



Neutral Citation Number: [2021] EWHC 2198 (Pat)

Case No: HP-2021-000021

**IN THE HIGH COURT OF JUSTICE**  
**CHANCERY DIVISION**  
**PATENTS COURT**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 2<sup>nd</sup> August 2021

**Before :**

**THE HON MR JUSTICE MELLOR**

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**Between :**

**(1) NEURIM PHARMACEUTICALS (1991)  
LIMITED**

**Claimants**

**(2) FLYNN PHARMA LIMITED**

**- and -**

**(1) GENERICS UK LIMITED T/A MYLAN  
(2) MYLAN UK HEALTHCARE LIMITED**

**Defendants**

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**Mr Andrew Waugh QC and Ms Katherine Moggridge** (instructed by **Gowling WLG**) for  
the First Claimant (and by **Pinsent Masons LLP**) for the Second Claimant  
**Mr Adam Gamsa** (instructed by **Taylor Wessing LLP**) for the **Defendant**

Hearing dates: 28<sup>th</sup> & 30<sup>th</sup> July 2021  
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**Approved Judgment (subject to editorial corrections)**

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

COVID-19: This judgment was handed down remotely by circulation to the parties' representatives by email. It will also be released for publication on BAILII and other websites. The date and time for hand-down is deemed to be 2pm on Monday 2<sup>nd</sup> August 2021.

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**THE HON MR JUSTICE MELLOR**

**Mr Justice Mellor:**

1. At an early stage in this action, the Claimants (Neurim) apply for an expedited trial of preliminary issues in their action against the Defendants (Mylan). This application came before me in a very busy last week of term stint as Chancery Interim Applications Judge, which was not ideal. I heard argument on 28<sup>th</sup> July and was going to give judgment on 30<sup>th</sup>, but IT issues and other urgent applications prevented that. Accordingly, I informed the parties of the outcome of the application, with reasons to follow. These are those reasons.
2. The action is for infringement of EP 3 103 443 (EP443) which was granted on 30<sup>th</sup> June 2021 and which expires on 12 August 2022. Like its parent (on which more below), it is entitled ‘Method for treating primary insomnia’. It relates to the use of melatonin for treating primary insomnia. The reason why this patent will have such a short life from grant to expiry is because it is a divisional which appears to have languished for years without being prosecuted to grant, being, as it were, kept in reserve. At least one of the reasons why it was allowed to languish by Neurim is because the earlier parent patent (EP 1 441 702, EP702) was granted in 2017, although it will be noted that even that patent took almost 15 years to proceed from filing to grant.
3. The parent patent EP702 was the subject of an infringement action brought by Neurim against Mylan in 2020, with Mylan counterclaiming for invalidity. There is much more I need to relate about the circumstances of that earlier action.
4. Although this action was commenced very promptly after grant of 443, with the claim form being issued on the day of grant, judgment on a full trial of infringement and validity would not be handed down until after the patent has expired, assuming no expedition.
5. However, Neurim say that the parties have already litigated all the issues of infringement and validity and say that Mylan are estopped from asserting otherwise. Hence Neurim apply for the trial of primarily but not exclusively the estoppel arguments as a preliminary issue, and seek expedition of that trial so that it is heard, if possible, in the Michaelmas term this year. Mylan say the position is more complicated than Neurim state, such that the Court should resist the siren song of a preliminary issue in this case.

**Applicable legal principles**

6. That very brief introduction indicates that this application engages well-settled principles of law in two areas:
  - i) The first is the caselaw concerning the circumstances in which the Court should or should not order the trial of a preliminary issue;
  - ii) The second is the caselaw regarding expedition.
7. As to the first, I was referred to the five factors identified by Mr Justice David Steel giving the main judgment in the CA in *McLoughlin v Jones* [2001] EWCA Civ 1743 at [66]:

‘66. In my judgment, the right approach to preliminary issues should be as follows:—

- a. Only issues which are decisive or potentially decisive should be identified;
- b. The questions should usually be questions of law.
- c. They should be decided on the basis of a schedule of agreed or assumed facts;
- d. They should be triable without significant delay, making full allowance for the implications of a possible appeal;
- e. Any order should be made by the court following a case management conference.’

8. I was also referred to the judgment of HHJ Birss QC (as he then was, sitting as a Deputy Judge of the High Court) in *Wagner v Earlex* [2011] EWHC 3897 (Pat) at [9], setting out the slightly longer list of some 9 criteria emanating from the Judgment of Neuberger J (as he then was) in *Steele v Steele* [2001] CP Rep 106:

- ‘(a) whether the determination of the preliminary will dispose of the whole case or at least one aspect of the case;
- (b) whether the determination of the preliminary issue will significantly cut down the cost and the time involved in pre-trial preparation and in connection with the trial itself;
- (c) if the preliminary issue is an issue of law, the amount of effort involved in identifying the relevant facts for the purposes of the preliminary issue;
- (d) if the preliminary issue is an issue of law whether it can be determined on agreed facts. If there are substantial disputes of fact it is unlikely to be safe to determine the legal issue until the facts are found;
- (e) whether the determination of the preliminary issue will unreasonably fetter either the parties or the court in achieving a just result;
- (f) the risk that an order will increase the costs or delay the trial and the prospects that such an order may assist in settling the dispute;
- (g) the more likely it is that the issue will have to be determined by the court, the more appropriate it is to have it determined as a preliminary issue;
- (h) the risk that the determination may lose its effect by subsequent amendments and statements of case; and
- (i) whether it is just and right to order the determination of the preliminary issue.’

9. I was also reminded of 3 trenchant warnings about preliminary issues:

- i) First, as Lord Scarman observed in *Tilling v Whiteman* [1980] AC 1,25: "*Preliminary points of law are too often treacherous short cuts*".

- ii) Second, Lord Neuberger (then Master of the Rolls) also cautioned against preliminary issues in *Bond v Dunster* [2011] EWCA Civ 455 at [107]: “*While they have their value, it is notorious that preliminary issues often turn out to be misconceived, in that, while they are intended to short-circuit the proceedings, they actually increase the time and cost of resolving the underlying dispute...*”
- iii) Third, that preliminary issues should normally be resisted, per Lord Neuberger in *Rossetti v Diamond Sofa* [2012] EWCA Civ 1021 at [1] (emphasis added):

This is an appeal from a decision of Cranston J determining certain preliminary issues arising out of a dispute between (i) Rossetti Marketing Ltd (“RML”) and Solutions Marketing Ltd (“SML”), and (ii) Diamond Sofa Co Ltd (“Diamond”). It represents yet another cautionary tale about the dangers of preliminary issues. In particular, it demonstrates that (i) while often attractive prospectively, the siren song of agreeing or ordering preliminary issues should normally be resisted, (ii) if there are none the less to be preliminary issues, it is vital that the issues themselves, and the agreed facts or assumptions on which they are based, are simply, clearly and precisely formulated, and (iii) once formulated, the issues should be answered in a clear and precise way.

- 10. As for the caselaw on expedition, the leading case is *Gore v Geox* [2008] EWCA 622 at [25], in which the CA identified four factors (repeated in *Petter v EMC Europe* [2015] EWCA Civ 480 at [12]):
  - a) whether there is good reason for the expedition;
  - b) whether expedition would interfere with the good administration of justice;
  - c) whether expedition would cause prejudice to the Defendant; and
  - d) whether there are any other special factors.
- 11. Notwithstanding the generally applicable guidance and warnings on preliminary issues and expedition, it seems to me that this particular situation has some special features which I must take into account. These are best explained after I have set out much more of the relevant factual background.
- 12. Finally, although it is not my role on this application to make any findings as to the validity or otherwise of the estoppels claimed, I will however cite here paragraph [22] from the judgment of Lord Sumption in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Limited* [2013] UKSC 46 because his third point provides a useful and succinct summary of issue estoppel. Having considered *Arnold v National Westminster Bank plc* [1991] 2 AC 93, Lord Sumption concluded as follows:

22. *Arnold* is accordingly authority for the following propositions:

- (1) Cause of action estoppel is absolute in relation to all points which had to be and were decided in order to establish the existence or non-existence of a cause of action.

(2) Cause of action estoppel also bars the raising in subsequent proceedings of points essential to the existence or non-existence of a cause of action which were not decided because they were not raised in the earlier proceedings, if they could with reasonable diligence and should in all the circumstances have been raised.

(3) Except in special circumstances where this would cause injustice, issue estoppel bars the raising in subsequent proceedings of points which (i) were not raised in the earlier proceedings or (ii) were raised but unsuccessfully. If the relevant point was not raised, the bar will usually be absolute if it could with reasonable diligence and should in all the circumstances have been raised.

13. Finally, Neurim naturally relied on what occurred in the *Lilly v Genentech* litigation concerning Genentech's EP822 (which was declared invalid and revoked by Arnold J (as he then was) in the first action, but would have been infringed by Lilly if it had been valid) and the later divisional EP084, the subject of the second action. In the first action, Genentech lodged an appeal from the Order of Arnold J. Subsequently, the TBA upheld the decision of the Opposition Division and revoked EP822 for added matter, a ground which had been considered and rejected by Arnold J. In the second action brought by Lilly for revocation of EP084, with Genentech counterclaiming for infringement, Birss J (as he then was) ordered that Lilly's plea that certain matters were *res judicata* should be determined as a preliminary issue, along with Lilly's application for summary judgment if successful on the preliminary issue.
14. These matters were decided by Mr Roger Wyand QC, sitting as a Deputy Judge of the High Court – see *Eli Lilly v Genentech* [2020] EWHC 261 (Pat). The outcome is instructive. The Deputy Judge determined that Genentech was estopped from arguing that the principal claims of EP084 were valid and he found those claims invalid. As for two remaining claims which were proposed to be inserted by amendment, he held that Genentech was estopped from arguing those claims were plausible at the priority date but had a real prospect of defending the plausibility of those claims as at the later filing date, on the basis of development in the common general knowledge in the meantime. Summary judgment was therefore refused on claims 10 and 11, which meant that the application to amend EP084 was stood over to the trial of the action.
15. I shall return to some aspects of Mr Wyand QC's judgment in *Lilly v Genentech* a little later.

### **The relevant factual background**

16. On the facts, there is a good deal of history, much of which concerns EP702. Although the opposition in the European Patent Office (EPO) to EP702 started first, it ran in tandem with the 2020 action between the parties until EP702 was revoked. The events are not in dispute, even though there is a dispute about the nature of the insufficiency argument raised before the EPO Technical Board of Appeal (TBA).

**10 May 2017:** EP702 granted.

**9 February 2018:** Mylan filed a Notice of Opposition. Oppositions also filed by Teva and Aspire Pharma.

**20 November 2019:** the Opposition Division at the EPO finds that EP702 lacked novelty. Neurim appealed to the TBA, which suspended the revocation of the Parent Patent pending the outcome of that appeal, in the usual way.

**Early 2020:** Mylan obtains obtaining a marketing authorisation for generic melatonin and refuses to provide notice of any launch of their product.

**14 February 2020:** Claim form in the EP702 action issued.

**17 February 2020:** Neurim serve proceedings on Mylan for infringement of EP702. Mylan denies infringement and counterclaims that EP702 is invalid by a Defence and Counterclaim served 1 April 2020.

**2 March 2020:** Neurim applies for a preliminary injunction (PI) pending trial in the light of Mylan's refusal to give any undertaking not to launch.

**6 March 2020:** Mylan applies for expedition of EP702 trial, to which Neurim agrees on 13 March 2020. On 19 March 2020, Nugee J ordered an expedited trial.

**20 May 2020:** Marcus Smith J hears the PI application, and in a judgment of 3 June 2020 refuses it. His refusal was upheld by the Court of Appeal in a judgment of 24 June 2020. The reasoning of both Courts was based partly on the fact that the trial had been expedited and there was limited time for damage to accumulate. The Supreme Court, despite considering that there was a point of law of public general importance, refused to give permission chiefly because of the imminence of trial

**September 2020:** Mylan launched its generic melatonin product.

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

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

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

**30 December 2020:** Marcus Smith J revokes his oral order of 16 December 2020, the terms of the order not having been settled in writing. The Judge made no order on Mylan's counterclaim and

recorded a declaration that EP702 had been revoked *ab initio*, a point he also stated in his judgment on the consequential issues.

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

17. Meanwhile, Neurim had revived its divisional application even though (as Mylan pointed out) it had previously been deemed to have been withdrawn on 17 October 2018, due to inactivity. The principal events relevant to EP443 are:

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

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

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

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

**30 June 2021:** EP443 granted.

**11 August 2021:** Mylan's Defence and Counterclaim due.

**October 2021:** Mylan has secured a date for the hearing of its application to stay this action pending the outcome of its opposition in the EPO.

18. Against that background, I turn to consider Neurim's application, which is not straightforward.

### **Neurim's application**

19. Neurim seek an Order with the following parts:

(a) That the issues the Claimants contend are the subject matter of issue estoppel as pleaded in paragraphs 9 and 10 of, and Annex B to, the Particulars of Claim be determined as a preliminary issue. In summary, this is the issue of whether Mylan is estopped from contesting the amendments to and the validity and infringement of the Patent (as so amended) in this claim. I shall refer to this as the "**Estoppel Preliminary Issue**";

(b) That the standing of Flynn in this claim as exclusive licensee subsequent to the execution of the agreement with Neurim dated 10 December 2020 as pleaded in paragraphs 19 to 25 of the Particulars of Claim be determined as a preliminary issue. I shall refer to this as the "**Exclusive Licence Preliminary Issue**";

(c) That Neurim's application to amend the Patent<sub>1</sub> (the "**Amendment Application**") be heard and determined at the same time as the hearing and determination of the Estoppel and Exclusive Licence Preliminary Issues (unless it is necessary to distinguish between them I shall refer to both of these preliminary issues as the "**Preliminary Issues**"); and

(d) That the determination of the Preliminary Issues and Amendment Application be heard with expedition as soon as possible after 1<sup>st</sup> October 2021 and before the end of November 2021.

20. Neurim, however, sought to portray its application as simple. They say that just like the previous action between these parties, this should be expedited so that commercial certainty is achieved as quickly as possible. They say this is all the more important now that Mylan is now on the market with its melatonin product. They say that consideration was given to an application for a preliminary injunction but, perhaps not surprisingly, Neurim evidently consider that an expedited trial of its estoppel arguments is a better route to securing an injunction against Mylan before the patent expires. Finally, Neurim seek to portray Mylan as taking any point which will put off the determination of this action until after EP443 expires, and there appears to be some truth in that.
21. Mylan had a number of points in response, which are best considered within a (perhaps slightly modified) *McLoughlin* framework.

*What are the issues*

22. First, Mylan made the valid point that the Court would not determine issue estoppel at the level of generality at which Neurim had apparently identified the 'issues'. The Particulars of Claim are not satisfactory in this regard. In paragraph 9, Neurim plead that '*The findings on which the Claimants rely as giving rise to issue estoppel in this action are set out in Annex B hereto.*' Annex B however is a copy of the main judgment of Marcus Smith J with certain paragraphs, sometimes long, highlighted. The prayer for relief seems to suggest that the 'issues' on which Mylan is estopped are infringement, validity, and that the amendments to the Patent are not allowable.
23. It is striking that in *Lilly v Genentech*, Lilly identified no less than 44 distinct issues on validity in that case. When I put that point to Mr Waugh, his response was that there had been a lot of argument in *Lilly* about fine points on many of the issues identified, but that does not provide a satisfactory answer. I had no intention of ordering the trial of preliminary issues which would require the Judge to pick through the highlighted paragraphs in Annex B to identify the findings which were said to be the subject of issue estoppel. However, this seemed to me to be something which was easily curable by Neurim if I was otherwise persuaded to order a trial of preliminary issues. I return to this point below.



24. Mylan's second point is that Neurim have pleaded *Henderson v Henderson* abuse separately to issue estoppel but does not seek resolution of the *Henderson* abuse issue as a preliminary issue. This is also a valid point which I have to consider further.
25. Third, Mylan say the outcome of the estoppel issues will not be decisive as a result of Mylan's intended counterclaim – that these proceedings based on the divisional EP443 amount to an abuse of a dominant position and hence preclude relief even if Neurim succeed on their preliminary issues. This intended counterclaim was not fleshed out in Mylan's evidence and it remains to be seen how it is pleaded in their Defence and Counterclaim. On the current information, I am not persuaded this is a serious impediment to ordering a preliminary issue. If there was or is 'abuse' in Neurim's behaviour in withdrawing EP702 so that it was revoked, then securing the grant of the divisional EP443 with the intention of amending the claims so they correspond to the claims in EP702, the better place for that to be considered is whether that gives rise to injustice to prevent the estoppels arising at all.
26. Fourth (and on perhaps another aspect of the injustice aspect of the claimed estoppels), Mylan says it is not an abuse for Mylan to counterclaim for revocation of EP443 in circumstances where EP702 was revoked at the EPO leaving Mylan deprived of the opportunity to appeal the findings of Marcus Smith J at first instance on validity which are now said to give rise to the estoppels.
27. Neurim appeared to me to suggest that this case is on all fours with the position in *Lilly v Genentech*. If so, I think Neurim are oversimplifying. Even at this preliminary stage it appears there are some differences between this case and what was considered in *Lilly v Genentech* which may prove to be significant. I mention the following.
28. First, it is apparent from the Judgment that the Court of Appeal was still considering whether to hear the appeal from the judgment of Mr Justice Arnold, even after the patent had been revoked by the TBA. At [64], the Deputy Judge said 'The appeal is still live...'. As I understand what happened, in the end the Appeal was never heard because the case settled for other reasons. Although Genentech argued that estoppel would create an injustice *if* it was not able to pursue its appeal because EP822 was deemed never to have existed (see [63]), and even though the Deputy Judge saw some force in that argument at [64], he did not have to confront squarely the oddity that revocation of EP882 by the TBA deprived Genentech of an appeal against the Order of Arnold J.
29. By contrast, in this case, this oddity will have to be confronted head on. When Neurim withdrew its appeal in the TBA, of course EP702 was revoked ab initio. It is as if that patent never existed. As I indicated, Mylan say that Neurim's action deprived Mylan of the opportunity of challenging the judgment of Marcus Smith J in the Court of Appeal. Although Mr Waugh disputed this before me and no doubt will dispute the point when the estoppel arguments come to be considered, Mylan correctly point out that appeals are against Orders and not judgments. Since Marcus Smith J did not dismiss their counterclaim for infringement, Mylan say they could not appeal against the fact that the Judge rejected their invalidity case in his judgment.
30. Thus, if the requirements for estoppel are otherwise made out, it seems that Mylan will argue that the claimed estoppel(s) will work an injustice, depriving Mylan of the opportunity to appeal the findings which Marcus Smith J made on their various validity attacks.

31. Second, I have already mentioned the point that the consequence of revocation of EP702 is that it is as if that patent never existed. This point does not seem to have been argued in *Lilly v. Genentech* as affecting the estoppel arguments. The Deputy Judge did refer to that effect of the TBA decision at the end of [4], but that effect was not thereafter referred to in any of the arguments on issue estoppel. Although Mr Waugh said the point was rightly not raised, I confess I consider this remains a tricky point which does not appear to have been considered before. The point is how a judgment on a patent can truly be said to be ‘final and binding’ when the patent which is the whole foundation for the action is to be treated as never having existed. The relevance of this point will have to be worked out when the estoppel arguments come to be considered and it may fall to be considered as part of consideration of whether the estoppels create injustice.
32. I should explain briefly the Exclusive Licence Preliminary Issue. In the main judgment, Marcus Smith J ruled that the claimed exclusive licence between Neurim and Flynn was not exclusive. The Claimants entered into a new licence on 10 December 2020 which addressed the reasons on which the Judge found the original licence not to be exclusive. Neurim assert the amended version as exclusive. Mylan accept this issue would not be decisive of this action, but claim it could be relevant to injunctive relief and will impact quantum. Although I have not seen the documents, this will be a short point on construction of the new licence.
33. The Amendment Preliminary Issue is not an estoppel argument. It arises because Neurim apply to amend the granted claims of EP443 into the form of the EP702 claims. Although Mylan have not yet pleaded their opposition to the proposed amendments, it is clear this will form part of Mylan’s abuse/injustice arguments.

*Are the issues questions of law*

34. Although the estoppel arguments will turn on issues of law, Mylan point out that a number of issues of fact will have to be resolved:
  - i) First, whether the insufficiency argument advanced before the TBA (which Mylan wish to run against EP443) was different to the insufficiency argument considered by Marcus Smith J. This will largely turn on the written submissions made in the TBA proceedings, and the pleadings and submissions made to Marcus Smith J. I can see there may be disputes over precisely what was said to and by the TBA (because there will be no transcript), but these will be minor.
  - ii) Second, Mylan say that Flynn’s status as an exclusive licensee depends on whether Neurim has permitted a third party (Teva) to launch in the UK via a settlement agreement. Teva is said to have concluded all regulatory steps needed before launch. It seems the point will turn on the interpretation of the settlement agreement. Mylan say that will require evidence of the matrix of fact.
  - iii) Third, Mylan says that facts will be involved in their opposition to amendment of EP443 on the grounds of abuse of process. Although this involves the first point, it does not seem to me to add much else by way of factual dispute.

*Can the issues be decided on the basis of a schedule of agreed or assumed facts*

35. On the basis of the points just mentioned, I must proceed on the basis that there will be facts in dispute, which will require hopefully short witness statements. I remain of the view however that most of the facts cannot be disputed.

*Can the issues be tried without significant delay, making full allowance for the implications of a possible appeal*

36. Although the lists are very full, it seems that it may be possible to fit a 2 day trial of preliminary issues (with 1 day pre-reading for the Judge) into the Michaelmas term. An appeal might require a degree of expedition so that it is determined suitably in advance of the expiry of EP443 for an injunction to bite.

*Are the issues decisive or potentially decisive*

37. I can leave aside the Exclusive Licence issue. The point really turns on the estoppel + amendment issues. On those, I can see a range of possible outcomes:
- i) Those issues may be decisive in favour of Neurim;
  - ii) They may also be decisive in favour of Mylan;
  - iii) However, I cannot rule out a middle ground, where the insufficiency issues in particular are not decided on estoppel grounds, but, in effect, the parties require a trial of the insufficiency issues. Thus, I see a considerable risk of ‘mission creep’ in that the Court will be asked to decide insufficiency. First, if Mylan are correct that the TBA argument was different to those considered by Marcus Smith J, I suspect that at least one side or the other will press for the argument to be determined at the preliminary stage, depending on their view as to the likelihood of success. Second, as part of that, Mylan are very likely to seek to argue what they would have argued on appeal from Marcus Smith J on his insufficiency findings. These considerations make this trial more complicated and these arguments will require expert evidence, but they have the advantage that they will be decisive, one way or the other.
38. These considerations also highlight the good sense in the fifth *McLoughlin* criterion – that any order should be made by the Court following a case management conference (i.e. once the pleadings are closed).
39. As for Neurim’s *Henderson* abuse argument, it seems to me unlikely that the argument will ever have to be the subject of a separate determination. If Neurim succeed on their estoppel arguments, the argument necessarily falls away. If Neurim fail on their estoppel arguments, it will be because either (a) no estoppels arise at all (and therefore it is highly likely there could be no *Henderson* abuse) or (b) the claimed estoppels rest on abuse by Neurim or they would create injustice – arguments in which Neurim will probably assert their *Henderson* points anyway.

*Special factors in this case*

40. Earlier I adverted to certain special factors which I consider I must take into account. These are:

- i) Neurim has a prima facie valid patent.
  - ii) It would appear that the product which Mylan has on the market infringes the patent.
  - iii) As Neurim submit, the final period when a patent is in force can often be particularly valuable commercially for the patentee before its period of monopoly comes to an end. Neurim says this is a particularly valuable drug for the Claimants.
  - iv) There are undoubtedly arguments to be had that Mylan are estopped in some perhaps all relevant respects. Equally, as I have indicated, my preliminary view is that the issues are not nearly as straightforward as Neurim suggest. The estoppel arguments raise, in my preliminary view, some interesting and tricky issues, on which Mylan may prevail.
41. If the estoppel arguments are left to be determined at a full trial of infringement and validity of the 443 patent:
- i) Judgment in that trial is almost certain to be given after expiry of the patent;
  - ii) The estoppel arguments would serve no real purpose, because the Judge will have had to determine the issues of infringement and validity anyway.
42. It follows that, in the ordinary course, and if it is possible to do so, it makes sense for any estoppel or abuse arguments to be heard first. If they are good arguments, then significant savings may be achieved both in costs expended by the parties and in the resources the court has to devote to resolving the case.
43. The circumstances here provide a good indication as to the likely cost savings which a preliminary issue might achieve. I am told the combined costs of the previous trial before Marcus Smith J amounted to around £3m. Even though the issues have been rehearsed already, the costs of a full trial may be around the same, as the industry of counsel will probably generate new and better ways of putting the arguments.
44. I am not overlooking the fact that the costs of the contemplated trial of the preliminary issues are likely to be substantial, but they should be considerably less than the costs of a full trial of infringement and validity with the estoppel arguments on top.

## **Conclusions**

45. Drawing the threads together, although the circumstances here do not present a set of preliminary issues which will necessarily be decisive, they are not purely questions of law, there will be some facts in dispute and Mylan has not yet pleaded out its points in its Defence and Counterclaim, I concluded, in the unusual circumstances of this case, that it is just and right that Neurim should be afforded the opportunity to establish its patent right by way of a trial of preliminary issues – this being the only realistic way in which Neurim can hope to secure injunctive relief before expiry of EP443.
46. The particular circumstances here provide a good reason for a degree of expedition, which will not interfere with the due administration of justice. Although Mylan complain that expedition is likely to deprive them of their chosen lead counsel, and they

complain that costs may be wasted if their stay application succeeds, I do not regard those points of potential prejudice as in any way sufficient to outweigh expedition. Mylan cited Neurim's conduct (in 'double patenting') as a special factor pointing away from expedition. Neurim dispute there has been any 'double patenting' at all, but I am satisfied that point is part and parcel of the abuse/injustice arguments to be considered as part of the estoppel issues. Finally, there was much discussion in the evidence about what was happening in the market, but (a) I am not in a position to resolve those disputes and (b) I do not see them as constituting a special factor pointing away from expedition.

47. For these reasons I indicated to the parties on 30<sup>th</sup> July 2021, that I would allow Neurim to secure a trial listing of 2 days, with 1 day pre-reading, after 1<sup>st</sup> October 2021 on a conditional basis. The conditions are:
- i) On or before 9<sup>th</sup> August 2021, Neurim must serve a Statement of Case which properly identifies each issue on which they say Mylan is estopped, together with such other issues as they require the Judge at the trial of the preliminary issues to determine;
  - ii) On or before 16<sup>th</sup> August 2021 (having served their Defence and Counterclaim on 11<sup>th</sup> August 2021), Mylan must serve their Statement of Case in response, which must also identify all the issues which Mylan wish to be determined at the trial of the preliminary issues;
  - iii) The parties must negotiate with the Listing Officer to secure a trial date. I will not direct that the trial must take place in the Michaelmas term – that will be a decision for the Listing Officer – but the trial should take place with a moderate degree of expedition and before the end of February 2022 at the latest;
  - iv) I propose to review the Statements of Case during the week of 16<sup>th</sup> August 2021, when I am one of the Vacation Judges, and I give the parties permission to apply to me during that week;
  - v) Further case management may be required to ensure that (assuming the action is not stayed at the hearing in October) the trial of preliminary issues is kept on track. If the preliminary issues appear to be going badly off track, the parties may face the prospect of losing the trial date I have directed, so it is in both their interests to co-operate to ensure that does not happen.
48. I have set directions for evidence to be served by reference to the trial date (once secured) with Neurim serving its evidence 8 weeks before trial, Mylan 6 weeks before trial, with Neurim's evidence in reply 4 weeks before trial. I invite the parties to seek to agree an order.