Neutral Citation Number: [2022] EWCA Civ 370

Case No: CA-2022-000413

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (ChD), PATENTS COURT
Marcus Smith J
[2022] EWHC 512 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29 March 2022

Before :

LORD JUSTICE NEWEY
LORD JUSTICE ARNOLD
and
LORD JUSTICE BIRSS

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Between :

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

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Adam Gamsa and **Mitchell Beebe** (instructed by **Taylor Wessing LLP**) for the **Appellants**
Katherine Moggridge (instructed by **Gowling WLG (UK) LLP**) for the **First Respondent**
and (instructed by **Pinsent Masons LLP**) for the **Second Respondent**

Hearing date : 16 March 2022

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Approved Judgment

This judgment was handed down remotely at 10.30 on 29 March 2022 by circulation to the parties or their representatives by email and by release to BAILII and the National Archives.

Lord Justice Arnold:

Introduction

1. On 16 March 2022 this Court (i) granted the Defendants ("Mylan") permission to appeal against an order made by Marcus Smith J on 7 March 2022, (ii) expedited the hearing of the appeal to be fixed in the weeks commencing 16 or 23 May 2022 and (iii) granted Mylan a stay of the injunction contained in Marcus Smith J's order pending the determination of the appeal, for reasons to be given in writing later. This judgment sets out my reasons for concurring in those orders.

Procedural background

2. Conceptually this claim is a sequel to a claim ("the First Claim") by the Claimants against Mylan for alleged infringement of European Patent (UK) No. 1 441 702 ("EP702"), although chronologically the proceedings have overlapped with the First Claim.

The proceedings concerning EP702

3. EP 702 was a second medical use patent which (as unconditionally proposed to be amended) claimed the use of a prolonged release formulation of melatonin in 2 mg dose form for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia characterised by non-restorative sleep. The First Claimant ("Neurim") was the proprietor of EP702. The Second Claimant ("Flynn") markets a product falling within the claims of EP702 under the trade mark Circadin in the United Kingdom pursuant to an exclusive licence granted by Neurim. The market for Circadin is worth around £30 million a year.

4. The history of the First Claim and of parallel proceedings in the European Patent Office concerning EP702 is summarised in my judgment on an appeal in the First Claim heard immediately before the hearing in this claim [2022] EWCA Civ 359 at [30]-[38]. For present purposes the key events are as follows.

5. EP702 was applied for on 12 August 2002 and granted on 10 May 2017. On 20 November 2019 the Opposition Division of the EPO held that EP702 lacked novelty and therefore revoked it. On 14 January 2020 Neurim filed a notice of appeal. That had the effect of suspending the revocation of EP702.

6. The First Claim was commenced on 14 February 2020. On 2 March 2020 the Claimants applied for an interim injunction to restrain Mylan from launching a generic version of Circadin. On 3 June 2020 Marcus Smith J refused to grant an interim injunction. The Claimants' appeal against that decision was dismissed by this Court on 24 June 2020 on the ground that the Claimants would be adequately compensated by an award of damages for losses suffered by them as a result of any infringing acts committed during the period prior to judgment following the expedited trial. The Supreme Court refused permission to appeal on 29 June 2020. In late September 2020 Mylan launched a generic version of Circadin in the UK under the name Melatonin Mylan.

7. The trial was heard by Marcus Smith J from 29 October 2020 to 5 November 2020. By that time Mylan did not dispute that they were infringing EP702 if it was valid, but

disputed its validity on a number of grounds. On 4 December 2020 the judge handed down a judgment concluding that (as proposed to be amended) EP702 was valid and had been infringed: [2020] EWHC 3270 (Pat) ("the December Judgment").

8. On 17 and 18 December 2020 the Board of Appeal at the EPO heard Neurim's appeal. On 18 December 2020 the Board of Appeal orally announced their opinion that EP702 was invalid for insufficiency. In the light of this decision, Neurim withdrew its appeal and EP702 was revoked.

9. Mylan's argument that was successful before the Board of Appeal ("the lay-patient argument") was helpfully summarised by Meade J in a judgment in these proceedings dated 24 January 2022 [2022] EWHC 109 (Pat) at [56] as follows:

> "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 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."

10. On 12 March 2021 Marcus Smith J made a final order dismissing the First Claim in the light of the revocation of EP702 and making consequential orders.

These proceedings

11. In this claim the Claimants allege infringement by Mylan of European Patent (UK) No. 3 103 443 ("EP443"). EP443 is a divisional of EP702, and therefore expires on the same date that EP702 would have expired had it not been revoked, namely 12 August 2022. The procedural history of these proceedings down to mid-December 2021 is recounted in some detail by Meade J in his judgment, but I must also outline what happened after his judgment. The key events in the chronology for present purposes are as follows.

12. EP443 was granted on 30 June 2021. Mylan filed a notice of opposition in the EPO on the same day. It is inevitable that the opposition proceedings will not be finally determined until after the expiry of EP443.

13. Also on 30 June 2021 the Claimants commenced these proceedings. On 1 July 2021 Neurim applied unconditionally to amend the claims of EP443 to make them patentably indistinct from the claims of EP702 as proposed to be amended in the First Claim. This course is open to Neurim because the existence of EP443 enables Neurim to have a second attempt to secure patent protection for the claimed invention even though its

first attempt came to grief in the Board of Appeal. That is a consequence of the facts that (i) the European Patent Convention places relatively few limits on the ability of applicants to file divisional applications and (ii) the Opposition Division and Board of Appeal hearing the opposition to EP443 will not be bound by the outcome of the opposition to EP702. (Indeed, Meade J found that one of Neurim's reasons for withdrawing its appeal against the revocation of EP702 was in order to avoid the Board of Appeal giving written reasons which might prove an obstacle to this second attempt.)

14. On 7 July 2021 Mylan applied to stay this claim pending the final determination of the EPO proceedings concerning EP443. On 29 October 2021 Ian Karet sitting as a Deputy High Court Judge dismissed that application.

15. On 12 August 2021 Mellor J made an order for the trial of preliminary issues arising out of a contention by the Claimants that the December Judgment gave rise to issue estoppels preventing Mylan from challenging the validity of EP443 as proposed to be amended and contentions by Mylan that Neurim's conduct in amending EP443 was an abuse of process and that the Claimants were abusing a dominant position by attempting to prevent Mylan from challenging the validity of EP443.

16. Those preliminary issues were tried before Meade J on 15-17 December 2021. At the trial the Claimants made it clear that their concern was to prevent Mylan from re-litigating all of the issues decided adversely to Mylan in the December Judgment with the attendant delay that would cause. For their part, Mylan made it clear that they did not want to re-litigate all those issues at first instance. Rather, Mylan were content to confine their challenge to the validity of EP443 in this jurisdiction to plausibility insufficiency, and in particular the lay-patient argument. Moreover, Mylan were also content to rely solely upon the evidence which was before Marcus Smith J at the trial in the First Claim. Mylan's concern was that they should not be prevented from advancing the lay-patient argument on the basis of that evidence, and in particular that they should not be prevented from seeking permission to appeal to this Court on the lay-patient argument by the fact that they were successful in their challenge to the validity of EP702 in the EPO.

17. In his judgment Meade J held, in summary, that (i) the Claimants' issue estoppel arguments failed, (ii) Mylan's abuse of process argument failed, (iii) it was unnecessary and inappropriate to decide the competition law issues and (iv) the trial of these proceedings should be listed before Marcus Smith J and confined to the evidence which was before him at trial in the First Claim, it being a matter for Marcus Smith J whether to deal with the matter on paper or whether to direct an oral hearing.

18. In the event Marcus Smith J elected to deal with the matter on paper in the light of written submissions from the parties. On 10 February 2022 he handed down a judgment in which he concluded that his reasoning in the December Judgment should stand, with the consequence that EP443 was valid and had been infringed, and that Mylan should be refused permission to appeal: [2022] EWHC 272 (Pat) ("the February Judgment"). He also concluded, however, that he should allow the parties to apply for the matter to be re-considered at an oral hearing; and Mylan duly did so. At least with the benefit of hindsight, it can be seen that it would have been better if the judge had directed an oral hearing in the first place. As it was, for reasons that will appear, he ended up giving three judgments on the matter.

19. At the conclusion of the oral hearing, which took place on 4 March 2022, Marcus Smith J gave a brief extempore judgment in which he maintained the conclusions in the February Judgment. He accepted, however, that his reasons for rejecting the lay-patient argument needed to be "fleshed out". He therefore indicated that he would prepare a further written judgment, and said that Mylan could renew its application for permission to appeal when that judgment had been handed down. In the meantime, he granted the Claimants an injunction to restrain Mylan from infringing EP443 with effect from 4pm on 10 March 2022. That period was to enable Mylan to make arrangements to comply with the injunction. On 7 March 2022 the judge approved an order agreed by the parties to give effect to his judgment of 4 March 2022.

20. The judge refused an application by Mylan for a stay of the injunction pending the determination of an application by Mylan to this Court for permission to appeal. Even so, I am surprised that the judge did not see fit to grant Mylan a stay of, say, 14 or 21 days in order to enable Mylan to make an orderly application to this Court following receipt of the further judgment and the judge's determination of Mylan's renewed application for permission to appeal in the light of that judgment. As it was, Mylan was forced to make an urgent application to this Court on 8 March 2022 when neither of those things had happened. Also on 8 March 2022 the judge handed down his further judgment [2022] EWHC 512 (Pat) ("the March Judgment") in which he explained his reasons for rejecting the lay-patient argument and for refusing permission to appeal. This in turn led to Mylan filing further submissions in support of their application to this Court and amending their grounds of appeal.

21. On 9 March 2022 I directed that Mylan's applications for permission to appeal and for a stay of the injunction be adjourned to an oral hearing before Newey LJ, myself and Birss LJ on 16 March 2022 and stayed the injunction until 4pm on 16 March 2022 or the determination of those applications, whichever was the later. I would like to record that, because neither side had leading counsel available for the hearing on 16 March 2022, both sides were represented by junior counsel who acquitted themselves well.

Permission to appeal

22. Marcus Smith J explained his reasons for refusing permission to appeal in the March Judgment. In essence, his reasoning was that the lay-patient argument failed due to the findings of fact he had made in the December Judgment. This reasoning was forcefully supported by counsel for the Claimants before us. Nevertheless I consider that Mylan's grounds of appeal concerning the lay-patient argument have a real, as opposed to fanciful, prospect of success.

Expedition of the appeal

23. Mylan sought expedition of the appeal. The Claimants supported that application. Given that EP443 expires on 12 August 2022, expedition is clearly appropriate in order to ensure that the appeal can be determined before then.

Stay pending appeal

24. Mylan's application to this Court for a stay is a renewed application rather than an appeal from Marcus Smith J's refusal of a stay. The application to this Court inevitably takes on a different complexion because this Court has granted permission to appeal

and expedited the appeal. Thus the issue for this Court is whether a stay should be granted for a period of between two and three months.

25. As was explained by Floyd LJ in *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 582, [2014] RPC 3 at [30]-[41], the applicable principles remain those stated by Buckley LJ in *Minnesota Mining and Manufacturing Co v Johnson & Johnson Ltd* [1976] RPC 671 at 676:

> "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 in the appellate court 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 impossible 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."

26. Thus the first question is whether, if a stay is granted, the Claimants would be adequately compensated by an award of damages in the event that Mylan's appeal is dismissed. As noted above, this Court dismissed the Claimants' appeal against the refusal of an interim injunction in the First Claim. Its reasoning was that damages would be an adequate remedy given that (a) there would only be a short period of assumed infringement prior to the expedited trial and (b) there was no evidence that any other generic supplier was likely to come on the market during that interval: see [2020] EWCA Civ 793 at [43]-[55] (Floyd LJ).

27. In my judgment there has been no relevant change of circumstances since then, and that reasoning holds good in the present context. Mylan have been on the market for nearly 18 months. Mylan filed a witness statement from Dr Amanda Britton, the Head of Mylan's Generic Business Unit, dated 28 February 2022 setting out Mylan's sales figures to the end of January 2022. The data shows a steady increase in sales over that period of time. Dr Britton also explained that Circadin remained in Category C of the Drugs Tariff. Given Flynn's track record of sales prior to and since September 2020, Mylan's track record of sales since September 2020 and the improbability of Circadin being re-categorised in the next two-three months, prima facie Flynn's loss of sales revenue, and hence its lost profits, due to the assumed infringement would appear readily quantifiable.

28. Counsel for the Claimants submitted that damages would not be an adequate remedy because the grant of a stay would be a green light to other generic companies to enter the market, which would cause a downward price spiral and hence unquantifiable damage to the Claimants. The difficulty with this submission is that it is not supported by the evidence.

29. The main third party about whom there is evidence is Teva. Teva obtained UK marketing authorisations for a generic equivalent to Circadin in September 2018, and the artwork for the packaging of its product was approved by the Medicines and Healthcare Regulatory Agency in May 2021. Although Dr Britton gave evidence suggesting that Teva had begun to market its product in October 2021, this evidence was contradicted by Dr David Fakes, Flynn's Chief Executive Officer, in a witness statement dated 2 March 2022. He explained that his company had been unable to find any sample of the Teva product in the marketplace and was not aware of any customers having purchased it. He did not suggest that there was any reason to think that the position would change in the next two-three months if Mylan were granted a stay.

30. Dr Fakes also explained that the Claimants had commenced proceedings against Teva. We were informed by counsel for the Claimants that they had recently applied for an interim injunction in those proceedings, but the Claimants had failed to place the evidence relied upon before this Court and so we do not know what the basis for that application is. Counsel for the Claimants nevertheless submitted that, if this Court granted Mylan a stay, that would adversely affect the Claimants' prospects of obtaining an interim injunction against Teva. I do not accept that that is necessarily so. The status quo is that there is only one generic supplier in the market place. In that situation it is generally not in the interests of the generic supplier to engage in a price war (as opposed to undercutting the patentee by a certain percentage), and there is no suggestion that Mylan have done so. By contrast, the presence of two or more generic suppliers commonly leads to a price war between the suppliers, and hence a downward spiral in the price which is apt to cause the patentee damage which is difficult to quantify even

if the patent monopoly is subsequently restored by an injunction. Just as preservation of the status quo favours a stay of the injunction against Mylan, it favours the grant of an interim injunction against Teva. In saying that, I am not intending to pre-judge the outcome of that application. As I have explained, we have not seen the Claimants' evidence in support of it, let alone any evidence filed by Teva resisting it. There may be good reasons for concluding that, in the particular circumstances of that case, an interim injunction against Teva should be refused. The point is that the outcome is not dictated by the grant of a stay in this case.

31. The only other competitor about whom there is any evidence is Neuraxpharm, which does not appear to have got any further than obtaining a marketing authorisation in January 2022. Like Teva, however, Neuraxpharm is plainly preparing to enter the Circadin market when EP443 expires.

32. Even if the Claimants would suffer damage which would not be adequately compensated by the payment of damages by Mylan if the appeal were to be dismissed, it would be necessary to consider whether Mylan could be adequately compensated by the payment of damages by the Claimants pursuant to the cross-undertaking offered by the Claimants if the appeal is successful. Mylan contend that they would suffer unquantifiable damage during the period after expiry of EP443 for three reasons: (i) loss of their current first mover advantage at the point of market entry by other generic suppliers upon expiry of EP443; (ii) the adverse effect on Mylan's contracts with two regions of NHS England and with NHS Wales for the supply of Circadin and other products and on Mylan's ability to tender successfully for future NHS tenders; and (iii) the adverse effect on Mylan's relationships with customers and market credibility if forced to withdraw its product for two-three months.

33. In my judgment Mylan's damage would be difficult to quantify and adequately compensate for at least the first of these reasons. As the sole incumbent generic supplier, Mylan have an advantage upon expiry of EP443 because they will have a right of first refusal of future contracts to supply pharmacies. Not only would they lose that advantage if a stay were refused, but also they would be faced with trying to re-establish their foothold in the market after having been forcibly removed from it. In my view it would be very difficult to quantify the extent of the resulting loss of sales compared to the counterfactual in which no injunction had been granted. In addition, I consider that the damage to Mylan would be likely to be more difficult to quantify and adequately compensate than the damage to Flynn.

34. Furthermore, even if I were of the view that both sides were equally likely to suffer damage that could not be adequately compensated, it would be prudent to preserve the status quo pending the appeal.

35. After we had announced the decision to grant the stay, counsel for the Claimants requested that the stay be made conditional upon the continuation by Mylan of an undertaking given by them to the judge on 4 March 2022 not to increase their sales prior to 4pm on 10 March 2022 above the daily average for the previous 60 days. This is a point that should have been raised earlier, but either way an immediate problem with the request was that the undertaking given to the judge was volunteered by Mylan to meet a concern expressed by the Claimants about Mylan "dumping" their product, but no evidence was directed to this. In any event, given the different circumstances that pertained in this Court, I see no justification for imposing that condition on the

stay. As counsel for Mylan pointed out, to do so would be likely to put Mylan in breach of their contracts with the NHS.

Stay pending the determination of the EPO proceedings

36. In the alternative to their application for a stay of the injunction pending the appeal, Mylan sought a stay pending the determination of the opposition to EP443, albeit that in practice such a stay would only last until EP443 expired. This application was not addressed by the judge in the March Judgment. Given that this Court has granted a stay pending appeal, the need for the application does not arise at this stage. It will arise if the appeal is dismissed, however. Accordingly we indicated that the parties should argue it together with the substantive appeal in order to avoid delay if and when the appeal is dismissed.

Lord Justice Birss:

37. I agree with all the conclusions reached by Lord Justice Arnold but there is one aspect of the matter of the stay in which I would put the emphasis slightly differently. I agree about the principles to be applied, I agree that a stay should be granted, and I agree the condition sought should not be imposed. I would hold that there is a material risk that damages will be an inadequate remedy for each party in the relevant circumstances (for Mylan if no stay is granted but Mylan win the appeal, and for Neurim/Flynn if a stay is granted and Mylan lose the appeal). This is clearly so for Mylan but I believe it is also true for Neurim/Flynn. If Neurim/Flynn win the appeal then there will be a damages enquiry relating to Mylan's patent infringement. The various features of this market and the complexities, actual and potential, are all matters which the Patents Court is familiar with and can handle. The court is well able to conduct a damages enquiry in the circumstances of this market and to arrive at a figure it finds to be just. However that does not mean that damages are an adequate remedy. The uncertainties in this case, relevant to either side, are very significant. In mathematical terms a numerical result can always be found but the error bars will be large. In my judgment the decisive factor here, given that the appeal has been expedited and will be resolved before the patent expires, is the preservation of the status quo. That status quo is that Mylan is on the market and has been since September 2020. The uncertainties do not justify disturbing that state of affairs.

Lord Justice Newey:

38. I too agree with all Lord Justice Arnold's conclusions. Like Lord Justice Birss, I take the view that damages will not necessarily be a fully adequate remedy for Neurim/Flynn should they succeed on the appeal, but it seems to me that the risk of uncompensatable loss to Mylan in the absence of a stay is greater and, perhaps more importantly, that preservation of the status quo favours the grant of a stay.