Neutral Citation Number: [2021] EWHC 2897 (Pat)

Case No: HP-2021-000021

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

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

Date: 29 October 2021

Before:

Ian Karet (sitting as a Deputy High Court Judge)

- -

Between:

(1) Neurim Pharmaceuticals (1991) Limited
(2) Flynn Pharma Limited

Claimants

- and –

(1) Generics (UK) Limited (T/A Viatris)
(2) Mylan UK Healthcare Limited

Defendants

Dr Justin Turner QC (instructed by **Gowling WLG** and **Pinsent Masons LLP)** for the **Claimants**
Mark Vanhegan QC and **Mitchell Beebe** (instructed by **Taylor Wessing LLP**) for the **Defendants**

Hearing date: 22 October 2021

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.

Ian Karet:

Introduction

1. This is an application by the Defendants ("Mylan") for a stay of these proceedings relating to EP(UK) 3,103,443 (the "Patent") pending the final determination of the validity of the Patent in opposition proceedings before the European Patent Office ("EPO").

2. Mylan is selling in the UK a 2mg prolonged release melatonin product for improving the restorative quality of sleep in patients suffering from primary insomnia characterised by non-restorative sleep. The Claimants ("Neurim") claim that is an infringement of the Patent.

3. The background to this application is complex. It follows a hearing before Mr Justice Mellor at the end of July 2021 at which he considered the Claimants' application for an expedited trial of preliminary issues relating to alleged estoppels. Mellor J granted that application and ordered that there be an expedited trial which is currently listed for December 2021.

4. In his judgment of 2 August 2021 [2021] EWHC 2198 (Pat) Mellor J described the position as follows:

> "2. The action is for infringement of EP 3 103 443 (EP443) which was granted on 30th 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.
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> 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.
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> 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.
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> 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.
>
> …

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 [[2020] EWCA Civ 793]. The reasoning of both Courts was based partly on the fact that the trial had been expedited and there was limited time for damage to accumulate. The Supreme Court, despite considering that there was a point of law of public general importance, refused to give permission chiefly because of the imminence of trial.

September 2020: Mylan launched its generic melatonin product.

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

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

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

> **30 December 2020**: Marcus Smith J 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.
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> **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).
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> 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:
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> **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.
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> **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.
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> **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
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> **4 June 2021**: the Examining Division issued its Decision to Grant.
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> **30 June 2021**: EP443 granted.
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> **11 August 2021**: Mylan's Defence and Counterclaim due.
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> **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."

5. Mellor J concluded that, in the unusual circumstances of this case, Neurim should have the opportunity to establish its patent right by way of a trial of preliminary issues. This was the only realistic way in which Neurim could hope to secure injunctive relief before expiry of the Patent in August 2022.

6. I understand that the reason Mellor J did not consider the stay application at the same time as the application for the hearing of preliminary issues was because there was insufficient court time for that. However, he understood that a stay application had been made, and he referred to it in his judgment.

7. Since the application before Mellor J, it appears that Teva, a third-party generic company, has come on to the UK market. There was some dispute about the exact chain of events and what was known at the time of the July application. It appears Mellor J was aware that Teva was preparing to enter the UK market, as noted at paragraph 34(ii) of his judgment.

8. The decisions on Neurim's unsuccessful application for an interim injunction against Mylan, described by Mellor J, appear to have been made on the assumption that Teva would not enter the UK market. The Court of Appeal assumed that this was not a case of multiple generic entry so that the price of the product would not spiral down as it might otherwise (see paragraph 50 of the Court of Appeal judgment).

9. It now appears that Neurim had been in correspondence with Teva's UK solicitors in July 2021, before the hearing before Mellor J, and that Teva had refused to agree not to enter the UK market.

10. There is, further, a contractual dispute between Neurim and Teva over whether Teva are allowed to enter the UK market under the terms of a settlement agreement. Neurim brought an application in the District Court of Tel Aviv seeking an interim injunction stopping Teva from entering the UK market. On 23 September 2021 the Israeli court refused that application. Neurim has appealed.

11. On 15 October 2021, Neurim sent a letter before action to Bird & Bird (for Teva) seeking an undertaking from Teva to cease any UK infringement until a decision is handed down in the preliminary issue trial. If Teva refuses then Neurim says it will commence infringement proceedings against Teva and will seek a preliminary injunction as soon as it receives a successful decision on the preliminary issues.

12. The reason, as I understand it, that Neurim will not seek a preliminary injunction against Teva until after judgment in the preliminary issue trial is that both Marcus Smith J and the Court of Appeal declined to order a preliminary injunction against Mylan on the parent patent. If Neurim failed against Mylan then it might similarly against Teva. It is not clear if the situation might be different on an interim injunction application if there is more than one generic on the market.

13. During the course of the hearing before me Neurim offered an undertaking to repay any damages or profits which are ordered to be paid in respect of infringement of the Patent if it is finally revoked either in the EPO or on an application by Teva in the UK courts. Mylan had sought an undertaking from Neurim before the hearing but Neurim had said that this was a matter that should be addressed at a later stage. It is not clear why Neurim did not offer this earlier. This was a significant development because of the affect an undertaking may have on the matters to be considered in a stay application.

14. Mr Vanhegan QC and Mr Beebe appear for the Mylan and Dr Turner QC for Neurim.

The parties' positions

15. Along with a substantial skeleton argument, Mr Vanhegan made a number points in argument in support of a stay.

16. First, it is unlikely that the Patent is valid. Mr Vanhegan said that every court that has issued a final order on the invention of the Patent (in considering the parent patent) has held it to be invalid. In particular the parent patent was held by the TBA to be insufficient.

17. Secondly, Mylan accepts that if a stay is granted then Neurim will not have the opportunity to remove Mylan's product from the UK market before the expiry of the Patent. If Neurim are able to establish infringement of a valid patent then they will be entitled to damages, which Mylan can afford and will be an appropriate remedy. In any event, Neurim will not have exclusivity as Teva is also on the UK market.

18. However, the failure to grant a stay risks Mylan suffering unquantifiable and potentially irrecoverable loss and damage as a result of the risk of being injuncted and having to pay damages. There would also be wasted costs. It is not certain that Mylan could be compensated for these.

19. There is a substantial asymmetry between Neurim and Mylan as to the nature of damage which will be suffered by the grant of a stay. Mylan has been on the UK market since September 2020. Damages for any infringement have always been quantifiable and would be an adequate remedy for the Claimants up to expiry in August 2022.

20. The third point is the issue of Teva's entry on the market. Neurim have not yet started proceedings against Teva in the UK despite knowing about Teva's intended launch since June 2021. If Mylan were to be injuncted then Teva would be well-placed to pick up Mylan's position as the generic supplier and Mylan would suffer harm due to the loss of its "first-mover advantage" (being the advantage the first generic supplier can achieve by agreeing sales in advance of anyone else so as to gain a large part of the market). The advantage is said to extend beyond simply supplying the product in question to longer term NHS supply contracts and Mylan's status. There may also be an impact on Mylan's reputation as a reliable supplier. If Mylan were to be injuncted at trial and then re-start sales on expiry of the Patent in August 2022 it would be starting behind Teva in an attempt to regain market share.

21. Fourthly, the UK proceedings will not determine any substantive issues of infringement or validity. Proceeding with the preliminary issues trial in December 2021 will, further, not give commercial certainty to Neurim or any third parties. The preliminary issues trial concerns novel points of law about issue estoppel and not question of validity. The losing party is likely to appeal to the Court of Appeal because each side makes similar points and there may be an appeal to the Supreme Court.

22. Fifthly, on timing of the various proceedings, while there will be some time between the decisions of the UK court and the EPO in the opposition, Neurim waited 14 years to file their divisional patent. That delay was of Neurim's own making because it sat on the divisional application which became the Patent. Further, the events surrounding Neurim's decision to drop the parent patent were not as Neurim had described them. Mylan alleges that Neurim has abused the EPO system for obtaining divisional patents and says that is something upon which the UK court frowns. The matter of abuse was raised before me but was not significantly developed.

23. An expedited EPO process might lead to an EPO Technical Board of Appeal ("TBA") appeal in late 2023 or early 2024. This appears to be agreed.

24. In the meantime, if UK proceedings continue and Mylan is injuncted then Teva will take any market share which Mylan have to give up so that Neurim will not be able to restore its monopoly. Neurim will not be able to obtain interim relief against Teva before the patent expires. The position in other countries in Europe will also not be made any more certain. There are disputes in Sweden, Finland and Denmark.

25. For Neurim, Dr Turner made the following points.

26. First, the position on the validity of the parent patent is not straightforward. The EPO Opposition Board found the parent patent invalid for lack of novelty. At the trial of infringement and validity of the parent patent Marcus Smith J held the patent was valid and

infringed. He refused leave to appeal. The attack on validity included insufficiency, and the judge rejected that attack.

27. Mylan then expanded and recast its attack on sufficiency before the TBA. The TBA allowed Mylan to make those arguments, but it did not give Neurim an opportunity to meet them. Neurim thus withdrew its appeal of the opposition decision.

28. At that point the Patent had not yet been granted by the EPO. Mylan's EPO patent attorneys then filed observations on sufficiency of the Patent making the points about the insufficiency of the parent patent which, Mylan says, had been accepted by the TBA. Neurim responded to those points by relying on the evidence it says it would have filed with the TBA on the parent patent (if it had been allowed to do so). The EPO, having all these submissions, then granted the Patent. Mylan complained to the EPO about this, but to no effect. The EPO said it had reviewed the position and stood by its decision to grant the Patent.

29. Secondly, if Neurim succeeds on the preliminary issue then Neurim will be able to restore its monopoly at least so far as Mylan is concerned and it will pursue Teva.

30. Neurim says that Mylan's arguments about unquantifiable loss appear to address issues that would arise on considering the grant of an interim injunction; but Neurim will at that point be seeking a final injunction, which is a different matter. Neurim has also committed to bringing proceedings against Teva as described above.

31. Thirdly, a decision of this court will increase commercial certainty because the parties will have in place further pieces of the legal jigsaw to give a determination of their rights.

The law

32. The law on the approach to be taken by a UK court considering an application to stay UK patent proceedings during an EPO opposition is set out by the Court of Appeal in ***IPCom GmbH v HTC Europe*** [2013] EWCA Civ 1496:

> "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.
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> 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 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."

33. This is the guidance given by the Court of Appeal in ***Glaxo v Genentech*** [2008] EWCA Civ 23 as considered by the court in the light of ***Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd*** [2013] UKSC 46.

34. In ***Adaptive Spectrum and Signalling Alignment Inc v British Telecommunications PLC*** [2014] EWCA Civ 1513 Floyd LJ said that it was now "more or less inevitable" that Adaptive would have to undertake, as a price of resisting a stay of UK proceedings, to repay (in the event of revocation or amendment) any financial relief subsequently obtained.

35. BT also sought a cross-undertaking in damages in relation to the final injunction ordered in that case in case the EPO subsequently revoked or materially amended the patent. The Court of Appeal rejected this. A cross-undertaking is appropriate to take account of the possibility that an earlier judgment is wrong (e.g., an interim injunction or an injunction pending appeal). A subsequent EPO revocation or amendment would mean that the final injunction would become ineffective or have to be discharged from the date of revocation/amendment, but not *ab initio*. There was no reason for Adaptive to pay for the harm during the period when the injunction was rightly granted.

Discussion

36. In approaching the question of a stay, I have the first six ***IPCom*** factors fully in mind. This court has a wide discretion on the application for a stay which is to be exercised to achieve the balance of justice. The possibility of concurrent proceedings before the UK courts and the EPO is inherent in the system. The EPC and the 1977 Patents Act provide context and condition the exercise of the discretion. It is for Neurim, as the party resisting the stay to show that a stay should not be granted. A stay would otherwise be the default position.

37. The seventh factor 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. Neurim has during the course of the hearing offered an undertaking to repay damages or profits, as described above.

38. While the undertaking was offered late in the day, that deals with a significant element of Mylan's argument about potential irrecoverable losses under the seventh factor if no stay is ordered. The absence of an offer of an undertaking to repay monetary compensation is a "weighty factor" in favour of the grant of a stay. That undertaking has now been given.

39. Mr Vanhegan maintains that there are further significant potential losses including Mylan's first-mover advantage and also irrecoverable costs that would arise if a final injunction were granted following the preliminary issues trial.

40. Mr Vanhegan thus invited me to take the opportunity to hold that a patentee opposing an application for a stay should offer to make good all the defendant's losses in the event that a final injunction was ordered in the UK that was discharged on the later revocation of the patent by the EPO. The patentee should in effect make the defendant whole for any harm suffered. It appears to me that would be contrary to the position set out by the Court of Appeal in ***Adaptive***. That accepts that a final injunction which would have a financial impact may be rightly ordered at the relevant time. I therefore decline his invitation.

41. He also suggested that Neurim should undertake to cover Mylan's costs of proceedings. However, the seventh factor is framed in terms of "monetary compensation" and in any event costs form part of the assessment.

42. The eighth factor concerns evidence of achieving commercial certainty at an earlier stage if the UK proceedings continue. Some certainty, sooner rather than later, and somewhere, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

43. Mylan say that if there is no stay and the UK proceedings continue to the preliminary issues then there will be no commercial certainty because the Patent will expire before anything has been determined in the UK. The preliminary issue trial can only decide questions of estoppel and not infringement or validity. In any event the decision on the preliminary issue will inevitably be appealed because there are opposing claims of a similar nature and the

loser is bound to appeal. There will be nothing to help the public know whether the Patent is valid. The market will not be any more certain for anyone because Teva will take Mylan's position.

44. Neurim's position is that it is seeking to assert its monopoly in the limited time left before patent expiry. If it is able to remove Mylan from the UK market in that time then it will also try to remove Teva so as to restore its patent monopoly, although it cannot be certain that it will succeed in doing that. Dr Turner said that that the commercial position would be clearer following the UK preliminary issue trial because the picture of the various rights would be clearer at an earlier stage in the UK than they would otherwise be if the proceedings before the EPO were allowed to take their course.

45. In this case it appears that there is a range of possible outcomes because of the preliminary issues trial and the recent entry of Teva on the market. Mellor J, who had less information about Teva than is now available, thought in these unusual circumstances that Neurim should have the opportunity to establish its rights before the Patent expired. Allowing the matter to proceed here should thus provide a measure of further commercial certainty in this unusual situation. Neurim may be able to seek an injunctions both against Mylan and Teva early in 2022.

46. It is clear, on the other hand, that if a stay is granted Neurim will not be able to obtain a final injunction at all, because the Patent will expire. So allowing the UK claim to continue does offers a chance of increased certainty at an earlier stage.

47. The ninth factor is that it is permissible to take into account the possibility of settlement. Neither party held out much hope that there would be a settlement, whatever the outcome of the preliminary issues trial. Settlement does not therefore appear to be particularly relevant at this stage.

48. The tenth factor is timing, considered in conjunction with the prejudice which any party will suffer from the delay, and lack of certainty, and what UK proceedings can achieve in terms of certainty.

49. There are a number of points here. The parties agree that if there is expedition the EPO position may be resolved as early as 2024. If there is no expedition then Neurim say that the EPO may resolve this sometime in 2025-2027. It is not clear that the EPO will expedite a case concerning an expired patent. I assume, however, for these purposes that there will be expedition in the EPO.

50. The preliminary issues trial will be held this year and is likely to be appealed. The Patent expires in August 2022. As I have said, Mellor J found the timing of patent expiry to be very important.

51. The potential delay to a final EPO resolution is not extreme, and given that both sides have indicated that the decision in the preliminary issue will be appealed it may be that gap between final determination in the UK and the EPO will not be that long. However, if the UK case does not continue it is certain that Neurim will not obtain a final injunction because the Patent will have expired. Thus, only the route ordered by Mellor J affords Neurim some chance of obtaining final relief during the patent term. This point on timing thus favours Neurim.

52. The eleventh factor is the public interest in dispelling the uncertainty surrounding the validity of monopoly rights. This case is unusual because the Patent is effectively in the

same form as the parent patent which was found valid and infringed in the UK and then revoked in the EPO in disputed circumstances. The preliminary issue trial is not going to affect that. It does not really assist either side.

53. The twelfth factor is wasted costs. Mylan says that if the UK court continues with this action there will clearly be significant wasted costs, and that this is in their favour. Neurim say that infringement and validity have already been determined and that the costs to be incurred relating to the preliminary issues are relatively small.

54. The ***IPCom*** guidance says that this factor will normally be outweighed by commercial factors concerned with early resolution. However, this is a case in which there are a number of potential ways forward following the preliminary issues trial. Mylan is right that if the UK case continues there may well be some wasted costs. In the overall context of the dispute, however, those will be relatively small.

55. As directed in ***IPCom*** paragraph 13, this court should avoid a mini-trial. That is particularly relevant here. The matter is unusual and has a complex history. The position continues to develop in the UK as Teva comes on to the market. There are also proceedings in other countries. While the courts there may be interested in any outcome here that would not be decisive in those courts.

56. Both sides have filed a substantial amount of evidence on this application and raised matters that it would be possible to explore in much greater detail. There are potentially significant disputes over what happened at the TBA hearing on the parent patent; Neurim's position against Teva in Israel; and Mylan's allegations that Neurim is abusing the patent system. There may yet be developments in the UK market caused by the entry of Teva. While there was significant evidence and some argument about these points, I am obliged to avoid too great an investigation at this stage.

57. I have to examine the issues at a "relatively high level of generality". The EPO may deliver a final view on the Patent in relatively short time, but that will be after the Patent has expired. As Mellor J said, by then Neurim will no longer have an opportunity to obtain a final injunction on the Patent. Neurim's path to any injunction is not necessarily straightforward. The preliminary issues are novel and complex and there is very likely to be an appeal whichever party succeeds.

Conclusion

58. Bringing together all of the ***IPCom*** factors with the relevant circumstances and noting again that this is a most unusual case, I decline to order a stay.

59. The balance of justice in all the relevant circumstances lies on the side of allowing Neurim to continue on the course of action ordered by Mellor J. A decision on the preliminary issues will give the parties some more commercial certainty within a relatively short time and during the life of the Patent. Granting a stay would open the possibility of generic competition which may well have a significant impact on Neurim at the very end of the Patent's life.