

Neutral Citation [2021] EWHC 530 (Pat)

Claim No: HP-2020-000005

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

Royal Courts of Justice <u>Rolls Building</u> <u>7 Rolls Buildings</u> <u>Fetter Lane</u> London EC4A 1NL

Date: 12 March 2021

Before:

THE HONOURABLE MR JUSTICE MARCUS SMITH

BETWEEN:

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

Claimants

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

Defendants

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

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

Mr Mark Vanhegan, QC and Mr Mitchell Beebe (instructed by Taylor Wessing LLP) for the Defendants

Hearing date: 22 February 2021

Judgment on Consequential Matters

I direct that no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

Mr Justice Marcus Smith:

A. INTRODUCTION

- 1. Over the course of four days in October and November 2020, I heard the trial of a patent claim brought by Neurim Pharmaceuticals (1991) Limited (**Neurim**) and Flynn Pharma Limited (**Flynn**) against Generics UK Limited and Mylan UK Healthcare Limited (collectively, unless the context otherwise requires, **Mylan**). The issues before me concerned the validity of a patent, EP (UK) 1,441,702 B1 (the **Patent**). Infringement was not a separate issue before me: Mylan accepted and admitted infringement <u>if</u> the Patent was valid.
- 2. For the reasons given in my judgment (the Judgment), handed down on 4 December 2020 under Neutral Citation Number [2020] EWHC 3270 (Pat), I concluded that the Patent was valid, and so infringed by Mylan. I do not propose, in this Consequentials Judgment, to repeat the Judgment, which I take as read for the purposes of this Consequentials Judgment. I also propose to adopt the terms and abbreviations used in the Judgment, as set out in Annex 1 to the Judgment.
- 3. For reasons that it will be necessary to explore in this Consequentials Judgment, the orders consequential on my Judgment are by no means straightforward and I have heard detailed submissions from both the Claimants and Mylan as to the orders I should make. At first sight, to a reader of the Judgment only, that might seem surprising. Apart from one point the question whether Flynn was an exclusive licensee within the meaning of sections 67 and 130 of the Patents Act 1977, which I shall term the Exclusive Licence Point I found in favour of the Claimants and concluded that Mylan's challenges to the validity of the Patent all failed, and that Mylan was either threatening to, or was, infringing the Patent.¹ On the face of the Judgment, therefore, one might expect an injunction enjoining Mylan from infringing the Patent to follow; and for the Claimants to obtain an order for all or substantially all their costs.
- 4. No order in these terms presently exists, although orders along these lines were made in the immediate aftermath of the Judgment on 16 December 2020 (the **16 December 2020 Orders**).
- 5. It is necessary, before describing the matters at issue before me, to set out the facts in some detail. I do so in the next section, Section B.

B. THE FACTS

(1) The history of these proceedings

6. The claim was commenced by the Claimants under a Part 7 Claim Form on 14 February 2020. Pleadings and amendments to pleadings followed, in the usual course, and it is unnecessary to consider these in any great detail. Paragraph 1 of the Amended Particulars of Infringement provided that:

¹ See my summary of conclusions at [148] of the Judgment.

"The Defendants [i.e., Mylan] threaten and intend to infringe the Patent by threatening and intending to do the following acts in the United Kingdom without the consent of the Claimants, namely: keep, use, dispose of and/or offer to dispose of a prolonged release melatonin product obtained directly by means of a process as claimed in at least claim 1 and being a product within the scope of claim 4 of the Patent."

- 7. There was, from the Claimants' perspective, considerable urgency in ensuring that Mylan did not infringe the Patent. The threat to the Claimants' United Kingdom monopoly, arising out of the Patent, and the threat to the market that the Claimants' had established in reliance upon the Patent, were to the Claimants both obvious and urgent. The urgency was exacerbated, in the Claimants' eyes, by two factors:
 - (1) First, a failure, on the part of Mylan, to offer any unequivocal undertaking not to infringe the Patent whilst these proceedings were on-going.
 - (2) Second, and relatedly, a failure on the part of Mylan to "clear the way" to bringing its (allegedly infringing) product to market by commencing revocation proceedings in these courts well before Mylan was at the stage of actually threatening to infringe. In short, as part of its preparations to bring a rival product to market, Mylan should according to the Claimants have "cleared the way" by having the issue of the Patent's validity and any separate questions of infringement resolved well-before there could be any question of actual or imminently threatened infringement.
- 8. As I have noted, the Claim Form was issued on 14 February 2020. It was served on Generics UK Limited (as the sole defendant, and now the First Defendant) on 17 February 2020. Thereafter:
 - (1) On 2 March 2020, the Claimants issued an application for an interim injunction against Generics UK Limited, which was fixed on 9 March 2020 to be heard between 18 and 20 May 2020 (the **Interim Relief Application**).
 - (2) On 13 March 2020 the Claimants issued an application for "interim interim" relief, seeking interim relief pending the hearing of the Interim Relief Application (the **Holding Application**).
 - (3) On 16 March 2020, the Claimants were informed that Mylan Healthcare UK Limited was performing the relevant acts about which complaint was made in the UK and thus should be a defendant to the proceedings.
- 9. The matter came before Nugee J on 19 March 2020. At this hearing:
 - (1) The Claimants sought permission to add Mylan Healthcare UK Limited as the Second Defendant. Mylan Healthcare UK Limited formally consented to be added as the Second Defendant and Nugee J gave permission to the Claimants to amend the Claim Form to add Mylan Healthcare UK Limited to the proceedings. The Claimants' Amended Claim Form, adding the Second Defendant, was sealed on 30 March 2020.

- (2) Mylan (as I can now safely refer to both Defendants) gave undertakings not to launch or deal in Mylan Melatonin product, the (allegedly) **Infringing Products**,² until 18 May 2020, thereby addressing the Holding Application. Nugee J accepted these undertakings.
- (3) At the same hearing, Mylan (with the consent and agreement of the Claimants) formally sought expedition of the UK trial. Nugee J directed that the trial be expedited for hearing on the first available date after 21 October 2020.³ As I have described, the trial was heard, as envisaged by Nugee J, in late October/early November 2020, and the Judgment was handed down after having been circulated in draft on 4 December 2020.
- 10. The Interim Relief Application came before me on 20 May 2020. The application was refused for the reasons given in my judgment of 3 June 2020 ([2020] EWHC 1362 (Pat)). Mylan continued to give the undertakings it had given to Nugee J so as to enable the Claimants to appeal my decision to the Court of Appeal. The appeal was heard by the Court of Appeal (Floyd, Males and Arnold LJJ) on 18 June 2020, and the outcome, affirming my order, was notified to the parties on 19 June 2020. The judgment of the Court of Appeal, explaining its decision, was handed down on 24 June 2020 ([2020] EWCA Civ 793). Permission to appeal to the Supreme Court was not given, although it was sought by the Claimants.
- 11. The consequence is that Mylan was not enjoined from (allegedly) infringing the Patent and was free to import into the United Kingdom, and sell, Infringing Products. In fact, although there was a clear suggestion by Mylan that the sale of Infringing Products was imminent and certainly that was the Claimants' concern and understanding the importation and/or sale of Infringing Products did not occur until rather later in the year, towards the end of 2020, in about September.⁴ Thus, importation and/or sale of Infringing Products had only just begun and/or was truly imminent at about the time I handed down the Judgment.

(2) **Proceedings in the European Patent Office**

12. The Patent was granted to Neurim on 10 May 2017. Mylan filed a notice of opposition to the Patent on 9 February 2018. This procedure – which operates post-grant – enables any third party to challenge the validity of a patent at the European Patent Office (the EPO). Mylan was not the only opponent of the Patent: notices of opposition were also filed by Aspire Pharma Limited and Teva Pharmaceutical Industries Limited.

² I have eschewed the undoubtedly more correct abbreviation of "Allegedly Infringing Product" just for the sake of brevity. I underline the point, however, that the Claimants were <u>alleging</u> infringement, which Mylan denied. As will become clear, Mylan was proved correct, as the Patent was revoked *ab initio*.

³ See paragraph 6 of the order of Nugee J dated 19 March 2020.

⁴ Because there was some suggestion that Mylan had either not been frank about the position or had even mislead the Claimants and the court about the imminence of any (alleged) infringement, I should be clear that I reject any such suggestion. These were obviously matters of extreme commercial sensitivity, and Mylan was (in my judgment, properly) circumspect in what is said. But I refuse to read anything into the delay in bringing the Infringing Products to market beyond the fact that for reasons that were, no doubt, good and proper, Mylan could not do it any sooner.

- **13.** The Opposition Division of the EPO published a preliminary opinion on the Patent on 8 March 2019, expressing the view that the Patent was invalid for lack of novelty. The precise reasons for this preliminary opinion do not matter.
- 14. There was an oral hearing before the Opposition Division on 20 November 2019. Mylan (as well as Neurim) attended: the other opponents did not. The Opposition Division confirmed the preliminary opinion that it had expressed, giving that decision orally at the conclusion of the hearing on 20 November 2019. In his evidence before me, Dr Royle (a partner at Taylor Wessing LLP, solicitors for Mylan) described the position as at 20 November 2019 as follows:⁵

"...The [Opposition Division] found that the Patent was invalid for lack of novelty over Haimov and its decision was given orally at the conclusion of the hearing on 20 November 2019. Other grounds of invalidity were raised by Mylan, but the EPO does not necessarily consider all grounds of invalidity as it stops the assessment once a patent is held to be invalid and there is no further claim set to consider. For this reason, in the present case, inventive step and sufficiency were not considered by the [Opposition Division] as the Patent had been found to be invalid for lack of novelty over Haimov. The written decision of the [Opposition Division] was issued on 2 January 2020..."

- 15. Neurim appealed this decision. There is an automatic right of appeal from a decision of the Opposition Division to the Technical Boards of Appeal of the EPO: permission to appeal does not have to be sought from, or given by, any organ within the EPO. A notice of appeal must be sent by the appellant. This simply states an intention to appeal; there is then a period within which substantive grounds of appeal have to be filed. The deadlines for these two stages are within two months and within four months of the written decision under appeal. In this case, a notice of appeal was sent by Neurim well within the applicable time limit on 14 January 2020; the substantive grounds of appeal were filed on 12 May 2020, shortly before the expiry of the applicable deadline.
- 16. The effect of an appeal against a decision of the Opposition Division to revoke a patent is suspensive. Thus, in this case, the Opposition Division's decision to revoke the Patent was not operative pending the outcome of the appeal by Neurim. The Patent would be treated as validly granted *pro tem*.
- 17. Appeals to the Technical Boards of Appeal can take some time. Without expedition, Neurim's appeal of the decision of the Opposition Division might have been heard as late as the first quarter of 2022. As it happens, both parties sought expedition of the appeal. It is entirely unsurprising that there was a coincidence of interest between the parties in having the appeal resolved quickly.⁶
- 18. Although I was told (at the hearing before me on 20 May 2020) that both parties had sought expedition, the parties were not able to tell me, at that time, whether their representations would bear fruit. My decision of 3 June 2020⁷ records that the Opposition Division's decision "has been appealed, but it is unlikely that a final decision on the

⁵ Sixth Witness Statement of Dr Matthew Royle (**Royle 6**) at paragraph 7.

⁶ There was some suggestion in the evidence before me that Neurim had dragged its feet in prosecuting the appeal and in supporting Mylan's request for expedition. I do not consider that these suggestions are well-founded, and I reject them.

⁷ See paragraph 10 above.

appeal will be made before 2022 at the earliest. It is perfectly possible that there will be no decision until the Patent has expired which, as I have said, will be on 12 August 2022."⁸

- 19. Until after the handing down of the Judgment, my understanding continued to be that the trial and determination of the proceedings in this court would pre-date by months, and possibly a year or more the hearing before the Technical Boards of Appeal. Much of what follows concerns the inter-relationship between these two sets of proceedings, which I shall refer to as the UK Proceedings and the EPO Proceedings.⁹
- 20. As it happens, the parties would have been aware <u>before</u> the trial of the UK Proceedings before me (but, to be clear, <u>after</u> the hearing on 20 May 2020) that their requests for expedition in the EPO Proceedings had borne fruit. On 3 June 2020, a summons was issued by the Technical Board of Appeal for oral proceedings to be held on 17 and 18 December 2020. Those dates were then lost (on 11 November 2020, the hearing was rescheduled by the Technical Board of Appeal to 20 and 21 July 2021) and then reinstated by the Technical Board of Appeal (on 20 November 2020).
- 21. I will come to the question of whether and, if so, how the parties should have kept the court in the UK Proceedings apprised of what was going on in the EPO Proceedings. That failure and I say this without criticism meant that when I handed down Judgment on 4 December 2020, I was immediately faced with a situation where a possibly inconsistent outcome in the EPO Proceedings was imminent (that is, would very likely occur at the end of the 18 December 2020). In a very real sense, this is the single factor that has resulted in two sets of consequential hearings and this, extremely lengthy, Consequentials Judgment.
- **22**. That said, I fully acknowledge the difficult position the parties were in:

⁸ [2020] EWHC 1362 (Pat) at [8].

⁹ In their corrections to the draft of this Judgment, the Claimants stated that the position regarding the EPO Proceedings was made clear in the parties' written submissions before the pre-trial review on 5 October 2020 and suggest that this Consequentials Judgment should state that my understanding as to the position before the EPO existed from early October onwards. Since that was very much not my subjective state of mind (which is as described in this paragraph), I have returned to the parties' written submissions for the pre-trial review. So far as I can tell, the Claimants' skeleton says nothing about the hearing scheduled before the Board of Appeal. Mylan's skeleton has this sentence at the end of paragraph 3: "Neurim has appealed that decision, and a hearing has been fixed before the Technical Board of Appeal for 17/18 December 2020". I regret that I did not pick this up or, if I did, I have forgotten that I did. It does seem to me that this sentence is nothing to the point. The pre-trial review was concerned mainly with the mechanics for trial, particularly in the COVID-19 circumstances that prevailed. Neither party sought to apply for an adjournment, or even suggested that that was a matter I should consider. As a counsel of perfection, I should have raised this of my own motion in light of the half-sentence in Mylan's written submissions and – to be clear – I failed to do so. But, as is clear from the substance of this Consequentials Judgment, the point to which I attach significance is the decision of the parties not to raise the matter formally - by way of application to adjourn or for directions - so that the interplay between the EPO Proceedings and the UK Proceedings could be explicitly handled. That did not happen. Notwithstanding the terms of Mylan's skeleton, and the Claimants' point on the draft judgment, I have retained the wording of the draft judgment because this reflects (for better or worse) my understanding at this and other times.

- The fact is that as the events in this case demonstrate the hearing date before (1) the Technical Board of Appeal was liable to change, and I can guite understand why the parties would wish to retain the expedited trial ordered by Nugee J. I do not know, and have not inquired, as to what Nugee J was told about the proceedings before the EPO when he made his order of 19 March 2020.¹⁰ As I shall come to describe, the procedural inter-relationship between patent actions in this jurisdiction, and revocation proceedings before the EPO, has been considered with some care by the courts of this jurisdiction; and I have no doubt that the material facts were properly described to Nugee J on 19 March 2020, and that his order for expedition was made in light of these facts. The parties may well have taken the view that it was senseless to seek to adjourn a trial expedited by Nugee J simply because the appeal before the Technical Board of Appeal had, itself, been expedited. As it happens, I do not agree with this, and I consider the matter should have been brought back before the court. But to say this was anything other than a difficult question would be to understate matters.
- It is certainly not the case that the decision of the Technical Board of Appeal in the (2) EPO Proceedings – which is typically given orally at the conclusion of the oral hearing, with written reasons to follow - would inevitably have been determinative of the UK Proceedings, rendering that trial of those proceedings essentially purposeless in all cases. True it is, that was one possibility - and, unfortunately, it is the possibility that eventuated here. As I shall describe further, if the EPO revokes a patent, that revocation holds good in relation to all territories of all states subscribing to the European Patent Convention (or **EPC**).¹¹ On this basis – even if I found the Patent valid, which is the conclusion I reached, that decision would be "trumped" by the decision of the Technical Board of Appeal. On the other hand, if the appeal before the Technical Board of Appeal had succeeded (and the Patent found to be valid) then a decision by me to revoke would have continued to stand (albeit only in the United Kingdom), notwithstanding the outcome in the EPO. One can therefore see exactly why Mylan, in particular, would have wished to hold the trial before me, because it enabled Mylan to take two shots in short order at revoking the Patent.
- 23. As I have described, the Judgment was handed down on 4 December 2020. I shall describe the events consequential on that Judgment in due course in Section B(3) below. To conclude the events in the EPO Proceedings, written submissions were made by both parties, and the hearing took place (by "mixed mode", that is part in person and part remotely) before the Technical Board of Appeal on Thursday 17 and Friday 18 December 2020.
- 24. It is not appropriate for reasons that I will come to to set out in any detail the events that took place before the Technical Board of Appeal. It is sufficient to say that during the course of the hearings, the Technical Board of Appeal expressed their opinion orally that the Patent lacked sufficiency (meaning that the appeal would be dismissed). Neurim was offered the opportunity to consider its position in a short adjournment of about an hour. After this adjournment, Neurim formally withdrew its appeal of the Opposition

¹⁰ See paragraph 9 above.

¹¹ I.e., the Convention on the Grant of European Patents (Munich, 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000)

Division's decision. As a result, there is no further expression of the views or position of the Technical Board of Appeal.

- 25. It is important that I stress that the withdrawal of an appeal before a Technical Board of Appeal even during the course of the hearing of the appeal itself is entirely normal and envisaged by the processes of the EPO. These processes were helpfully described by Mr Thomas Leonard, a partner in Kilburn & Strode LLP and a qualified European Patent Attorney:¹²
 - (1) The withdrawal of an appeal before the Technical Board of Appeals is a basic right available to any patentee. It is a standard procedural step, even during the course of oral proceedings. Indeed, certain incentives (notably, reimbursement of a part of the appeal fee) exist to encourage withdrawal of appeals at any time.
 - (2) In this case, although the Technical Board of Appeals had expressed their oral opinion that the claims of the Patent would lack sufficiency, that decision had not been announced or made in any formal sense in the EPO Proceedings. The adjournment was offered, I infer, at precisely this stage in the proceedings, so as to give Neurim a real choice in how to proceed.
 - (3) Neurim's choice was essentially twofold:
 - (a) It could proceed with the appeal, in which case in the ordinary course the Technical Board of Appeal would announce their final decision to dismiss Neurim's appeal, thus ending the appeal's suspensive effect on the earlier decision of the Opposition Division to revoke the Patent. The decision of the Opposition Division would become final at that time and in due course (some two to six months later) a written decision giving reasons would be issued. The real point of proceeding to a final decision would be to enable Neurim to file a petition for review of the Technical Board of Appeal's decision. Such petitions for review may only be filed on limited ground; and are rarely successful.
 - (b) It could act as it did, and withdraw the appeal, in which case the Technical Board of Appeal would not issue a written decision (or even announce a formal decision orally), Neurim being the sole appellant. The appeal proceedings would then be terminated following the withdrawal, and the earlier decision of the Opposition Division to revoke the Patent would become final.
- 26. The effect of an unsuccessful appeal and the effect of the withdrawal of an appeal is unsurprisingly exactly the same. The earlier decision of the Opposition Division to revoke the Patent would become final and the Patent would be revoked. That revocation is *ab initio*. It is as if the Patent never was.¹³ That is what occurred on 18 December 2020.

¹² Mr Leonard gave a witness statement on behalf of Neurim (**Leonard 1**), which I found very helpful. I should say that Mr Leonard was commenting after the event and was not instructed in the appeal before the Technical Board of Appeals. Rather, he reviewed the file after the event, and it was that review that formed the basis of the witness statement.

¹³ See Article 68 of the European Patent Convention.

27. In the course of argument, I was invited to speculate as to the thinking and strategy that might have informed Neurim's conduct. It seems to me that it would be very difficult to do so without invading clearly privileged matters. Furthermore, for reasons that I give later on in this Consequentials Judgment, to do so would not assist me in determining the matters before me. Accordingly, I consider this question no further.

(3) Matters consequential on the Judgment

- 28. My Judgment was handed down on 4 December 2020, and had been circulated in draft for several days before then. As I have stated,¹⁴ Neurim was (with the exception of the Exclusive Licence Point) the successful party. By the Judgment, I had found the Patent to be valid and (because there was no self-standing argument on infringement) infringed.
- **29.** Given the threat of infringement and the absence of an interim injunction enjoining infringement,¹⁵ Neurim was concerned to put in place final injunctive protection as soon as possible, and in any event before the end of term, which was Monday 21 December 2020. Given the absence of an interim injunction, it seemed to me that if Neurim was pressing for an early hearing of consequential matters, a hearing ought to be accommodated, if at all possible. Given the diaries of all concerned and, in particular, the diaries of leading counsel and the court the hearing was fixed for Wednesday 16 December 2020, which was later than I would have liked.
- **30.** By this time, I had been informed of the imminent hearing before the Technical Board of Appeals on Thursday 17 and Friday 18 December 2020. In an ideal world, given that the outcome of the appeal before the Technical Board of Appeal was anticipated on Friday evening, the consequentials hearing would have been held on the last day of term, Monday 21 December 2020. But that was not possible.¹⁶
- 31. Accordingly, with all parties and the court appreciating that the Patent, which I had found to be valid and infringed, might (some 48 hours after the hearing consequential on Judgment on 16 December 2020) be revoked *ab initio* in the EPO Proceedings, the hearing consequential on my Judgment in the UK Proceedings came on. At my instance, the hearing covered all outstanding consequential matters, and not just the question of an injunction.¹⁷
- 32. Mylan's position was stated very clearly in its written submissions on this occasion:
 - "2. There was no urgency for the form of order hearing to occur prior to the end of term. Neurim's appeal against the decision of the EPO Opposition Division revoking the Patent as invalid by anticipation by Haimov is fixed to be heard by the Technical Board of

¹⁴ See paragraph 3 above.

¹⁵ As to which, see paragraphs 9 to 11 above.

¹⁶ The problem might also have been averted had Mylan offered suitable undertakings to Neurim. I do not know what transpired on this point – and I do not need to know for the purposes of this Consequentials Judgment. What is important is that no such undertakings were agreed – and, given the difficulties of the argument on 16 December 2020, it is easy to see why the parties needed the intervention of the court to resolve their differences. This is not, in any way, intended to be a criticism of the parties, but merely an explanation as to why I considered a hearing to be necessary.

¹⁷ The reason the Claimants wanted an early hearing was because of the injunction, but it seemed to me sensible to use the day that had been allocated to cover as much as possible.

Appeal ("TBA") in oral proceedings on either 17 or 18 December 2020. On 27 November 2020, the TBA issued a provisional opinion which suggests that at the oral hearing the TBA will consider all grounds of invalidity, not just novelty as was considered by the Opposition Division...

- 3. Unless Neurim are successful with their appeal, the Patent will be revoked *ab initio* for all European countries, including the UK. If found invalid, it would be as if the Patent (including all designations) had never been granted. In accordance with the usual practice it is expected that the TBA's decision will be announced at the oral proceedings on 17 or 18 December 2020 with written reasons to follow...
- 4. Should it transpire that the Patent is found invalid by the TBA, then the Claimants will not be entitled to any substantive relief by way of injunctions or any financial remedies. Mylan will also contend that it should be entitled to its costs of these UK proceedings. However, if following this hearing this Court were to have ordered any such relief, the parties would be required to return to Court to rectify the situation. The procedural way forward is not necessarily straightforward and may depend on whether this Court has become *functus officio*. These procedural difficulties could have been avoided had Neurim taken a sensible approach and agreed for the final order hearing to be listed early in Hilary Term in 2021."
- **33.** Granted the premiss that Neurim's appeal would fail, and the Patent be revoked, there is much to agree with in these paragraphs. But the premiss was in dispute: Neurim's position was that its appeal would succeed, and that there was real need to set in place an injunctive regime that would commence as soon as possible after the Judgment for the life of the Patent.
- 34. I was in no position to anticipate the outcome of the EPO Proceedings, and I regard the parties' contentions on this point as no more than informed crystal-ball-gazing. Accordingly, it seems to me that the premiss in Mylan's written submissions that there was "no urgency" for the hearing to occur before the end of term is, and was, wrong in the most fundamental sense, in that it disregarding entirely:
 - (1) The legitimate interest of Neurim to have an order consequential on my Judgment; and
 - (2) The legitimate interest of Neurim to have such an order in place quickly, given (*i*) the threat or actuality of infringement by Mylan of a Patent I had found to be valid and infringed, (*ii*) the absence of an interim injunction and (*iii*) the absence of any undertakings from Mylan regarding its future conduct.
- 35. I quote from these paragraphs in Mylan's written submissions, not to highlight my disagreement with Mylan's basic premiss (although I do disagree with it, for the reasons I have given), but because they articulate extremely clearly the basis upon which the hearing on 16 December 2020 proceeded. All parties (and the court) were aware of the potential significance of the hearing before the Technical Board of Appeals in the EPO Proceedings. Mylan's written submissions were making crystal clear that any order made on 16 December 2020 might have to be revisited in light of the outcome of the appeal before the Technical Board of Appeal. Indeed, Mylan's point anticipating the failure of Neurim's appeal was that any order seeking to implement the consequences of my Judgment would have to be revisited and "the parties would be required to return to court to rectify the situation".

- **36.** At the hearing, the usual matters the injunction, permission to appeal and costs were debated and I made a series of orders (which I have termed the 16 December 2020 Orders¹⁸). As to these:
 - (1) The 16 December 2020 Orders were made in the course of a long day, during the course of which I heard submissions and made rulings on a whole variety of points.
 - (2) The orders that I made were intended to be drawn up by the parties in the usual way. I made clear, in the course of argument, that I wanted a finally drawn order in place <u>before</u> the outcome of the appeal before the Technical Board of Appeal.¹⁹
 - (3) In the event, the parties were unable to agree the terms of an order. Over the course of the next fortnight, I was presented with various draft orders from both sides. No order setting out the precise wording of the 16 December 2020 Orders was ever agreed by the parties. In these circumstances, it is difficult to set out in writing precisely the wording of the orders that I made, given that no order was formally drawn (not because of any "slip", but because the parties were at odds on the substantive wording).
 - (4) Nevertheless, it is important that I set out at least in relatively broad-brush terms²⁰ what was ordered, so that it is clear from the face of this Consequential Judgment what orders were made. The 16 December 2020 Orders comprised and/or made provision for:
 - (a) A declaration of validity of the Patent and a declaration of infringement of the Patent by Mylan.
 - (b) A declaration that Flynn was not an exclusive licensee under the Patent.
 - (c) A certification that the validity of the claims of the Patent had been unsuccessfully contested by Mylan pursuant to section 65 of the Patents Act 1977.
 - (d) A dismissal of Mylan's counterclaim for invalidity.
 - (e) Permission to amend the Patent.
 - (f) An injunction enjoining Mylan from infringing the Patent. That injunction was to commence effect from 9:00pm on Friday 18 December 2020, but was subject to a "sunset" provision in the event of Neurim's appeal before the Technical Board of Appeal being unsuccessful. (The prospect of Neurim

¹⁸ See paragraph 4 above.

¹⁹ See page 120 of the transcript: "...What I am going to invite the parties to do is take away the draft [order that was before me] in light of the ruling that I am going to be giving at the end of the submissions and work it up, I hope with helpful indications from me as to the direction in which it should go, and I will look at it with a view to having it made before 9 o'clock on Friday. So we are not drafting here, but indicating the direction of the draft of the order, so that is where I am coming from."

²⁰ Clearly, some of the detail does not matter, and where that is the case, I have omitted it. My statement of what was ordered is derived from the (contentious) draft orders that were submitted to me, both at the hearing and subsequently, and the transcript of what was said on 16 December 2020.

withdrawing the appeal was not canvassed before me. Had it been, I obviously would have included it as one of the events that would cause the injunction to lapse.) Pending the coming into force of the injunction, Mylan offered, and I accepted, various undertakings as to how the Infringing Products might be dealt with.

- (g) The delivery up of and/or destruction of Infringing Products.
- (h) An inquiry as to damages or an account of profits.
- (i) Costs. Essentially, the Claimants were awarded their costs, subject to a deduction reflecting the Claimants' failure in respect of the Exclusive Licence Point.
- (j) Permission to appeal. Essentially, I gave permission to the Claimants to appeal the Exclusive Licence Points, and I refused Mylan permission to appeal my declarations of validity of the Patent.
- (k) The protection of confidential material under CPR 31.22.
- (5) Even <u>after</u> the outcome of the appeal in the EPO Proceedings was known and the Patent therefore revoked *ab initio* Neurim sought to persuade me to make an order effectively embodying that which had been ordered on 16 December 2020. It seemed to me that this was an inappropriate course, for two reasons:
 - (a) First, it was something of an exercise in futility. The precise terms of the 16 December 2020 Order were, as I have described, simply not agreed between the parties. It would have been difficult for me particularly knowing the outcome of the appeal before the Technical Board of Appeal even to attempt to draw up precisely the order that I would have made before knowing the outcome of the appeal, given the absence of agreement between the parties.
 - (b) Secondly, and much more seriously, although not drawn, the 16 December 2020 Orders <u>had been made</u>. There was, given the inevitable lack of clarity arising from the fact that the precise wording of these orders was <u>not</u> agreed, a very real risk that Mylan might inadvertently end up in breach of something that had been ordered on 16 December 2020 in circumstances where (*i*) there was a lack of clarity in the orders, but (*ii*) there was a case to be made that at least some of those orders ought not to stand.²¹ It seemed to me then, and seems to me now, that this was a situation that ought to be avoided. In particular, given that it was common ground between the parties that the injunction could no longer stand, in light of the outcome of the

 $^{^{21}}$ This was most evident in the draft orders that Neurim submitted to me. Neurim clearly recognised – for example – that a declaration of validity (as had been made) could not be maintained, and neither could the injunction that had been granted continue. On the other hand, Neurim did seek to hang onto the costs orders that had been made and the permission to appeal that had been given. Thus, Neurim seemed to be advancing a rather selective approach as to which elements of the 16 December 2020 Orders should continue to stand, with which selection, of course, Mylan disagreed.

Technical Board of Appeal, it was important that it be unequivocally discharged.²²

(6) Accordingly, the order that I did make on 30 December 2020 (the 30 December 2020 Order) sought to "hold the ring" pending a, second, consequentials hearing. It is appropriate to set out the terms of the 30 December 2020 Order more or less in full:

"**UPON** the trial of this claim and counterclaim being heard before the Honourable Mr Justice Marcus Smith on 29, 30 October and 2 and 5 November 2020

AND UPON hearing Mr Andrew Waugh, QC and Ms Katherine Moggridge for the Claimants and Mr Mark Vanhegan, QC and Mr Mitchell Beebe for the Defendants

AND UPON the Applications of the First and Second Claimants to amend [the Patent] (the patent so amended being hereafter referred to as the "Patent")

AND UPON Judgment being handed down on 4 December 2020 (the "Judgment")

AND UPON the Court making an oral order at the form of order hearing heard on Wednesday 16 December 2020 that in this Claim *inter alia*: (i) the Patent was held valid and infringed, (ii) the Second Claimant is not and has never been an exclusive licensee of the Patent, (iii) the validity of the claims of the Patent were unsuccessfully contested at the trial, (iv) the Defendants counterclaim for invalidity of the Patent is dismissed, (v) the First Claimant has permission to amend the Patent, (vi) an injunction is granted against the Defendants commencing at 9:00pm on Friday, 18 December 2020, (vii) the Defendants shall deliver-up and/or destroy any infringing products, (viii) there be an inquiry as to damages or at the First Claimant's election an account of profits, (ix) the Claimants have permission to appeal the Court's decision that the Second Claimant was not an exclusive licensee under the Patent and (x) the Defendants are refused permission to appeal on the issue of validity and (xi) further consequential orders relating to costs and confidentiality (together, the "16 December 2020 Orders")

AND UPON the Defendants undertaking at the hearing on Wednesday, 16 December 2020 to use best endeavours not to enter into any further sales of Melatonin Mylan 2mg prolonged release tablets ("Infringing Product") and in any event not to enter into any new sales of their Infringing Product from 9am (GMT) on Thursday 17 December 2020 (the "Defendants' Undertakings")

AND UPON the First Claimant at about 12 noon on Friday, 18 December 2020 withdrawing its appeal before the Technical Board of Appeal of the European Patent Office, against the Opposition Division of the European Patent Office's judgment that European Patent No 1441702 is invalid, *ab initio*, thereby terminating the suspensive effect of the First Claimant's appeal against the invalidity of the Patent

AND UPON the Patent being held invalid *ab initio* by the European Patent Office, Opposition Division and thereby revoked upon the First Claimant's withdrawal of its appeal

²² Of course, that was the point of the "sunset" provisions. But these had not been finally drawn.

AND UPON the Claimants consenting to the Defendants being released forthwith from the Defendants' Undertakings and this Court confirming the said release by email from the Honourable Mr Justice Marcus Smith on Friday, 18 December 2020

AND UPON the Claimants accepting in light of the First Claimant's withdrawal of its appeal before the Technical Board of Appeal, and accepting that the Patent has been revoked *ab initio*, that the Claimants are not entitled to any substantive relief against the Defendants in respect of the Patent, whether by way of injunctions or by way of inquiry as to damages or account of profits or otherwise howsoever

AND UPON the Defendants' application under CPR 3.1(7) that the Claimants are liable for the costs of this Claim as a result of a material change of circumstances namely the First Claimant's withdrawal on Friday, 18 December 2020 of its appeal against the decision of the European Patent Office Opposition Division revoking the Patent, and the Claimants' acceptance that the Patent should be and has been revoked *ab initio* (the "Application")

AND UPON considering the matter on the papers

IT IS ORDERED THAT:

- 1. Save as set out in paragraphs 3 to 4 below, the 16 December 2020 Orders are hereby revoked, but without prejudice to any contention that (after a further hearing) the same or similar orders may be made.
- 2. The hearing of the Application is to be fixed for the first convenient date for the Court and the parties in Hilary Term 2021 and the parties are to liaise with the Court to arrange fixing of the same..."

Paragraph 3 and 4 of the 30 December 2020 Order are immaterial and I do not set them out. I explained my reasons for making the 30 December 2020 Order in the following paragraphs:

- "(1) The 16 December 2020 Orders were made at a hearing arranged as a matter of urgency at the request of the Claimants in order to ensure prompt injunctive relief in light of the Judgment. I considered it right to hear the matter urgently because of the importance to the Claimants of obtaining swift injunctive relief but of my own motion also stated that all consequential matters should (so far as possible) be determined also.
- (2) That direction was given notwithstanding the imminent hearing before the appeal before the Technical Board of Appeal. Self-evidently, the outcome of that hearing was not known on 16 December 2020.
- (3) Given the possibility that the Technical Board of Appeal would declare the Patent invalid, the 16 December 2020 Orders contained "sunset" provisions in respect of the injunction granted. However, the effect of the outcome of that appeal on <u>other</u> aspects of the 16 December 2020 Orders was not specifically considered, albeit that I gave a provisional indication that I considered the costs orders consequential on the Judgment to be independent of the appeal before the Technical Board of Appeal.
- (4) The outcome of the appeal before the Technical Board of Appeal is now known. In my judgment, this constitutes a sufficient change in circumstance to warrant further submissions on the question of costs and (perhaps) other aspects of the 16

December 2020 Orders. I am not, of course, acceding to the Defendants' submissions on the orders that should be made, I am merely declining to formalise the 16 December 2020 Orders in light of the subsequent developments that I have described. Had the parties been able to agree the terms of an order formalising the 16 December 2020 Orders, then matters might be different. But, in point of fact, no agreed draft was presented before close of business on Thursday 17 December 2020 or at all.

- (5) In these circumstances, it seems to me that the most appropriate course is to formally revoke the 16 December 2020 Orders and not to embody them in a final, sealed, order; and instead to re-visit the subject matter of the 16 December 2020 hearing at a further hearing. I am grateful to the Defendants for issuing the Application, but (given the somewhat unusual circumstances) such an Application may be strictly not be needed."
- **37.** The hearing envisaged by paragraph 2 of the 30 December 2020 Order took place remotely on 22 February 2021, and I reserved my judgment. This is that judgment.

C. JURISDICTION TO VARY THE 16 DECEMBER 2020 ORDERS, AND THE EXERCISE OF THAT JURISDICTION

- 38. The Claimants' logically first submission was that the 16 December 2020 Orders were made after a final judgment the Judgment had been handed down and that either I did not have jurisdiction to vary those orders or if I did I could not properly exercise that jurisdiction, and should not do so. The Claimants' position was that the 16 December 2020 Orders operated perfectly well on their own terms, and that the provisions in those orders (particularly the "sunset" provisions regarding the injunction) anticipated the fact that the appeal before the Technical Board of Appeal in the EPO Proceedings might fail, and that there was no need to re-visit the 16 December 2020 Orders at all.
- 39. On this basis, of course, the 30 December 2020 Order was wrongly made. I do not consider that the fact that the 30 December 2020 Order was made precludes me from considering this, Neurim's first, point.²³ Although paragraph 1 of the 30 December 2020 Order revokes the 16 December 2020 Orders, it does so "without prejudice to any contention that (after a further hearing) the same or similar orders may be made". Accordingly, if I conclude that the Claimants are right, and that the 16 December 2020 Orders were wrongly revoked, I shall simply re-make them pursuant to this paragraph.
- **40.** Rule 40.7(1) of the Civil Procedure Rules (**CPR**) provides that a "judgment or order takes effect from the day when it is given or made, or such later date as the court may specify".²⁴ In this case, the 16 December 2020 Orders were generally made on that date, albeit that there were a number of cases where I specified a later date. In particular, the injunction would not enter into force until 9:00pm on Friday 18 December 2020 and if the "sunset" provisions were satisfied would never enter into force.

²³ And, to be clear, neither party suggested otherwise.

²⁴ This is no more than a statement of the common law position. A judgment or order takes effect from the time when the judge pronounces it, and the subsequent entry of it (in the case of a judgment) or sealing of it (in the case of an order) is in obedience to the rules of court: *Holtby v. Hodgson*, (1890) LR 24 QBD 103.

41. It is, however, clear law that an order²⁵ can be varied by the judge at any time until the order is drawn up and perfected.²⁶ However, that is a jurisdiction that cannot be exercised capriciously and represents an exceptional jurisdiction. In *Re Barrell Enterprises*, Russell LJ stated:²⁷

"When oral judgments have been given, either in a court of first instance or on appeal, the successful party ought, save in the most exceptional circumstances, to be able to assume that the judgment is a valid and effective one. The cases to which we were referred in which judgments in civil courts have been varied after delivery (apart from the correction of slips) were all cases in which some most unusual element was present."

42. The Supreme Court in *Re L (Children)* appeared to consider that this stated the law too narrowly, and that the test was not exceptionality but the need to deal with cases justly.²⁸ Of course, an important part of dealing with cases justly is for decisions, once made, to stand, so that they can be relied upon. It may be, therefore, that there is little difference between a test of exceptionality and the need to deal with cases justly. In *Cie Noga d'Importation et d'Exportation SA v. Abacha*,²⁹ Rix LJ (sitting in the Commercial Court) referred to the need to balance the concern for finality against the "proper concern that courts should not be held by their own decisions in a straitjacket pending the formality of drawing up the order". He went on:³⁰

"Provided that the formula of "exceptional circumstances" is not turned into a straitjacket of its own, and the interests of justice and its constituents as laid down in the overriding principle are held closely to mind, I do not think that the proper balance will be lost. Clearly, it cannot be in every case that a litigant should be entitled to ask the judge to think again. Therefore, on one ground or another, the case must raise considerations, in the interests of justice, which are out of the ordinary, extraordinary or exceptional. An exceptional case does not have to be uniquely special. "Strong reasons" is perhaps an acceptable alternative to "exceptional circumstances". It will necessarily be in an exceptional case that strong reasons are shown for reconsideration."

43. In their submissions to me, the Claimants did not refer me to this law regarding the *Barrell* jurisdiction. Instead, they relied upon the case law that relates to the variation of orders <u>after</u> they have been drawn and sealed. That is, of course, not this case. I will, however, consider the law in this area, first because it formed the basis of Mr Waugh, QC's submissions to me on behalf of the Claimants, and secondly (as the Supreme Court noted in *Re L (Children)*) it would be curious if sealing made "all the difference" and that the law regarding the changing of orders was radically different depending on the happenstance of when the order was sealed.³¹

²⁵ The same is true of judgments, but in this case my judgment was handed down.

²⁶ *Re Barrell Enterprises*, [1973] 1 WLR 19; *Re L (Children)*, [2013] UKSC 8 at [19].

²⁷ *Re Barrell Enterprises*, [1973] 1 WLR 19 at 23-24.

²⁸ *Re L (Children)*, [2013] UKSC 8 at [27].

 ²⁹ [2001] 3 All ER 513 at [42]. (Curiously, although reported, the case has no Neutral Citation Number.)
 ³⁰ At [43].

³¹ In short, whilst the drawing and sealing of an order must be a relevant factor in choosing not to vary an order made (not least because of the increased chances of parties, including third parties, relying on the sealed order), it is difficult, as a matter of principle, to see why it should be any more than that. Indeed, if there is a radical difference between the regime for varying sealed and unsealed orders, a whole range of perverse incentives are introduced not to agree orders speedily.

- 44. CPR 3.1(7) provides that "[a] power of the court under these Rules to make an order includes a power to vary or revoke the order". Although there is a great deal of case law relating to CPR 3.1(7) to which I shall come it does appear at first blush that CPR 3.1(7) is a codification of the power to vary orders, covering both the case of an unsealed order and that of a sealed order.
- 45. Turning, then, to the law in this area, the starting point is the judgment of Rix LJ in *Tibbles v. SIG plc*:³²

"In my judgment, this jurisprudence permits the following conclusions to be drawn:

- (i) Despite occasional references to a possible distinction between jurisdiction and discretion in the operation of CPR 3.1(7) there is in all probability no line to be drawn between the two. The rule is apparently broad and unfettered, but considerations of finality, the undesirability of allowing litigants to have two bites at the cherry, and the need to avoid undermining the concept of appeal, all push towards a principled curtailment of an otherwise apparently open discretion. Whether that curtailment goes even further in the case of a final order does not arise in this appeal.
- (ii) The cases all warn against an attempt at an exhaustive definition of the circumstances in which a principled exercise of the discretion may arise. Subject to that, however, the jurisprudence has laid down firm guidance as to the primary circumstances in which the discretion may, as a matter of principle, be appropriately exercised, namely normally only (a) where there has been a material change of circumstances since the order was made, or (b) where the facts on which the original decision was made were (innocently or otherwise) misstated.
- (iii) It would be dangerous to treat the statement of these primary circumstances, originating with Patten J and approved in this court, as though it were a statute. That is not how jurisprudence operates, especially where there is a warning against the attempt at exhaustive definition.
- (iv) Thus there is room for debate in any particular case as to whether and to what extent, in the context of principle (b) in (ii) above, misstatement may include omission as well as positive misstatement, or concern argument as distinct from facts. In my judgment, this debate is likely ultimately to be a matter for the exercise of discretion in the circumstances of each case.
- (v) Similarly, questions may arise as to whether the misstatement (or omission) is conscious or unconscious; and whether the facts (or arguments) were known or unknown, knowable or unknowable. These, as it seems to me, are also factors going to discretion: but where the facts or arguments are known or ought to have been known as at the time of the original order, it is unlikely that the order can be revisited, and that must be still more strongly the case where the decision not to mention them is conscious or deliberate.
- (vi) *Edwards v. Golding* is an example of the operation of the rule in a rather different circumstance, namely that of a manifest mistake on the part of the judge in the formulation of his order. It was plain in that case from the master's judgment itself that he was seeking a disposition which would preserve the limitation point for future debate, but he did not realise that the form which his order took would not permit the realisation of his adjudicated and manifest intention.

³² [2012] EWCA Civ 518 at [39].

- (vii) The cases considered above suggest that the successful invocation of the rule is rare. Exceptional is a dangerous and sometimes misleading word: however, such is the interest of justice in the finality of a court's orders that it ought normally to take something out of the ordinary to lead to variation or revocation of an order, especially in the absence of a change of circumstances in an interlocutory situation."
- **46.** Although the jurisdiction is widely stated, it is one that is to be exceptionally exercised, bearing in mind of course that the term "exceptional" is, indeed, a dangerous and sometimes misleading word. I use it in the sense used by Rix LJ himself in *Abacha*, quoted in paragraph 42 above. It is clear that, generally speaking, the jurisdiction will only be exercised where (*i*) there has been a mistake in drawing up or expressing the order, (*ii*) there has been a material change of circumstance or (*iii*) the facts on which the original decision was made were (innocently or otherwise) misstated in a material way.
- 47. There has been some case-law on what constitutes a material change of circumstance. In *Optis v. Apple*,³³ Birss J stressed that the mere existence of a new factor that could be called "material" in the sense that it would have played a part in the balance when the order was originally made would <u>not</u> be sufficient to cause the order to be re-visited:³⁴
 - "14. The correct approach is that when assessing materiality there must be a relationship between the change in circumstances relied on and the conclusion reached, in this case, to list Trial F separately. In saying that, I am following the judgment of Jefford J in *Processing Centre v. Pitney Bowes*, [2012] EWHC 3903 (QB). In particular I agree with the following sentence, which is part of [25]:

"Rather, the question I should ask myself is whether the change in circumstance is such that it seems to me either that Slade J would have reached a different conclusion or that it is such that in my judgment the injunction must be varied."

- 15. I will approach this application by asking if the change relied on makes a sufficient difference to justify changing the order made. In other words would it, taking all the circumstances into account, justify rescheduling Trial F to be heard with Trial E."
- **48.** It is also important to note that there is a difference between varying an interlocutory order and varying a final order. *Tibbles* expressly did not consider the question of a final order, but the point was addressed in *Allsopp v. Banner Jones*,³⁵ where it was clearly stated that whilst CPR 3.1(7) might on its wording extend to final orders (as clearly it does) the justification for disturbing a final order needed to be even greater than in the case of an interlocutory order:
 - "24. There is, thus, a particular form of finality that attaches to final decisions at first instance. It is important to differential final decisions from interlocutory decisions, and appeals from decisions at first instance.
 - i) CPR 3.1(7) lists as one of the court's general powers of case management the power to vary or revoke a prior order made. It is very clear that this provision cannot generally be used to vary or revoke final orders (that is, orders that give rise to a *res judicata* estoppel) and equally clear that even interlocutory decisions will generally only be varied or revoked where either (a) there has been a

³³ [2021] EWHC 131 (Pat).

³⁴ At [14].

³⁵ [2021] EWCA Civ 7.

material change of circumstance since the original order was made or (b) where the facts on which the original decision was made were (innocently or otherwise) misstated: *Tibbles v. SIG plc...*

- ii) The proper route for reviewing a decision particularly a final decision is through the appeal process. It is trite, however, that appeals are not generally rehearings but reviews of the lower court...New factual evidence, not before the lower court, will generally only be admitted where "special grounds" are met. In the civil courts, these are described in *Ladd v. Marshall*, [1954] 1 WLR 1489. These "special grounds" are: (a) the evidence could not have been obtained with reasonable diligence for use at the trial; (b) the evidence must be such that, if given, it would probably have an important influence on the result of the case, though it need not be decisive; and (c) the evidence must be such as is presumably to be believed: it must be apparently credible, although it need not be incontrovertible. Family courts apply a more liberal version of this rule, but the general point holds good.
- 25. Apart from appeals, and without intending to be exhaustive, there are two main ways in which a final judgment that gives rise to a *res judicata* estoppel can be re-visited by a party who would otherwise be bound by or estopped from challenging that decision in other litigation. These are where:
 - i) A party seeks to have a judgment set aside on grounds that it was fraudulently obtained: *Takhar v. Gracefield Developments Limited*, [2019] UKSC 13;
 - ii) New facts come to light that fundamentally change the complexion of the case. This is the ratio of *Phosphate Sewage Company Limited v. Molleson*, (1879) 4 App Cas 801 at 814, where Lord Cairns LC held:

"As I understand the law with regard to *res judicata*, it is not the case, and it would be intolerable if it were the case, that a party who has been unsuccessful in a litigation can be allowed to re-open that litigation merely by saying, that since the former litigation there is another fact going exactly in the same direction with the facts stated before, leading up to the same relief which I asked for before, but it being in addition to the facts which I have mentioned, it ought now to be allowed to be the foundation of a new litigation, and I should be allowed to commence a new litigation merely upon the allegation of this additional fact. My Lords, the only way in which that could possibly be admitted would be if the litigant were prepared to say, I will shew you that this is a fact which entirely changes the aspect of the case, and I will shew you further that it was not, and could not by reasonable diligence have been, ascertained by me before.""

49. The Claimants' point, shortly stated, was that the 16 December 2020 Orders were final (and not interlocutory) orders of this court and that the normal justifications for varying an order of the court -(i) mistake in drawing up or expressing the order, (*ii*) a material change of circumstance or (*iii*) the facts on which the original decision was made misstated in a material way (in the case of interlocutory orders) and (*iv*) fraud or (*v*) new facts fundamentally changing the complexion of the case (in the case of final orders) – simply did not exist.

- **50.** I agree. However, the jurisdiction under CPR 3.1(7) and if different the *Barrell* jurisdiction in relation to unsealed orders, is a generally expressed jurisdiction, where examples of how that jurisdiction should be exercised have helpfully been framed, but where (to adopt the words of Rix LJ in *Tibbles*) "[t]he cases all warn against an attempt at an exhaustive definition of the circumstances in which a principled exercise of the discretion may arise". Mylan's position was that this was an exceptional case even amongst exceptional cases, and the fact that this sort of situation had, to the knowledge of both leading counsel, never arisen before should not, in and of itself, prevent me from re-visiting the 16 December 2020 Orders. I agree with this proposition also. I consider that: (*i*) the jurisdiction to vary the 16 December 2020 Orders exists³⁶ and (*ii*) (more importantly) that it is a jurisdiction that, in my discretion, I should exercise on the (very special) facts of this case. My reasons are as follows:
 - (1) None of the cases concerning the exercise of varying an order of this court have considered the significance (or otherwise) of parallel jurisdictions considering precisely the same question at more or less the same time, whilst reaching different conclusions. That, of course, is exactly what I am faced with here, in terms of the inter-relationship between my Judgment in the UK Proceedings and the outcome of Neurim's appeal in the EPO Proceedings.
 - (2) However, this <u>is</u> a matter that has been considered by the Court of Appeal in the very different area of case management and stays of proceedings. Although, as I say, it concerns the question of a stay of proceedings in this court, it is necessary to set out very fully parts of the judgment of Floyd LJ, giving the judgment of the Court of Appeal, in *IPCom GmbH & Co KG v. HTC Europe Co Ltd.*³⁷ Floyd LJ began by setting out the twin routes to the revocation of a patent:
 - "20. The relevant background is the European Patent Convention ("the EPC"), an international treaty, and the Patents Act 1977 ("the 1977 Act"). The EPC contains provisions which enable any person to apply for revocation of a granted patent. Thus under art.138 of the EPC a European Patent may be revoked by a national court of a Contracting State (e.g. in proceedings by way of direct action for revocation or counterclaim to an infringement action). Revocation in such circumstances will apply only to the designation of the Patent in that Contracting State.
 - 21. A party who contends that a granted European Patent is invalid, and should be revoked, can also do so by means of the opposition procedure in the EPO. An opposition in the EPO must be launched within 9 months of grant, but there is no provision for when such proceedings must end. Experience has shown that opposition proceedings before the EPO are likely to take many years. There are numerous reasons for this. One reason is the EPO's serial approach to decision making. Where an opponent raises a variety of grounds of opposition, the practice of the EPO is to decide the issues in a given order. If, on consideration, a ground succeeds, it is rare for the OD to go on and decide the other issues in the sequence, as a first instance court in this country might consider itself obliged to do. As a

³⁶ In the Claimants' corrections to the draft judgment, it was suggested that I delete the words: "(no-one before me disputed this)". I have done so, but I wish to be clear that the argument before me centred on discretion, not jurisdiction. I certainly did not understand Mr Waugh, QC, to be taking any point on jurisdiction – as opposed to whether I should, in my discretion, exercise that jurisdiction, which was a point Mr Waugh, QC did take.

³⁷ [2013] EWCA Civ 1496.

result, if the OD's decision is overturned on appeal, the TBA will normally have to remit the case to the OD for it to consider the next issue. And so on. Some of that has happened in this case.

- 22. The EPO has been a victim of its own success. In the normal run of things an appeal from the OD to the TBA may take four years. Mr Carr showed us T 0612/09, CUBIST PHARMACEUTICALS, INC/Daptomycin (unreported), a decision of the TBA on an appeal against a decision of the OD dated 19 January 2009 revoking a patent, some two years after the opposition proceedings had been commenced. The Board's decision remitting the case to the OD is dated 11 April 2013, more than four years later, and six years from the commencement of the proceedings. The OD's attempt to decide more issues than necessary were dismissed as *obiter dicta* by the TBA. The Board's discussion of whether it should remit the case in these circumstances is revealing:
 - "25. As already mentioned, the present appeal was filed in January 2009. The oral proceedings were held on 10 April 2013 and the decision issued on 11 April 2013. The appeal proceedings thus lasted a little over four years. While it gives the board no pleasure to say so, four years is currently the average time taken to dispose of the appeals in its list of pending cases.
 - Against that background the board, in considering the respondents' 26. argument that better justice would be done by the board itself reconvening at a later point in time, has to ask when that point in time would, or should, be? Quite clearly it could not, at the very earliest, be before any of the board's currently scheduled oral proceedings in other cases, and thus not in 2013. If, on the one hand, it should be before oral proceedings have taken place in all, or some, of the other cases in the board's list of pending cases, then clearly there would be a possible argument that the board was giving unfair preference to this case, in which oral proceedings on the issue giving rise to the appeal have already taken place and that issue has been decided, over other cases which have also been pending for four years and in which oral proceedings have not yet taken place. If, on the other hand, the board were now to treat this case as a newly-filed appeal for the purpose of the undecided issues, the parties might, indeed in the currently prevailing conditions probably would, have to wait another four years for a final decision. In the board's opinion, neither of those solutions would lead to better justice, and certainly not necessarily to an earlier final decision, as the respondents argued.
 - 27. The board understands that currently the time taken to dispose of opposition proceedings is (as happened in the present case) about two years so assuming that, after a remittal, the opposition division gives this case no particular preference, the parties would have a decision in half the time they might have to wait for a decision from the board. Of course, if one or more parties were then to appeal, a further long wait for a final decision might then ensue just how long would depend on the length of the board's list of pending cases at that future point in time. But, in the absence of a further appeal, the likelihood must be that the parties will achieve a final decision sooner if there is a remittal and that is significant. Thus the board considers, not without regret, that the question of delay and the possible injustice delay may cause points, on balance, in favour of remittal."

- 23. A procedure which allows disputes over patent rights to take in excess of a decade cannot meet the needs of industry, particularly in rapidly moving areas of technology. Although such a procedure may technically comply with art.6 of the European Convention on Human Rights, which guarantees a trial before an independent tribunal within a reasonable time, the opportunity for successive appeals and remittals means that there is in practice no final determination of the parties' rights for many years. Given their procedures, the Boards have a difficult task in seeking to achieve justice and finality.
- Although the ODs and TBAs have shown sensitivity to acceleration of their proceedings in cases of commercial urgency, the serial nature of their procedures is not well adapted to arriving at early decisions even in cases where expedition is granted. The present case is an illustration of that fact. Even with expedition, the OD and TBA in this case have resolved only one of the issues in the oppositions since the opposition period closed on 17 December 2010. When the OD sits again on the currently predicted date of 22 Jan 2014 to consider lack of novelty and inventive step, the proceedings will have passed their third anniversary. An expedited appeal might take another year. By contrast, all the issues of infringement and validity in the Nokia action were considered by two instances in this jurisdiction in just over two years from service of the claim form.
- 25. Whilst the delays which occur in the opposition procedure of the EPO cannot be described as part of the architecture of the system, they form an important part of the background to any application for a stay of national proceedings pending the outcome of proceedings in the EPO.
- 26. It is inherent in the scheme provided by the EPC and the Act that the twin routes to revocation of a patent may be pursued at the same time. This is visible in a number of places in the Act. Thus s.77(3) provides that:

"(3) Where in the case of a European patent (UK) –

- (a) proceedings for infringement . . . have been commenced before the court or the comptroller and have not been finally disposed of, and
- (b) it is established in proceedings before the European Patent Office that the patent is only partially valid,

the provisions of section 63 or, as the case may be, of subsections (7) to (9) of section 58 apply as they apply to proceedings in which the validity of a patent is put in issue and in which it is found that the patent is only partially valid."

- 27. That section recognises that a decision of the EPO may be made at a time when infringement proceedings are before the national court, and provides that the effect of any amendment to the patent made by the EPO is the same as if the amendment had been ordered by the court.
- 28. It is important to keep in mind the range of possible consequences of the two sets of proceedings, and their impact on one another. It is these features of the system created by the EPC which make the considerations affecting the grant of stays in patent cases different from those in other types of case: see in this connection the observations of Lewison J in *Glaxo Group Ltd v. Genentech Inc* [2007] EWHC 1416 (Pat) at [37] to [38]. Thus, in the EPO the patent can be revoked, maintained in an amended form or maintained as granted. Whilst revocation operates *in rem*, a finding that the patent is valid as granted in opposition proceedings does not

operate as an issue estoppel between the parties thereto: see *Buehler AG v. Chronos Richardson Ltd*, [1998] RPC 609, [1998] 2 All ER 960. Moreover, the EPO has no jurisdiction over the issue of infringement, which is within the exclusive jurisdiction of the national court. The jurisdiction of the national court is, however, territorial both in relation to infringement and in relation to validity. A decision by the national court to revoke a patent with effect for its own jurisdiction cannot be affected by a later decision of the EPO. The same is true of a finding of non-infringement."

- (3) Thus, the Court of Appeal recognised that twin routes to revocation might be in play, in any given case, and that these different routes might impact on one another. That, as Floyd LJ rightly said, was a matter that made "the considerations affecting the grant of stays in patent cases different from those in other types of case".³⁸ At [68] of his judgment, Floyd LJ provided guidance as to how the question of staying proceedings ought to be approached in this particular context:
 - "1. The discretion, which is very wide indeed, should be exercised to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case.
 - 2. The discretion is of the Patents Court, not of the Court of Appeal. The Court of Appeal would not be justified in interfering with a first instance decision that accords with legal principle and has been reached by taking into account all the relevant, and only the relevant, circumstances.
 - 3. Although neither the EPC nor the 1977 Act contains express provisions relating to automatic or discretionary stay of proceedings in national courts, they provide the context and condition the exercise of the discretion.
 - 4. It should thus be remembered that the possibility of concurrent proceedings contesting the validity of a patent granted by the EPO is inherent in the system established by the EPC. It should also be remembered that national courts exercise exclusive jurisdiction on infringement issues.
 - 5. If there are no other factors, a stay of the national proceedings is the default option. There is no purpose in pursuing two sets of proceedings simply because the Convention allows for it.
 - 6. It is for the party resisting the grant of the stay to show why it should not be granted. Ultimately it is a question of where the balance of justice lies.
 - 7. One important factor affecting the exercise of the discretion is the extent to which refusal of a stay will irrevocably deprive a party of any part of the benefit which the concurrent jurisdiction of the EPO and the national court is intended to confer. Thus, if allowing the national court to proceed might allow the patentee to obtain monetary compensation which is not repayable if the patent is subsequently revoked, this would be a weighty factor in favour of the grant of a stay. It may, however, be possible to mitigate the effect of this factor by the offer of suitable undertakings to repay.
 - 8. The Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a

³⁸ At [28].

considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

- 9. It is permissible to take account of the fact that resolution of the national proceedings, whilst not finally resolving everything, may, by deciding some important issues, promote settlement.
- 10. An important factor affecting the discretion will be the length of time that it will take for the respective proceedings in the national court and in the EPO to reach a conclusion. This is not an independent factor, but needs to be considered in conjunction with the prejudice which any party will suffer from the delay, and lack of certainty, and what the national proceedings can achieve in terms of certainty.
- 11. The public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of a patent is also a factor to be considered.
- 12. In weighing the balance it is material to take into account the risk of wasted costs, but this factor will normally be outweighed by commercial factors concerned with early resolution.
- 13. The hearing of an application for a stay is not to become a mini-trial of the various factors affecting its grant or refusal. The parties' assertions need to be examined critically, but at a relatively high level of generality."
- (4) Although this guidance is, self-evidently, concerned with the question of a stay, rather than with the re-opening of a prior order of the court, the guidance in *IPCom* clearly demonstrates the inter-connectedness of the two jurisdictions. It is absolutely clear that the existence of revocation proceedings before the EPO is a factor in and of itself capable³⁹ of justifying a stay of proceedings in England involving revocation of the same patent. To this extent, therefore, I reject the contention made by Neurim that the 16 December 2020 Orders cannot be revisited because the "UK proceedings are separate and distinct from those at the EPO". They are, of course, separate and distinct, but that does not mean to say that they do not inter-relate and are not inter-connected. They obviously do and are. Equally obviously, the extent to which that inter-connectedness should affect matters like orders as to costs is a matter untrammelled by case-law, and something to which I will come.
- (5) It seems to me, however, that it is obvious that the imminent hearing and determination of an appeal of a decision of the Opposition Division of the EPO before the Technical Board of Appeal is a matter that a judge of the High Court, hearing proceedings regarding the patent whose revocation is at issue both before him or her <u>and</u> the EPO, would want to know about and take into consideration. It seems to me that that is true, whether the matter before the judge is the question of stay; or the question of the making of a costs order or an order providing injunctive

 $^{^{39}}$ Whether it does in fact justify a stay depends on a consideration of all the factors set out in paragraph 50(3) above.

relief; or the question of whether such an order, having been made, should be reviewed or varied.

- I do not say that subsequent determinations at the EPO always and inevitably entitle (6) a party to English proceedings to go back to the trial judge in those proceedings and ask him or her to review or vary a prior order made. All I am saying is that such subsequent determinations can (but need not necessarily) justify such a review or variation. Whether they in fact do so, will depend on all the circumstances. Suppose – as had originally been anticipated – the appeal to the Technical Board of Appeal had not taken place in December 2020, but in the first quarter of 2022. By that time, the 16 December 2020 Orders would have been formalised and an injunction enjoining Mylan against infringement would have been operating for 14 months; Mylan would, in accordance with those orders, have delivered up or destroyed infringing product; and Mylan would have paid substantially all of the costs of the proceedings. I hesitate to say what the appropriate orders and directions would be in such a case – and, fortunately, these are not matters that I have to consider. But, in those circumstances, I would have been very hesitant about using the CPR 3.1(7) jurisdiction and would probably have considered that the most appropriate course would be for the 16 December 2020 Orders to be appealed to the Court of Appeal and for the Court of Appeal to give the appropriate directions regarding the 16 December 2020 Orders and to give the appropriate directions (if any)for Mylan to claim to recover its losses as a result of orders (that is, the 16 December 2020 Orders) that were, taking account subsequent events, wrongly made and causative of loss.
- (7) This case is much more clear-cut. The imminent appeal before the Technical Board of Appeal was known about at the hearing on 16 December 2020 and to a certain extent the variety of possible outcomes of the appeal factored in. Thus, in order to ensure that Mylan was not injuncted for no justification, the injunction was timed to start at 9:00pm on Friday 18 December 2020, by which time (it was anticipated) the outcome of the appeal would definitely be known. Had the appeal succeeded, and the decision of the Opposition Division to revoke been overturned, the injunction would have had effect from that time onwards. If as proved to be the case the appeal failed, then the "sunset" provisions would have been engaged, and the injunction would never have come into force at all. Up to 9:00pm on Friday, Neurim was afforded the rather more limited protection of the undertakings from Mylan that I have described.⁴⁰ And, at various points in time <u>after</u> Monday, 21 December 2020, Mylan would, in accordance with the 16 December 2020 Orders, have delivered up or destroyed Infringing Product.
- (8) The 16 December 2020 Orders regarding delivery up or destruction of Infringing Product did <u>not</u> have sunset provisions. This, to my mind, demonstrates in the clearest possible way the error in Neurim's suggestion that the 16 December 2020 Orders cannot be re-visited. Of course, there is no doubt that Neurim would have consented to the deletion of these orders for delivery up or destruction, in just the same way as Neurim rapidly consented to release Mylan from its undertakings.⁴¹ But that is not the point: the correct question to ask is what would the position have

⁴⁰ See paragraph 36(4)(f) above.

⁴¹ As described in the 30 December 2020 Orders.

been, had Neurim contended – as it is now contending in relation to the costs orders and the order permitting an appeal on the Exclusive Licence Point – that the orders for delivery up or destruction of Infringing Product were somehow set in stone and could not be varied by the trial judge. The question only has to be stated to be answered. It would have been frankly absurd, and a waste of time and costs, to oblige Mylan, in this eventuality, to trouble the Court of Appeal to set aside orders which – self-evidently – could not stand in light of the outcome of the appeal before the Technical Board of Appeals in the EPO Proceedings.

- (9) Although it obviously cannot be said that the costs order made and the permission to appeal granted self-evidently cannot stand in light of the outcome of the appeal before the Technical Board of Appeals these are difficult questions to which I will turn it is to my mind clear that these orders can and should be reviewed by me under either CPR 3.1(7) or (if different) the *Barrell* jurisdiction. That is because:
 - (a) Of the proximity in time of the outcome of the appeal and the 16 December 2020 Orders.
 - (b) The fact that the 16 December 2020 Orders were not drawn up, and consequential orders do need to be drawn.
 - (c) It would be grossly unfair to Mylan for it to be unable to contend that in light of the outcome of the appeal the 16 December 2020 Orders should not be varied. The fact is that the hearing on 16 December 2020 only took place because for good reason it was very important to Neurim that the matter be heard in December 2020 rather than January or February 2021. The fact that the hearing took place before the appeal hearing in front of the Technical Board of Appeal was no more than an unfortunate consequence of the diaries of the persons most involved. It obviously would have been better to have the hearing <u>after</u> the outcome of the appeal was known.
 - (d) Indeed, I consider that the hearing before me on 16 December 2020 was if not explicitly, then certainly implicitly – conducted on the basis that any orders made could and would (if appropriate) be re-visited. Not only did Mylan's written submissions, which I have quoted at paragraph 32 above, strongly suggest this, it is also clear from the terms of the orders for delivery up or destruction of infringing product⁴² and from certain exchanges between me and counsel on 16 December 2020. One example will suffice. Relatively early on in the hearing, I said:⁴³

"The EPO appeal does have other implications. There is a suggestion by Mylan that if the EPO appeal were to be unsuccessful and the patent voided, then the costs of the process, this process, this trial process would need to be revisited. Provisionally speaking, I disagree. I was personally very surprised to hear that the appeal came on as soon as it did, and the reason I was surprised was I am pretty certain I was told in terms by both parties that the EPO grind slow and we were

 $^{^{42}}$ See the point made in paragraph 50(8) above. As I there note, the 16 December 2020 Order did <u>not</u> contain sunset provisions.

⁴³ See pages 11-12 of the transcript.

looking at 2021/2022 before this matter would be resolved. The reason I am disinclined to permit any revisiting of the costs order would be simply this: it is quite clear, I think, that if we had known that the EPO appeal would be determined at about the same time as these proceedings, Nugee J, as he then was, would not have ordered expedition. It would have been pointless. The thinking, as I see it, behind expedition was that there was an urgency, which I accept, which because the EPO grinds slow had to be met by this jurisdiction, which we did. So it seems to me these proceedings were properly ordered and of course it is great that the EPO moved faster than everyone thought, but the consequence of that is that it may prove that these proceedings were entirely a waste of time and money. That is very unfortunate, but my present thinking is I am really not minded to blame either party for that. It is simply a fact of life that these proceedings and the EPO proceedings are coming to the boil at pretty much the same time. There we are."

Neurim contended that this reasoning was "unimpeachable"⁴⁴ (which it may or may not be: it is certainly a matter that I will be re-visiting in this Consequential Judgment), but Neurim also contended that this passage demonstrated that the 16 December 2020 Orders could not be re-visited because there was no material change in circumstance. Neurim's contention was that the 16 December 2020 Orders expressly catered for every eventuality of the appeal, and that (for this reason) the orders should not be re-visited. Later on in its written submissions, Neurim said this:

- "18. On the facts of these proceedings, there is nothing that can be relied upon which makes a significant difference, let alone a material difference, to justify changing the original costs order. The "material change of circumstances" that Mylan seeks to rely on is the revocation of the Patent. But those circumstances were <u>precisely</u> what was before the Court on 16 December. Both the parties and the Court expressly considered the alternative outcomes of the TBA hearing:
 - (a) that the Patent was valid;
 - (b) that the Patent was invalid; and
 - (c) exceptionally, that the matter would not be finally determined.
- 19. This was discussed at some length in the context of the discussions about the framing of the injunction, see the transcript at p.110 line 24 to p.115 line 9. What is clear that both parties and the Court had in mind and expressly addressed the possibility of the Patent being invalid in the light of the TBA hearing.
- 20. This ought to be the end of the matter. In fact, all that has happened is that one of the anticipated outcomes of the 16 December Order has been realised (or "crystallised"). This is the very opposite of a material change of circumstances."

This betrays a misunderstanding of what was going on at the hearing before me on 16 December 2020. At my instance, I sought to deal with all outstanding consequential matters at one hearing. Practically speaking, that was only possible if one proceeded on the basis that the appeal would be

⁴⁴ See Neurim's written submissions for this hearing at paragraph 12.

successful and that the same outcome would be reached by the two different revocation actions (the one before me; and the one before the EPO).

It might, of course, have been possible to have an order dealing with all contingencies. But the 16 December 2020 Orders did not seek to do so. Neurim's suggestion that the orders <u>did</u> seek to cover all bases is not right:

- (i) The <u>only</u> provision which sought to deal with all contingencies was the injunction. That was because Neurim wanted an injunction in place from as early a point in time as the court was prepared to give it. Indeed, Neurim sought an immediate injunction, which I did not grant because that would involve Mylan in taking irrevocable steps which – if the appeal in the EPO Proceedings was not successful – should not be ordered. I granted an injunction from when the outcome of the appeal would be known, and only on terms that it would come into effect if the Patent was not revoked in the EPO Proceedings. The reason, therefore, for the covering of all contingencies was that Neurim wanted the guarantee of an injunction operating from 9:00pm on Friday night, and Mylan needed the assurance that such an injunction would <u>only</u> bite if the Patent continued unrevoked.
- (ii) All of the other provisions did not deal with the contingencies arising out of the concurrent UK and EPO Proceedings. Thus, as I have said, the orders for delivery up or destruction of Infringing Products did not contain provisions as to their expiry in the event of the Patent being revoked.⁴⁵ Nor were the undertakings given by Mylan so limited: they were withdrawn with the consent of Neurim and with my approval.
- (iii) The need to revisit the orders for delivery up and destruction makes clear that Neurim's contention that the 16 December 2020 Orders are "set in stone" is unsustainable. The only reason Neurim's submissions have any plausibility is because these orders do not exist as formal, sealed orders; and so the need for their revocation by my Order of 30 December 2020 is less obvious.
- (iv) The orders that Neurim seeks to maintain the costs order and the permission to appeal the Exclusive Licence Point were similarly predicated on the Patent not being revoked. Again, it might have been possible to craft contingent orders, covering all future eventualities in the EPO, but there was not the time for this on 16 December 2020. It would not have been possible to agree or resolve, without extensive argument, what the appropriate costs order would be if the Patent were revoked. As I have noted, I raised the question of what the

⁴⁵ For obvious reasons, these orders have never been formalised in writing: that is because (*i*) no order was agreed before the outcome of the appeal in the EPO Proceedings and (*ii*) after the outcome was known Neurim had no right to insist on their inclusion, and Mylan would have resisted any attempt to include them. Yet Neurim was maintaining that some of the orders made on 16 December 2020 must continue to stand and could not be revisited. That, of course, is the reason for this Consequentials Judgment and why the 30 December 2020 Order is drafted as it is.

appropriate costs order might be in the form of a "provisional" view. I never heard argument on the point – not least from Mr Vanhegan, QC, who would have had a lot to say on Mylan's behalf. The reason I did not is because I was determining matters on the basis that my judgment and the outcome of the EPO Proceedings would be aligned, and that (on that basis) no further hearing would be necessary. The corollary – that if the outcomes of the UK Proceedings and the EPO Proceedings were <u>not</u> aligned, a further hearing and a revision of the 16 December 2020 Orders would be necessary – was, as I have said, either explicit or else implicitly clear to all.

- 51. For all these reasons, I conclude that I have the jurisdiction to re-visit the 16 December 2020 Orders and that that jurisdiction should be exercised in favour of re-visiting them. Strictly speaking, I exercised that jurisdiction on 30 December 2020, when I made the 30 December 2020 Order. I have explained in the course of this Consequentials Judgment why I considered it necessary to do so. Had I concluded that I exercised that jurisdiction improperly or wrongly, then I would have re-made the 16 December 2020 Orders without more.
- 52. As it is, I turn to the question of whether, and if so to what extent, the (revoked) 16 December 2020 Orders should be re-made.

D. VARIATION OF THE 16 DECEMBER 2020 ORDERS

(1) Introduction

- **53.** As I have described in paragraph 36(4) above, a considerable number of orders were made on 16 December 2020. Of these, there are a number that not even Neurim contends should be re-made. Thus, and without attempting to be comprehensive, Neurim does not seek:
 - (1) A declaration of validity of the Patent and a declaration of infringement of the Patent by Mylan.
 - (2) A certification that the validity of the claims of the Patent had been unsuccessfully contested by Mylan pursuant to section 65 of the Patents Act 1977.
 - (3) A dismissal of Mylan's counterclaim for invalidity.
 - (4) An injunction enjoining Mylan from infringing the Patent.
 - (5) The delivery up of and/or destruction of Infringing Product.
 - (6) An inquiry as to damages or an account of profits.

Of course, the fact that Neurim does not – indeed, cannot properly – seek such orders now, even though they were made on 16 December 2020, is the clearest of pointers that my conclusion that it is appropriate to re-visit the 16 December 2020 Order is correct.

- 54. The orders that Neurim seeks to maintain are:
 - (1) The costs order that was made in the Claimants' or, rather, Neurim's favour.

- (2) The permission I gave to the Claimants to appeal the Exclusive Licence Point.
- 55. At the 16 December 2020 hearing, I refused Mylan permission to appeal my findings in relation to validity/revocation of the Patent. Mylan does not ask me to re-visit the question of permission to appeal on this point. That was because orders and not judgments are appealed;⁴⁶ and there is no order on the question of revocation for Mylan to appeal. The order made on 16 December 2020 has been revoked by the 30 December 2020 Order, and (as I have said) Neurim does not invite me to re-make that order.
- **56.** I therefore only need to consider the two orders described in paragraph 54 above.

(2) Permission to appeal the Exclusive Licence Point

- 57. The point at issue before me was whether Flynn was the exclusive licensee of the Patent. The point was important because it was only if Flynn was the exclusive licensee of the Patent that it had standing to bring these proceedings as one of the Claimants.⁴⁷ I concluded that – for the reasons I gave in Section H of the Judgment – Flynn was not an exclusive licensee and that it had no standing in these proceedings.⁴⁸
- 58. As is clear from the terms of my Judgment, this was not an easy point, and I indicated early on in the hearing on 16 December 2020 that subject to any points that Mr Vanhegan, QC might make on behalf of Mylan I was minded to give Neurim permission to appeal on this point. Mr Vanhegan, QC did not seek to dissuade me.
- **59.** My view on the difficulty of the point is unchanged. Indeed, it is very difficult to see how the outcome of the appeal before the Technical Board of Appeals could cause that view to change. The problem is that the Exclusive Licence Point <u>presumes</u> the existence of the Patent. By way of example, section 67(1) of the Patents Act 1977 refers to the "holder of an exclusive licence under a patent". The Patent having been revoked *ab initio*, Flynn is the exclusive licensee of, quite literally, nothing.
- 60. This situation is not going to change: the Patent has been revoked once and for all, and there is going to be no (further) appeal of this outcome.
- 61. In these circumstances, it is extremely difficult to identify the order that Neurim would seek to appeal. I suppose I could give a declaration that "Flynn would not be the exclusive licensee of the Patent, had the Patent itself not been revoked", but that exposes the essentially pointless and artificial nature of the matter that Neurim now seeks to appeal.
- 62. The question of whether permission to appeal should be granted generally turns on whether the appeal against the order would have a real prospect of success. Here, there is either no order that can be sensibly framed <u>at all</u> or else, if an order can sensibly be framed, the appeal has zero prospect of success because <u>whatever</u> construction the appellate court gives to the licence, Flynn will never be an exclusive licensee of a patent, because <u>there is no patent</u>. Critically, as I have said, the point that there is no patent <u>cannot</u> be appealed.

⁴⁶ See Note 52.0.6 in Vos (ed), *Civil Procedure 2020*.

⁴⁷ Judgment at [9].

⁴⁸ Judgment at [147].

- **63.** It would, therefore, seem to be the case that Neurim is contending that I should give permission to appeal because there is some other compelling reason for the appeal to be heard.
- 64. Mylan helpfully referred me to the decision of Lord Neuberger MR in *Hutcheson v*. *Popdog Limited* which considered the factors that ought to be borne in mind where a party to a private dispute was seeking to appeal a matter which had been rendered academic:⁴⁹
 - "12. The mere fact that a projected appeal may raise a point, or more than one point, of significance does not mean that it should be allowed to proceed where there are no longer any real issues in the proceedings as between the parties. In *Gawler v. Raettig*, [2007] EWCA Civ 1560, the Court of Appeal refused permission to appeal on the ground that the issue it would raise was academic as between the parties. In his judgment, Sir Anthony Clarke MR gave helpful guidance as to the correct approach in such cases. He said, at [36], that before an appeal could proceed in those circumstances, the court must be satisfied that it would be in the public interest for the projected appeal to proceed, but he added that it would be "a very rare event, especially where the rights and duties to be considered are private and not public". Nonetheless, in the following paragraph he emphasised that all must "depend upon the facts of the particular case" and that he did not "intend to be too prescriptive".

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- 15. Both the cases and general principle seem to suggest that, save in exceptional circumstances, three requirements have to be satisfied before an appeal, which is academic as between the parties, may (and I mean "may") be allowed to proceed: (i) the court is satisfied that the appeal would raise a point of some general importance; (ii) the respondent to the appeal agrees to it proceeding, or is at least completely indemnified on costs and is not otherwise inappropriately prejudiced; (iii) the court is satisfied that both sides of the argument will be fully and properly ventilated."
- **65.** With this guidance in mind, I turn to the reasons the Claimants advance to justify giving permission to appeal in this case:
 - (1) First, it is suggested that the point is one of general public importance, the correctness and application of which has major ramifications outside this particular case. Whilst I agree that the definition of an exclusive licence in the Patents Act 1977 is by no means free from difficulty, at the end of the day this case turned on the wording of the licence actually granted by Neurim to Flynn. I have no evidence before me to justify finding that this wording is one that raises issues of general importance, and indeed Mr Vanhegan, QC made the point that there has been no particular reaction one way of the other in the intellectual property community to suggest that the point <u>is</u> one of general importance. The fact that Neurim and Flynn agreed a series of changes to the licence agreement between them over time also strongly suggests that the Exclusive Licence Point is actually a narrow one, and specific to this case.
 - (2) Secondly, it was suggested by the Claimants that the Exclusive Licence Point might be relevant to licences granted by Neurim to Flynn under a pending divisional patent being claimed by Neurim. I fail to see how this can be relevant. As events

⁴⁹ [2011] EWCA Civ 1580

post my Judgment show, Neurim and Flynn are perfectly capable of agreeing further variations to the licence between them, with a view to eliminating those aspects of the licence that I found rendered it non-exclusive.⁵⁰ So the goal-posts have shifted a number of times already, and it seems to me that any dispute arising out of a licence to any divisional patent (were such a dispute to emerge) would be different to the dispute resolved by me in the Judgment. Of course, it would be the dispute resolved in the Judgment – and not any fresh dispute – that would be the subject-matter of the appeal.

- (3) Thirdly, it was suggested that the Judgment might be deployed against the Claimants in any future dispute regarding intellectual property rights <u>other than</u> the Patent, arising out of the amended licence agreement. Of course, that may happen: the judgment may well be cited in support of a contention that, under this amended licence, Flynn is not an exclusive licensee. But Neurim goes further, and suggests that some sort of *Henderson v. Henderson* abuse argument could be deployed against Flynn. I consider this point to be unarguable: I can see no risk of a contention of abuse of process where what is being litigated is the question of whether Flynn is an exclusive licensee of a patent other than the Patent.⁵¹
- (4) Fourthly, it is said that as a result of the Judgment, the Claimants (and specifically Flynn) "were deprived of their solicitor costs of this issue, which were significant, approximately £355,995 between 2 February 2020 and 6 December 2020...A successful appeal would result in [Flynn] recovering those costs". I agree that a successful appeal <u>might</u> have this consequence. But it does seem to me that an appeal that can only be justified by the possibility or probability of the trial judge's costs order being overturned is not a strong reason to permit an appeal from going ahead.
- 66. In short, I am entirely unpersuaded that there is any proper purpose to be served by giving permission to appeal on this point. Turning to the *Popdog* criteria referenced above, there is no point of general importance; and there has been no offer to hold Mylan harmless against the costs of the appeal. I do not know whether both sides of the argument would properly be ventilated in the Court of Appeal: much would depend on whether Mylan would choose to incur costs in resisting the appeal. I can see a real prospect of it not doing so, in which case the Court of Appeal would be presented with a very one-sided appeal.
- **67.** If permission to appeal is to be given, this is one of those cases where permission to appeal should be sought from, and (if the Court of Appeal considers appropriate) given by, the Court of Appeal.

⁵⁰ In its written submissions before this hearing, Neurim stated at paragraph 61: "...the Court will be aware that the Claimants have put in place a new agreement which they contend overcomes what were held to be the issues with the previous agreements...".

⁵¹ This argument appears to be based on a suggestion I made that a summary judgment application by Flynn against Mylan, seeking judgment against Mylan in respect of Mylan's infringement of the Patent, based upon a combination of (i) the findings in my Judgment and (ii) the amended licence agreement. This application is now clearly unsustainable because the Patent is revoked. I cannot see any relevance of the point I made to the situation where what is at issue is a different licence in respect of different rights.

(2) Costs

(a) Introduction

- **68**. The Civil Procedure Rules provide in CPR 44.2 as to the discretion of the court in relation to costs. The court has a general discretion,⁵² but if it decides to make an order about costs "the general rule is that the unsuccessful party will be ordered to pay the costs of the successful party".⁵³ However, the court can make a different order.⁵⁴
- 69. In this case, both sides contended that they were the successful party. It is easy to see why. Absent the outcome of the EPO Proceedings, Neurim is self-evidently the successful party, as Mylan acknowledged at the hearing on 16 December 2020. Quite properly, Mr Vanhegan, QC there accepted that, on the basis of the Judgment (and disregarding the EPO Proceedings), Neurim was the winner, and Mylan the loser.
- **70.** However, as I have described, Mylan's written submissions on 16 December 2020 put down the clearest of markers that Mylan considered that the appropriate costs order would be different if the Patent should be found to be invalid by the Technical Board of Appeals. Mylan said in terms that it would "contend that it should be entitled to its costs of these UK proceedings". That is exactly what Mylan has contended for in its submissions to me on this, second, consequentials hearing.
- 71. Neurim's primary point was that I could not re-visit the costs order made on 16 December 2020. For the reasons I have given, I have rejected that contention.
- **72.** In their submissions, the parties contended for a costs order in their favour for three distinct (and fairly broad) reasons:
 - (1) First, as I have indicated, both Neurim and Mylan contended that they were the successful party for the purposes of CPR 44.2.
 - (2) Secondly, both parties relied upon the EPO Proceedings themselves in support of a contention that even if they were <u>not</u> the successful party they should have costs awarded in their favour.
 - (3) Thirdly, both parties referred to the manner in which the UK Proceedings had been conducted to support their contention that the costs of the trial should be awarded in their favour (again, even if they were <u>not</u> the successful party).

I propose to consider these factors in turn.

(b) Who is the "winner"?

73. The courts have long noted that where a party is a successful party, that fact is an important one to which proper weight must be attached when making any costs order. Costs should, all other things being equal, "follow the event".

⁵² CPR 44.2(1).

⁵³ CPR 44.2(2)(a).

⁵⁴ CPR 44.2(2)(b).

- 74. That said, it is often difficult to identify the "successful" party. This is often a contentious matter, and that is not surprising given the multifarious circumstances in which civil proceedings may arise, and the complexity of this litigation. In *Roache v. Newsgroup Newspapers Limited*,⁵⁵ Sir Thomas Bingham MR said: "The judge must look closely at the facts of the particular case before him and ask: who, as a matter of substance and reality has won?" "Success" is not a <u>not</u> technical term it is the "result in real life", to be determined "with the exercise of common sense".⁵⁶
- 75. As I have noted, but for the outcome of the EPO Proceedings, it was uncontroversial that Neurim was the winner, and Mylan the loser. Mr Waugh, QC, for Neurim, contended that the adverse outcome (for Neurim) of the EPO Proceedings, and the fact that the Patent had by reason only of the withdrawal of Neurim's appeal before the Technical Board of Appeal, and not by reason of anything done in this jurisdiction, where Neurim had succeeded been revoked *ab initio* could not and should not alter this conclusion as to who the winner was. The "UK proceedings are separate and distinct from those at the EPO", according to Neurim. That, of course, is a contention previously made by Neurim as an argument for not revisiting the 16 December 2020 Orders <u>at all</u>. For the reasons I have given, I have rejected that contention and as it seems to me the contention is untenable in the context of costs. As I noted previously, of course, the UK Proceedings and the EPO Proceedings are separate and distinct, but that does not mean to say that they do not inter-relate and are not inter-connected. They obviously do and are.
- **76.** So, I do not consider that it can rightly be said that the "twin-tracks" of revocation in UK Proceedings and revocation in EPO Proceedings can be treated as hermetically sealed, one from the other. I consider that the effect of the EPO Proceedings on the <u>outcome</u> of the UK Proceedings is a relevant factor that I must bear in mind.
- 77. Viewing the matter from the point of view of <u>outcome</u>, it is obvious that Mylan is the winner and Neurim the loser. Referring to the issues arising on the pleadings, Neurim contended that the Patent was valid and infringed; Mylan contended that the Patent was invalid, and should be revoked. Viewing the matter through the prism of the pleadings, Mylan is clearly and unequivocally the winner. The oddity if it can be called that is that this outcome has been achieved despite and not because of the Judgment in the UK Proceedings, which (as I have said) went more or less entirely Neurim's way.
- **78.** I conclude that, given the interaction that exists between the EPO Proceedings and the UK Proceedings, which is fully taken into account when considering whether a stay of the UK Proceedings should be granted,⁵⁷ the "result in real life" in this case is to be determined by comparing the remedies and relief sought by the parties to the UK Proceedings with what they have actually obtained. As I have said, viewed through this prism, there is only one winner: although Neurim contended that the Patent was valid and infringed, the recitals to the 30 December 2020 Order⁵⁸ make clear that this outcome has not been achieved. By contrast, Mylan's contention that the Patent should be revoked

⁵⁵ [1998] EMLR 161.

⁵⁶ Bank of Credit and Commerce International SA v. Ali, (1999) 149 NLJ 1734.

⁵⁷ See *IPCom*, considered above.

⁵⁸ See paragraph 36(6) above.

has succeeded, albeit by a curious (and hopefully not to be repeated) interaction between the UK Proceedings and the EPO Proceedings.

- 79. Accordingly, at this stage of the analysis, I conclude that Mylan is and is very clearly the successful party. However, I consider that this is, in the circumstances of the present case, a "soft" and not a "hard" conclusion, and that I need to consider most carefully whether and if so to what extent a different costs order ought to be made to reflect the extremely unusual circumstances of this case. In short, I treat this as the costs order that I should make unless it is displaced by other factors (to which I shall come).
- **80.** I should say that I do not consider that the usual alternative of an issues-based costs order to be appropriate here. The fact is that the issues all go one way or they all go the other way depending on whether one looks at the outcome as stated in the Judgment or the outcome as it will appear in the new consequential order that I will, in due course, make. In other words, an issues-based costs order is not, in my judgment, a particularly helpful tool in the present case, extremely useful though it normally is.
- 81. Nor do I consider that it would be appropriate to make an order along the lines of "everyone's a winner, and everyone's a loser". Tempting though it is to make no order as to costs, I consider that that would be inconsistent with my provisional finding that Mylan <u>is</u> the winner. What I must do is consider whether there are other specific factors in play that can properly justify a different costs order.

(c) The significance of the EPO Proceedings

- 82. Obviously, I have attached and do attach considerable significance to the <u>outcome</u> of the appeal before the Technical Board of Appeals in the EPO. In essence, it is the outcome of the appeal that has rendered Mylan the successful party and Neurim the unsuccessful party.
- 83. Both parties sought to persuade me that the conduct of the EPO Proceedings and, in particular, the events on 17 and 18 December 2020, which resulted in Neurim withdrawing its own appeal, were in themselves significant in terms of their effect on my decision as to the costs in the UK Proceedings. Thus:
 - (1) Mylan contended that the point that had persuaded the Technical Board of Appeal to its provisional view that Neurim's appeal should be dismissed and the Patent revoked was identical to one of the points raised by Mylan before me and on which I reached the opposite conclusion. Mylan's position was that if as, of course, it cannot now do, because there is no order to appeal against⁵⁹ Mylan had been able to appeal my Judgment, it would have succeeded before the Court of Appeal, my Judgment (on this point at least) would have been overturned and Mylan would have been the successful party in the Court of Appeal, with the result that any costs order adverse to Mylan in the court below would also have been varied in Mylan's favour.

⁵⁹ See paragraph 55 above.

- (2) I was, initially, attracted by this counter-factual approach, but the more one tries to use it, the less helpful it becomes. The fact is that Mylan's counterfactual case on costs was robustly disputed by Neurim. Neurim's position was that:
 - (a) The point before the Technical Board of Appeal was actually entirely different from the points that were before me in the UK Proceedings. There was, according to Neurim, absolutely no reason to suggest that the outcome of any appeal of the Judgment would be any different to the terms of my Judgment even assuming permission to appeal were given. Mr Waugh, QC noted that the point that had persuaded the Technical Board of Appeal, and which Mr Vanhegan, QC contended was the same as one of the points before me, was a point on which I had in fairly robust terms refused permission to appeal.
 - (b) Indeed, Mr Waugh, QC went further than this. He contended that not only was the point that persuaded the Technical Board of Appeal in the EPO Proceedings a <u>different</u> point to the points before me in the UK Proceedings, it was also a <u>new</u> point before the Technical Board of Appeal, which Mylan should not have been permitted to advance. In short, according to Mr Waugh, QC, Neurim were "ambushed" by Mylan and the ambush should not have been permitted by the Technical Board of Appeal. Furthermore, according to Mr Waugh, QC, the Technical Board of Appeal compounded their error in not permitting Neurim to adduce further or additional material in order to respond to the "ambush".
- It should, by now, be clear that the counter-factual approach contended for by Mr (3) Vanhegan, QC no longer commends itself to me. It requires me to re-visit and reach an independent view of the points considered by the Technical Board of Appeal. This is very difficult in this case, because Neurim withdrew its appeal, and the Technical Board of Appeal never actually gave a formal decision, and will now never hand down any written reasons in the EPO Proceedings. But, even if the appeal had not been withdrawn, and full reasons had, in due course, been rendered in the EPO Proceedings by the Technical Board of Appeal, I consider that it would be invidious for me to seek to "second guess" the findings and reasoning of the Technical Board of Appeal. I consider that, for the reasons I have given, it is appropriate to look at the outcome of the EPO Proceedings: but to go further than this and to seek to re-assess the findings and the reasoning in the EPO Proceedings is inappropriate in circumstances where I have no appellate or review function of any kind in relation to the EPO Proceedings. It seems to me that the EPO's processes are its processes, which it is right to consider to the extent they affect processes running in parallel before the English court, but not right to second guess.
- (4) That, of course, means that not only do I regard Mr Vanhegan, QC's counterfactual argument as to what might have happened in the Court of Appeal on an appeal from my Judgment as substantially irrelevant to my analysis, but that the same goes for Mr Waugh, QC's contentions as to what he submitted had "gone wrong" in the EPO Proceedings. (I should make clear that in articulating Mr Waugh, QC's contentions, I am in no sense endorsing them: for the reasons given, this is subject-matter on which I cannot and should reach or express any view.)

84. For all these reasons, there is nothing in the EPO Proceedings, nor in the effect of points taken in the EPO Proceedings on hypothetical appeals in this jurisdiction, that assists me on the question of costs.

(d) Conduct of these proceedings

- **85.** This was hard-fought patent litigation. Each side suggested that the other had spurned one or more opportunities of saving costs by (for instance) avoiding, or rendering unnecessary, the trial before me in the UK Proceedings. Thus and I raise these purely by way of example Neurim contended that Mylan's failure to "clear the way" by an early revocation action (instead of merely opposing the Patent in the EPO) would have rendered the trial (at least in the form it took) unnecessary. For what it is worth, that is probably right: on this basis, there would have been a far earlier trial, with an outcome (at least in the UK) well-before the time my Judgment was handed down.
- 86. To take another example, Neurim suggested that if Mylan had at some point, but even as late as June/July 2020, when the hearing before the Technical Board of Appeal was expedited undertaken not to import or sell Infringing Product, the trial in the UK Proceedings might have been avoided or at least adjourned pending the outcome in the EPO Proceedings. Again, that is probably right: had Mylan offered such an undertaking, and the parties jointly approached the court with an agreement to adjourn pending the outcome of the appeal to the Technical Board of Appeal, then an adjournment of the UK Proceedings would have been "on the cards" and once the appeal in the EPO Proceedings had been determined a trial in the UK Proceedings would clearly not have been needed.
- 87. I am unsure whether such "what if" questions are particularly helpful unless they evidence, clearly and distinctly, conduct that goes beyond hard-fought litigation and strays into what might be called the "blameworthy" or, perhaps, the "reprehensible".⁶⁰ The cases use different words and the test might be:

Has one or other of the parties acted in a manner out of the ordinary which, without justification, has caused costs materially to be incurred which might have been avoided?

How far this test differs from the "blameworthy" is, perhaps, open to debate. My thinking is that this is simply a longer – but perhaps more focussed – statement of what is "blameworthy". "Reprehensible" conducts seems to me to be several stages further down the spectrum of culpability.

88. I am satisfied – subject to one point, which I will come to – that there is nothing in the conduct of either party – and, specifically, in the conduct of Mylan, which is presumptively the "successful party" – to cause me to alter the incidence of costs that I have provisionally concluded should fall in favour of Mylan and against Neurim. In reaching this conclusion, I remind myself that although Neurim repeatedly described Mylan as the "infringing party", that was only ever a <u>contention</u> on the part of Neurim. For a brief period – between 4 December and midday on 19 December 2020 – that contention was supported by the Judgment, but in the entire period up to the Judgment it was only ever Neurim's <u>allegation</u> that Mylan was infringing the Patent. The court's processes are intended to achieve justice between the parties in the period up to trial, by,

⁶⁰ See *Abbott v. Long*, [2011] EWCA Civ 874 at [14] to [15].

as appropriate, ordering interim remedies. In this case, although it was found to be arguable that Mylan was infringing the Patent, no interim injunction was granted, and Mylan was free – within the limits of proper conduct of litigation – to follow what strategy it wished with regard to bringing onto the market Infringing Product: that strategy would, of course, have informed Mylan's decisions in the course of these UK Proceedings. As I have said, both parties' took a fairly aggressive approach in the UK Proceedings, but not an improperly aggressive one. This was, simply, hard-fought litigation.

- **89.** That is subject to this one, final, point. As I have found,⁶¹ both Neurim and Mylan knew, in early June 2020, that the hearing before the Technical Board of Appeals had been expedited and was due to be heard on 17 and 18 December 2020. Had the parties jointly sought an adjournment, I suspect it would have been granted. As it is, I infer that one or both of the parties did not want an adjournment, and one can understand why: Mylan, for its part, would have wanted its two bites of the revocation cherry; and Neurim, having failed to obtain an interim injunction, would have wanted a final injunction in place as soon as possible in the event of it succeeding in both the UK and the EPO Proceedings. The quickest way of achieving that was by way of maintaining the expedited trial in the UK Proceedings, whilst pressing on with the EPO Proceedings.
- **90.** Without in any way wishing to criticise or be prescriptive, whilst the parties may very well have had their own reasons for wanting the EPO and the UK Proceedings to proceed in parallel, their conduct (in not referring the matter to the court) deprived the court of considering whether a stay of the UK Proceedings was or was not appropriate. In effect, the parties prevented the court from re-visiting, or considering re-visiting, Nugee J's order expediting the trial. Nugee J's order would have been premised on an appeal in the EPO Proceedings in the first quarter of 2022: an appeal in the EPO actually listed for hearing and determination on 17 and 18 December <u>2020</u> is a very different matter.
- **91.** I remind myself of Floyd LJ's twelfth proposition or guidance in *IPCom*: in weighing the balance of staying or not staying English proceedings, it is material to take account of costs liable to be wasted. In this case, the picture changed dramatically between March 2020 (when expedition was ordered by Nugee J) and June 2020 (when, in my judgment, there was a material change, such that a party would have been justified in bringing the matter back before the court for re-consideration). As I see it, the following possibilities existed as at June/July 2020:
 - (1) An application to adjourn could have been made by both parties: in such a case, and in such circumstances, it is difficult to see a court declining the application but, even if it had been declined, there would have been the opportunity to consider in advance what would happen on the question of costs if the EPO Proceedings proceeded in parallel with and with outcomes at roughly the same time as the UK Proceedings, simply because the UK Proceedings were not adjourned
 - (2) An application to adjourn could have been made by one party, and resisted by the other. In such a case, the court would obviously need to understand why an adjournment was being resisted, and it may be that the adjournment would not be granted. All would depend on the facts and matters advanced by the parties on the application. If the adjournment was refused, the court would be in a strong position

⁶¹ See paragraph 20 above.

to articulate which party would bear the costs of the trial of the UK Proceedings if the outcomes of the EPO and UK Proceedings diverged.

- The third possibility is the one that occurred: no application to adjourn was made (3) by either party. In June/July 2020, both Neurim and Mylan knew that there was a clear potential for the outcome of the UK Proceedings to be rendered pointless in light of the imminent hearing before the Technical Board of Appeal in the EPO Proceedings. The parties would have been well aware of potentiality. In my judgment, in not seeking to engage with the court on the question of adjournment, each of the parties assumed the risk of costs being wasted and of a costs order being made that followed the outcome of the interaction between the UK and the EPO Proceedings, as opposed to the reasoning (whatever it might be) of the UK Proceedings. I do not say that an outcome based order will always, or even generally, be the right one, although in this case I consider it to be the correct starting point when assessing the incidence of costs, for the reasons I have given. It seems to me that Neurim cannot now complain that it bears the entire costs of the trial simply because – although the Judgment favoured it – the outcome of the interaction between the EPO Proceedings and the UK Proceedings has resulted in Neurim being the losing party. The costs of the UK Proceedings were costs thrown away because the decision of the Technical Board of Appeal in the EPO Proceedings rendered the trial in the UK Proceedings unnecessary. That is something that Neurim could have avoided, and I consider there is no reason why I should alter the provisional view on costs that I have reached. Indeed, I consider the fact that it lay within Neurim's power to bring this issue before the court to support and further justify the provisional view on costs that I have reached.
- **92.** I should make clear that I am in no way singling out Neurim for particular blame. Had the outcome of the interaction between the EPO Proceedings and the UK Proceedings favoured Neurim, then I would have considered that a provisional costs order in the UK Proceedings ought to favour Neurim, and I would have considered <u>Mylan's</u> failure to raise the matter of an adjournment in June/July 2020 in exactly the same way as I have considered Neurim's.

(e) An interesting question

- **93.** At paragraph 50(6) above, I raised, but did not answer, the difficult hypothetical question of what might have happened had the trial of the UK Proceedings gone ahead, with the outcome those proceedings had (as *per* the Judgment), but with the hearing before the Technical Board of Appeal not taking place until the first quarter of 2022. In those circumstances, the 16 December 2020 Orders would have been formalised and an injunction enjoining Mylan against infringement would have been operating against Mylan for around 14 months. For that period of time, Mylan would have been prevented (and, given the outcome of the EPO Proceedings I am hypothetising, which is the actual outcome only later, <u>wrongly</u> prevented) from bringing the Infringing Product (now clearly <u>not</u> an infringing product) to market in the UK. Furthermore, Mylan would, in accordance with those orders, have delivered up or destroyed Infringing Product; and Mylan would have paid substantially all of the costs of the UK Proceedings.
- **94.** It is an open question what the legal position is, in such circumstances. *Goff & Jones* would appear to suggest that this would be a case of the recovery of benefits by Mylan conferred on Neurim under an order (namely the 16 December 2020 Orders)

subsequently reversed or set aside by reason of the outcome of the EPO Proceedings. If so, then one of the benefits conferred would or might be any costs that Mylan in fact paid to Neurim.⁶²

95. If that is right, then that outcome would confirm the costs order that I am minded to make in Mylan's favour. However, I write these paragraphs to make clear that I did not hear full argument on this point (although the point was touched upon in the course of argument) and I am emphatically not deciding it. I have placed no weight on the fact that – if the law is as I have suggested it <u>might</u> be – it confirms the conclusion I have reached on costs. To the contrary, even if there were no restitutionary (or other) remedy enabling Mylan to recover benefits conferred in obedience to the 16 December 2020 Order, I consider the outcome that I have reached, both on the question of costs and the question of permission to appeal, to be the correct one. In short, I have reached my conclusions without this point being taken into account, either way.

E. **DISPOSITION**

- **96.** For reasons I have given:
 - (1) I was right, in the 30 December 2020 Order, to re-visit and revoke, *pro tem*, the 16 December Orders 2020. Accordingly, I am obliged to re-consider the 16 December 2020 Orders in light of the later circumstances, specifically the fact that Neurim's appeal to the Technical Board of Appeal was withdrawn, with the result that the Patent was revoked *ab initio*.
 - (2) Having re-considered both the question of permission to appeal the Exclusive Licence Point and the question of costs, I hold and find that:
 - (a) Permission to appeal on the Exclusive Licence Point should be refused.
 - (b) Mylan should have the costs of and arising out of these proceedings, save to the extent that prior costs orders are inconsistent with this. (In this, obviously, I do not include the 16 December 2020 Orders, which have been revoked.) I will leave it to the parties to draw up a yet further order, but I indicate now that I consider a payment on account of costs of £750,000 to be appropriate, although I will of course hear the parties (ideally on paper) if an order cannot be agreed.
 - (c) For the avoidance of doubt, Mylan should have the costs of the two consequential hearings that have taken place since the Judgment was handed down.

⁶² Goff & Jones: The Law of Unjust Enrichment, 9th ed, Ch 26.