagreement with what Mr Potter had said and then gone on to discuss the position of Neurim/Flynn separately.

vii) Third, although Mr Williams was clearly aware of the 'first mover advantage' issue, he was inconsistent in taking account of it. To my mind, he did not take it into account as part of the loss which Teva would incur if injuncted.

16. I will have to discuss the expert evidence in more detail below. Despite the points I have just made, overall I found the expert evidence illuminating and helpful. It has certainly allowed me to reach better and more reliable findings as to the position post-expiry than in my First Judgment.

Applicable legal principles.

17. These fall into three categories.

18. First, Teva naturally raised the *Chanel v Woolworth* issue that the reconsideration of an interlocutory order requires the applicant to demonstrate a significant and material change in circumstances. Teva drew my attention to *Thervarajah v Riordan & Ors* [2015] UKSC 78 at [18] and *Koza Ltd v Koza Altin Isletmeleri AS* [2021] 1 WLR 170 CA at [42], which reinforce this long-standing requirement.

19. Second, on the general *American Cyanamid* test, both sides were content to adopt the principles I set out in my First Judgment at [5]-[11], but especially at [5]-[6]. Naturally I have reminded myself of all those points.

20. In addition, Neurim/Flynn were keen to impress on me the point that the stages outlined by Lord Diplock in *American Cyanamid* were guidelines or an aid to analysis as opposed to a checklist of points to be rigidly applied in that order and no other. In this regard, Neurim/Flynn drew my attention to the following cases and passages:

i) *R v Secretary of State for Transport, ex parte Factortame Ltd (No.2)* [1991] 1 A.C. 603, per Lord Goff of Chieveley at 671F-H, where he emphasised that Lord Diplock had laid down *guidelines* for the exercise of the Court's jurisdiction to grant interim injunctions.

ii) *National Commercial Bank Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16 at [17], where Lord Hoffmann, giving the decision of the Privy Council, made a similar point:

> [17] In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. The basic principle is that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other. This is an assessment in which, as Lord Diplock said in the *American Cyanamid* case [1975] AC 396, 408:
>
> > "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."

iii) The decision of the Irish Supreme Court in *Merck, Sharp & Dohme v Clonmel Healthcare* [2019] IESC 65 at [35]-[36], [60]-[65] but especially the list of 8 factors in [64], submitting that there is no material difference between those 8 factors or steps and *American Cyanamid* but that they usefully emphasise the point that the court should make an order which causes 'the least irremediable prejudice to one party or the other'.

21. Mr Campbell was kind enough to submit that my First Judgment did follow these principles i.e. that I did not previously fall into the 'trap' of applying the *American Cyanamid* steps in rigid sequence. However, it seems that there were two main reasons why Neurim/Flynn wished to emphasise that the broader approach was the correct one. The first stemmed from the reasons given by the Supreme Court on 29th June 2020 when a three-member panel of Lords Kerr, Lloyd-Jones and Kitchin JJSC refused Neurim/Flynn permission to appeal against the Court of Appeal's decision to uphold Marcus Smith J.'s refusal to grant Neurim/Flynn an interim injunction against Mylan at the beginning of this melatonin litigation. The material part of their reasons read as follows:

> 'The panel considered that there is a point of law of public general importance touching on the question whether the four-stage test outlined by Lord Diplock in *American Cyanamid v Ethicon* [1975] AC 396 should be applied in a rigid and strictly sequential manner or whether a more overarching and flexible approach to the issues adumbrated by Lord Diplock would be appropriate - cf the observations of Lord Goff in *R. v Secretary of State for Transport Ex p. Factortame Ltd (No.2)* [1991] 1 A.C. 603.

> The panel decided, however, that permission should not be given in this case. Prominent among the reasons for this decision was the imminence of the trial in the action. (It is scheduled to begin in October 2020).'

22. Mr Campbell noted that such reasons have no precedential value, as is made clear in the Supreme Court Practice Direction 3 at [3.3.3], but he submitted these were clearly persuasive. I agree.

23. However perhaps the second (but unstated) reason was because Neurim/Flynn were very keen to impress upon me the value to their case of the fact that the validity of the Patent had been upheld by the Court of Appeal.

24. This leads me to the third category of potentially relevant case law concerned with the circumstances in which a judge may take the merits into account. Neurim/Flynn indicated this point was considered in *Clonmel*, but naturally referred me to the judgment of Laddie J. in *Series 5 Software v Clarke* [1996] FSR 273 and this passage at 286 (with Neurim/Flynn's emphasis):

> 'It follows that it appears to me that in deciding whether to grant interlocutory relief, the court should bear the following matters in mind:
>
> 1. The grant of an interlocutory injunction is a matter of discretion and depends on all the facts of the case.
>
> 2. There are no fixed rules as to when an injunction should or should not be granted. The relief must be kept flexible.
>
> 3. Because of the practice adopted on the hearing of applications for interlocutory relief, the court should rarely attempt to resolve complex issues of disputed fact or law.
>
> 4. Major factors the court can bear in mind are (a) the extent to which damages are likely to be an adequate remedy for each party and the ability of the other party to pay, (b) the balance of convenience, (c) the maintenance of the status quo, (d) <u>any clear view the court may reach as to the relative strength of the parties' cases.</u>

25. Neurim/Flynn also cited the slightly later observation of Robert Walker J. (as he then was) in *Barnsley Brewery v RBNB* [1997] FSR 462 at 472:

> "Mr Hamer referred me to the recent decision of Laddie 1. in **Series 5 Software Ltd v. Clarke** [1996] 1 All E.R. 853, [1996] F.S.R. 273. That decision is sometimes, it seems, regarded as surprising or even heretical. I do not see it that way. I see it as a valuable reminder of the background and context of **American Cyanamid** and indeed of its basic message. The basic message is that applications for interlocutory injunctions cannot be mini trials of disputed issues of fact and that the court has to do the best it can on a provisional basis, with the relatively modest aim of reducing so far as possible the risk

> of the provisional decision ultimately proving to have produced an unjust result."

Material change of circumstance?

26. Teva accepted that the circumstances had changed, but suggested the change(s) were not material or significant. Neurim/Flynn relied on two matters: first, the judgment of the Court of Appeal against Mylan and second, the fact that Mylan had been removed from the market. Whilst I was somewhat sceptical as to whether these constituted a material change in circumstances, Teva pragmatically accepted that this was a somewhat arid debate because if new circumstances favoured the grant of an injunction when they did not before, then they would amount to a material change and if not, not. For this reason, I concluded it was right to consider this second application on the basis of the evidence now before me.

The merits

27. It is convenient to deal with the merits point next. Neurim/Flynn submitted that, following the Court of Appeal's decision in the Mylan case on the same patent, the present case is one where the Court *can* properly form such a clear view (cf *Series* 5) (at the same time, as I understood their position, as accepting there was a serious issue to be tried). Neurim/Flynn acknowledged that it was 'feasible' that Teva's validity attack would succeed where Mylan's failed but submitted that this is unlikely, not least given that Mylan's validity attack was no half-hearted matter.

28. I will say at once that I am unable to form any clear view on the merits, for a number of reasons. In this regard, the Court of Appeal Judgment is helpful because it confirmed in much more specific detail some inchoate views I had formed about what had happened in the Mylan litigation and why I was entirely content to accept in my First Judgment that there was a serious issue to be tried on validity. Mylan ran a single point on appeal, that the Patent is invalid for insufficiency or (as Arnold LJ put it at [1]) 'more specifically, lack of plausibility'. Mylan contended that the Patent did not plausibly disclose the effect that it claims because of what became known as the 'lay patient argument'. Arnold LJ set out Mylan's 'lay patient argument' in [32]-[40], including the point that the last sentence of [0039] of the Patent contradicts the suggestion that the responses to the question about 'quality of sleep' in Examples 2 and 3 related to or were specific to non-restorative sleep. In [41] he said it was important to note two points before considering the Judge's reasoning: the first was that this argument had not been articulated very clearly before the Judge, and second, that the point about the last sentence of [0039] of the Patent was not advanced at trial and was not put to either expert. At [50]-[56], Arnold LJ rejected Mylan's argument for 5 reasons and the fifth reason in [56] is pertinent, where Arnold LJ described the point about the last sentence of [0039] as Mylan's best point. It was however, a point not open to Mylan because its expert had given no evidence about it, nor had the point been put to Neurim/Flynn's expert.

29. Naturally, Teva emphasise that at their trial this point will be covered in the expert evidence and the argument fully articulated. Furthermore, Teva point out they have cited somewhat different prior art (although some is similar or closely related to that run by Mylan). The expert evidence will be different. Finally, Teva are running a non-infringement point (which Mylan dropped about a week before trial). In these

circumstances I am not inclined (nor am I permitted) to examine the merits any further but, as I have already stated, I am unable to form any clear view as to who will win. Accordingly I can turn to the *American Cyanamid* guidelines.

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

30. As before, I will consider the pre-expiry and post-expiry periods separately. Before I do so, I will make one additional observation about adequacy of damages, prompted by Floyd LJ's observation in *Neurim CA Int Injn Jmt* that the boundary between adequate and inadequate is not a precise one (quoted in [6iii)]). Damages awarded in an inquiry in a case such as the present may prove to be inadequate because of uncertainty as to the following factors: (i) the volume of lost sales; (ii) the price at which such sales would have been made; but also (iii) the size of the overall loss and I suppose also (iv) whether such damage is recoverable in law. Leaving (iv) aside, it may be helpful to explain what I mean concerning the size of the overall loss. There will be some cases where it is impossible to predict the size of the loss in advance, other than that it will be considerable. In other cases, it may not be possible to calculate the loss with precision but the significance of the difference between the perfect figure and the figure awarded depends on the figures themselves - compare £100 and £90 versus £1m and £900k.

Pre-expiry

31. At [63] in my First Judgment I concluded that the loss suffered by the Claimants pre-expiry would be capable of being ascertained with a reasonably high degree of accuracy. I must consider this issue afresh in the light of the evidence on this application.

32. The factual position concerns what happens if no injunction is granted. At the inquiry as to damages, the Court will have the sales volumes and prices of Neurim/Flynn and Teva respectively over the pre-expiry period, along with data as to the overall size of the market.

33. In the counterfactual, Teva would be injuncted and off the market for the period until expiry.

34. In his witness statement Dr Fakes suggested that it was uncertain whether, in the event that Teva was injuncted, Neurim/Flynn would be able to achieve a concessionary price of the previous Category C Drug Tariff Price of £15.39. However, the experts agreed that the Claimants would 'likely' regain 100% of the market at their historic monopoly price based on Circadin's NHS list price of £15.39 and that the Pharmaceutical Service Negotiating Committee and the Department of Health would implement a price concession.

35. Dr Fakes' other point was that it may take time to unwind some of the brand equalisation deals Neurim/Flynn have agreed with customers. Neurim/Flynn did not put in evidence any details concerning these deals, but their effect will be readily calculable against the monopoly price.

36. It may be that some wholesalers and retailers would hold off purchasing until after expiry with a view to buying at a lower price. The evidence suggests this effect will be

small because purchasing is on a 'just in time' basis, although the Teva data suggests that some purchase monthly and some purchase larger quantities on a three-monthly basis. I consider the detailed data will reveal if this has occurred.

37. I have also considered the situation in the unlikely event that other generics enter the market before expiry. There will be additional downward pressure on price. However, the loss sustained by Neurim/Flynn will still be readily calculable. As I said before at [63], the attribution of that loss between the generics may well be the subject of fierce argument, but Neurim/Flynn will be compensated adequately.

38. In all the circumstances, the evidence now available points even more firmly to the same conclusion as before in [63], namely that the loss suffered by Neurim/Flynn over the period pre-expiry will be capable of being ascertained with a reasonably high degree of accuracy.

Post-expiry

39. Neurim/Flynn appeared to submit that they had the benefit of my finding in the last sentence of [74]. However, in view of the evidence it is necessary to revisit my previous analysis at [72]-[75] of my First Judgment, even though [73] continues to apply.

40. The evidence is that more generics have obtained or have applied for marketing authorisations. Thus it is entirely feasible that on expiry there will be up to 6 (and possibly more) entities competing in the market for melatonin.

41. Mr Potter expressed the clear view that the price spiral on expiry will be rapid and a new post-expiry equilibrium price will be achieved within days, regardless of the starting point. Teva's Counsel sought to illustrate this in their Skeleton Argument with curves showing the decay of the price from the two starting points (factual and counterfactual). However, in practice (and with the Teva data in mind), the price is unlikely to follow a smooth curve. It is far more likely that the price will reduce step-wise. Indeed, if customers anticipate a rapid reduction in price, they are likely to play one supplier off against others to obtain the best price which will accelerate the process.

42. Mr Williams did not disagree with Mr Potter on this (see his paragraph 22.1.3 which I quoted above). Thus, I have a more detailed and firmer picture than before of what is likely to happen on expiry to the price.

43. The other important point concerns volumes. In the factual (no injunction), Neurim/Flynn's volumes and price at expiry will be lower than in the counterfactual (where Teva is injuncted and Neurim/Flynn has 100% of the market at its monopoly price, albeit that volumes might temporarily reduce in anticipation of expiry, but the data will be available to measure that).

44. Although Neurim/Flynn's existing customer relationships may be a factor post-expiry in assisting Neurim/Flynn to retain sales, in my view they will be largely discarded if, as is likely, lower prices are available. This means that the difference in Neurim/Flynn's starting volumes between the counterfactual and the factual is unlikely to give rise to any significant difference in the amount of business they are able to secure post-expiry. Again, that will depend on price.

45. This analysis points to a conclusion in line with what Mr Potter suggested, that, if the price reduces as fast as Mr Potter says, then Neurim/Flynn's loss post-expiry will not be significant. Even if the price takes a little longer to come down to a post-expiry equilibrium, Neurim/Flynn may be able to point to particular sales contracts awarded post-expiry and identify reasons why, in the counterfactual, they would have secured those contracts. The arguments over such contracts represent uncertainty and therefore an element of inadequacy in Neurim/Flynn's damages, but the Court will be able to achieve a just result with an application of the principle I mentioned in [73] of my First Judgment.

46. In view of the point I make at paragraph 53 below about customer relationships, I have considered whether the same point applies to Neurim/Flynn's customer relationships. I have concluded that Neurim/Flynn sit in a different position to Teva for at least the following three reasons:

    i) first, because Neurim/Flynn are a single product entity (at least at the moment);

    ii) second, because a customer's relationship with a (single-product) monopolist seems to me to be different from the relationship a customer would have with Teva, a company with a significant range of products and which would be viewed as only temporarily a duopolist but as generally competitive on price;

    iii) third, because with Neurim/Flynn, I am considering a situation where, until expiry, it continues to have [……..] share of the market for melatonin. It seems to me that Neurim/Flynn are very unlikely to recover, post-expiry, those customers they have already lost to Teva (and if they do, it will only be because of price). By contrast, for the reasons I explain below, Teva's existing customer connections would lead to further business post-expiry. The loss of (at least some, if not most of) those customer connections will be a loss to Teva over which there will be considerable uncertainty.

47. Mr Campbell made a point a number of times that if no injunction was granted, Neurim/Flynn would lose its monopoly once and for all. He contrasted that with his characterisation of the position if Teva was injuncted: '*Teva will merely lose whatever money it would have made selling its infringing products.'* Leaving aside the implicit appeal to the merits, in order to test whether his distinction gave rise to something which I should take into account when assessing the balance of irremediable harm, I asked him how does Neurim/Flynn's monopoly manifest itself other than through Neurim/Flynn's ability to exploit their monopoly by making sales at monopoly prices: in other words, why is it not also a question of money for Neurim/Flynn? I did not get a convincing answer which left me in the familiar position: the loss of the ability to exclude Teva has to be assessed using the *American Cyanamid* guidelines

Will damages be an adequate remedy for Teva, if an injunction is granted?

48. The factual will be that Teva is injuncted and off the market until expiry of the Patent. In the counterfactual, the Court will have to estimate the damage suffered by Teva by being kept off the market i.e. estimating the sales Teva would have made if not injuncted.

Pre-expiry

49. The arguments were centred on my reasoning at [76]-[82] and what, if anything had changed.

50. Neurim/Flynn and Mr Williams contended that the three weeks of data relating to Teva's sales since Mylan was injuncted would provide a reliable basis on which to estimate the sales which Teva would have made in the 7 weeks until expiry. I do not agree, for a number of reasons:

    i) First, the June data in LR-5 shows a relatively small number of individual sales, with a very wide range of volumes at 3 different price points. The same pattern of variability is shown in earlier months as well. In particular the volumes sold by Teva each month vary considerably, and, consequently, Teva's market share. Neurim/Flynn's suggestion that one could average Teva's market share over several months (whilst excluding the exceptional sales made in March 2022) would not, in my view, provide any reliable guide as to the sales which Teva would otherwise make in the 7 weeks until expiry.

    ii) One might assume that Teva's turnover over the two months to 12th August could be estimated by assuming it was similar to one or more of April or May, but there would be considerable argument over which month or months to use as the basis, and, looking at the turnover figures in LR-5, the estimate for the 7 week period could be out by [……..]. The estimate would not yield adequate compensation.

    iii) The overall average price per pack for June is [……] which, in my view, tends to indicate that the benefit of the duopoly established by the injunction against Mylan have not yet had an effect. I bear in mind the possibility that the duopoly now in existence might make no difference to the price and volumes which Teva is able to sell pre-expiry. Overall, this is a relatively small effect.

51. In the light of the evidence now available, the points I accepted at [82], namely those in [77] (Teva's sales fluctuate) and [78] (Teva's market share fluctuates) continue to apply and they are confirmed by the additional evidence from Teva in LR-5 and LR-6. Thus, even without considering any other factors, the conclusion I reached in the final sentence of [82] (damages not an adequate remedy for Teva, largely because the uncertainties in trying to ascertain their damages would be considerable) continues to hold. Although I stated previously that I was less impressed by Teva's third reason, concerning its reputation in the marketplace as a reliable supplier and its customer relationships, I still took some account of it. The evidence on this application persuades me that I underestimated this reason before, so it adds to the conclusion. However, the significance of Teva's customer relationships has greater significance to the post-expiry position, to which I now turn.

Post-expiry

52. My previous analysis in [83] was stated in brief terms. The additional information I have now allows me to form a better and more reliable view.

53. Teva's position post-expiry is intimately tied up with the position pre-expiry. I refer to paragraphs 40-42 above, which apply equally here. As regards what I considered in paragraphs 43 (volumes), and 44 (customer relationships) Teva would stand in a very different position to Neurim. It is convenient to consider customer relationships first. In the counterfactual, Teva would enter the post-expiry period with a number of continuing relationships with the customers it had acquired by expiry, which would be likely to include at least the customers identified in LR-5. This is Teva's 'first mover advantage'. Although price would be the determining factor, if I assume that Teva would compete on price (and there is no reason to assume otherwise), existing customers would be likely to continue to order from Teva, because the mechanisms for servicing those orders would already be in place, and the more so if they purchased other drugs from Teva and all their purchases contributed to achieving an annual rebate for a certain level of overall sales.

54. In the factual, Teva would have to enter the melatonin market afresh, along with the other market entrants. I consider that Teva would be able to maintain some of its customer relationships over the seven weeks of the injunction, but it is likely that most of its customers would have had to purchase supplies of melatonin from Neurim/Flynn in the meantime. There would also be some incentive for customers to return to Teva if they had annual rebates in their sights. In the factual, the Court would know the volumes and prices which Teva was able to achieve in the post-expiry period. In the counterfactual, there would be considerable uncertainty over the volumes and customers which Teva would have managed to establish by the point of expiry (see above re pre-expiry).

55. Thus the big difference between the factual and the counterfactual would be that the Court would not know what volumes and prices Teva would have achieved over the 7 weeks to expiry and their position on the verge of expiry. It might be said that it would be a reasonable assumption that Teva would have retained (in the counterfactual) all its present customers and the sales which Teva would have made could be estimated from the sales made by Neurim/Flynn to those customers. That assumption would compensate Teva to a reasonably significant extent, but uncertainties would remain over what new customers and volumes Teva would capture in the interim period and hence over the assessment of the loss of Teva's first mover advantage. The sales which Teva achieve post-expiry in the factual (following an injunction) would not be a reliable guide to the sales Teva would have made in the counterfactual, precisely because of the loss of the first mover advantage.

56. Although the downward price spiral on expiry would drive down Teva's prices as ruthlessly as Neurim/Flynn's (and Teva might even attempt to drive the market), there remains a big difference in Teva's position as between the factual (entering the market) and the counterfactual (entering the post-expiry period with existing customer relationships and a continuing track record of sales). This analysis demonstrates why, in my view, it is essential to consider the position of each party separately and why the arguments presented by Neurim/Flynn that the effect on Teva and Neurim/Flynn would be the same (see paragraph 22.1.3 of Williams II) are wrong.

57. To summarise my conclusions so far:

i) Damages would be an adequate remedy for Neurim/Flynn pre-expiry and post-expiry their damages would not be significant. Overall, I conclude damages would be an adequate remedy for Neurim/Flynn.

ii) Pre-expiry, damages would not be an adequate remedy for Teva in view of the considerable uncertainty of what volume of sales it would have made in the 7 weeks until expiry. This uncertainty also translates into the post-expiry period (where damages would also be an inadequate remedy) and the assessment of the loss of Teva's first mover advantage.

iii) In terms of adequacy of damages, the balance on this second application has shifted further in Teva's favour. Thus the balance of the risk of irremediable harm comes down in favour of Teva.

58. In terms of other factors, Neurim/Flynn placed heavy emphasis on the failure of Teva to clear the way and repeated its loss of monopoly argument, contending that the balance of the risk of injustice had changed along with the status quo. I have addressed the loss of monopoly argument already: it begs the question as to which side will emerge the victor at the trial and on any appeal.

59. Neurim/Flynn contend that Teva had several opportunities to clear the way but I found these contentions unconvincing. First, Neurim/Flynn suggested that upon grant of the (divisional) Patent, Teva could have taken steps in June/July 2021 to revoke it. This is unrealistic because even with an expedited trial, Teva would not have achieved a final cleared way probably until after expiry (assuming an appeal). Second, Neurim/Flynn contended that Teva could have applied to be joined to the Mylan action and/or have their own action heard alongside it. Again, I consider this an unrealistic suggestion because Teva would have had either no or virtually no control over the running of that action. Furthermore, from observing those proceedings, I apprehend that Teva might already have concluded they would be able to mount a better case if it proved necessary. It was understandable for Teva to wait to see whether Mylan prevailed. Furthermore, as Ms May pointed out, it is not as if Neurim/Flynn sought to bring Teva into the second Mylan action. It is entirely understandable why Neurim/Flynn did not do that, because joinder of Teva would probably have destroyed Neurim/Flynn's chances of getting a result before expiry. This indicates that Neurim/Flynn would have fiercely resisted any attempt by Teva to join into that action.

60. As I indicated in my First Judgment at [87], the primary reason why Teva did not realistically have an opportunity to clear the way was because of Neurim/Flynn's own manoeuvring at the EPO in allowing EP443 to be invalidated and then bringing forward the divisional to be granted with only slightly more than a year to expiry.

61. As for the status quo, in my First Judgment at [89] I applied the dictum of Lewison LJ (Kitchin LJ agreeing) at [19] from *Frank Industries v Nike* and concluded the relevant status quo was that which existed at the date the first Application Notice was deemed served on Teva – 15th March 2022. On this application, in addition to the dictum of Lewison LJ, Mr Campbell reminded me of the additional point made in [21]: '…*I do not consider that Nike can improve its position by pushing on in the face of reasoned complaints*.'

62. That additional point arose in the very different circumstances where Nike were very slow in responding to the initial letter of complaint and the interval between the start of the campaign complained of and that letter was very short. In the present case, I found in the First Judgment at [47] that Teva did make their intentions clear to the Claimants. Teva proceeded and Neurim/Flynn made no attempt to stop Teva's sales of melatonin until some 5 months after Teva entered the market. This additional point does not assist Neurim/Flynn in any way.

63. On this second application, the relevant status quo is that which existed at the date of deemed service of this second application notice, 8th June 2022. By then, Teva had been on the market for nearly 8 months and there was just over 2 months until expiry. This points firmly in favour of no injunction.

64. Neurim/Flynn's final argument posed this question:

> '…if the Court does not grant an injunction now then litigants in cases such as the present are, in our submission, entitled to ask whether the UK patent system and specifically the way interim injunctions are considered is actually fit for purpose. It is common for there to be multiple generic companies entering or making moves to enter the market where a valuable pharmaceutical is for one reason or another coming off patent. Is a patentee supposed to sue all of them at once, and create one "pharma-mega action"? Is the patentee supposed to fight, win, and then start all over again against another Defendant? Neither of these approaches is satisfactory for industry. Nor is it acceptable simply to wait until trial since markets move much faster than trials and interim injunctions are there to prevent injustice pending trial.'

65. In response, it is worth bearing in mind that Neurim/Flynn did start this action against Teva on 5 November 2021, although, as I indicated in my First Judgment, Neurim/Flynn was faced with a sufficient threat from Teva from early July 2021 onwards. It was Neurim/Flynn's decision not to seek interim injunctive relief on Teva's launch in mid-October 2021, even though Neurim/Flynn had sufficient information to bring an application prior to launch. I realise that Neurim/Flynn had been refused interim relief against Mylan more than a year before and Mylan had been on the market since September 2020. It is not easy to predict what would have happened if Neurim/Flynn had launched an application for interim relief against Teva in mid-October 2021, when the trial of the preliminary issues in the Second Mylan action was pending. I can see there would have been considerable obstacles (and resistance) to Teva being joined into that Second Mylan action. It is unlikely that Teva would have agreed to be bound by the outcome. However, just because one generic is on the market does not mean that the second entrant (Teva) would not be injuncted. After all, the relevant status quo at that point would have been that Teva was not on the market.

66. All these considerations indicate, in my view, that the system is fit for purpose. The fact that Neurim/Flynn have faced a highly unusual set of circumstances does not detract from that conclusion, particularly where Neurim/Flynn's own decisions contributed to the creation of those circumstances. Although this is scant consolation at present, as I said in the first sentence of [86], I continue to have some sympathy for Neurim/Flynn because they are relatively small entities fighting two powerful generic

entities. However, if Neurim/Flynn establish that the Patent is valid and infringed by Teva, I have concluded they will receive adequate compensation and consolation then.

67. For all these reasons, I refuse this second application for interim relief.

68. As before, this judgment exists in a version which is confidential to the parties. I provided a draft Judgment to the parties with the invitation to agree redactions so that a non-confidential version could be made public. This was done.

Costs

69. Teva had made their submissions as to costs in their Skeleton Argument, seeking an order for their costs in any event on the indemnity basis. With the draft Judgment, the parties received my provisional view on costs and were able to make submissions. Neurim/Flynn noted that on the First Application, I ordered them to pay Teva's costs in any event, but nonetheless submitted that the costs of this Second Application should be reserved. I do not agree, for the same reasons as I set out at [3]-[4] in my Order of 7th June 2022, principally because none of the central issues on this Second Application will be considered at trial. I order Neurim/Flynn to pay Teva's costs of this application in any event.

70. Neurim/Flynn also resisted costs on the indemnity basis for a number of reasons. The principle on which costs may be awarded on the indemnity basis is not in dispute. As Teva submitted and Neurim/Flynn accepted:

> 'The case law makes clear that it is appropriate to exercise this discretion where the circumstances include "something outside the ordinary and reasonable conduct of proceedings" sufficient to take the case "out of the norm" (see *Esure Services Ltd v Quarcoo* [2009] EWCA Civ 595, citing and explaining *Excelsior Commercial and Industrial Holdings Ltd* [2002] EWCA Civ 879).'

71. Teva submitted that indemnity costs were appropriate because this '*Second Application was outside the ordinary and reasonable conduct of proceedings because it is nothing more than a rehash of the First Application and fails the American Cyanamid test for all the same reasons.'*

72. Neurim/Flynn submitted this was not a rehash because, in my judgment above, I recognised the evidence was different – see e.g. [5] above. They pointed also to my observation in [66] that Neurim/Flynn '*have faced a highly unusual set of circumstances',* to their position vis-à-vis Teva and Mylan and to the two developments which they relied upon as changing the circumstances.

73. I have explained above why I considered it right to consider this application on the basis of the updated evidence which was before me. Despite the fact that I had more information to assist me regarding the post-expiry period, overall the conclusions were the same. Indeed, as I held at paragraph 57 iii) above, the balance came down more firmly in Teva's favour. Furthermore, on the First Application the issue I decided was whether Teva should be restrained pending expiry of the Patent. Although the period in question was shorter, this Second Application raised the same issue again. In all the circumstances I consider this was outside the ordinary and reasonable conduct of

litigation and sufficiently so to take this application out of the norm. Accordingly, I order the costs of this application are to be assessed on the indemnity basis if they cannot be agreed.

Interim payment on account

74. Once again, the costs incurred on both sides were very high for a day's application. Teva's total costs amounted to £166,600. Neurim's costs were £90,390 and Flynn's costs were £99,143, yielding total costs on the Claimants' side of £189,533. Neurim/Flynn submitted it was understandable that their costs were higher than Teva's because they filed more witness statements and two expert's reports rather than the single report filed by Teva. They also highlighted the alleged high use of grade A solicitor time. I do not find that surprising bearing in mind that my order for expedition of this application (as sought by Neurim/Flynn) put Teva's solicitors under time pressure. Overall Neurim/Flynn submitted the interim payment should be no more than £80,000.

75. Bearing in mind I have thought it right to order costs on the indemnity basis, I consider a reasonable sum by way of payment on account of Teva's costs is £100,000, such sum to be paid within 14 days.

Permission to Appeal

76. Neurim/Flynn provided me with reasonably detailed draft Grounds of Appeal and draft Skeleton in support of such Appeal. They submit I was wrong on virtually every point including (a) in failing to form a clear view on the merits, submitting I should have concluded that it was unlikely that Teva's case would succeed; (b) on damages being an adequate remedy for Neurim/Flynn, contending that their damages would be more difficult to quantify and much more substantial than any unquantifiable damage suffered by Teva, alternatively that the damage to both sides was unquantifiable to a similar extent; (c) on the point that Teva had had several opportunities to clear the way; (d) on the point as to whether the patent system is still fit for purpose in the light of the facts of this case; and finally (e) in failing to take proper account of the fact that no injunction would mean the Claimants would lose their monopoly once and for all, submitting that I was wrong to construe the value of their statutory monopoly as merely 'a question of money'. I do not think I did this. What I concluded, in the absence of a convincing answer to my question, was that the loss of Neurim/Flynn's ability to exclude Teva had to be assessed using the *American Cyanamid* guidelines - see paragraph 47 above.

77. Notwithstanding all these allegations that I got it wrong, I did not find, either in the draft Grounds or the draft Skeleton, any reasons why I was wrong or, at least, any reasons beyond the arguments originally presented by Neurim/Flynn on this Second Application and which I rejected. In paragraph 47 above, I stated I did not get any convincing answer to my question and none was provided in Neurim/Flynn's submissions seeking permission to appeal.

78. In the circumstances I was not able to identify any issue of principle sufficient to give rise to a real prospect of success on appeal nor do I consider that there is some other compelling reason for an appeal to be heard. Accordingly, I refuse permission to

appeal. If the Court of Appeal disagrees and considers that their judgment in the Mylan action made all the difference, then they can give permission.