Neutral Citation Number: **[2022] EWHC 512 (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

7 Rolls Building
Fetter Lane, London,
EC4A 1NL

8 March 2022

Before:

THE HONOURABLE MR JUSTICE MARCUS SMITH

- -

Between:

(1) NEURIM PHARMACEUTICALS (1991) LIMITED **(2) FLYNN PHARMA LIMITED**	**Claimants**
- and -	
(1) GENERICS (UK) LIMITED T/A VIATRIS **(2) VIATRIS UK HEALTHCARE LIMITED**	**Defendants**

Justin Turner QC, David Scannell QC and Katherine Moggridge (instructed by **Gowling WLG (UK) LLP and Pinsent Masons LLP**) for the **Claimants**
Mark Vanhegan QC, Adam Gamsa and Daniel Piccinin (instructed by **Taylor Wessing LLP**) for the **Defendants**

Hearing dated 4 March 2022

Approved Judgment

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.

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MR JUSTICE MARCUS SMITH

Mr Justice Marcus Smith

Introduction

1. In a provisional judgment (the **Provisional Judgment**) dated 10 February 2022 under Neutral Citation Number [2022] EWHC 272 (Pat), I provisionally determined on the papers the validity of what I shall refer to as the Divisional, being a divisional of European Patent No 1 441 702. I concluded that judgment with the following words:

   "For reasons that are obvious, given my reasoning, I have decided this matter on the papers and without oral argument. However, given the unusual circumstances, I consider that it is appropriate to offer the parties the opportunity, if either one of them wishes to take it, of appearing before me to persuade me to follow a different course. That is the normal course where a ruling is given on the papers, and without an oral hearing, which is the case here. For that reason, although I am circulating this judgment to the parties, and do so openly, I do so labelling it explicitly as a provisional judgment, from which I can resile if appropriate."

   Mylan has taken up my invitation, and this judgment affirms – albeit for different reasons – the provisional judgment and deals, additionally, with permission to appeal and injunctive relief.

2. This judgment takes as read and adopts the terms and abbreviations used in:

   i) The Main Judgment: [2020] EWHC 3270 (Pat).

   ii) The Judgment on Consequential Matters: [2021] EWHC 530 (Pat).

   iii) The judgment of Meade J dated 24 January 2022 (the **Meade Judgment**): [2022] EWHC 109 (Pat).

   iv) The Provisional Judgment already referred to.

Affirming the Provisional Judgment

3. One of the issues in the Trial that led to the Main Judgment was the insufficiency of the Patent: Judgment at [8(3)], in particular what the Judgment termed "lack of plausibility insufficiency" (Judgment at [8(3)(d)]). This was considered in Section G of the Judgment, specifically at [104]*ff*.

4. In the Judgment, and for the reasons given therein, I concluded that the Patent was not insufficient.

5. Mylan contended that the conclusion I reached in the Trial was incorrect and should be reversed in relation to the Divisional because of what was termed the **lay-patient argument**. This was summarised by Meade J at [56] of the Meade Judgment in the following terms:

> "(i) Because the invention is a second medical use, the clinical result must be made plausible by the specification.
>
> (ii) Since the claims are to specifically addressing non-restorative sleep they must render that plausible, not merely some more general improvement in sleep quality.
>
> (iii) There is no objective test or measurement of sleep quality and it is assessed by asking patients about their subjective experience.
>
> (iv) The relevant materials in the Patent (Examples 2 and 3) relate to asking patients about their sleep, but there is no description showing that what they were asked was about restorative sleep, or that is what they reported on. They may just have interpreted the questions as being about improvement in sleep generally and if they reported an improvement it may just have been an improvement in, for example, getting to sleep."

6. The lay-patient argument turned on the contention that Examples 2 and 3 were insufficient to render the Patent (and so the Divisional) plausible. This was because the questionnaire that may have been used to interrogate the patients as to their sleep referred only to the "quality of sleep".[1] As is clear from the Main Judgment, the term "quality of sleep" "contains within it a critical ambiguity: it can refer to the technical, ICD-10, term; but it can, equally, be used in the ordinary sense of "I had a bad night's sleep". Which meaning is intended is a question of context and construction to which I shall have to pay attention in this judgment".[2]

7. At the Trial, the expert evidence of Professor Morgan was that the Skilled Person would not understand the questionnaire in this way,[3] and the contention was that the questions in the questionnaire "were directed at quality of sleep in the non-technical sense".[4] If that contention had succeeded, the force of the Examples in the Patent would have been undermined.

8. I rejected the contention in no uncertain terms at [64(6)] of the Judgment, concluding that "I have no doubt that the Skilled Person would attach a technical meaning to the term "quality of sleep".

9. The lay-patient argument contends that – notwithstanding the finding I have made as regards the Skilled Person's understanding of the questionnaire – the patient and the clinicians the subject of the trials recorded in the Examples were not the Skilled Person and might understand the term "quality of sleep" in the non-technical sense. The Examples would, for that reason, "not be worth the paper they were written on":[5]

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[1] The example questionnaire deployed in the Trial was the Leeds Sleep Evaluation Questionnaire, described at [64] of the Main Judgment. The Examples in the Patent (or the Divisional) provide no precise statement of how the experiments were carried out. They may have used this questionnaire; they may have been conducted in other ways.

[2] Main Judgment at [53(3)].

[3] See footnote 76 of the Judgment.

[4] See [64(3)] of the Judgment.

[5] See paragraph 22 of Mylan's submissions.

> "The upshot is very simple. There is no dispute[6] that the skilled person (a sleep medicine clinician) would attach a technical meaning to "quality of sleep" when used in the context of ICD-10, namely as a reference to [non-restorative sleep]. However, that is irrelevant when it comes to the critical issue in relation to plausibility, namely what the skilled person would understand by the data in the Examples – in other words what the reported results actually disclose…"

10. The point is that notwithstanding the Skilled Person's understanding of the terms of the questionnaire, the Skilled Person would expect the clinicians in charge of the trials recorded in the Examples so to botch the trials that they produced meaningless data. Put this way – and Mr Vanhegan, QC put it far more elegantly for Mylan – the point is hopeless. The Skilled Person would expect the trials to be conducted in line with the Skilled Person's understanding of what was under investigation (i.e., quality of sleep in the technical sense) and – more to the point – the presumption has to be that clinicians conducting trials intended to evaluate quality of sleep in this technical sense would do their job competently.

11. Although the attack on the Skilled Person's understanding of the terms of the questionnaire was mounted at the Trial, the lay-patient argument was not, or not very explicitly, run. Mr Vanhegan contended that because this was a new trial, and Mylan were not issue estopped, if I needed any additional evidence on the point, then I should direct a trial on this basis, limited to obtaining this evidence, and adjudicating upon it.

12. It seems to me that as a matter of principle Mr Vanhegan must be right: if the evidence before me at the Trial and my findings in the Main Judgment are insufficient for me properly to determine the lay-patient argument then justice requires that the additional necessary evidence be got in and the point determined by reference to that evidence, as well as the evidence at the Trial.

13. However, although I am entirely satisfied that Mr Vanhegan is right on the point of principle, I am equally satisfied that further evidence is entirely unnecessary to determine the lay-patient argument. I have asked myself what further questions I would have wanted put to Professor Morgan and Professor Roth had the lay-patient argument been put with the force that it has been today. I can see nothing that I would have asked Professor Morgan or Professor Roth that does not clearly emerge from the evidence heard at the Trial.

14. As a counsel of perfection, the experts might have been asked:

> "Do you agree that, even if the Skilled Person understands the term "quality of sleep" in the technical sense, the subjects of the trials recorded in Examples 2 and 3 would not have done?"

15. The answer would have been along the lines of "No: only if the trial was badly conducted". That is the point that I was attempting to articulate in [64(4)] of the Main Judgment:

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[6] Although there was at trial. What is meant is that the findings I made in the Main Judgment on this point are accepted for the purposes of this trial.

"…The fact is that the questionnaire is only as good as the use it is put to by a clinician or researcher. In a poorly conducted trial, participants may not be appropriately selected in terms of what is being tested for, and the questionnaire may not be fit for purpose or appropriately explained. Context is everything, and I do not consider that I am particularly assisted by consideration of the questionnaire independent of a particular study or research programme."

16. Had the lay-patient argument been put with full force in closing, I would no doubt have had my attention drawn to the following exchange between Mr Vanhegan and Professor Roth:[7]

Q: Mr Vanhegan, QC	…A patient who is being asked these questions is not given any education as to how they should answer these questions, are they?
A: Professor Roth	They are given directions, as I understand it, to judge the quality of the nature of the sleep the night before.
Q: Mr Vanhegan, QC	They are simply asked the questions which you see at the appendix, and then they are asked to mark that on a scale, is that not correct, Professor?
A: Professor Roth	On the previous night's sleep?
Q: Mr Vanhegan, QC	Yes. So what I am putting to you, Professor, as a matter of common sense, is that any patient answering Question 4 will take into account all the aspects of that previous night's sleep when deciding whether that patient has had a restful or less restful night's sleep?
A: Professor Roth	No, I do not agree with that.
Q: Mr Vanhegan, QC	What I suggest to you is that that is what Professor Morgan understands, and that is exactly what the skilled person would understand if you…
A: Professor Roth	No, I…[8]
Q: Mr Vanhegan, QC	…sleep evaluation questionnaire.

[7] Transcript Day 1, pp.167*ff*.

[8] Professor Roth was giving evidence by video-link from the United States. Although, generally, the quality of the link was outstanding, occasionally transmission delays or lack of complete audio-visual synchronisation caused one party to think the other had finished speaking. That is what happened here. All of the cross-examination was conducted with great courtesy on all sides, and there were only accidental interruptions, such as this.

A: Professor Roth	Is that a question or a statement?
Q: Mr Vanhegan, QC	I am putting to you that that is what the skilled person would understand. If you ask a patient Question 4, they will answer by taking into account all of the aspects of the sleep they previously had?
A: Professor Roth	My Lord, I am still confused here. Are you making a statement or are you asking me whether I agree with that?
Marcus Smith J	Professor, I think I should make clear what counsel is doing. He is putting his case, as we would say in England. He is articulating what his argument is, and he is putting statements to you for you to agree or disagree. By all means disagree. The record will then reflect that, but at least he will be able to say his argument was put to you, and you were given an opportunity to respond. So it is a question. It is a question framed a bit like a statement, but do please answer it.
A: Professor Roth	Thank you, my Lord. I disagree.

The cross-examination then proceeded to a different topic. But it is easy to see why the lay-patient argument was not pressed in closing.

17. Accordingly, I affirm the conclusion reached in the Provisional Judgment, but I do so having explicitly taken into account the "new" point articulated by Mylan, namely the lay-patient argument. I reject that argument, for the reasons I have given, and I am entirely satisfied that I can do so on the basis of the evidence before me at the Trial.

Permission to appeal

18. Mylan applies for permission to appeal the order consequential on the judgment set out in the preceding paragraphs. It seems to me that I need to consider this from three aspects.

19. First of all, there is the extent to which I should revisit the question of permission to appeal insofar as it relates to the Main Judgment. Mylan asked for permission to appeal that judgment. I refused permission essentially because the issues I decided in the Main Judgment were factual and not legal, and I could see no real prospect of any appeal succeeding.

20. It seems to me that although the Main Judgment has served to resolve the vast majority of the issues arising in relation to the Divisional, I must consider permission to appeal anew, because the issues regarding the Divisional have been resolved by a second trial, albeit one that is procedurally extremely unusual. So I consider permission to appeal *de novo* but – for the reasons given in paragraph 19 above – it seems to me that permission to appeal the issues arising out of the Main Judgment should be refused for substantially the same reasons as I gave in relation to the Main Judgment itself.

21. The second aspect is the one that I found most troubling. I was – as was clear during the course of submissions – troubled by the notion that I could determine this trial by reading across, without substantial further consideration, the Main Judgment.

22. This is, in effect, what the Provisional Judgment did and – had I maintained the Provisional Judgment without more – I would have given permission to appeal on this point. However, I have now determined – after full hearing – the lay-patient argument and I have done so explicitly considering whether I can only do so after hearing further evidence. I have concluded that no further evidence was required to determine the point on the merits, and I have determined the point on the merits. No question of read-across of the Main Judgment arises, and accordingly I am not going to give permission to appeal on this basis or in relation to this aspect.

23. The lay-patient argument is also substantially factual, and I certainly do not consider that permission to appeal is appropriate in relation to the substance of this argument.

24. The third aspect concerns the weight that should be given to the "non-decision" of the Technical Board of Appeal of the European Patent Office. The history is fully set out in the Meade Judgment at [64] to [81]. What is clear is that rather than obtain an adverse outcome before the Technical Board of Appeal, the appeal that was before it was withdrawn by Neurim before it could be adjudicated upon. What one therefore has is an outcome which is undoubtedly different from the outcome that was obtained before me on the Main Judgment, and that different outcome appears to be in relation to a point that was common before the two tribunals: namely, what we now call the lay-patient argument.

25. However, it seems to me that it would be an error on my part to treat the EPO jurisdiction as anything other than a parallel jurisdiction that can, depending on the outcome reached by the exercise of that jurisdiction, arrive at different conclusions which may have an affect on the cases being heard in this Division. The EPO jurisdiction does not have any further significance than that, and I do not consider that even a contrary decision of the EPO (which is not the case here) should be a ground for appealing a different judgment in this Division.

26. For all these reasons, I refuse permission to appeal.

Injunctive relief

27. In light of my judgment and my refusal to give permission to appeal, Neurim applies for a permanent injunction to enjoin infringement of the Divisional for the remainder of its life. Related to that, I have an application from Mylan that any injunction that I am minded to grant should be stayed for a sufficient period of time to enable the Court of Appeal to consider the question of permission to appeal itself.

28. The essential principles that I am obliged to apply in this sort of case are not in serious dispute between the parties. I was taken to a variety of cases, but it is probably best to begin and end with the decision of Buckley LJ in *Minnesota Mining & Manufacturing Company v. Johnson & Johnson Limited* [1976] RPC 671:[9]

> "It is not in dispute that where a plaintiff has at first instance established a right to a perpetual injunction, the court has a discretion to stay the operation of that injunction pending an appeal by the defendant against the judgment. On what principles ought such a discretion to be exercised? The object where it can be fairly achieved must surely be so to arrange matters that, when the appeal comes to be heard, the appellate court may be able to do justice between the parties whatever the outcome of the appeal may be. Where an injunction is an appropriate form of remedy for a successful plaintiff, the plaintiff, if he succeeds at first instance in establishing his right to relief, is entitled to that remedy upon the basis of the trial judge's findings of fact and his application of the law. This is, however, subject to the defendant's right of appeal. If the defendant in good faith proposes to appeal, challenging either the trial judge's findings or his law, and has a genuine chance of success on his appeal, the plaintiff's entitlement to his remedy cannot be regarded as certain until the appeal has been disposed of. In some cases, the putting of an injunction into effect pending appeal may very severely damage the defendant in such a way that he will have no remedy against the plaintiff if he, the defendant, succeeds on his appeal. On the other hand, the postponement of putting an injunction into effect pending appeal may severely damage the plaintiff. In such a case a plaintiff may be able to recover some remedy against the defendant appellant in respect of this damage in the event of the appeal failing, but the amount of this damage may be difficult to assess and the remedy available in the appellate court may not amount to a complete indemnity. It may be possible to do justice by staying the injunction pending the appeal, the plaintiff's position being suitably safeguarded. On the other hand, it may, in some circumstances, be fair to allow the injunction to operate on condition that the plaintiff gives an undertaking in damages or otherwise protects the defendant's rights, should he succeed on his appeal. In some cases it may be possible to devise any method of ensuring perfect justice in any event, but the court may nevertheless be able to devise an interlocutory remedy pending the decision of the appeal which will achieve the highest available measure of fairness. The appropriate course must depend upon the particular facts of each case."

[9] [1976] RPC 671 at 676.

29. The first question that I must consider is the significance of my refusal of permission to appeal. Obviously, Mylan are entitled to apply to the Court of Appeal, and I have no doubt that such an application will be made with extreme expedition. But – for the reasons I have given – I consider that such an application is very unlikely to succeed. The issues in the Main Judgment and those I have decided today are essentially factual.

30. According to the test propounded by Buckley J, I need to consider first whether there is "a genuine chance of success" on appeal. Treating this as no more than the equivalent of the test for an application for permission to appeal, it seems to me that my refusal of permission to appeal should be regarded as a hard or a safe one that will not be overturned on appeal. Of course, one should never say never, but it does seem to me that unless there can be seen to be a realistic basis for the matter coming before an appellate court, the proper course is to ensure that there is in place the permanent injunction that the claimant, Neurim, is entitled to. That right should only be derogated from where there is a genuine chance of success on the appeal. In my judgment, that chance does not exist here.

31. Accordingly, I am going grant a permanent injunction and refuse any stay of that injunction. However, it does seem to me to be appropriate, given that the point was argued carefully before me, to say a few words on the assumption that I am wrong on this entry-level question.

32. If, contrary to my conclusion, there is a genuine chance of success on appeal, then a form of balancing exercise comes into play. I make clear that Neurim has offered all the undertakings that could reasonably be expected in the event of a successful appeal. There is an undertaking in damages and there is an undertaking to maintain the necessary records to enable a quantification exercise to be carried out.

33. Looking at the balancing exercise, one is therefore faced with a situation where there is a market for a product where there are at the moment only two participants.[10] One participant has a monopoly right because of the patent that I have today upheld. The other has no right per se to be in the market, but has been in the market for some considerable time because of the time it has taken to vindicate the rights of the claimant.

34. The question that I would have to ask, if I had reached a different view on the question of genuine chance of success, concerns the relative benefits and disbenefits, given there are undertakings both ways, of either excluding or permitting Mylan to remain in the market.

35. This is a question that is one of extreme difficulty at the interlocutory stage. The question is not, I must emphasise, which party will suffer the most harm. Rather, the question is which party will suffer the most harm that cannot properly be

[10] In subsequent correspondence, I have been informed that another pharmaceutical company, Teva, claims to be on the market. This is contrary to the evidence that was before me, and I do not consider that it would be appropriate to take this point into account. Both Neurim and Mylan proceeded on the basis that they were the only persons on the market, and I determined the issue on this basis.

compensated for in damages. It is the adequacy or otherwise of a monetary payment that drives the outcome of this question.

36. It seems to me that this question of ability to quantify harm is one which should be informed by the assessments of damages that are regularly made in competition cases. Such cases almost always involve some kind of anti-competitive conduct that eliminates or reduces a claimant's right to compete in a market fairly, which requires consideration of the loss that such conduct has caused. Quantification of harm in counterfactual cases is the bread and butter of competition cases and one must start, it seems to me, with the presumption that the harm resulting from an exclusion from a market is prima facie quantifiable. It may be difficult, it usually is, but it is achievable and regularly achieved.

37. In this case, Mylan say that if I were to injunct without a stay, there would be a loss of "first mover" advantage, which would be unquantifiable. Essentially, Mylan are competing in the market with only one other entity, Neurim. If I were to grant Neurim an injunction without any stay, Neurim's monopoly under the Divisional would be upheld and when in 5½ months' time the Divisional expires, Mylan will enter the market along with other third parties, and would lose the foothold in the market that it has established.

38. Leaving on one side the fact that as matters stand that foothold has been improperly gained (I must leave it on one side, because I am considering the case where Mylan's putative appeal succeeds), the question is whether the loss of that foothold can be quantified.

39. I am not persuaded that this is a matter that is unquantifiable. It seems to me that there will be the data of what has been sold by Neurim in the remaining life of the patent, and it will be possible to chart how those sales vary over the remaining life of the Divisional. We will at least be able to understand the significance of a monopoly right in the remaining life of the Divisional, which is something that at the moment is rather difficult to assess because of the competition in the market. That, as is well known, can have a significant effect on prices, whilst leaving volumes intact. I must accept that the removal of Mylan from the market may very well result in surprising changes in the price which are very hard to anticipate absent real-world evidence.

40. In short, I consider that the first-mover advantage is quantifiable, but I am rather less confident about the ability of a court to attribute proper value to Neurim's monopoly right. That, to my mind, is a clear indicator in favour of granting an injunction without a stay.

41. It is also relevant to ask what would happen if I stayed the injunction until the appeal was determined. In such a case, it seems to me that what would likely happen is that more competitors would enter the market right away, given that the stay would be for the rest of the Divisional's life. (It might be possible to get an appeal on quickly, but to get the appeal heard and determined in this time frame would be very difficult.) Why should they not? A competitor, Mylan, in the face of a patent found to be valid and effective and infringed is nevertheless not enjoined. What are the chances, I ask rhetorically, of a further competitor in the generic market, Teva or someone else, coming in and taking the chance of not

being injuncted themselves? Certainly, it would be a brave judge to permit one generic (Mylan) into the market or to countenance that market participation continuing, whilst enjoining everyone else.

42. The risk of not enjoining Mylan is that we will get a sooner competitive situation with more than two participants in the market more or less immediately. That, as it seems to me, is going to make the quantification of the loss of the injunction to which Neurim is prima facie entitled rather difficult to quantify. I do not know what is likely to be the effect of a new entrant or entrants into the market in a situation where there is a monopoly that is being disrespected, as it were, by the court. It seems to me that the difficulties in quantification are, in this case, rather greater than those of computing the loss of the first mover to Mylan.

43. Mylan also contended that the nature of the contracts that it had entered into were such that – if there was no stay – it would be in breach of contract, and would suffer reputational harm. I do not accept this: Neurim made the point that what purchasers would want was the pharmaceutical product, which Neurim can provide. Provided supplies are maintained, the risk of reputational damage – even if there is a breach of contract, which I doubt would arise – is not material.

44. In these circumstances, it seems to me that even if I were persuaded that there should be consideration of a stay – and I am not persuaded, for the reasons I have given – I would not be minded to grant a stay in this case.