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Case Nos: CA-2021-000571/572/573/574/575/576

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

[2020] EWHC 3270 (Pat), [2021] EWHC 530 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29 March 2022

Before :

LORD JUSTICE NEWEY
LORD JUSTICE ARNOLD
and
LORD JUSTICE BIRSS

Between :

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

Andrew Lykiardopoulos QC and Katherine Moggridge (instructed by Gowling WLG (UK) LLP) for the First Appellant and (instructed by Pinsent Masons LLP) for the Second Appellant

Mark Vanhegan QC and Mitchell Beebe (instructed by Taylor Wessing LLP) for the Respondents

Hearing dates : 14-15 March 2022

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. This is an appeal by the Claimants against orders made by Marcus Smith J on 30 December 2020 and 12 March 2021 in proceedings brought by the Claimants against the Defendants (“Mylan”) for alleged infringement of European Patent (UK) No. 1 441 702 (“EP702”). EP702 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 a licence granted by Neurim. The market for Circadin is worth around £30 million a year, and so the amount at stake in the proceedings was substantial even though EP702 was due to expire on 12 August 2022.
2. The appeal raises two issues. The first is whether the judge was correct to hold that Flynn was not an exclusive licensee under EP702, and thus had no standing to sue for infringement. The second is whether the judge was correct to order the Claimants to pay Mylan’s costs of the proceedings even though the Claimants had succeeded on all issues except the exclusive licence point at trial before him because, at the conclusion of a hearing before the Technical Board of Appeal of the European Patent Office shortly afterwards, Neurim withdrew its appeal against an order of the Opposition Division revoking EP702. Such an order is said to have effect *ab initio* or *ex tunc*, meaning that the legal effect of the order is that the patent is deemed never to have existed.
3. It might be thought that, EP702 having been revoked, the first issue is now academic. It is common ground, however, that this is not the case because the issue is material to subsequent proceedings between the same parties concerning a divisional of EP702, namely European Patent (UK) No. 3 103 443 (“EP443”).

The exclusive licence issue

The statutory provisions

4. Section 67 of the Patents Act 1977 provides:

“Proceedings for infringement by exclusive licensee

- (1) Subject to the provisions of this section, the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence; and references to the proprietor of the patent in the provisions of this Act relating to infringement shall be construed accordingly.
- (2) In awarding damages or granting any other relief in any such proceedings the court or the comptroller shall take into consideration

any loss suffered or likely to be suffered by the exclusive licensee as such as a result of the infringement, or, as the case may be, the profits derived from the infringement, so far as it constitutes an infringement of the rights of the exclusive licensee as such.

- (3) In any proceedings taken by an exclusive licensee by virtue of this section the proprietor of the patent shall be made a party to the proceedings, but if made a defendant or defender shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.”

5. Section 130(1) contains the following definition:

“*exclusive licence*’ means a licence from the proprietor or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates, and ‘*exclusive licensee*’ and ‘*non-exclusive licence*’ shall be construed accordingly”.

6. Section 125(1) provides that “an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be”.

Previous case law

7. The definition of “exclusive licence” in section 130(1) of the 1977 Act and its predecessor in section 101(1) of the Patents Act 1949 have been considered in a number of first instance decisions. For the purposes of this appeal the most pertinent exposition is that by Pumfrey J in *Spring Form Inc v Toy Brokers Ltd* [2002] FSR 17 at [20]:

“This definition is essential to an understanding of subsection 67(2). There can be more than one exclusive licensee under a patent, as there is more than one ‘right in respect of the invention’. In my judgment this term does not merely relate to the list of ways of infringing the patent set out in section 60, which are not described as rights, but to any subdivision of the monopoly conferred on the proprietor. To take an example proposed in argument, in the case of a pharmaceutical product, one manufacturer may have an exclusive licence in respect of manufacture and sale of dosage forms for veterinary purposes and another may have an exclusive licence in respect of manufacture and sale of material of dosage forms for administration to humans. The veterinary licensee has no interest in recovery in respect of human products although he has a cause of action in respect of them. Subsection 67(2) is directed to ensuring that the exclusive licensee obtains compensation, to use a neutral term, only where the

infringement affects his slice of the monopoly conferred by the patent.”

The claims of EP702

8. It is sufficient for the purposes of the appeal to refer to claims 1 and 2 of EP702 as proposed to be amended. These claims were in “Swiss” form, but there were parallel claims in EPC 2000 form:

- “1. Use of a prolonged release formulation comprising melatonin in unit dosage form, ~~each unit dosage comprising 0.025 to 10.2~~ mg of melatonin, in the manufacture of a medicament for improving the restorative quality of sleep in a patient aged 55 years or older suffering from primary insomnia **characterised by** non-restorative sleep, wherein the medicament comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers, adjuvant or carrier.
2. Use according to claim 1, wherein the medicament is further **characterised by** at least one of the following features:
 - (i) it is adapted for oral, rectal, parenteral, transbuccal, intrapulmonary (e.g., by inhalation) or transdermal administration;
 - (ii) it is in depot form which will release the melatonin slowly in the body, over a preselected time period.”

The Circadin marketing authorisation

9. A company in the same group as Neurim holds a marketing authorisation for Circadin which was originally granted by the European Medicines Agency on 29 June 2007 and, by virtue of post-Brexit arrangements, continues to cover the UK. The authorisation is Circadin 2 mg prolonged release tablets containing 80 mg lactose monohydrate as excipient indicated as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.

The agreements between Neurim and Flynn

10. Neurim and Flynn entered into three relevant agreements: (i) a Licence and Distribution Agreement dated 26 November 2011, (ii) an Amendment and Common Interest Agreement dated 22 January 2020 and (iii) a Clarification Agreement dated 19 May 2020. The relevant terms of the agreements are either set out or summarised in the judge’s judgment dated 4 December 2020 [2020] EWHC 3270 (Pat) (“the December Judgment”) at [129]-[131]. For the purposes of the appeal, it is sufficient to refer to the following provisions.
11. Clause 3.1 of the 26 November 2011 agreement as amended by the 22 January 2020 agreement provides:

“Neurim grants Flynn which accepts, under the Neurim Patents, the Neurim Confidential Information, the Existing Marketing Authorisation and the Trademark, an exclusive licence to Distribute the Product in the Territory for use in the Field during the Term.”

12. “Neurim Patents” are defined as meaning EP702 and any divisionals. “Distribute” is defined as meaning import, distribute, promote, market, sell or offer for sale. “Territory” is defined as meaning the United Kingdom and the Republic of Ireland. As amended by the 19 May 2020 agreement, “Product” is defined as follows:

“the prolonged release prescription product containing 2mg Melatonin known as Circadin including any generic equivalent or version thereof”.

13. Clause 17 of the 26 November 2011 agreement as amended by the 22 January 2020 agreement contains a series of provisions concerning proceedings to restrain infringement of Neurim Patents. Clause 17.1 provides that the parties must notify each other of any alleged or threatened infringement of the Neurim Patents of which they become aware. Clause 17.2 provides that “they will jointly take appropriate steps to enforce any Neurim Patent” and that “Neurim shall take steps including the initiation, prosecution and control of” any proceedings subject to further provisions. Clause 17.2.3.1 provides that, if the parties jointly bring any proceedings, then Flynn agrees to be joined as plaintiff or defendant if necessary for any of several reasons including claiming the maximum amount of damages, but that neither party will be required to transfer any rights to the other. Clause 17.2.3.2 provides that Neurim will take the lead. Clause 17.2.3.3 provides that Flynn will provide reasonable assistance. Clause 17.2.3.4 provides that Neurim will not settle any claim without the prior written consent of Flynn, not to be unreasonably withheld. Clause 17.2.3.5 makes provision for the division of any damages and costs. The precise details are confidential, but do not matter. It is not in dispute that the upshot is that Flynn is not able to bring proceedings for infringement of Neurim Patents independently of Neurim. At one point in his submissions, counsel for Mylan went further and suggested that clause 17.2.3.1 entitled Neurim to refuse to sue an infringer whom Flynn wished to sue, but I do not accept that.
14. For reasons that will appear, it does not matter whether Flynn was an exclusive licensee of EP702 prior to the 19 May 2020 agreement. It is therefore only necessary to consider Flynn’s position after the conclusion of that agreement.

Mylan’s arguments and the judge’s conclusions

15. Before the judge Mylan contended that the agreements did not constitute an exclusive licence for two reasons. The first reason was that they did not confer an exclusive right in respect of the invention because the scope of the licence was not coextensive with any claim of EP702. The second reason was that, by virtue of the provisions in clause 17, Flynn did not have the right to bring infringement proceedings independently of Neurim. The judge rejected the first argument, but accepted the second. The Claimants appeal against his conclusion on the second argument, while Mylan challenge his rejection of the first argument by a respondent’s notice.

The appeal

16. The judge's starting point when considering Mylan's second argument in the December Judgment at [142] was as follows (emphasis in the original):

“Section 67(1) of the Patents Act 1977 provides that the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence. This is expressed to be a consequence of the grant of an exclusive licence as defined by section 130(1). The right to bring proceedings for infringement is not expressed to be a necessary condition for ‘exclusivity’.”

17. Despite this, the judge went on to hold that the agreements between Neurim and Flynn did not constitute an exclusive licence because clause 17 prevented Flynn from bringing a claim independently of Neurim. As the judge put it at [146] (emphasis in the original):

“The upshot is that what appears, on its face, to be an exclusive licence to Flynn, is actually no such thing when the provisions regarding the enforcement of Flynn's rights under the licence are taken into account. These provisions make absolutely clear that Flynn has no rights independent of Neurim, and that an infringement action such as this is in reality being prosecuted as a single cause of action by Neurim, with Flynn as little more than a cypher. ... Viewing the licence agreement between Neurim and Flynn as a whole, this is not a case where two interested persons can separately prosecute separate rights. Rather, this is a case where the apparently separate and exclusive rights of Flynn are eliminated by the ostensibly procedural, but in truth substantive, provisions of clause 17.”

18. The Claimants contend that the judge's starting point at [142] was correct, that it should have been his end point as well and that the judge was wrong to hold that this was affected by clause 17. I agree with this. In my judgment the judge's reasoning suffers from four flaws.
19. First, it ignores the contractual effect of clause 3.1, which entitles Flynn to work the invention of EP702 to the exclusion of Neurim within the scope of clause 3.1. If Neurim did exploit the invention within the scope of the licence, Flynn could sue Neurim for breach of contract. Subject to Mylan's other argument, this satisfies the key requirement for an exclusive licence.
20. Secondly, the provisions of clause 17 do not alter the effect of section 67(1), which is to give an exclusive licensee a right of action it would not otherwise have. Nothing in clause 17 prevents Flynn from being a claimant, which is why it is the Second Claimant in these proceedings. Rather, what clause 17 does is regulate how the parties should proceed in the event of litigation. This does not detract in any way from the agreements constituting an exclusive licence as defined in section 130(1).

21. Thirdly, nothing in section 67(1) requires the exclusive licensee to be able to take action independently of the patentee. Counsel for Mylan submitted that this was the effect of the words “the holder of an exclusive licence ... shall have the same right as the proprietor to bring proceedings” in section 67(1). Section 67(1) does not say that the licensee has the right to bring proceedings independently of the proprietor, however. Still less does it require the licence to provide for this. Furthermore, section 67(3) contradicts any such reading of section 67(1) because it requires the proprietor to be joined as a party if proceedings are taken by an exclusive licensee. It is true that section 67(3) allows for the patentee to be joined as a defendant if unwilling to be a claimant, but all that shows is that the legislature anticipated that the patentee might or might not be willing to be a claimant.
22. Fourthly, as is apparent from section 67(2), and confirmed by paragraphs 129-134 of the Final Report of the Departmental Committee on the Patents and Designs Acts chaired by Kenneth Swan QC (Cmd 7206, September 1947) which led to the introduction of the predecessor provision into the 1949 Act, the purpose of section 67 is to enable an exclusive licensee to recover its own losses (or its share of the infringer’s profits) in the event of infringement. Mylan’s argument would defeat that purpose being achieved in the present case, or now in the subsequent proceedings, which is of course precisely why Mylan advance it.

The respondent’s notice

23. Mylan contend that, in order to fall within the definition in section 130(1), an exclusive licence must be co-extensive with a claim of the patent, although they accept that it is possible to have multiple exclusive licences of one claim which differ as to the acts licensed, the market or the territory. In support of this, Mylan rely upon section 125(1). Mylan postulate two examples of product falling within the claims of EP702 which fall outside the grant contained in clause 3.1. The first is a prolonged release tablet containing 2 mg melatonin, with any “pharmaceutical acceptable diluent, preservative, antioxidant, solubilizer, emulsifier, adjuvant or carrier”, which is not bioequivalent to Circadin. The second is a medicament adapted for “rectal, parenteral, transbuccal, intrapulmonary (e.g. by inhalation) or transdermal administration” which is not in the same pharmaceutical form or route of administration as Circadin.
24. The judge rejected this argument at [140(2)] on the basis that he was unpersuaded that these examples “amount to second medical uses within the Patent that are at the same time not within the exclusive grant to Flynn”. As Mylan point out, and the Claimants do not contest, the judge was simply wrong about this. In fact, each example falls within the claims, but not within clause 3.1.
25. The judge went on, however, to consider what the position would have been if the claims of EP702 were not amended. (It is not clear to me why he did this given that the amendment would take effect from the date of grant and does not appear to have been opposed save on the ground that it did not cure the alleged invalidity of EP702; but that is by the bye.) In that context he held, albeit with some misgivings, that the argument would still fail for the reason he gave at [140(3)(g)]:

“The critical language in section 130(1) is ‘conferring...any right in respect of the invention’. Provided that right is

exclusive, even if it is only a sliver of a claim of a patent, it seems that the requirements of section 130(1) are met. In this case, therefore, I conclude that Flynn has been granted an exclusive licence in relation to 2 mg doses of melatonin in those aged 55 and over, and that even though the unamended Patent claims unit dosages between 0.025 and 10 mg, so far as 2 mg does are concerned, Flynn has the exclusive right to work the Patent, to the exclusion of Neurim.”

26. Subject only to a potential qualification arising out of the use of the word “sliver”, I consider that the judge was right. In my judgment “any right” means what it says. There is nothing in section 130(1), or in the previous case law, to support Mylan’s contention that an exclusive licence must be coextensive with a claim of the patent. I am content to assume that “the invention” in section 130(1) is to be understood in the manner stipulated by section 125(1), but that does not compel the conclusion for which Mylan contend because a right in respect of part of the field covered by a claim is still a “right in respect of the invention”. An obvious and common example of this would be an exclusive licence covering either a single chemical compound or a sub-class of compounds within a wider class covered by a claim.
27. This interpretation of section 130(1) is supported by section 67(2). It is also supported by the case law, and in particular the passage from Pumfrey J’s judgment in *Spring Form* cited above. In the example given by Pumfrey J it could easily be the case that the claims covered both human and veterinary uses. The nearest the case law offers to support for Mylan’s argument is some tentative observations of Robert Walker J in *Peadouce SA v Kimberly-Clark Ltd* [1996] FSR 680 at 691, but they were directed to a slightly different issue in different circumstances when deciding only that the issue before him was arguable.
28. The interpretation of section 130(1) set out above is also supported by the Swan Report, which recommended at paragraph 134 that “exclusive licensee” be defined as including “any person who has the sole and exclusive right to work the invention within any particular field of its application”.
29. Counsel for Mylan submitted that reading section 130(1) in this manner would enable a multiplicity of exclusive licences to be granted in respect of the same claim in a patent, which could lead to exclusive licensees competing with each other in the market, and that that could not have been intended. He accepted, however, that a multiplicity of exclusive licences could be granted in respect of the same patent provided that they were in respect of different claims, which could equally lead to the same consequence. There may be a limit as to how far one can salami-slice the monopoly in a claim for this purpose, but I do not think the licence conferred by the agreements between Neurim and Flynn is near to any possible limit. On the contrary, the exclusivity is coextensive with the Circadin marketing authorisation and generic equivalents. Thus it covers a commercially valuable market.

The costs issue

The procedural history

30. The procedural history of these proceedings and of the parallel proceedings in the EPO is recounted in detail by the judge in his judgment dated 12 March 2021 [2021] EWHC 530 (Pat) (“the March Judgment”) and in even greater detail by Meade J in a judgment in the proceedings concerning EP443 dated 24 January 2022 [2022] EWHC 109 (Pat). The key events in the chronology for present purposes are as follows.
31. EP702 was applied for on 12 August 2002 and granted on 10 May 2017. Mylan filed a notice of opposition in the EPO on 9 February 2018. Two other companies also opposed the grant of EP702. On 20 November 2019 the Opposition Division held that EP702 lacked novelty over an item of prior art referred to as “Haimov”, and therefore revoked it, for reasons given in writing on 2 January 2020. On 14 January 2020 Neurim filed a notice of appeal. That had the effect of suspending the revocation of EP702. Subsequently both parties applied for expedition of the appeal, and on 3 June 2020 the Board of Appeal issued a summons to oral proceedings on 17-18 December 2020.
32. The claim form in these proceedings was issued on 14 February 2020 (i.e. after the Opposition Division had held that EP702 was invalid). On 2 March 2020 the Claimants applied for an interim injunction to restrain Mylan from launching a generic version of Circadin, since Mylan had obtained a marketing authorisation but declined to undertake not to launch prior to the determination of the infringement proceedings. On 9 March 2020 the Claimants proposed that the English proceedings be stayed pending the outcome of the EPO proceedings on the basis of an undertaking by Mylan not to launch a generic version of Circadin until then, but did not offer a cross-undertaking in damages to cover any loss suffered by Mylan if EP702 was revoked. On 11 March 2020 Mylan rejected that proposal, but did not offer to agree to it if the Claimants gave a cross-undertaking. On 19 March 2020 Nugee J directed an expedited trial in late October/early November 2020. On 3 June 2020 Marcus Smith J refused to grant an interim injunction following a hearing before him on 20 May 2020. 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.
33. Although Marcus Smith J was informed by the parties on 20 May 2020 that they had applied to expedite the Board of Appeal hearing, he was not told on 3 June 2020 that the application had been successful and that the Board of Appeal hearing had been fixed for dates only about six weeks after the English trial. Although the fact that hearing had been fixed for 17-18 December 2020 was mentioned in passing by Mylan in their skeleton argument for a pre-trial review before Marcus Smith J on 5 October 2020, its significance was not flagged by either side before him on that occasion.
34. 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: lack of novelty over Haimov; obviousness over Haimov and two other items of prior art; and several insufficiency attacks. In addition, Mylan disputed that Flynn was an exclusive licensee under EP702. In the December Judgment Marcus Smith J concluded that (as proposed to be amended) EP702 was valid and had been infringed, but that Flynn did not have an exclusive licence.

35. On 16 December 2020 there was a hearing before Marcus Smith J as to the orders which should be made in the light of the December Judgment. By that time the judge had been made aware of the imminent Board of Appeal hearing. At the hearing on 16 December 2020 Marcus Smith J orally made a number of orders. Amongst those orders were: (i) an injunction which did not come into effect until 9pm on 18 December 2020 and which would lapse if Neurim's appeal to the Board of Appeal was unsuccessful; (ii) orders for delivery up of infringing goods and for the taking of an inquiry as to damages or an account of profits; (iii) a declaration that Flynn was not an exclusive licensee under EP702; and (iv) an order that Mylan should pay the Claimants' costs of the proceedings subject to a deduction to reflect the outcome of the exclusive licence issue. The judge refused Mylan permission to appeal, but granted the Claimants permission to appeal on the exclusive licence issue. No sealed order recording those orders was issued, however, because of a dispute between the parties as to the wording of the order. (I note in passing that the judge declined to approve the transcript of his extempore judgment(s) on 16 December 2020 because of what happened subsequently. I do not agree that that warranted the course adopted by the judge: there was still a need for an accurate record of the judge's reasons for making the orders on 16 December 2020.)
36. On 17 and 18 December 2020 the Board of Appeal at the EPO heard Neurim's appeal against the Opposition Division's order revoking EP702. 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. Although the Board did not rule upon the novelty issue, formally the outcome was that EP702 was revoked for lack of novelty over Haimov.
37. On 30 December 2020 Marcus Smith J made an order revoking his orders made on 16 December 2020 (save for an order under CPR rule 31.22) without prejudice to any contention that, after a further hearing, the same or similar orders should be made. This order included, among other recitals, the following recital:

“AND UPON the Claimants accepting in the light of the First Claimant's withdrawal of its appeal before the Technical Board of Appeal, and accepting that the Patent has been revoked ab initio, that the Claimants are not entitled to any substantive relief against the Defendants in respect of the Patent, whether by way of injunctions or by way of inquiry as to damages or account of profits or otherwise howsoever”.
38. There was a further hearing as to what orders should be made on 22 February 2021. On 12 March 2021 Marcus Smith J handed down the March Judgment and made an order which declared that Flynn was not an exclusive licensee under EP702 and ordered the Claimants to pay Mylan's costs of the proceedings. He refused the Claimants permission to appeal on the exclusive licence issue, but only on the ground

that it was academic. Subsequently I granted permission to appeal and later still Mylan accepted that the issue was not academic. On 12 April 2021 Marcus Smith J granted the Claimants permission to appeal the costs order on ground 1 considered below. Subsequently I granted permission to appeal on grounds 2 and 3.

39. It can be seen from this account that the judge essentially reversed his order as to costs as a result of the outcome of the proceedings in the EPO.

The judge's reasoning

40. The judge cited the statement of Sir Thomas Bingham MR in *Roache v Newsgroup Newspapers Ltd* [1998] EMLR 161 at 168 that, when deciding who is the successful party for the purpose of determining the incidence of costs:

“The judge must look closely at the facts of the particular case before him and ask: who, as a matter of substance and reality, has won?”

41. Applying this test, the judge reasoned that, although the effect of the December Judgment was that the Claimants were the successful parties on all issues save for the exclusive licence issue, the effect of the revocation of EP702 by the EPO was that Mylan were the successful parties. As the judge explained (emphasis in the original and footnotes omitted):

“77. Viewing the matter from the point of view of outcome, it is obvious that Mylan is the winner and Neurim the loser. Referring to the issues arising on the pleadings, Neurim contended that the Patent was valid and infringed; Mylan contended that the Patent was invalid, and should be revoked. Viewing the matter through the prism of the pleadings, Mylan is clearly and unequivocally the winner. The oddity – if it can be called that – is that this outcome has been achieved despite and not because of the Judgment in the UK Proceedings, which (as I have said) went more or less entirely Neurim's way.

78. I conclude that, given the interaction that exists between the EPO Proceedings and the UK Proceedings, which is fully taken into account when considering whether a stay of the UK Proceedings should be granted, the ‘result in real life’ in this case is to be determined by comparing the remedies and relief sought by the parties to the UK Proceedings with what they have actually obtained. As I have said, viewed through this prism, there is only one winner: although Neurim contended that the Patent was valid and infringed, the recitals to the 30 December 2020 Order make clear that this outcome has not been achieved. By contrast, Mylan's contention that the Patent should be revoked has succeeded, albeit by a curious (and hopefully not to be repeated) interaction between the UK Proceedings and the EPO Proceedings.”

42. The judge went on to consider whether there was any reason in this case to depart from the principle that the unsuccessful parties should pay the successful parties' costs. He began by saying (emphasis in the original):

- “80. I should say that I do not consider that the usual alternative of an issues-based costs order to be appropriate here. The fact is that the issues all go one way or they all go the other way depending on whether one looks at the outcome as stated in the Judgment or the outcome as it will appear in the new consequential order that I will, in due course, make. In other words, an issues-based costs order is not, in my judgment, a particularly helpful tool in the present case, extremely useful though it normally is.
81. Nor do I consider that it would be appropriate to make an order along the lines of ‘everyone's a winner, and everyone's a loser’. Tempting though it is to make no order as to costs, I consider that that would be inconsistent with my provisional finding that Mylan is the winner. What I must do is consider whether there are other specific factors in play that can properly justify a different costs order.”
43. The judge proceeded to consider, first, the significance of the EPO proceedings and, secondly, the conduct of the English proceedings. He concluded that there was nothing in the EPO proceedings (apart from their outcome) which assisted him on the question of costs. As for the English proceedings, he concluded that there was nothing in the conduct of either side to cause him to alter the incidence of costs which would otherwise flow from Mylan being the successful parties. This was subject, however, to the point that both sides had known in early June 2020 that the Board of Appeal hearing had been fixed for 17-18 December 2020.
44. As to that, he reasoned as follows (emphasis in the original):
- “89. ... Had the parties jointly sought an adjournment, I suspect it would have been granted. As it is, I infer that one or both of the parties did not want an adjournment, and one can understand why: Mylan, for its part, would have wanted its two bites of the revocation cherry; and Neurim, having failed to obtain an interim injunction, would have wanted a final injunction in place as soon as possible in the event of it succeeding in both the UK and the EPO Proceedings. The quickest way of achieving that was by way of maintaining the expedited trial in the UK Proceedings, whilst pressing on with the EPO Proceedings.
90. Without in any way wishing to criticise or be prescriptive, whilst the parties may very well have had their own reasons for wanting the EPO and the UK Proceedings to proceed in parallel, their conduct (in not referring the matter to the court) deprived the court of considering whether a stay of the UK Proceedings was or was not appropriate. In effect, the parties prevented the court from re-visiting, or considering re-visiting, Nugee J’s order expediting the trial. Nugee J’s order would have been premised on an appeal in the EPO Proceedings in the first quarter of 2022: an appeal in the EPO actually listed

for hearing and determination on 17 and 18 December 2020 is a very different matter.

91. I remind myself of Floyd LJ's twelfth proposition or guidance in *IPCom [GmbH & Co KG v HTC Europe Co Ltd]* [2013] EWCA Civ 1496, [2014] Bus LR 187 at [68]: in weighing the balance of staying or not staying English proceedings, it is material to take account of costs liable to be wasted. In this case, the picture changed dramatically between March 2020 (when expedition was ordered by Nugee J) and June 2020 (when, in my judgment, there was a material change, such that a party would have been justified in bringing the matter back before the court for re-consideration). As I see it, the following possibilities existed as at June/July 2020:
- (1) An application to adjourn could have been made by both parties: in such a case, and in such circumstances, it is difficult to see a court declining the application – but, even if it had been declined, there would have been the opportunity to consider – in advance – what would happen on the question of costs if the EPO Proceedings proceeded in parallel with and with outcomes at roughly the same time as the UK Proceedings, simply because the UK Proceedings were not adjourned
 - (2) An application to adjourn could have been made by one party, and resisted by the other. In such a case, the court would obviously need to understand why an adjournment was being resisted, and it may be that the adjournment would not be granted. All would depend on the facts and matters advanced by the parties on the application. If the adjournment was refused, the court would be in a strong position to articulate which party would bear the costs of the trial of the UK Proceedings if the outcomes of the EPO and UK Proceedings diverged.
 - (3) The third possibility is the one that occurred: no application to adjourn was made by either party. In June/July 2020, both Neurim and Mylan knew that there was a clear potential for the outcome of the UK Proceedings to be rendered pointless in light of the imminent hearing before the Technical Board of Appeal in the EPO Proceedings. The parties would have been well aware of potentiality. In my judgment, in not seeking to engage with the court on the question of adjournment, each of the parties assumed the risk of costs being wasted and of a costs order being made that followed the outcome of the interaction between the UK and the EPO Proceedings, as opposed to the reasoning (whatever it might be) of the UK

Proceedings. I do not say that an outcome based order will always, or even generally, be the right one, although in this case I consider it to be the correct starting point when assessing the incidence of costs, for the reasons I have given. It seems to me that Neurim cannot now complain that it bears the entire costs of the trial simply because – although the Judgment favoured it – the outcome of the interaction between the EPO Proceedings and the UK Proceedings has resulted in Neurim being the losing party. The costs of the UK Proceedings were costs thrown away because the decision of the Technical Board of Appeal in the EPO Proceedings rendered the trial in the UK Proceedings unnecessary. That is something that Neurim could have avoided, and I consider there is no reason why I should alter the provisional view on costs that I have reached. Indeed, I consider the fact that it lay within Neurim’s power to bring this issue before the court to support and further justify the provisional view on costs that I have reached.

92. I should make clear that I am in no way singling out Neurim for particular blame. Had the outcome of the interaction between the EPO Proceedings and the UK Proceedings favoured Neurim, then I would have considered that a provisional costs order in the UK Proceedings ought to favour Neurim, and I would have considered Mylan’s failure to raise the matter of an adjournment in June/July 2020 in exactly the same way as I have considered Neurim's.”

Grounds of appeal

45. The Claimants appeal on three grounds. Ground 1 is that the judge was wrong to conclude that Mylan’s success in the EPO meant that Mylan were the successful parties in the English proceedings, or at least was wrong to conclude that Mylan’s success in the EPO should be determinative of the incidence of costs in the English proceedings. Ground 2 is that the judge should not have reversed his previous costs order. Ground 3 is that, even if the judge was correct to conclude that Mylan were the successful parties overall, he should have made an issues-based costs order which better reflected the reasons for Mylan’s overall success.

Appeals on costs

46. As is well known, appeals on costs face a high hurdle to overcome. There are many decisions of this Court to that effect, but the reasons for it were explained with particular clarity by Wilson J, with whom Waller and Rix LJJ agreed, in *SCT Finance Ltd v Bolton* at [2002] EWCA Civ 56, [2003] 2 All ER 434 at [2]:

“This is an appeal ... from the county court in relation to costs. As such, it is overcast, from start to finish, by the heavy burden faced by any appellants in establishing that the judge’s decision

falls outside the discretion in relation to costs conferred upon him under rule 44.3(1) of the Civil Procedure Rules 1998 . For reasons of general policy, namely that it is undesirable for further costs to be incurred in arguing about costs, this court discourages such appeals by interpreting such discretion very widely.”

47. In the present case, however, a substantial sum of costs is at stake. More importantly, as the judge recognised when giving permission on ground 1, it raises an issue of principle as to the correct approach in the unusual circumstances of this case.

Ground 2

48. Logically, it seems to me that ground 2 comes first. The Claimants contend that the judge was correct to conclude that, as matters stood on 16 December 2020, the Claimants were the overall winners and therefore should have their costs (subject to a deduction to reflect their failure on the exclusive licence issue). The Claimants do not dispute that the judge had jurisdiction to re-consider his costs order in the light of the subsequent revocation of EP702 by the EPO, but they contend that there had been no material change of circumstances because the revocation was not material to the assessment of the costs of the English proceedings and therefore the judge should not have changed his order.
49. I do not accept this argument. I will assume that the premise for the argument, namely that Mylan had to demonstrate a material change of circumstances since 16 December 2020, is correct, although the contrary is arguable given that no order had been sealed. In my view the revocation of EP702 was plainly a material change in circumstances since the Claimants’ objective in these proceedings was to enforce the monopoly conferred by EP702 and thereby exclude a competitor from the market in order to be able to continue to charge a monopoly price for Circadin. The revocation of EP702 meant that the Claimants could not achieve that objective. More specifically, it meant that they could not obtain the relief against Mylan (namely an injunction, delivery up of infringing goods and an inquiry as to damages alternatively an account of profits) which they claimed in these proceedings. Both legally and commercially, therefore, revocation meant that the Claimants had failed. The fact that EP702 was revoked after the judge had given the December Judgment does not alter this.
50. Counsel for the Claimants submitted that revocation of the patent was material to other matters the judge had to decide (for example, the order for delivery up, which was made on 16 December 2020 but had to be discharged on 30 December 2020), but not to the incidence of costs. That is an impossible submission to accept, because the incidence of costs should generally reflect, although it is not necessarily dictated by, the substantive result of the proceedings.
51. Faced with this difficulty, counsel for the Claimants was driven to submit that the revocation would have been equally immaterial if it had occurred at an earlier stage of the proceedings, but that submission parts company with reality. What if, for example, the revocation had happened the day after the trial, but before the judge had started writing his judgment? Counsel’s answer was that the judge was nevertheless obliged to write the judgment in order to determine the incidence of costs. But even that

answer, unpalatable though it is, would not work if the patent was revoked half-way through the trial.

52. The question cannot depend on timing, at least if the revocation happens prior to a final order of the English court being sealed. It is the sealing of the order which matters for these purposes, because that is the stage at which the first instance court becomes *functus officio* (meaning that it ceases to have authority to decide the case) for most purposes and thus the stage at which considerations of finality bite. In saying this, I am deliberately leaving out of account questions, which do not arise in this case, as to the circumstances in which a final order may be re-opened. I am also leaving out of account the question, which does not arise in this case either, as to whether a party in the position of Mylan would have some other remedy if the final order was sealed before the patent was revoked.

Ground 1

53. Counsel for the Claimants advanced three submissions under this heading. The first was that the judge was wrong to treat Mylan's success in the EPO proceedings as determinative of the question of who were the successful parties in the English proceedings. The second was that, even if the judge was right to conclude that Mylan were the successful parties, he was wrong to treat that as determinative of the incidence of costs. The third was that, when he came to consider other factors, he failed to take into account the Claimants' success in the December Judgment and he wrongly put all the costs risk arising out of the EPO proceedings onto the Claimants and none onto Mylan.
54. I do not accept the first submission for the same reasons as I have given for rejecting ground 2. As a result of the revocation of EP702 the Claimants failed to get any of the relief they claimed in the English proceedings and failed to achieve their commercial objective. There is nothing more that Mylan could have achieved so far as resisting claims based on EP702 was concerned. Accordingly, I consider that the judge was entirely correct to conclude that Mylan were the successful parties.
55. I should mention for completeness that in the Claimants' skeleton argument reliance was placed in this context on the reasons given by Floyd LJ delivering the judgment of this Court in *Adaptive Spectrum and Signal Alignment Inc v British Telecommunications plc* [2014] EWCA Civ 1516 at [9] for refusing to grant a stay of an injunction pending the outcome of parallel proceedings in the EPO. In oral argument counsel for the Claimants did not place weight on that decision, and as a result its correctness was not explored. At some point, whether in this or another case, it will be necessary to consider whether it can be reconciled with the decision of the Supreme Court in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 36, [2014] AC 160 and, if so, whether this Court was right to distinguish it in *Smith & Nephew plc v ConvaTec Technologies Inc* [2015] EWCA Civ 803. For the present it suffices to say that the decision does not in any event address the issue which arises in the present case.
56. I can take the second and third submissions together. In my judgment these have much more force. It should be acknowledged before proceeding further that the judge was faced with a difficult, and unprecedented, situation. Within days of concluding that EP702 was valid and infringed, and making orders which reflected those

conclusions, EP702 had been revoked. As the judge correctly held, that meant that Mylan, who had been unsuccessful in the December Judgment, were now the successful parties. That being so, the judge was also correct to take the general rule that the unsuccessful party will be ordered to pay the costs of the successful party as his starting point: CPR rule 44.2(2)(a). As the judge clearly recognised, however, the court may make a different order: rule 44.2(2)(b). Moreover, in deciding what order, if any, to make about costs, the court must have regard to all the (relevant) circumstances: rule 44.2(4).

57. The crux of counsel for the Claimants' argument was that, although the judge had mentioned the possibility of making a different order, in reality he had treated Mylan's success as dispositive of the incidence of costs. I agree with this. Although the argument ranged more widely, it seems to me that the error in the judge's approach can be seen from what he said at [80]-[81].
58. First, the judge rejected the possibility of an issues-based order on the ground that "the issues all go one way or they all go the other way depending on whether one looks at the outcome as stated in the [December] Judgment or the outcome as it will appear in the new consequential order". For reasons that I will explain when addressing ground 3, this is not correct.
59. Secondly, the judge rejected the possibility of making no order as to costs on the ground that "that would be inconsistent with my provisional finding that Mylan is the winner". Again, for reasons that I will explain, this is not correct.
60. I therefore conclude that the judge erred in principle when determining the incidence of costs. That leaves the difficult question of what order should be made. It is convenient before reaching a conclusion on this question first to consider ground 3.

Ground 3

61. The Claimants contend that the judge should have made an issues-based costs order which better reflected the reasons for Mylan's overall success. Before addressing this contention, it is necessary to explain how the argument on this point proceeded before the judge.
62. In their skeleton argument for the hearing on 22 February 2021 the Claimants submitted that (original emphasis) "[e]ven if a new 'issues-based assessment' is the right one then the Claimants should still have their costs (bar on the Exclusive Licence issue, the Defendants having lost on all the invalidity issues they elected to litigate in the UK proceedings)". The same submission was made orally by counsel then appearing for the Claimants. Thus the Claimants' position was that an issue-based assessment would lead to the same costs order as the judge had made on 16 December 2020, namely that Mylan should pay all the Claimants' costs save for a deduction to reflect Mylan's success on the exclusive licence issue. The Claimants did not advance an alternative submission that the Claimants should get the costs of some of the validity issues, and the general costs of the action, even if Mylan got the costs of other validity issues. No doubt for that reason, the Claimants did not adduce any evidence as to the breakdown of their costs between the various issues in the English proceedings.

63. Mylan's primary submission was that an issues-based assessment of costs was not appropriate. In the alternative, Mylan submitted that, if there were to be an issues-based assessment, the Claimants should pay Mylan's costs subject to an 18% deduction. The rationale for this was that Mylan should be deemed to have succeeded on lack of novelty (that being the finding of the Opposition Division which formed the basis of the order for revocation) and insufficiency (that being the opinion of the Board of Appeal), and should therefore pick up the general costs of the proceedings, whereas Mylan accepted that they could not point to anything in the EPO proceedings to show that they were right on obviousness. Indeed, counsel for Mylan accepted that Mylan would not have appealed to this Court on obviousness. Mylan did adduce evidence as to the breakdown of their costs between the various issues in the English proceedings. This breakdown gave a figure of approximately 18% for Mylan's costs incurred on the obviousness issues. Although Mylan did not concede that it would have been appropriate notionally to require Mylan to pay the Claimants' costs of those issues in addition to depriving Mylan of recovery of their own costs, it would have been open to the judge to take that view.
64. The absence of any evidence before the judge as to the breakdown of the Claimants' costs gives rise to a practical question as to how, if this Court considered that in principle an issue-based assessment was appropriate, that should be carried out. At one stage in his argument counsel for the Claimants suggested that the matter should be remitted to the judge, but subsequently he accepted that that would not solve the problem. One possibility, as Birss LJ pointed out, would be to make an order under rule 44.2(6)(f) rather than a percentage-based order under rule 44.2(6)(a) of the kind normally made by the Patents Court. That, however, would impose a difficult exercise of assessment on the parties and the costs judge. Faced with this difficulty, counsel for the Claimants submitted the Court could take Mylan's breakdown as fairly representing the distribution of costs between the various issues. I accept that that would be a permissible approach. On that basis it would be possible, for example, to make an order that the Claimants pay 64% of Mylan's costs following the logic of Mylan's alternative submission to its ultimate conclusion (and assuming, in the absence of evidence to the contrary, that the Claimants' total costs were roughly the same as Mylan's total costs).
65. I turn therefore to the question of principle. In my view Mylan's alternative submission illustrates the error in the judge's approach, since it shows that the fact that Mylan succeeded overall does not justify an order which requires the Claimants to pay Mylan's costs of the obviousness issues given that Mylan did not succeed on obviousness before any of three tribunals. On the other hand, it also demonstrates why an issues-based assessment is not an appropriate response to the problem. The rationale for issues-based costs orders (whether or not expressed in percentage terms) is to reflect the degree of success achieved by the parties, and thus to incentivise parties only to run good points and not to run bad points. But that rationale does not work here. The Claimants were successful on all points (except for the exclusive licence issue) before the judge, including novelty and insufficiency. Why should they be deemed to have lost on novelty and insufficiency when in fact they won? Moreover, why should they be deemed to have lost on all the insufficiency arguments advanced by Mylan (apart from one which Neurim effectively conceded by its application to amend the claims) when even in the Board of Appeal Mylan only prevailed on one of them (an argument of lack of plausibility)? The reality is that

Mylan won, but they won for a reason extraneous to the English proceedings. The possibility of this occurring is, however, inherent in the parallel jurisdictions of the English courts and the EPO to revoke (UK designations of) European patents.

What order should be made?

66. I have set out [89]-[92] of the March Judgment in full in paragraph 44 above because I have come to the conclusion that it provides the key to the problem. It can be seen from what the judge said there that he considered that the costs incurred by the parties in the English proceedings following the decision of the Board of Appeal on 3 June 2020 to expedite the hearing before it had in essence been wasted. Moreover, he found at [89]-[90] that both sides were equally at fault for that having happened. Neither side has challenged that finding before us.
67. As counsel for the Claimants pointed out, however, the judge went on at [91(3)] to say that the Claimants could have avoided the waste of costs without at that stage acknowledging the point he himself had just made that Mylan could also have done so. Moreover, what the judge said at [92] is incorrect: if Neurim had succeeded in the EPO and the Claimants had succeeded before the judge, then there would have been no basis for making any different order for costs to the order which the judge in fact made on 16 December 2020.
68. In my judgment the judge was fully entitled to conclude that the costs of the English proceedings at first instance after 3 June 2020 had been wasted. Given his unchallenged finding that both sides were equally at fault for that, I consider that it follows that the correct response was to make no order for costs save with regard to the exclusive licence issue. In that way each side would be left to bear the costs that it wasted. (The costs of the interim injunction application and the appeal had already been dealt with, and the other costs incurred prior to 3 June 2020 are likely to have been a relatively minor part of those in issue.) The costs of the exclusive licence issue stand in a different position because they were not wasted. On the contrary, the judge's determination has provided the foundation for this Court's decision on that issue, which as I have already explained is material to the subsequent proceedings.
69. It is common ground that neither side submitted to the judge, even by way of fall-back position, that there should be no order as to costs. As the judge clearly appreciated, however, it would nevertheless have been open to him to make that order. When exercising its discretion as to the costs, the court is not limited to the orders sought by the parties and it is common to make an order somewhere between those extremes. Given that this Court is re-exercising the discretion, it is in the same position.
70. When asked why no order for costs was not the right order in this case, counsel for Mylan's response was that: (i) the Claimants had chosen to bring the English proceedings after EP702 had already been held invalid by the Opposition Division, taking advantage of the suspensive effect of an appeal; (ii) Mylan had had no choice but to defend themselves; and (iii) the fact that the Claimants had failed to obtain an interim injunction because damages were an adequate remedy showed that the Claimants could have waited until after the conclusion of the EPO proceedings.
71. I do not accept this argument. The Claimants were seeking to preserve their monopoly. Given the absence of any undertaking not to launch from Mylan, the

Claimants had to bring proceedings when they did if they were to have any chance of keeping Mylan off the market prior to trial in England. Furthermore, Mylan were not the only generic competitors potentially interested in this market. As this Court held when dismissing the Claimants' appeal against the refusal of an interim injunction, damages were only an adequate remedy because (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).

72. None of this detracts from the point that, as the judge correctly recognised, the Board of Appeal's decision on 3 June 2020 to expedite the hearing before it was, to put it in colloquial terms, a game-changer. Prior to that, the parties had anticipated that a hearing before the Board would not take place until some time in 2022, and possibly not until after the expiry of EP702. It was against that background that in March 2020 they were unable to agree a stay of the English proceedings pending the determination of the EPO proceedings, a failure for which both sides can be blamed but which in any event was understandable in those circumstances. As the judge also correctly recognised, the Board of Appeal's expedition decision put an entirely different complexion on Nugee J's decision to expedite the trial of the English proceedings, but the parties prevented the court from revisiting that decision. As Meade J stated in his judgment dated 24 January 2022 at [181], the parties should have kept the court actively and fully informed. It is fair to say that, had the parties done that, the judge would have been faced with a challenging exercise in case management in order to hold the ring while avoiding wastage of costs. But the parties deprived the Patents Court of the chance to undertake that exercise, both sides were equally at fault for that, and costs were wasted as a result.

Conclusion

73. For the reasons given above I would allow the Claimants' appeal on the exclusive licence issue, and I would allow the Claimants' appeal on the costs issue to the extent that I would substitute an order that (i) Mylan should pay the Claimants' costs of the exclusive licence issue and (ii) otherwise there be no order as to the costs below. I would invite written submissions as to what should happen with regard to the assessment of the Claimants' costs of the exclusive licence issue if they cannot be agreed.

Lord Justice Birss:

74. I agree.

Lord Justice Newey:

75. I also agree.