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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**

Rolls Building  
Fetter Lane  
London, EC4A 1NL

24 January 2022

**Before :**

**MR JUSTICE MEADE**

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**Between :**

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

(2) **FLYNN PHARMA LIMITED**

**- and -**

(1) **GENERICS (UK) LIMITED T/A VIATRIS**

(2) **VIATRIS UK HEALTHCARE LIMITED**

**Andrew Waugh QC, David Scannell QC and Katherine Moggridge** (instructed by **Gowling WLG (UK) LLP and Pinsent Masons LLP**) for the **Claimants**

**Piers Acland QC, Adam Gamsa and Daniel Piccinin** (instructed by **Taylor Wessing LLP**) for the **Defendants**

Hearing dates: 15-17 December 2021, 19 January 2022

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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.

**Covid-19 Protocol: This Judgment was handed down remotely by circulation to the parties' representatives by email and release to Bailii. The date for hand-down is deemed to be 24 January 2022.**

**Mr Justice Meade:**

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## **INTRODUCTION**

1.

This is my judgment following a three-day trial on (15-17 December 2021) of certain preliminary issues in this patent action. This judgment also addresses a further hearing on 19 January 2022 which took place because Mylan raised an issue on my draft judgment that I thought merited further oral submissions. I deal with that in the last substantive section of this judgment, “Case management”. I have amended and supplemented my original draft judgment (by adding that section and by amending the section “Practical matters and the real justice of the situation”) in the light of that issue, as will appear below.

2.

In the action, the Claimants allege that the Defendants infringe European Patent (UK) 3,103,443. I will refer to this as “**EP443**” or (for reasons that appear below) “**the Divisional**”. EP443 will expire in August 2022.

3.

I will refer to the Claimants collectively as “**Neurim**”, save occasionally where it is necessary to refer to them individually in connection with the status of the Second Claimant as alleged exclusive licensee, the First Claimant being the patentee.

4.

I will refer to the Defendants collectively as “**Mylan**” (I will stick to this, although it recently changed its name to “Viatrix”).

5.

A detailed account of the context and history appears below. By way of introduction I will outline the main points, so that I can explain what the preliminary issues that I have tried are.

6.

In previous proceedings, started in 2020 (“**the 2020 Action**”), Neurim sued Mylan for infringement of European Patent (UK) 1,441,702, the parent patent of the Divisional. I will refer to it as “**EP702**” or “**the Patent**”. Those proceedings concerned (as does this action) the market for melatonin for use in treating a certain kind of insomnia which I explain in further detail below. Neurim’s product is called Circadin and Mylan wishes to sell a generic competitor.

7.

In a detailed judgment in the 2020 Action, handed down on 4 December 2020 (“**the Main Judgment**”), Marcus Smith J held that the Patent was valid and infringed, but that the Second Claimant (“**Flynn**”) was not an exclusive licensee under the Patent.

8.

On 16 December 2020 Marcus Smith J made various Orders at a hearing. They were not reduced to writing because the parties failed to agree wording. The Orders included an injunction and delivery up, and refusal of permission to appeal for Mylan on validity; the Claimants obtained permission to appeal on the exclusive licence issue.

9.

The trial before Marcus Smith J took place at a time when the Opposition Division (“**OD**”) of the European Patent Office (“**EPO**”) had revoked the Patent. That revocation was suspended pending appeal by Neurim, but on 18 December 2020 the Technical Board of Appeal (“**TBA**”) brought that suspension to an end when Neurim withdrew its appeal on the second day of a two day hearing. So the Patent was revoked ab initio for the UK (and all other designated member states) by operation of the European Patent Convention (“**EPC**”), Article 68.

10.

Marcus Smith J then made an Order on 30 December 2020 on the papers, revoking all the material parts of his 16 December 2020 Order (“**the 30 December Order**”). The parties returned to Court in February 2021 for a full “consequential” hearing and Marcus Smith J gave a judgment dated 12 March 2021 (“**the Consequentials Judgment**”), and made a written Order. Aspects of the Consequentials Judgment are under appeal.

11.

However, Neurim had the Divisional in prosecution, and obtained its grant on 30 June 2021, whereupon it began these proceedings. In these proceedings, Neurim has applied to amend the claims

of the Divisional into a form identical for practical purposes to the claims of the Patent as they stood at the time of the trial before Marcus Smith J.

12.

Neurim alleges that issue estoppel arising from the Main Judgment prevents Mylan from challenging the validity of the Divisional in these proceedings. For its part, Mylan says that Neurim's conduct in amending the Divisional is an abuse of process, and it says that Neurim's conduct in seeking to shut out its challenge to the validity of the Divisional is an abuse of a dominant position under s. 18 of the Competition Act 1998.

13.

On Neurim's application, Mellor J made an Order of 12 August 2021 for the expedited trial of certain preliminary issues, including in particular the issue estoppel allegations. At that stage, Mylan had not pleaded its defence. When it had done so, and raised the competition issues, Mellor J made a further Order of 27 August 2021 adding to the preliminary issues whether "in principle", and on the assumption that Neurim had a dominant position in a relevant market, Neurim's conduct would be an abuse.

14.

The reason for Mellor J considering the application for preliminary issues in the vacation, and for ordering expedition, is Neurim's desire to be able to obtain an injunction on the Divisional before it expires.

15.

In this unusual and fast-moving situation, Mellor J left it to the parties to draw up the detailed list of preliminary issues. The list runs to 14 paragraphs with many sub-paragraphs and it was not much used at the trial before me. It is enough to say for now that the preliminary issues that I have to determine are in substance:

i)

Whether Mylan is issue-estopped from challenging the validity of the Divisional in the light of the 2020 action.

ii)

Whether Neurim's conduct in amending the Divisional is an abuse.

iii)

Whether Neurim's conduct amounts to an abuse of a dominant position (on the assumption of dominance and market definition).

16.

There were to have been preliminary issues about Flynn's status as exclusive licensee, but they were disposed of by agreement and I need say no more about them.

## **CONDUCT OF THE TRIAL**

17.

Initially, the trial was conducted in Court. There was only one witness to give live oral evidence, and that was Mr Inman of Neurim's solicitors. He gave his evidence right at the start of day 1. All the rest of the time was taken up in oral argument.

18.

Unfortunately, one of the parties' solicitors tested positive for COVID overnight between the first and second days, and given the need for the Court to be deep-cleaned and the obvious risk of further spread, the rest of the trial was conducted remotely.

19.

Mr Waugh QC, Mr Scannell QC and Ms Moggridge appeared for Neurim. Mr Scannell addressed me on competition issues with Mr Waugh undertaking the rest of the oral advocacy. Mr Acland QC, Mr Gamsa and Mr Piccinin appeared for Mylan; Mr Acland and Mr Piccinin shared the oral advocacy in a similar way to Neurim, with Mr Piccinin addressing competition law. After the oral hearing of the trial I directed further written submissions on some discrete points.

## **THE AGREED FACTS**

20.

As one would hope for a trial of preliminary issues, many facts were agreed. At the PTR I directed the preparation of an Agreed Statement of Facts, which, with only slight amendments, forms the basis of this section of my judgment. I then return to some aspects of the history where more detail is required and/or resolution of factual issues is necessary.

21.

EP443, the Divisional, was granted on 30 June 2021. It will expire on 12 August 2022. The Application for EP443 was published on 14 December 2016.

22.

The Patent, EP702, was granted on 10 May 2017. It was opposed at the EPO by, amongst others, the First Defendant.

23.

EP443 and EP702 relate to the First Claimant's commercial product, Circadin, which is a 2mg prolonged release melatonin product indicated for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over. Circadin is commercialised in the UK by the Second Claimant.

24.

On 20 November 2019 the OD found EP702 lacked novelty over a piece of prior art referred to in this action and the action concerning EP702 as "Haimov".

25.

In early 2020, the Claimants became aware that the Defendants had obtained an MA for 'Melatonin Mylan', relying on the Claimants' MA.

26.

The Defendants declined to give notice of any launch of their generic product in early 2020, in the light of which the Claimants brought infringement proceedings under EP702. These were served on the Defendants on 17 February 2020. The Defendants counterclaimed for invalidity and served a Defence and Counterclaim on 1 April 2020.

27.

The Claimants applied on 2 March 2020 for a preliminary injunction in the light of Mylan's refusal to give undertakings or notice of launch. That was heard on 20 May 2020 and on 3 June 2020 Marcus Smith J refused to grant a preliminary injunction. The Claimants appealed this decision. The Court of

Appeal dismissed the appeal on 24 June 2020 and the Supreme Court refused permission to appeal on 29 June 2020.

28.

Also in March 2020, the Defendants applied for expedition of the EP702 trial, which the Claimants agreed to on 13 March 2020. An expedited trial was ordered by Nugee J, as he then was, on 19 March 2020.

29.

In late September 2020, the Defendants launched their Mylan Melatonin product in the UK.

30.

The validity and infringement trial concerning EP702 was heard by Marcus Smith J on 29 October 2020 – 5 November 2020. In the Main Judgment of 4 December 2020, Marcus Smith J found EP702 valid and infringed. By the time of trial, the Defendants admitted infringement if EP702 was found to be valid.

31.

On 16 December 2020, Marcus Smith J heard the form of order hearing in the light of his judgment of 4 December 2020. At that hearing, Marcus Smith J made a number of oral orders, and refused the Defendants permission to appeal.

32.

On 17-18 December 2020, the TBA at the EPO heard the appeal from the OD's finding that EP702 lacked novelty over Haimov. On 17 December, disputes arose concerning the First Claimant's reliance on two documents referred to as "D19" and "D20" and the scope of the First Defendant's insufficiency arguments. On 18 December 2020 the TBA ruled that (i) D19 and D20 were not admitted (ii) the admissibility of the First Defendant's insufficiency arguments were not in issue (iii) refused to remit the case to the OD for consideration of those arguments and delivered their oral opinion that EP702 was invalid for insufficiency, in the light of which the First Claimant withdrew its appeal against the OD's finding. In the circumstances, the suspensive effect of the decision of the OD ceased, and EP702 was revoked.

33.

On 30 December 2020, Marcus Smith J revoked his oral orders made on 16 December 2020.

34.

A further consequential hearing took place regarding EP702 and on 12 March 2021 Marcus Smith J handed down the further Consequentials Judgment and made a further order in that action.

35.

On 5 November 2020, the Examining Division at the EPO issued an Examination Report regarding EP443. Patent attorneys for the First Claimant filed a reply to this report on 10 January 2021, and on 28 January 2021 the Defendants filed third party observations at the EPO regarding EP443. As part of these, the Defendants brought the insufficiency argument which had been accepted by the TBA to the attention of the Examiner.

36.

The First Claimant filed a response to those third party observations on 22 February 2021 to which the Defendants filed further third party observations on 17 March 2021.

37.

On 14 April 2021, the Examining Division issued a Notice of Intention to Grant EP443 and stated that the Defendants' third party observations had been examined but had been found not to be relevant.

38.

The Defendants filed a complaint that the Examining Division had not properly considered their third party observations on 19 April 2021; the EPO replied on 4 May 2021 confirming that the third party observations had been debated, that a reasoned decision had been taken internally about how to consider them, and that the point relating to sufficiency of disclosure had been thoroughly discussed.

39.

On 4 June 2021, the Examining Division issued its Decision to Grant, and on 30 June 2021 EP443 was granted.

40.

The Claimants commenced infringement proceedings in respect of EP443 on the day of grant. The Defendants opposed the grant of EP443 that same day. On 1 July 2021, the First Claimant applied unconditionally to amend EP443 in the UK to make its claims "patentably indistinct" from those of EP702.

41.

On 7 July 2021 the Defendants applied to stay the UK proceedings pending the final decision of the EPO including any appeals on the validity of EP443.

42.

The Claimants applied for permission to have issues heard as preliminary issues and that application was heard by Mellor J on 28 July 2021. On 2 August 2021, Mellor J handed down judgment granting permission for the issues be heard as preliminary issues with a degree of expedition. The trial was shortly thereafter fixed to be heard in December 2021.

43.

The Defendants served their Defence and Counterclaim, Grounds of Invalidity and Statement of Opposition in relation to the proposed unconditional amendments to EP443 on 11 August 2021. In an order of 12 August 2021, Mellor J gave directions for the hearing of the preliminary issues.

44.

On 27 August 2021, Mellor J granted permission for the further competition law issue to be considered as a preliminary issue at the December 2021 hearing.

45.

By Orders of 13 October 2021 Arnold LJ gave Neurim permission to appeal in the 2020 Action in relation to whether Flynn was an exclusive licensee and in relation to the costs aspects of Marcus Smith J's 12 March Order (in which Order Marcus Smith J had refused permission to appeal on the exclusive licence issue).

46.

On 26 October 2021, the parties agreed a list of preliminary issues for determination at the December 2021 hearing. On 6 December 2021 the Defendants sought the Claimants' consent to delete 3 of the issues alleged by the Defendants, as well as to amend two of their other issues. The Defendants also sought to amend their Defence and Counterclaim and Statement of Opposition. The Claimants consented to this on 7 December 2021.

47.

On 22 October 2021, the Defendants' application for a stay of the claim regarding EP443 pending final determination of the validity of EP443 in opposition proceedings before the EPO was heard by Mr Ian Karet sitting as a Deputy Judge of the High Court. On 29 October 2021 judgment was handed down by Mr Karet, refusing the Defendants' application; the order recording this dismissal was made on 1 November 2021.

#### **TEVA**

48.

I have explained that this trial was expedited because of Neurim's desire to get an effective injunction before expiry of the Divisional. At an earlier stage in the 2020 Action it failed before Marcus Smith J and in the Court of Appeal to get an interim injunction against Mylan based on the Patent. Neurim has said that it will try again based on the Divisional if sufficiently successful before me.

49.

Another generic company, Teva, has also indicated an intention to enter the market. Neurim has sued Teva but no defence had been filed at the time of the hearing before me. It is unclear whether Teva is actually selling product in the UK yet, although it seems to have made fairly advanced preparations. Neurim has brought proceedings in Israel which may hinder or prevent Teva's ability to enter the UK market, it was argued. Neurim has said that it will seek an interim injunction against Teva if necessary.

50.

The situation with Teva forms an important part of the commercial picture. It seemed to me at one stage that it might possibly be relevant to the special circumstances exception to issue estoppel, if Neurim was going to have to fight the validity of the Divisional in any event. But I accept Neurim's argument that it is uncertain whether Teva will enter the market at all, and the question of issue estoppel is primarily one between the parties. So I will say no more about Teva and simply include this short explanation to give context.

#### **AREAS OF FACTUAL DISPUTE/WHERE MORE DETAIL IS NECESSARY**

51.

Against that background, I turn to address areas where more detail is needed.

#### **The nature of the Patent and the Divisional**

52.

The claims of the Patent were second medical use claims directed (I paraphrase) to the use of melatonin for the treatment of insomnia characterised by non-restorative sleep. Amendments limited the dosage to a narrower range than that originally granted, and the use was limited to patients over 55, but the details of this do not really matter.

53.

Non-restorative sleep refers to the situation where a patient spends time asleep but does not feel refreshed. It is therefore distinct from not being able to get to sleep, having trouble maintaining sleep, or getting to sleep but waking up too early.

#### **The attacks on the Patent and the Divisional**

54.



In the 2020 Action at the trial before Marcus Smith J, Mylan attacked the Patent on various grounds. The relevant ones to mention are:

i)

Obviousness over various citations. This failed and Mylan does not seek to run it in this action.

ii)

Anticipation over Haimov. This also failed. Mylan does seek to run it in this action, but only, as was explained to me by Mr Acland, for the limited purpose of holding Neurim to a narrow construction of the claims where effective treatment of specifically insomnia characterised by non-restorative sleep is actually required. I do not think Neurim has any intention of advancing any different construction and so there is no real significance to this attack in these proceedings. It was, however, the attack which succeeded in the OD.

iii)

Various insufficiencies, including uncertainty insufficiency (not pursued in this action) and lack of plausibility insufficiency. They failed. I explain next one of the lack of plausibility insufficiencies, which is central to the issues at this trial and was referred to as the “**lay-patient**” argument. This is the key argument that Mylan wants to pursue.

### **The lay-patient argument**

55.

It is necessary to try to encapsulate this argument for the purposes of my judgment, but since the argument has been articulated at some length and in multiple contexts (before Marcus Smith J, at the TBA, for this trial) it is not possible to capture all possible nuances in a few sentences.

56.

As I understand it, however, the central points of the argument by Mylan are that:

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.

57.

Neurim has a number of responses to this, but a critical one is on the facts. Neurim says that as a matter of common general knowledge, in situations such as those described in Examples 2 and 3,

there was a sufficient interchange between clinician and patient to ensure that the patients responded in terms which at least covered and elucidated the restorative quality of their sleep.

58.

The argument spans a number of legal issues including interpretation of Examples 2 and 3, interpretation of the questionnaires given to patients, common general knowledge as it related to clinical trials in this field and to the different kinds of insomnia, and the nature of the skilled addressee.

59.

I am asked by the parties to assess whether the argument was run before Marcus Smith J, whether it was the same as the argument that prevailed in the TBA, and when it was raised with the TBA.

### **Was the lay-patient argument run before Marcus Smith J?**

60.

This is not a decisive question since the parties agree that issue estoppel can bar the re-running both of points that were run and points that could have been run. Nonetheless, I think I should address it.

61.

My view is that the argument or at least something very similar to it was run, but was not articulated very clearly. I base this conclusion on Mylan's written arguments at the trial, the written evidence of Mylan's expert, parts of the cross-examination as referred to in Annex A to Mylan's skeleton for this trial, and the Main Judgment (at [104] to [116] and in particular [112(1)-(3)] and [115]).

62.

It is notable that Mylan does not put forward any specific pleading from the 2020 Action setting out the argument in the sort of detail that I have given above; it seems to have been developed under a more general umbrella of lack of plausibility. It seems that there remained real doubt about what precisely the argument had been at the hearing on 16 December 2020 when Mylan sought, and was refused, permission to appeal. Such note as there is of the hearing says that Marcus Smith J refused permission to appeal on the basis that the patient and clinician would be "speaking as part of the same experiment" (Marcus Smith J understandably decided not to approve the transcript of his ex tempore judgment on permission to appeal in view of his later revocation of the 16 December Orders, and explained to the parties why he was taking that course).

63.

I note at this stage that one element of the reasons why the argument failed was that Marcus Smith J assessed Mylan's expert Prof Morgan as having been very poor. Mylan's response as I understand it is that the point would nevertheless have prospects of success on appeal because, among other things, Marcus Smith J wrongly treated the point as one of the textual interpretation of the Patent and the questions posed to the patients, and not one of fact.

### **Events at the TBA**

64.

In the Consequential Judgment Marcus Smith J expressed a concern about delving in to the facts concerning events at the TBA on limited evidence and when some aspects of Neurim's behaviour could not be assessed without its waiving privilege. Those limitations are not relevant to me as matters have developed procedurally since.

65.

It is common ground that the lay-patient argument was not run before the OD, which revoked the Patent as anticipated by Haimov. There is a dispute however as to when the lay-patient argument was introduced in the appeal proceedings.

66.

It was in relation to events at the TBA hearing (which was conducted in a hybrid form using video technology) and the run up to them that Mr Inman gave evidence. I thought he was a fair and honest witness, although allowance must be made for the fact he is one of Neurim's legal representatives and for understandable reasons did not always distinguish between the primary facts and his client's position. He lapsed into advocacy on some occasions as a result, but this was excusable and understandable and while I have taken account of it I do not doubt what he said about the facts, and the state of mind of Neurim and its advisers at the relevant times.

67.

In my view it is clear that the lay-patient argument was introduced in Mylan's filing of 29 September 2020, at section 8.1. That included all the elements I have set out above. It also referred to and relied on the evidence of Mylan's expert for the UK proceedings, Prof Morgan, and Neurim stresses that one passage relied on was one specifically deprecated by Marcus Smith J in his judgment ([112(3)] and footnote 140).

68.

Based on the evidence of Mr Inman and on Neurim's subsequent filings with the TBA (especially the former) I find that Neurim thought the lay-patient argument was weak and unlikely to succeed (in part, Mr Inman said that Neurim was confident on sufficiency because there had been an earlier successful appeal from the Examining Division to the TBA on it during prosecution, but it did not cover the lay-patient argument). This assessment seems to have led to Neurim not taking all the steps to meet it that would have been possible. At this stage, Neurim chose not to respond at all.

69.

On 27 November 2020 the TBA issued its preliminary opinion in advance of the hearing. Preliminary opinions of this kind vary; some just identify the key points for discussion while others give specific statements of the Board's preliminary view of the correct answer and result. It is a spectrum. In this case, the opinion was more towards the points-for-discussion end of the spectrum, although plainly sceptical about the merits of the Haimov anticipation argument (at 6.8). Paragraph 7.1.1 encapsulates the lay-patient argument neatly and reinforces my view that Mylan had indeed raised it in its September filing.

70.

Mylan put in further submissions on 14 December 2020 reinforcing the lay-patient argument. The opportunity to make one last round of submissions in response to the preliminary opinion is commonly taken in the EPO and in the present case an additional reason for doing so was that Neurim had filed the Main Judgment on 7 December, relying on Marcus Smith J's criticisms of Mylan's expert Prof Morgan.

71.

Neurim submits that Mylan's 14 December 2020 filing was the first time that the lay-patient argument was made to the TBA. I reject that for reasons already given. The argument was made by Mylan in September and then summarised by the TBA in the preliminary opinion in November.

72.

The TBA hearing then took place over 17 and 18 December 2020. I need not go into all that transpired, but key points are that the TBA allowed Mylan to run the lay-patient argument but refused to allow Neurim to put in two documents, referred to as D19 and D20, to meet the argument. D19 was the EMA Assessment Report for Circadin and D20 was the SmPC for it. Each was in evidence in the proceedings before Marcus Smith J and each is said by Neurim (as I understand it) to show a cooperation between clinician and patient, and that patients understood that they were supposed to report whether their sleep was restorative, which of course if true would help Neurim on the facts underlying the lay-patient argument. I note that Mylan says that neither was used for that purpose before Marcus Smith J, however, and that their inclusion in the trial was incidental.

73.

The TBA also allowed in the Main Judgment, but not for the purpose of substantiating facts or as evidence in its own right.

74.

Before me at the trial, Mr Waugh for Neurim made extensive complaints about the way Neurim was treated by the TBA. He made clear, when I asked, that he was not submitting as a matter of law that I had jurisdiction to review the TBA's decision (Lenzing AG's Patent, [1997] RPC 245). He was however equivocal about whether it was part of Neurim's case that the TBA was wrong in its application of the procedures of the EPO, and as I understand his submissions they finally settled on the proposition that while it was accepted that the TBA had jurisdiction to do what it did, Neurim's representatives were objectively reasonable in forming the view that they were not getting a fair hearing, and in acting the way that they did. I do not find this satisfactory since holding that Neurim's representatives had an objectively reasonable view that the TBA was acting unfairly is close to a disguised way of asking me to conclude that it was wrong.

75.

On the second day of the hearing the TBA announced its decisions mentioned above, and that it considered the Patent was insufficient in the light of the lay-patient argument. Neurim's representatives took the decision to withdraw the appeal. This had the effect that the OD's decision was left in place. Formalistically, this meant that the Patent was revoked for lack of novelty over Haimov, but in substance the real cause was insufficiency based on the lay-patient argument.

76.

On the evidence, I find that Neurim made the decision to withdraw the appeal for two closely related reasons:

i)

**Timing:** if the appeal were not withdrawn then in practical terms the Examining Division would not proceed with the application for the Divisional until it saw the TBA's reasons, which could take some weeks or months. Withdrawing the appeal meant that there would be no reasons from the TBA.

ii)

**No reasons:** if the TBA gave reasons supporting the finding of insufficiency their substance might adversely affect the prosecution of the application for the Divisional. Neurim wanted to avoid this. This was referred to in argument at trial as "contamination".

77.

In any event, the appeal was withdrawn and no reasons were given. I find that the EPO allows the withdrawal of appeals and its procedures encourage withdrawal by giving a partial refund of the appeal fee (Rule 103(4)(a) of the EPC as amended in 2019, coming into force in April 2020). The purpose of that procedure, I find, is to incentivise appellants to withdraw their appeals even at a late stage and to try thereby to reduce the burden on the TBA of writing reasons.

78.

While one can understand the strategic benefit to Neurim of withdrawing the appeal, it is frustrating not to have the TBA's reasons, as it could be useful to know whether they hinged on a factual question which would be answered by different evidence such as was before Marcus Smith J, or were more fundamental. They might also have made clear whether D19 and D20 were excluded for lateness, or because the TBA thought they could not help.

79.

I also find it unattractive for Neurim to argue or hint that it did not get a fair hearing when it itself forestalled the TBA's giving reasons for allowing the lay-patient argument to be run and for refusing the admission of D19 and D20 (TBA reasons usually or at least frequently, in my experience, cover procedural decisions such as this, in addition to the substantive questions).

80.

As I have said, I do not have the jurisdiction to review what the TBA did, but in the light of the way Neurim has advanced its arguments, and after careful consideration as to whether I should enter into the matter at all, I make the following comments, without attempting to assess whether the TBA was actually right or wrong:

i)

I have already said that the lay-patient argument was advanced by Mylan in September 2020.

ii)

Neurim had an opportunity to respond to that and I have no doubt that if it had filed D19 and D20 promptly in response to Mylan's September filing then they would have been admitted.

iii)

The most likely reasons for the TBA's refusal to allow in D19 and D20 are simply that Neurim's putting them in on the day of the appeal was late and untimely given that the lay-patient argument had been in issue for some months, and the TBA considered it did not have an adequate opportunity to consider them. It is not possible to know this for sure because of the absence of reasons to which I have referred already and which Neurim has caused.

iv)

The TBA regards itself as a specialist tribunal which makes its own decisions about scientific/technical matters. It is therefore not surprising that it allowed in the Main Judgment for limited purposes only. It may well, for the same reasons, not have been attracted to deciding the issues before it on the basis of e.g. what the parties' UK expert reports said, or how Marcus Smith J assessed oral evidence that the TBA did not see.

v)

Likewise, Neurim's especially vehement complaint that the TBA ought not to have given any weight to the evidence of Prof Morgan in the light of the Main Judgment assumes that the TBA did give weight

to it. It is unknown whether it did so, as it may have relied on its own ability to assess technical matters.

81.

I do not doubt that Neurim's representatives in fact and subjectively felt aggrieved as a result of the TBA's decisions, but I do not accept any submission that they had objectively grounded reasons for thinking they had not had a fair hearing. At the end of the day though these were all just jury, prejudice points by Neurim, and a waste of substantial amount of time at trial, since I was not asked to found my decision as to issue estoppel on the quality of the TBA's decision making.

### **Events in the proceedings before Marcus Smith J**

82.

I also need to go further into events before Marcus Smith J at this time.

83.

I have referred to the hearing on 16 December 2020. At that hearing, which was brought on with urgency because Neurim wanted an injunction, it is common ground, Marcus Smith J made oral Orders (recorded by him in the Consequential Judgment at [36(4)]) as follows:

i)

A declaration of validity of the Patent.

ii)

A declaration that Flynn was not an exclusive licensee.

iii)

A certificate of contested validity under s. 65 of the Patents Act 1977.

iv)

A dismissal of Mylan's counterclaim for revocation.

v)

Permission to amend the Patent.

vi)

An injunction.

vii)

An Order for delivery up.

viii)

An inquiry as to damages or account of profits.

ix)

Giving Neurim its costs subject to a deduction in relation to the exclusive licensee point.

x)

Giving permission to appeal to Neurim on the exclusive licence point but refusing it to Mylan on validity.

xi)

An Order as to confidentiality under CPR 31.22.

84.

These were, it is not disputed, Orders and expressed by the judge to be so. They were, however, not reduced to writing because, regrettably, the parties failed to agree the wording. The following matters are particularly relevant:

i)

The injunction granted was framed so as not to have effect until 18 December 2020 (the anticipated end of the TBA hearing), with limited undertakings until then, and also so as to lapse if Neurim's appeal failed.

ii)

The delivery up provisions did not have any "sunset" provision of this kind.

85.

On 30 December 2020, Marcus Smith J made his written Order, with included reasons, revoking all of the 16 December 2020 Orders except for (which is not relevant to my decision) the provisions concerning confidentiality under CPR 31.22. So that included the delivery up provisions, the refusal of permission to Mylan to appeal, and costs. The 30 December Order expressly provided for permission for an application to be made in due course for the re-making of like Orders.

86.

There was then the further consequential hearing in February 2021 leading to the Consequentials Judgment of March 12 2021. I think that Judgment is important to what I have to decide. In it, Marcus Smith J reasoned that:

i)

The TBA decision "trumped" the Main Judgment.

ii)

He was right to revoke the 16 December 2020 Orders, under either CPR 3.1(7) or the Barrell jurisdiction.

iii)

That the 16 December 2020 Orders were made in the anticipation that they might need to be reviewed, revoked or altered if Neurim lost its TBA appeal.

iv)

That Mylan could not appeal the findings in the Main Judgment because they were the winners and "orders not judgments are appealed", citing Note 52.0.6 in the 2020 Edition of the CPR ([55]). Marcus Smith J had foreshadowed that analysis in a detailed email to the parties of 15 February 2021, which is also where he explained why he did not intend to approve the transcript of his rulings of 16 December 2020.

v)

That Flynn should not have permission to appeal on the exclusive licence point.

vi)

That Neurim should pay the costs.

87.

Neurim's submissions to me, particularly in its written submissions after trial, were to the effect that Marcus Smith J was wrong in some of that reasoning. Neurim submitted he was wrong to revoke the

16 December 2020 Orders, that the 16 December 2020 Orders did not need to be reviewed or revoked following the TBA decision because on their own terms they fell away when the Patent was revoked, and that Marcus Smith J was wrong about Mylan's ability to appeal.

88.

As to last of those points, I do agree that Marcus Smith J heard only limited argument about whether Mylan could appeal, and it was not central to his reasoning or the result (though it is clear that he was made aware of Floyd LJ's treatment of Lilly v Genentech, which I address below). Since it is now of critical importance to the issues facing me I think it is appropriate to consider it again, although in the event I agree with Marcus Smith J's view. By contrast, his decisions as to whether to revoke the 16 December 2020 Orders and whether those Orders were made in the anticipation that they might have to be reviewed were central to what he was doing and intimately connected with his own management of the proceedings before him. In addition, what he did was based on his own appreciation of events on 16 December 2020 and the Orders he made, which were not put into writing. In those circumstances I would only depart from what he decided if there were very strong reasons to think he was wrong, and/or there was something material not drawn to his attention. I do not think either applies.

89.

I note that Neurim has been given permission to appeal against two aspects of Marcus Smith J's decisions of 30 December 2020 and/or 12 March 2021, by Arnold LJ on 13 October 2021. One is whether Flynn could appeal on the exclusive licence point. In the Consequentials Judgment, Marcus Smith J refused permission, not because of the merits of the underlying argument, which he thought was arguable and had led to him giving permission on 16 December 2020, but because he thought it had become academic with the revocation of the Patent. Arnold LJ decided that the question of whether the point was academic was arguable. The second is whether Neurim should pay the costs of the 2020 Action (on which Marcus Smith J reversed the decision of 16 December 2020), and part of Neurim's argument on that is that Marcus Smith J should not have revoked his Orders of 16 December 2020; again Arnold LJ gave permission. I was not shown the materials on this in detail and I do not know if Neurim is to argue that Marcus Smith J was wrong to revoke all the Orders of 16 December 2020, or whether its contentions focus solely on the costs Order.

90.

Neurim effectively relied on the giving of permission to say that Marcus Smith J was indeed wrong. Of course this does not follow – it just means that the Court of Appeal thought the appeals are sufficiently arguable to be allowed to proceed. I remain of the view expressed above that I should proceed on the basis that Marcus Smith J was right on these points.

91.

Neurim also relies on the fact that it raised, at the February 2021 hearing leading to the Consequentials Judgment, the notion that it should be allowed to appeal the decision on the exclusive licence point given the possibility of an issue estoppel for the future. Neurim says, as I understand it, that this put Mylan on notice of the issue estoppel point. I do not think there is anything in this. It is just something that Neurim argued and that Marcus Smith J rejected, and in any event Neurim's position on the exclusive licence point was different from that of Mylan on validity. Neurim had by any reckoning lost on that point, and the issue was a different one, relating to the legal effect of a contract, not patent validity where the TBA's decision was paramount. Mylan took the position that it could not appeal, and Marcus Smith J accepted that. Also, I do not believe that Neurim said that



Mylan would be estopped on validity if it did not appeal; so far as I can tell Neurim did not even challenge Mylan's position that it (Mylan) could not appeal.

## **PRACTICAL MATTERS AND THE REAL JUSTICE OF THE SITUATION**

92.

The parties have very different concerns about this new action.

93.

Mylan's key concern, as it emerged at this trial, is that it would be unjust if, having won at the TBA, Neurim's litigation strategy in withdrawing its EPO appeal, suing on the Divisional with claims amended to be identical in substance to the Patent, and then relying on issue estoppel, meant that it, Mylan, never had a full chance to ask for permission to appeal on the lay-patient argument.

94.

As is explored below, I do not think that Mylan could in the end have sought to appeal the eventual result on the Patent, because it ultimately won (it sought and was refused permission to appeal on 16 December 2020, prior to the TBA decision, but Marcus Smith J revoked that part of his Order). Yet the fact that the TBA accepted the lay-patient argument suggests that there could at least be something to consider on permission to appeal, albeit that it might be concluded that the facts as found in the UK mean that the argument must fail despite its success, on different evidence, before the TBA. So there is much to be said for the view that it would be unjust not to at least permit Mylan to ask for permission, if there are procedural means to achieve that.

95.

On the other hand, Neurim's concern is that if there is no issue estoppel, Mylan would be able to, and would, insist on a further, full trial with attendant delay, taking resolution of the UK litigation past the expiry of the Divisional and meaning that there could never be a meaningful final injunction.

96.

This too is a reasonable concern, but it assumes that if there is no issue estoppel there must be a further, full trial. That does not follow in my view, and I asked Mr Acland during oral submissions on the first day of trial if a full trial is what Mylan envisaged. It seemed to me that it would make little sense and be contrary to the overriding objective to follow that course, and that I would have the power, if I rejected the issue estoppel arguments, to case manage this action by directing that it be tried only on the materials and arguments before Marcus Smith J, and/or by adopting his treatment of the issues in the Main Judgment and the conclusions in it, and by making appropriate case management Orders, so that it could be ensured that Mylan could at least seek permission to appeal on the lay-patient argument in a short time from now (another way to achieve the same result might have been to give Mylan permission to seek permission to appeal from the Court of Appeal out of time in the 2020 Action, but the parties agreed that I did not have power to do that). I also referred in my draft judgment to the possibility of refusing Mylan permission to appeal without further consideration, on the basis that that is what Marcus Smith J concluded on 16 December 2020, and leaving it to seek permission from the Court of Appeal.

97.

I think this sort of approach would accord with the overriding objective in that it would allow the case to be dealt with justly and at proportionate expense (CPR 1.1), by saving the expense of a further trial (CPR 1.2(b)), ensuring a fair and expeditious determination (CPR 1.2(d)), and giving the dispute an appropriate share of the Patent Court's resources, given that there has already been one trial of the

issues and the lists are busy (CPR 1.2(e)). It is admittedly an uncommon approach to case management, but it is in response to an uncommon situation.

98.

After considering the matter overnight, Mr Acland addressed me on this on the second day of the trial. I understood him, pragmatically, to agree that I would have the power to proceed in such a way and that it would address the key injustice of which Mylan was complaining, i.e. the lack of a chance to ask for permission to appeal. He suggested that such case management ought to be considered along with the Teva proceedings, but I do not agree that that is necessary or appropriate. From the competition perspective, Mr Piccinin similarly accepted that with that kind of case management there would not be any ongoing abusive effect (although he contended that Neurim's conduct to date had already constituted an abuse, and I address that below).

99.

For Neurim, Mr Waugh accepted that such a course would not be unjust and did not submit that it was beyond my powers. He raised a proviso that there would have to be an injunction pending Mylan seeking permission to appeal, or any appeal. In my view, it is obviously right that Neurim could seek an injunction, but it is not right for it to impose that as a condition on such case management, which after all gives it (Neurim) the maximum it could hope for if its issue estoppel arguments fail, and avoids its key anxiety of a further trial.

100.

In my view there is an obvious overall justice in such a solution. In my draft judgment I said that I was in fact going to do it, and it is to that that Mylan objected in its submissions on the draft judgment; I deal with it under "Case Management", below. But it would not be open me to impose it if Neurim were right about issue estoppel, since then there would be no second trial to manage, so I have to decide that. At the same time, the availability of this case management approach might be relevant to special circumstances under the law of issue estoppel.

## **ISSUE ESTOPPEL**

101.

On this issue I will identify the points of law that are common ground, then address those which are disputed, and then apply them to the facts. Lastly I will touch on the special circumstances exception to issue estoppel, although it is not necessary to my conclusion as I think there is no issue estoppel.

### **Main legal principles not in dispute**

102.

The following basic principles of issue estoppel were not in dispute:

i)

Issue estoppel arises where there is a decision on an issue in a cause of action as an essential step in the reasoning (Spencer Bower and Handley Res Judicata, 5<sup>th</sup> Ed 2019 ("**Spencer Bower**"), 8.01).

ii)

Issue estoppel can also arise in relation to issues which were not raised in an earlier proceeding, but could and should have been (Spencer Bower, 8.11). It is necessary that if raised and decided, the issue would have been essential.

iii)

The determination of the decision must have been fundamental, not collateral (Spencer Bower, 8.23).

iv)

The effect of issue estoppel is subject to an exception for special circumstances, if fresh material comes to light, because the doctrine is intended to do justice and might not do so in such circumstances (Spencer Bower, 8.31, citing *Arnold v NatWest Bank* [1991] 2 AC 93 at 109).

103.

The areas of disagreement focused on the proper approach to be taken to situations where an estoppel is alleged against the “winner” of the earlier litigation, especially if they could not appeal.

### **Disputed legal principles - appealability and “winner’s appeals”**

104.

Spencer Bower says the following at 8.24 and 8.25:

#### **IDENTIFYING THE FUNDAMENTAL**

##### **[8.24]**

The difficulty<sup>1</sup>, said Dixon J<sup>2</sup>:

"is to distinguish the matters fundamental or cardinal to the prior decision or judgment, or necessarily involved in it as its legal justification or foundation, from matters which, even though actually raised and decided as being in the circumstances of the case the determining considerations, yet are not in point of law the essential foundation or groundwork of the judgment."

The question is whether the determination was so fundamental that the decision cannot stand without it<sup>3</sup>. Dixon J says that there is a further test viz: 'Whether the determination is the 'immediate foundation' of the decision or 'no more than part of the reasoning supporting the conclusion'.

1 This paragraph in the 2nd edn was cited in *Spens v IRC* [1970] 3 All ER 295, [1970] 1 WLR 1173, 1184, *Duhamel v R (No 2)* (1981) 131 DLR (3d) 352, 358 Alta CA; affd [1984] 2 SCR 555, 35 Alta LR (2d) 1 Can SC; *Angle v Minister of National Revenue* (1974) 47 DLR (3d) 544, 556 Can SC; *Re State of Norway's Application (No 2)* [1990] 1 AC 723, 752 [1989] 1 All ER 701 CA; *P&O Nedlloyd BV v Arab Metals Co* [2007] 2 All ER (Comm) 401, [2007] 1 WLR 2288, 2299 CA.

2 *Blair v Curran* (1939) 62 CLR 464, 533.

3 *Re Allsop and Joy's Contract* (1889) 61 LT 213. This may explain *Rowling v Takaro Properties Ltd* [1988] AC 473, 504 where the Board held that, although a decision in judicial review proceedings that a particular fact was an irrelevant consideration 'may' have been *res judicata*, the construction of the legislation was not; *Johnson v Felton* [2006] 3 NZLR 475, 486-487 CA. *Duedu v Yiboe* [1961] 1 WLR 1040 PC does not appear relevant in this context. This passage in the 3rd edn was cited in *Meretz* [2006] EWHC 74 (Ch), [2007] Ch 197, 253.

## NO ESTOPPEL AGAINST SUCCESSFUL PARTY ON ISSUE HE LOST

[8.25]

Another useful test is whether, given a right of appeal, the losing party could effectively appeal against the determination. If there can be no effective appeal against a determination this normally indicates that it was not fundamental. The test is not universally valid because decisions of a court of final appeal and decisions of lower courts from which there is no right of appeal create issue estoppels in the normal way. The ultimate test is whether the determination is such that without it the judgment cannot stand. A decision of fact or law against the party who succeeded<sup>1</sup> or one which was not necessary to the decision will not found an estoppel because it cannot be fundamental to the decision. It would be unjust for such a decision to create an estoppel because the person who failed on that issue cannot effectively appeal against it<sup>2</sup>. An application for production of documents was refused although the court held it had power to make the order. There was no estoppel on this issue because that ruling against the defendant could not be essential to the decision in its favour<sup>3</sup>. Where a claim that a statute was *ultra vires* was rejected, but the plaintiff won on another ground he was not estopped on the constitutional issue because the adverse decision was not necessary to the judgment in his favour<sup>4</sup>.

The same principle applies where the court finds alternative grounds in favour of the successful party. Those findings do not create issue estoppels because the losing party could not effectively appeal against any of them separately<sup>5</sup>, and if one was upheld the appeal would fail<sup>6</sup>. There may be a cause of action estoppel or merger but no issue estoppel because no single finding could be 'legally indispensable to the conclusion' or the 'essential foundation or groundwork of the judgment, decree, or order' as Dixon J said in *Blair v Curran*<sup>7</sup>. Findings not amenable to appeal cannot be corrected under the slip rule<sup>8</sup>.

1 This passage in the 3rd edn was cited in *Sim Life [2005] 1 Lloyd's Rep 606, 621–622 CA*, and is supported by *Midnapur Zamindari Co Ltd v Roy (1920) LR 48 Ind App 49, 55* per Lord Dunedin.

2 *Concha v Concha (1886) 11 App Cas 541, 552* per Lord Herschell LC: '... it would be very strange, if although the finding in the decree as to the testator's domicile could not be appealed from because it was not essential to the decision, nevertheless it conclusively determined that fact against all the world', 554, and per Lord Bramwell at 567.

3 *Penn-Texas Corp v Murat Anstalt (No 2) [1964] 2 QB 647, 660, [1989] 1 All ER 745 CA* per Lord Denning MR: 'One of the tests in seeing whether a matter was necessary to the decision, or only incidental to it, is to ask: Could the party have appealed from it? If he could have appealed, and did not he is bound by it ... if he could not have appealed from it (because it did not affect the order made) then it is only an incidental matter, not essential to the decision, and he is not bound'; *Re State of Norway's Application (No 2) [1990] 1 AC 723, 743, 752, 772 CA*; *Arbuthnot v Chief Executive of the Department of Work and Income [2008] 1 NZLR 13, 27 SC*.

4 *James v Commonwealth (1935) 52 CLR 570, 584* per Rich J: 'Although the Court ruled that he was wrong upon his first ground, he is not estopped, because the decision passed in his favour. He could not appeal from the Court's ruling', and at 590–591 per Dixon J: '... it is true that the question was decided against him. He submitted the contention to the Court which announced an opinion that he was wrong; but that ... was not translated into a decree or order, because upon an independent contention he succeeded. There was no judgment from which he could ... appeal, none which estopped him'.

5 In *The Good Challenger [2003] EWCA Civ 1668, [2004] 1 Lloyd's Rep 67* the court left open the correctness of this proposition; *Meretz [2006] EWHC 74 (Ch), [2007] Ch 197, 253*.

6 *Lake v Lake [1955] 2 All ER 538 CA* (finding of adultery against wife but petition dismissed because of condonation, wife having succeeded could not appeal against finding of adultery); *Cie Noga D'Importation Et D'Exportation SA v Australia & New Zealand Banking Group Ltd (No 3) [2003] 1 WLR 307, 321–322, 328, [2002] All ER (D) 484 (Jul)*; *Talyanchik v Index Developments Ltd [1992] 3 NZLR 28*

*CA*; *Johnson v Felton [2006] 3 NZLR 475, 487 CA*; *Murphy v Abi-Saab (1995) 37 NSWLR 280 NSW SC, 288*; *Arbuthnot v CE Dept of Work [2008] 1 NZLR 13, 25–27 SC*; *Lee v Tang [1997] 3 SLR 459, 498 CA*.

7 *Blair v Curran (1939) 62 CLR 464, 532, 533*; *Re Hawksley's Settlement [1934] Ch 384, 397* (opinion on incidental question not mentioned in order, and no right of appeal); *R v Sillim, The Alexandra (1864) 10 HL Cas 704, 724* per Lord Westbury: 'An appeal is a right of entering a superior Court and invoking its aid and interposition to redress the error of the Court below'; *Commonwealth of Australia v Bank of New South Wales [1950] AC 235, 294*: 'An appeal is the formal proceeding by which an unsuccessful party seeks to have the formal order of a court set aside or varied in his favour by an appellate court'; *Driclad Pty Ltd v Federal Comr of Taxation (1968) 121 CLR 45, 64*. There is no right of appeal against a court's reasons as such: *Caie v A-G [2006] 3 NZLR 289 SC*.

8 *Re A (a child) [2014] EWCA Civ 871, [2014] 1 WLR 4453*.

105.

This makes clear that the question of whether the party alleged to be estopped could effectively appeal is "a useful test" going to the question of whether a determination is fundamental. However, the "ultimate test" remains whether the determination is such that without it the judgment cannot stand. So appealability is important but is not the question that I have to answer as such.

106.

I was taken to some of the cases cited in these passages.

107.

In *Concha v. Concha* (1886) 11 App Cas 541 the Court determined whether a will was valid and in the course of that determination also found that the testator was domiciled in England. The finding as to domicile was not necessary to the determination of validity so there was no appealability and no estoppel: see the quote from Lord Herschell in footnote 2 to 8.26 in *Spencer Bower* above.

108.

In *Penn-Texas Corp v Murat Anstalt (No 2)* [1964] 2 QB 647, an application for production of documents was refused because the relevant power required that the documents be specifically identified and they were not. In other words, the application failed on the facts. But as part of the same decision, the Court had held that it had the necessary jurisdiction. The finding as to jurisdiction could not be appealed because the respondent to the application had won and there was no estoppel: see the quote from Lord Denning at footnote 3 to 8.26.

109.

These cases generally support Mylan's position that if there is no possibility of appeal because the party alleged to be estopped has won there is no estoppel. They are perhaps rather different situations from the case before me because they involve picking out from a number of matters in a single judgment those which are fundamental on the basis of the result and the possibility of appeal, whereas I have to deal with a case where one judgment (the Main Judgment) has been "trumped" by a later event (the TBA decision). But I do not see why that should make any difference, and it is not much more than a quirk of timing resulting in the Main Judgment coming out just before the TBA hearing. Mylan does not dispute that each of the attacks on the Patent was a fundamental issue to the result in the Main Judgment, but says that they were not fundamental to the result once the TBA result was known.

110.

There was a profound disagreement before me about the proper approach to determining when there was a possibility of appeal by a winner, and in particular what it means to appeal a "judgment" or an "order".

111.

The 2021 Edition of the CPR at note 52.0.6 says this:

**"Appeals are against orders, not reasoned judgments**

In a number of cases it has been stated that the function of an appeal court, in particular of the Court of Appeal, is to deal with "judgments", "orders" or "determinations", that is to say, to deal with the "result" or "outcome" (to use non-technical terms) of the hearing in the lower court, and not with "findings" or "reasons" given in the judgment; see e.g. *Compagnie Noga d'Importation et d'Exportation SA v Australia and New Zealand Banking Group Ltd (No.3)* [2002] EWCA Civ 1142; [2003] 1 W.L.R. 307, CA; *Morina v Secretary of State for Work and Pensions* [2007] EWCA Civ 749; [2007] 1 W.L.R. 3033, CA, at para. 6 per Maurice Kay LJ. The law in this respect restricts "winner's appeals" and is in part based on the Senior Courts Act 1981 s.16 (Appeals from High Court)."

112.

On the basis of the equivalent passage in the 2020 Edition Marcus Smith J held in the Consequentials Judgment at [55] that Mylan could not appeal on validity. Neurim submit that he misunderstood the position and was not addressed in sufficient depth or detail on the underlying case law.

113.

The key cases and principles can in my view be identified from *Compagnie Noga d'Importation et d'Exportation SA v. Australia and New Zealand Banking Group (No 3)* [2002] EWCA Civ 1142, which is referred to in the CPR in the note quoted above, and which formed the heart of Neurim's submissions on this part of the case.

114.

The facts were rather complicated and related to whether or not a Respondent's Notice was needed. At [1] Waller LJ explained as follows:

"1. This appeal raises an important point in relation to the position of a respondent to an appeal and in particular as to the circumstances where a respondent needs permission to raise points in a respondent's notice. In particular it raises the question whether a judge should grant a declaration in relation to a conclusion to which he had come on the facts (the trial of which had taken up most of the time of the court), albeit he had found despite that conclusion that the respondent should succeed at first instance. In this case Noga (for whom Mr Gee QC appeared both here and below) had sought a declaration that an action had been compromised in return for payment of the sum of \$100 million by the SJ Berwin Defendants (for whom Mr Pollock QC appeared both here and below). Noga also sought a judgment for \$100 million. In considering whether a valid compromise had been reached, a key issue was whether \$100 million had either been agreed or even mentioned, and a further issue was whether if it had, the agreement was only conditional. After a lengthy trial the judge concluded that the \$100 million had both been mentioned and indeed agreed, but also held that the agreement was only conditional, and thus that no valid compromise had been reached. Noga sought to get him to change his mind about the conditional nature of the agreement which the judge refused. He did however give Noga permission to appeal on the conditional aspect. The position of the SJ Berwin defendants was that as respondents they would seek to uphold the judge's conclusion that there was no settlement agreement on the basis that his findings of fact in relation to the \$100 million were wrong, and that no permission to appeal was needed for them to be entitled to confirm his judgment on those grounds in the Court of Appeal. Both parties accepted before the judge that if the form of declaration made by the judge was limited to declaring that "no settlement had been concluded", the SJ Berwin defendants were right. The judge (who it is right to say even at this stage was resistant to the notion the SJ Berwin defendants were right), following a suggestion of Mr Gee inserted as part of the declaration "no settlement", a declaration that he found that the \$100 million had been agreed. On that basis the SJ Berwin defendants accepted that they would now need permission to appeal, and albeit protesting the form of declaration, applied for permission. That permission was refused by the judge, but the judge gave permission to appeal his ruling as to the form of the declaration. This is the appeal from the ruling on the form of order, the reasons for which the judge gave in a written judgment of 23 October 2001 known as Noga 3."

115.

I include this only to provide a better basis for understanding what follows; it is not necessary to my analysis.

116.

At [14]-[15] Waller LJ said:

“14. The submissions in this court were wide ranging, and I hope I shall be forgiven for not summarising them all. In essence Mr Pollock's submission was that up until the introduction of the new rules it had been well recognised that a respondent could either be someone who was cross-appealing because he was seeking to vary the judgment or order of the first instance judge, or a defensive respondent simply saying that he would seek to uphold the decision of the judge at first instance but on grounds different from those of the judge. He submitted that *Lake v Lake* was still good law as to what was an “order” or “judgment” since the statutory provision under consideration in that case relating to the jurisdiction of the Court of Appeal, was in the same terms so far as material today [see section 16(1) of the Supreme Court Act 1981]. It was thus the formal order that the court drew up after the decision in the case which had to be looked at. Thus, without the declaration in the form ultimately made by the judge, the “decision” on the factual issue of \$100 million would not have formed part of the formal judgment or order, and could not be appealed on its own, would not be the subject of a cross-appeal by a respondent, and could simply be challenged by a respondent seeking to defend the formal order of the judge on different grounds.

15. In the light of the decision *In re B* [2000] 1 WLR 790 to which my lady drew the court's attention, Mr Pollock modified his submission as to the degree of formality required. The case under consideration by the Court of Appeal *In re B*, was a County Court case and thus the question was whether certain facts decided on a preliminary basis without being recorded in any formal order were a “determination” within section 77(1) of the County Courts Act 1984. No-one before us suggested that the word “determination” should have a different meaning from “judgment” or “order”. The court held that the findings were a “determination”, and thus that they had jurisdiction to grant permission to appeal and consider whether the judge had reached a correct conclusion. Mr Pollock submitted that even if formality was not required the court's jurisdiction was confined to appeals against what had actually been determined by the court, and did not stretch to having jurisdiction to consider findings of fact however major where the judgment or determination of the court was not itself being challenged.”

117.

I pause here to record that the parties before me were agreed that the jurisdiction of the Court of Appeal to hear appeals is statutory and to be found in s. 16(1) of what is now called the Senior Courts Act 1981. I also note that the Court of Appeal identified that the word “determination”, which is used in the relevant provision concerning appeals from the County Court (s. 77(1) of the County Courts Act 1984) means the same as “judgment or order” in s. 16 of the 1981 Act.

118.

The core of the reasoning relevant to my task appears at [25] to [28]:

“25. Although it was common ground in the court below, and was not pressed hard by Mr Gee ultimately, it is important to start with the position as if the words of the declaration had not been inserted by the judge. It is important in this context to keep in mind the distinction between the jurisdiction of the Court of Appeal to hear an appeal, the jurisdiction of the Court of Appeal to make it a requirement that permission be obtained to bring an appeal, and in that context the jurisdiction of the court to make a challenge by a respondent subject to permission. It is in the context of the court's jurisdiction that one should then examine the rules.

26. The jurisdiction of the Court of Appeal is statutory and its jurisdiction is to “hear and determine appeals from any judgment or order of the High Court” or “any determination of the County Court”.

27. *Lake v Lake* can at first sight be read as an authority about the importance of a “judgment” or “order” being contained in a formal document. But that I think may be by virtue of the way it was argued, and in any event is too restrictive an interpretation. A formal order was made in the then usual form in favour of the wife in matrimonial proceedings, but the Commissioner in his reasoned judgment, and by virtue of questions asked of him at the conclusion of the proceedings, had found that the wife had committed adultery. In the Court of Appeal, counsel sought to get an amendment to the formal order; that was rejected. Counsel then sought to argue that even without something in the formal order he should be allowed to appeal the finding of adultery. The appeal was rejected by the Master of the Rolls, at least as the first ground, on the basis that the formal order “records accurately the conclusion which, in the end of all, the commissioner reached” [342] and on the ground that even if successful there was nothing in the formal order that would be varied [343]. Hodson LJ's initial reasoning appears to me to be the same. It is true that in the Master of the Rolls' judgment and in Hodson LJ's judgment some reliance is placed by them on the order or judgment being the “formal order” but that is as compared (I suggest) with the “reasons for it”. It is difficult to think that there simply could be no appeal without a formal order. Many appeals are brought on the basis of an order made by a judge prior to the formal document being drawn up, and *In re B* demonstrates that the correct reading of *Lake v Lake* is not that some formal document recording the order must exist. *Lake v Lake* properly understood means that if the decision when properly analysed and if it were to be recorded in a formal order would be one that the appellant would not be seeking to challenge or vary, then there is no jurisdiction to entertain an appeal. That is in my view consistent with *In re B*. That this is so is not simply by virtue of interpretation of the words “judgment” or “order”, but as much to do with the fact that the court only has jurisdiction to entertain “an appeal”. A loser in relation to a “judgment” or “order” or “determination” has to be appealing if the court is to have any jurisdiction at all. Thus if the decision of the court on the issue it has to try (or the judgment or order of the court in relation to the issue it has to try) is one which a party does not wish to challenge in the result, it is not open to that party to challenge a finding of fact simply because it is not one he or she does not like.

28. The decision on a preliminary issue will be a judgment or order even if it is limited to a finding of fact. There is no difficulty where the only issue to be decided at a preliminary stage is one of fact. It is that issue on which the court has been asked to pronounce a judgment and, even if the court exercises its power to give judgment against a party on the whole of the case, since that was the issue the court was asked to determine, and since it is that issue on which the whole case ultimately turns, it will be the determination of that issue which will be the relevant judgment or determination so far as jurisdiction is concerned. *In Re B* is a good example of a decision on preliminary issues of fact. Furthermore the case having been adjourned, and the facts making a difference as to what might flow from the adjournment, the facts in Mr Pollock's words were pregnant with legal consequences. If however in that case the court had gone on to make a decision in relation to the legal consequences which one party would not seek to challenge, in my view that party would not be entitled simply to appeal the findings because it did not like the reasons for the decision in his or her favour. It is in that context that it might be appropriate for the court at first instance to consider whether some declaration should be granted to provide a “judgment” or “order” or “determination” which could be the subject of an appeal. If for example the findings of fact might be relevant to some other proceedings, (and Mr Pollock accepted this), it might be appropriate to make a declaration so as to enable a party to challenge those findings and not find him or herself prejudiced by them. The findings would still be pregnant with legal consequences. It is to go beyond the scope of this judgment to consider precisely what circumstances might allow for the granting of a declaration where findings of fact might affect other proceedings. If an issue estoppel might arise that I suppose might provide a



basis. Even in *Lake v Lake* it might at least through the modern eyes relating to declarations have been appropriate to grant a declaration even though issue estoppel did not apply in that context [see the judgments of the Master of the Rolls and Hodson LJ at 345 and 347]. The fact that there may be circumstances shows the breadth of the discretion that the court has in relation to granting declarations, but the circumstances envisaged are not the circumstances that are suggested as allowing the court to make the form of declaration that Rix LJ did in this case.”

119.

Neurim submits that *Noga* shows that the matter is not a formalistic one, in the sense that there does not have to be a written order before the Court of Appeal can have jurisdiction to hear an appeal. I agree with this; *In re B* makes that clear, as Waller LJ expressly pointed out in [27], just after he made the broader statement that many appeals are brought before a formal document is drawn up.

120.

At the oral hearing of this trial I had understood Mylan to argue that there did have to be a written or at least distinct and formal order for the Court of Appeal to have jurisdiction, and a judgment would not do. I would reject this on the basis of *Noga* for the reasons just given. The argument also seemed to face the difficulty that s. 16 of the 1981 Act refers to “a judgment or order” of the High Court. I thought that Mylan’s argument, which I have to say I did not find very clear, was that “judgment” and “order” meant the same thing, which would make the provision tautologous. In submissions made after I provided this judgment in draft, Mylan clarified and expanded what it was saying, by way of further reference to paragraph 40.1.1 of the CPR and the history of the RSC and CCR. I now understand its submission to be that “judgment” and “order” are two words from different procedural and historical contexts, but each connoting a final decision. Its point was that as used in s. 16 “judgment” means a final decision, but in the CPR it may sometimes mean the reasons for the decision as opposed to the decision itself. I am content to deal with this expansion of Mylan’s submissions but it does not affect my conclusion that there does not have to be a written order for there to be jurisdiction to hear an appeal from the High Court. I have spelt this point out in more detail in the light of Mylan’s submissions on my draft judgment simply because Mylan attached such importance to it. The expansion does not affect my overall reasoning and has no interaction with the modifications to my draft judgment on case management and the issues canvassed at the oral hearing on 19 January 2022.

121.

In any event, the more important part of the reasoning in *Noga* for my purposes is in my view to be found in the last three sentences of [27] quoted above. For there to be an appeal a loser has to be seeking to challenge a result. If that is not the case, a party cannot challenge a finding because they do not like it.

122.

That being so, I think Note 52.0.6 accurately captures the position and I find the terms “result” and “outcome”, to be contrasted with “findings” or “reasons”, to be helpful, and indeed more so than “judgment”. I appreciate of course that “judgment” is one of the words in the relevant statutory provision, but if used loosely it may be rather ambiguous as to whether reference is being made to the reasons in a judgment, or to the outcome of it.

123.

I was referred to a number of other cases on this topic.

124.

In *Secretary of State for Work and Pensions v. Morina* [2007] EWCA Civ 749 the Secretary of State won an appeal on the merits, but the social security commissioner also found that he had jurisdiction to hear the appeal. The commissioner refused permission to the Secretary of State to appeal on the jurisdiction issue, because he was the winning party.

125.

At [6] Maurice Kay LJ said:

“6. Although we have received no submissions discouraging us from hearing these appeals, it is common ground that our entitlement to do so is not beyond dispute and requires resolution. This is because of the traditional reluctance to permit an appeal at the behest of a litigant who succeeded below and who seeks to take issue with the reasoning of the decision rather than with its outcome.”

126.

But he went on to point out that the Court of Appeal’s power to hear appeals from the commissioner arose not under s. 16 of the 1981 Act but under s. 15 of the Social Security Act 1988 which was broader and allowed an appeal against any “decision” of a commissioner.

127.

CPR Note 52.0.6 cites [6] of *Morina* along with *Noga* for the general proposition that the Court of Appeal deals with judgments, order and determinations in the sense of results and outcomes rather than findings or reasons. While [6] of *Morina* supports that, the case is really about the special situation created by s. 15 of the 1988 Act. In my view there is a degree of understatement in the formulation in [6] (if taken in isolation) that there is only a “traditional reluctance” on the part of the Court of Appeal to hear appeals by winners merely against reasons, and this is clear from [7] where by reference to *Lake v. Lake* Maurice Kay LJ recognised that it is actually a matter going to jurisdiction under s. 16 of the 1981 Act.

128.

*Secretary of State v. Morina* was referred to by Floyd LJ in his reasoned order in *Lilly v. Genentech* in circumstances that I describe in more detail below.

129.

In *Iraqi Civilians v. Ministry of Defence* [2018] EWHC 690 (QB), Leggatt J, as he then was, said the following at [30]-[32]:

“30. On 14 December 2017 I handed down a long judgment giving the reasons for my decisions in the four cases which have been tried as lead cases in this litigation. On the same day an order was made in terms agreed between the parties recording the decisions. In each case judgment was entered for the claimant for a sum of damages. The claimants have not applied for permission to appeal from any of the decisions, nor has the defendant. However, the defendant has applied for permission to appeal from certain conclusions reached in the judgment about the application of the doctrine known as Crown act of state.

31. I mean no discourtesy to the defendant's representatives in expressing my view that this application suffers from a fundamental flaw. Under section 16 of the Senior Courts Act 1981, the Court of Appeal has jurisdiction to hear and determine appeals from any judgment or order of the High Court. However, the defendant is not seeking to appeal from the court's judgment or order in these cases. The term "judgment" in section 16 refers to a final order made by the court after a trial and not to a judgment in the wider sense of a document which gives the reasons for the court's order.

32. The defendant recognises that, if the conclusions on the question of Crown act of state which it wishes to challenge were found to be wrong, that would have no effect on the judgment or order of the court in any of the four cases. That is because Crown act of state was relied on by the defendant as a defence to the claims made by the claimants in tort, and those claims were all entirely defeated in any event, as they were held to be time barred. The claims on which each claimant succeeded and obtained a judgment for damages were claims under the Human Rights Act, to which it is common ground that the doctrine of Crown act of state does not apply. As the appeal which the defendant seeks permission to bring is therefore not an appeal from any judgment or order of the court, the Court of Appeal would have no jurisdiction to hear it.”

130.

This is a conventional approach based on the principles referred to above: the tort claims all failed in any case because they were time-barred, so the Crown act of state point did not matter to the result on them one way or another, while the Human Rights Act claims that succeeded could never be met by Crown act of state. So the Crown act of state point could not affect the result and could not be appealed. That supports Mylan’s overall position.

131.

The last sentence of [31] was relied on by Mylan in support of its argument that “judgment” in s. 16 of the 1981 Act means “order”, but that is not a fair treatment of the sentence and is simply an attempt to exploit the ambiguity in the word “judgment” to which I refer above. The judge was clearly distinguishing the result in a judgment from the reasons that it contains.

132.

I was also referred by Mylan to *Thomas v. Luv One* [2021] EWCA Civ 732. It was a case on complex facts that it is unnecessary to set out and that was mainly about the two ratio problem in relation to identifying fundamental issues that also arose in *Lilly v. Genentech* (see below). The Court of Appeal held that it was doubtful whether there was an estoppel, but that even if there was, there were special circumstances, including the non-availability of an appeal against one of the two ratios, which would enable the party alleged to be estopped to take the point in question. See [39], [51] and [75] in particular. The decision is consistent with Mylan’s position and may offer some slight support for it but the non-appealability point was not the subject of much argument, and was only one point in a section on special circumstances which I think was obiter.

#### Lilly v. Genentech

133.

In *Lilly v. Genentech* [2020] EWHC 261 (Pat) a factually somewhat similar situation to the present one arose. After a long and extremely complex earlier trial, Arnold J (as he then was) had held that the patent in suit before him (called the “822” patent), owned by Genentech, was invalid for a number of reasons, but would have been infringed by Lilly if valid. He gave permission to appeal and an appeal was initiated by Genentech.

134.

However, the 822 patent was then revoked by the TBA for added matter (a ground which failed before Arnold J). Genentech brought to grant another patent, the “084”, a divisional of the 822 patent, with claims which were similar. Lilly sued to revoke it (Genentech counterclaiming for infringement), and said that issue estoppels arose from the earlier decision.

135.

The issue estoppel arguments came for trial before Roger Wyand QC sitting as a Deputy High Court Judge. The main argument was over whether findings of Arnold J were “fundamental” to his decision to revoke the 822 patent, given that there were multiple grounds of invalidity that succeeded. This “two ratio” point is not relevant to my consideration, although it is dealt with in the same part of Spencer Bower and is a facet of the question of whether findings are fundamental.

136.

One of the matters relied on by Genentech was its inability to appeal Arnold J’s decision on the 822 patent. At [63] – [65], in a section titled “Injustice” Mr Wyand QC said this:

“63. Mr Michael Tappin QC, who appeared for Genentech together with Mr Stephen Moriarty QC and Mr William Duncan, raised one further ground of unfairness. He pointed out that Genentech had been granted leave to appeal. This, he submitted, was on the basis that they must have a good prospect of success. If I find that issue estoppel prevents them from running the arguments on which they are held to have a good prospect of success on appeal and they are unable to pursue that appeal because the 822 Patent is held never to have existed, this, Mr Tappin says, would create an injustice.

64. I see some force in this argument but at this time this is only a possibility and its potential for causing injustice is outweighed by the certainty that a finding that issue estoppel does not apply would result in a rerun of the lengthy and expensive trial. This cannot be in the public interest and would be an injustice to Lilly. The appeal is still live at the moment and it is in the hands of the Court of Appeal to determine what is in the public interest and the interests of the parties. I cannot make my judgment based on trying to second guess what course of action the Court of Appeal will take. If all the formal requirements for issue estoppel are otherwise met, I do not see this possibility of injustice justifying me departing from the application of issue estoppel.

65. The underlying public interest referred to by Lord Bingham of Cornhill in *Johnson v Gore Wood & Co.* is a strong factor in this case. The fact that, in the absence of issue estoppel, there would be the prospect of a further trial on exactly the same issues as were determined in the earlier litigation at a combined cost of £11 million suggests that there would be a grave injustice were issue estoppel not to apply here. This case is as close to giving rise to cause of action estoppel as it is possible to get without it applying as all the issues on obviousness are identical in both actions. I find that this is a case where issue estoppel does potentially arise and it is necessary for me to go through each of the pleaded issues to determine whether they are fundamental to the decision.”

137.

Despite the similarity in the sense of there being a later TBA decision after a UK trial, the procedural context there was different from that before me. Genentech had initiated a conventional and entirely proper appeal against the result of the 822 proceedings, in which it was the loser, and it remained to be seen whether that appeal would be allowed to proceed given the TBA decision (although in due course it was – see below). So there was just no consideration of whether a winner can appeal on reasons without challenging the overall result.

138.

In those circumstances, I do not think that what Mr Wyand QC said can stand for the proposition that where a “winner’s appeal” is not possible, as in situations of the kind I have analysed above, and that leads to the conclusion, applying the test referred to in *Spencer Bower* at 8.25, that an issue is not fundamental, then there is a general balancing of the loss of the right to appeal against the burden of fresh proceedings. The right analysis is simply that the issue is not fundamental and no estoppel arises. But as I say, he was not addressing that situation.

139.

Mr Wyand QC then held that there were extensive issue estoppels, but rejected some. He gave permission to appeal to both parties.

140.

Subsequently, Floyd LJ had to deal with the management of the appeal in the 822 proceedings. He made an Order on 31 March 2020, with the following reasons:

**“Reasons**

These appeals arise in circumstances which are, so far as I am aware, unprecedented. Arnold J has held the 822 patent invalid, albeit that he granted permission to appeal. The 822 patent has subsequently been revoked by the European Patent Office. In normal circumstances there would be no possibility of an appeal to this court from the judgment of Arnold J, as the subject matter of the appeal no longer exists.

Subsequently, however, Lilly has successfully relied on the findings made by Arnold J in relation to the 822 patent to obtain, in separate proceedings heard by Mr Wyand QC (“the 084 proceedings”), conditional summary revocation of the 084 divisional patent on the basis of issue estoppel. Mr Wyand QC considered and rejected an argument that it was unfair to allow reliance on the findings of Arnold J, given that it had been recognised that an appeal from the judgment would have a real prospect of success. Mr Wyand QC gave both parties permission to appeal.

Neither side objects in principle to these appeals (from Arnold J’s revocation of the 822 patent) proceeding.

However, in general, appeals are against judgments and orders, not findings: see e.g. *Secretary of State for Work and Pensions v Morina and others* [2007] EWCA Civ 749 at [6].

Given the impact of the findings made by Arnold J in the 822 proceedings on the 084 proceedings, I am persuaded that it is in the interests of justice, in the highly unusual circumstances of this case, to allow the appeals to go ahead. That does not mean that every issue which Arnold J decided is open to appeal. The appeals must be shaped by the purpose for which they are being allowed to proceed. The appeals should be restricted to the findings made by Arnold J which are relevant to the validity of the 084 divisional patent.”

141.

Thus he permitted the appeal to go ahead on a limited basis in the exceptional circumstances. He cited [6] from *Secretary of State v. Molina* that I have dealt with above, but it is not clear on what other cases or principles he received argument, and indeed, as he records, neither side objected to the appeal going ahead.

142.

I reiterate that this was a different situation from that which faces me. An appeal by the loser against a result had been given permission and had begun; Floyd LJ was considering whether to let it progress. It was not argued to him that there was no jurisdiction to continue with the appeal.

143.

I therefore do not think it is possible to read across from Floyd LJ’s reasoned order that an appeal by a winner against reasons that it does not like, but without challenging the result, can be initiated. He

was not considering that, and there is authority binding on me (Noga and the cases cited in it, Concha, Penn-Texas) that it cannot.

144.

In a broad and general sense, I think that Floyd LJ's approach indicates a willingness on the part of the Court to adapt its procedures flexibly to deal justly with unusual situations that arise from collisions between national and central (EPO) proceedings in the context of the EPC, and I find comfort in that in relation to my overall decision as to how to deal with this litigation.

### **Analysis**

145.

The real issue with the present situation is the proper characterisation of the result of the proceedings before Marcus Smith J, the reasons for the result, and who was the "winner", and when.

146.

In my view, what Marcus Smith J had to determine was Neurim's claim that Mylan had infringed the Patent, involving decisions on validity and on infringement. He had jurisdiction over that question throughout the trial before him, at the time when he gave his judgment on 4 December 2020, at the time of the hearing on 16 December 2020, when he made his Order of 30 December, and then throughout the consequential hearing in February and until he gave judgment on it in March 2021. He became functus when he made the Order of 12 March 2021. I recognise that his jurisdiction was right at its limits, but within them, between 16 December 2020 and 12 March 2021 when he was considering acting, and did act, under CPR 3.1(7) and the Barrell jurisdiction to revoke his Order of 16 December 2020 and when he affirmed that course in the Consequential Judgment.

147.

During part of this time, Mylan could validly have filed an Appellant's Notice. In particular, it could have done so prior to the revocation of the Patent by the TBA on 18 December 2020. That is because there was the judgment of 4 December 2020, and indeed the Order of 16 December 2020, under which it was the loser.

148.

However, it clearly was not expected by the parties or by Marcus Smith J that Mylan was going to do that. The whole situation was provisional because of the imminent TBA hearing, and the provisional nature of the situation was inherent to the Order of 16 December 2020. It is also relevant that Mylan's time for filing an Appellant's Notice was repeatedly extended.

149.

In these unusual circumstances, I think that the relevant time for the purposes of assessing whether there was a possibility of appeal is not the short period between the Main Judgment and the revocation by the TBA, but only thereafter. At that point, Mylan had won. It is not that Marcus Smith J's Main Judgment was "wrong" - on the evidence he heard I am sure he still considered that it was correct - but as he himself recognised, it had been "trumped" by the TBA decision. He retained the power to deny Neurim's claim, and he did so.

150.

So I conclude that Mylan could not appeal on validity at the relevant time, in which conclusion, having heard full argument on the law, I am in agreement with Marcus Smith J's own view as expressed at

[55] in the Consequentials Judgment. Since Mylan could not appeal, the general rule is that there can be no issue estoppel, and I see no reason not to apply that general rule.

151.

Neurim's fall back argument was that Mylan could and should have appealed later, especially when it became apparent that Neurim was going to be granted, or likely to be granted, the Divisional. I do not think this can help Neurim and does not take matters further. Mylan remained the winner of the 2020 Action and I struggle to see how it could meaningfully have "appealed", because in a sense any "appeal" would have been bound to succeed because the Patent had been revoked in the EPO. It may be that this is just another way of illustrating that no appeal against the result was possible. Neurim's arguments in this respect were also unconvincing because it was unable, in my view to identify, in its post-trial written submissions, when I asked, a rational analysis of when Mylan's time for appealing on this footing revived and expired.

152.

I would reach the same conclusion - that there is no issue estoppel - on the basis that the reasons and findings in the Main Judgment were not fundamental to the overall, eventual result. The only and truly fundamental reason was the central revocation of the Patent following Neurim's withdrawal of its TBA appeal. As Mylan points out, if Marcus Smith J had found the Patent invalid on one or more grounds, rather than valid, that would have made no difference to the eventual outcome. Of course, as I have said, the reasons and findings in the Main Judgment (that all the validity attacks failed) were fundamental to the position as it stood on 4 December 2020, but that is not the relevant time at which to consider matters, for reasons given above. I acknowledge that this is largely a different label applied to the same analysis.

153.

I also consider that there was a lack of the finality necessary for issue estoppel. In particular the 16 December 2020 Orders were provisional in that they themselves anticipated that they could be changed in the light of the result of the imminent TBA hearing, as Marcus Smith J held; and he also decided on 30 December 2020, and affirmed in the Consequentials Judgment, that he could and should revoke those Orders.

### **Special circumstances**

154.

As I have said above, there is a special circumstances exception to issue estoppel, albeit that it is rarely invoked successfully (Arnold v NatWest itself was a rare case, where the refusal of permission to appeal and the later change in the law were key).

155.

Since I have held that there is no issue estoppel in the first place this does not arise for decision. I do not think it makes sense for me to make a conditional finding on whether special circumstances would exist in the event that I were wrong about the existence of the estoppels, since it would depend too much on the reasons why I was wrong. I have in any event made all the findings of fact that I was asked to and believe are relevant, so if I am wrong about the existence of the estoppels and if this matter goes on appeal, the Court of Appeal can consider whether sufficient special circumstances exist. I will at least say that the argument is a real one; the supervening decision of the TBA could be said to provide the necessary new material, and the complexity of whether an appeal was possible at all, Marcus Smith J's own view that it was not, and the fact that Mylan's core desire is only to achieve

the opportunity to ask the Court of Appeal to consider whether to grant permission would all be significant and unusual features.

### **MYLAN'S ABUSE ARGUMENT**

156.

Mylan contends that Neurim's application to amend the Divisional is an abuse of process. The application to amend is very important because it is unconditional, so if it is not allowed the Divisional will be revoked.

157.

The relevant plea, contained in paragraph 3 of its Amended Statement of Opposition to the amendment application, is as follows (Mylan is referred to as "Viatris" in the original, which is its new name, but I have reinstated "Mylan" for readability):

"3. In support of [Mylan's] contentions above in respect of abuse, [Mylan] relies upon paragraphs 2, 3, 5, 7, 8 and 9 of the Defence and Counterclaim and upon the following matters (separately and collectively):

a. EP 1,441,702 (the "Parent Patent") was in force until 18 December 2020 when Neurim withdrew its appeal in EPO appeal proceedings T302/20 against the decision of the Opposition Division ("OD") dated 20 November 2019 revoking the Parent Patent, the effects of that decision having been stayed pending the appeal.

b. The Technical Board of Appeal ("TBA") had indicated that the Parent Patent was insufficient during the hearing on 17 and 18 December 2020 (the "TBA Hearing"). On 18 December 2020 the TBA expressed their opinion orally that the Parent Patent lacked sufficiency. Neurim then formally withdrew its appeal of the OD's decision. As a result of Neurim's withdrawal of its appeal, there has not been and will be no written assessment by the TBA of the sufficiency arguments presented at the TBA Hearing. The only ground of invalidity considered by the TBA at the TBA Hearing was article 83 (sufficiency).

c. Neurim's withdrawal of the EPO appeal prior to a decision of the TBA was and was intended to be procedurally favourable to its prosecution of the Patent by shielding the Patent from a written decision of the TBA regarding the invalidity of the Parent Patent. This was confirmed by the evidence of Neurim's patent attorney, Mr Thomas Leonard, who acknowledged that the TBA's written decision could have had an adverse effect on the prosecution of the Patent.

d. By withdrawing its appeal, Neurim accepted that the Parent Patent is invalid for anticipation by the Haimov prior art pleaded in [Mylan's] Grounds of Invalidity and/or for insufficiency.

e. In the premises, it is an abuse for Neurim to apply to put the form of the Patent into materially the same form as the Parent Patent. The Application therefore constitutes an abuse. The paragraphs of the Defence and Counterclaim to which reference back is made in the introductory part of the paragraph, are matters of factual background and/or repetitive of paragraph 3."

158.

Mylan's abuse argument was developed only very thinly in its written and oral arguments at trial. The substance of its written opening consisted of just two paragraphs:

"42. Furthermore, it is an abuse of the Court's process for the Claimants to assert the same claim twice in the UK, having accepted that the Parent Patent was invalid at the EPO. As set out in the



section on the law, above: "It is an abuse to bring vexatious proceedings, i.e. two or more sets of proceedings in respect of the same subject matter which amount to harassment of the defendant in order to make them fight the same battle more than once with the attendant multiplication of costs, time and stress". Johnson v Gore Wood explains that a broad, merits-based judgment should be adopted, taking account of all the public and private interests involved and all the facts of the case.

43. Neurim's answers are:

a. There was a procedural defect at the EPO - addressed above. There wasn't.

b. Neurim would be entitled to amend a divisional patent to the same form as its parent at the EPO and so they should be entitled to do so before this Court. However, this Court has the jurisdiction to prevent abuse, including by preventing steps that would otherwise be permissible.

c. The Patent is a separate right to the Parent Patent so they are not asserting the same patent twice. That is an argument of form over substance. The Court's powers to prevent abuse (including double vexation) are not so limited. The claim is in respect of the same subject matter (i.e. the claimed invention) in relation to the same product. It should not be allowed to proceed because Mylan would be forced to fight the same battle twice with the attendant multiplication of costs, time and stress."

159.

Here and as developed orally by Mr Acland, the argument focused not so much on the nature of the proposed amendment to the Divisional, and much more on Neurim's overall strategy of using a divisional (regardless of its precise form) as a backup in case of failure of the Patent, and on the contention that it was unfair for Mylan to be sued twice in the UK on the same invention. This led to an objection by Mr Waugh that that was not pleaded and would raise different, broader and fundamental issues.

160.

I agree with Mr Waugh on this. The use of divisionals as backups is a well-established practice that is widely used. It can raise serious problems, which the UK Courts have sought to address, including by the availability of Arrow declarations where appropriate, and by case management. An argument that the practice amounts to an abuse of process would be an important and complex one, and I do not think it is covered by Mylan's pleading, or fair for it to be raised without a pleading. Quite apart from anything else, I agree with Mr Waugh that Mylan's pleading does not even mention the abuse residing in Mylan being sued twice in the UK. There clearly would have been the scope for more evidence if this argument had been pleaded.

161.

Additionally, this is an unusual context for the use of divisionals as a backup. Neurim is not trying to use a divisional to have another bite of the cherry in case of, or following, losing on the merits in the UK. It won in the UK before Marcus Smith J, and is using the Divisional because it came to grief in the EPO. Yet, as Mylan accepted, the EPO's own procedures do not prevent seeking a very similar or even identical claim set in a divisional, and indeed Mylan had to withdraw as ill-founded an allegation that Neurim's approach was contrary to the rule against double-patenting. It was also common ground before me that decisions of the EPO do not create an estoppel in national courts of EPC member states: Buhler v. Chronos Richardson [1998] RPC 609.

162.

I am by no means expressing an opinion on the rights or wrongs of these matters (and at a high level I accept Mylan's submission that merely because the rules are followed does not mean there cannot be an abuse). Rather, I mention them to illustrate how complex an argument that the use of divisionals as backups was itself capable of being an abuse of the UK Court's process would be.

163.

So I will limit my consideration to what Mylan has pleaded, and having regard to the fact that it is not alleged that using a divisional as a backup is an abuse in itself. The objection is to the form of the amendment, the proposed amended claims being effectively identical to those of the Patent that the TBA revoked.

164.

Mylan's argument in substance raises three things.

i)

The first (paragraph 3c) is that Neurim's withdrawal of the TBA appeal was to avoid the effect of a written decision. I have held that that is factually correct but I do not see that it can make the application to amend the Divisional in UK proceedings an abuse. If Neurim had let the appeal go to a written decision it would still have been able to seek the Divisional and very probably would have, just later and more slowly. Whether the Divisional results in a valid patent will be capable of being contested in the EPO in any event.

ii)

The second (paragraph 3d) is that Neurim, by withdrawing its appeal in the TBA, accepted that the Patent is invalid. That is incorrect as a matter of fact. Neurim has always been clear that it thinks the Patent is valid, and proved as much in the UK proceedings. Its withdrawal of the appeal was a practical response to the situation it faced, not an acceptance of the invalidity of the underlying right.

iii)

The third (paragraph 3e) is that "[i]n the premises" it is an abuse to put the Divisional Patent into materially the same form as the Patent. Since I have rejected the premises, this cannot help Mylan.

165.

Further, in the absence of an allegation that the course of conduct of using divisionals as backup and bringing a second action as a whole was an abuse, I do not think that the precise form of the claims of a divisional and their degree of similarity to that of the Patent can give rise to one.

166.

In any case, stepping back and looking at the matter more generally in terms of the broad, merits-based judgment required by *Johnson v. Gore-Wood* [2002] 2 AC 1 I think Mylan's argument is unconvincing and it is not being harassed:

i)

Mylan has long known that Neurim was prosecuting divisional applications and would be likely to use them as backups if necessary.

ii)

That meant that Mylan would be subject to litigation uncertainty for a period which might well be longer than the original UK proceedings. That is inherent to patent proceedings under the EPC when divisionals are in play.

iii)

Given my decision on issue estoppel and how to manage the case in the light of it, the burden on Mylan of allowing Neurim to make the amendment application and hence this action to continue is only of Mylan trying to appeal the decision of Marcus Smith J, and running that appeal if permission is given. It is not going to be subjected to another full action, and it was always subject to the risk that the proceedings on the substance of validity would go to the Court of Appeal.

iv)

Mylan's abuse argument depends on the claims of the Divisional being essentially identical to those of the Parent. It seems to me to be implicit in that that Mylan's argument could not run if Neurim had put forward claims for the Divisional which were more different from the Patent, but which addressed the lay-patient argument and still gave Neurim another opportunity to succeed in the UK, yet required a fuller trial and a greater burden on the parties.

167.

I therefore reject Mylan's abuse argument.

### **THE COMPETITION ISSUES**

168.

When Mellor J allowed competition law to be added to the list of preliminary issues by his Order of 27 August 2021, he expressed the view that there was "considerable if not complete overlap between the events which are alleged to give rise to the estoppels pleaded (by each side) and nearly all of the conduct which is alleged by the Defendants in support of their case on abuse of dominant position". I agree, and subsequent events have proved him right. As I see it, my factual findings on estoppel cover all the facts raised by the parties on competition law in their pleadings.

169.

I do not think the parties were in disagreement on the overlap on factual issues, and the overlap can be seen from the key allegation of abuse, which was as follows:

"31. In the premises, the Claimants have pursued a strategy of:

- a. Appealing the OD's decision;
- b. Seeking to enforce the Parent Patent in the UK, culminating in the Judgment;
- c. Withdrawing the appeal to the TBA:
  - i. after the Judgment but before the Defendants could appeal the Judgment; and
  - ii. to shield the Patent from a written decision of the Technical Board of Appeal in respect of the Parent Patent because such a decision would have "an adverse effect on the prosecution of [the Patent]"
- d. Seeking to enforce the Patent on the basis of issue estoppels said to arise from the Judgment."

170.

At its core, this relies on a combination of preventing reasons emerging from the TBA so as to get the Divisional, and thereafter seeking to use issue estoppel to prevent an effective appeal in the UK.

171.

I should mention that there was at one stage a dispute, which came up at the PTR, about what the preliminary issue set out at paragraph 1.a) of the 27 August 2021 Order meant:

“a) whether the strategy and/or conduct pleaded in paragraphs 28 - 34 of the Defence and Counterclaim dated 11 August 2021 (the “Defence”) would in principle constitute an abuse of a dominant position in the relevant markets within the meaning of s 18(1) of the Competition Act 1998 as pleaded in paragraph 35 of the Defence;”

172.

Specifically, at the PTR before me Mylan took the position that “in principle” meant that the issue was to be determined on the assumption that the facts alleged in the sections of its pleadings identified were true, while Neurim said that the terms of the issue envisaged that the Court would make findings about the facts alleged. I directed written submissions on the point and I must say that my initial view was that Mylan was right. But, pragmatically, it indicated prior to the trial that it would not insist on the point and that I should make findings. Essentially, the allegations on which this focused were those concerning Neurim’s intentions at the TBA and I have made findings about that, including in relation to its intentions in avoiding the giving of written reasons.

173.

For the reasons given above, I have found that there is no issue estoppel in the circumstances of this case. For the future, that means that the competition law issues do not have any additional significance and Mylan is able to seek to appeal to the Court of Appeal.

174.

The key role of the competition law allegations from Mylan’s point of view was to enable it to say that even if the law of issue estoppel as a matter between the parties could prevent Mylan from an effective opportunity to appeal the Main Judgment, the different and additional considerations of competition law and especially the public interest in competition, could lead to a different result (paragraph 80 of Mylan’s opening written submissions).

175.

Mylan also has, at least in theory, a claim for damages. The allegation was contained in paragraph 33 of the Defence and Counterclaim:

“33. Further, even if the Claimants do not obtain an injunction, the fact of seeking damages on the basis of the alleged issue estoppels imposes a contingent cost of competition on the Defendants, in the form of the possibility that they may need to compensate the Claimants for the loss of their opportunity to earn monopoly profits in this market, without ever having the opportunity to defend themselves from that claim. That contingent cost is a deterrent to effective competition in the Melatonin market, because each additional sale that the Defendants obtain through competition in the market gives rise to greater potential liability to the Claimants.”

176.

And paragraph (4) of the Prayer:

“(4) An inquiry as to the damages equal to any damages that the Defendants are ordered to pay to the Claimants, as well as damages for lost profits from any period for which they are enjoined.”

177.

As I see it, these only claim damages in the event that Neurim were to succeed in using issue estoppel to get an injunction to which it was not otherwise entitled; hence the use of “contingent” and

“possibility” in the pleading. That will not happen because I have rejected the issue estoppel arguments. To put it another way, Mylan is not claiming damages for Neurim merely having tried to assert issue estoppel in the circumstances pleaded. Even if I were wrong about that, it seems to me that if I am right about issue estoppel it is extremely unlikely that the competition law allegations have any practical significance and I would have declined to determine them now in the exercise of my case management powers.

178.

That being so, I do not propose to decide the competition law arguments, for the following main reasons:

i)

The legal questions which they raise are very complicated and are on any view at the outer edges of developing areas of this field. Neither side said that I could decide the issues by applying any single strand of authorities, with Mr Piccinin arguing that I had to decide the question of “normal competition” or “competition on the merits” at large with no structured guidance, and Mr Scannell arguing for a novel combination of two lines of authority represented by *ITT Promedia v Commission T-111/96* and *Astra Zeneca v Commission C-457/10 P*. I do not think the law should be developed in this sort of situation in haste or on outline facts. This is in no way a criticism of the way in which the submissions to me were made; they were extremely concise, clear and helpful.

ii)

Although I have made the factual findings that I was asked to, I am not at all comfortable that I was asked to, or put in a position, to decide all that is necessary. For example, it may well be that there would need to be a proper decision about how common or “normal” it is for patentees to withdraw TBA appeals to avoid the giving of adverse reasons, a matter touched on only lightly in written evidence which was not tested in cross-examination.

iii)

The definition of the issues by the (very short) pleadings may not be complete or settled. For example, it was a major feature of Mr Scannell’s submissions in justifying the application of the legal approach for which he argued that Mylan’s pleading did not allege an overall strategy but only a number of distinct elements. If that were right, it could be addressed by an amendment.

iv)

Pragmatically speaking, it would appreciably delay the provision of this judgment for me to deal with the very complex legal submissions, and there is some need for speed in the light of the commercial situation and the approaching expiry of the Patent.

179.

If I turn out to be wrong on this, then at least I have made the factual findings which I can, and the Court of Appeal can, if it thinks it necessary, consider the significance of the competition law issues on that basis.

180.

Overall, I do not think, in the light of the way matters have developed, that the competition issues were suitable to be determined as preliminary issues. I agree with Mellor J’s analysis in the Reasons for his 27 August Order that it was fair to allow Neurim to try to obtain a speedy resolution so that it might succeed in getting an injunction if it won on issue estoppel. But Mellor J clearly also saw the

possibility that the approach might be unsuitable or that the decision on issue estoppel might render competition law irrelevant to the result.

### **THE PROCEDURAL SITUATION THAT OCCURRED**

181.

There have been many actions in the Patents Court where it has been necessary, if difficult, to co-ordinate and manage national proceedings in the light of parallel proceedings in the EPO. To do this successfully the parties need to co-operate with each other and with the Court. It is unfortunate that in these proceedings so much complexity and confusion has arisen and so much resource used up, which could have been avoided if the trial had been scheduled just a little later, after the TBA. Marcus Smith J commented on this with characteristic courtesy and restraint in the Consequentials Judgment (at [89-92]). I strongly agree with him. As he said, the parties probably had their own strategic reasons for wanting to keep the UK trial date once they knew the date of the TBA hearing, and perhaps they would have persuaded the Court that that was the right course had they brought the situation to its attention. However, what is clear is that they should have kept the Court actively and fully informed<sup>1</sup>. The Court might have wanted to make its own decision to put the UK trial a little later in case (as turned out) the EPO revoked the Patent and made it unnecessary. This is an important lesson for the future and parties in litigation in the Patents Court where there are parallel EPO proceedings should regard themselves as under a duty to inform the Court about scheduling issues and scheduling changes, whether or not they intend to make a case management application themselves and whether or not it suits their strategy.

### **CASE MANAGEMENT; SUBMISSIONS AFTER MY DRAFT JUDGMENT**

182.

As I have indicated above, following my draft judgment Mylan questioned what I had said in it about the right procedural way forward, the key points of which were that I would deal with the trial of this action (a) on the basis only of the materials and arguments before Marcus Smith J, (b) by adopting and giving effect to the Main Judgment, and (c) by refusing permission to appeal just as Marcus Smith J did on 16 December 2020.

183.

Mylan does not object to (a) and so the trial of this action will take place on that basis. But Mylan does object to (b) and (c). Its key points on each are as follows:

i)

As to (b) - my adopting the Main Judgment - Mylan submits that even if strictly I would have power to do that, which I understand in fact it still concedes, it would not be a proper exercise of a judicial function simply to adopt a judgment of another judge if I had not satisfied myself that it was sound. In its written submissions following the draft judgment it referred to *Crehan v Innpreneur Pub* [2007] 1 AC 333 in relation, it said, to the deference which one judge ought to show the decision of another. Mylan submitted that it had thought at trial that it would have a chance to make submissions about what case management was needed if there were no issue estoppel, and that there needed to be at least written submissions to enable me (or whichever judge decided the trial of this action) to be satisfied that it was right to adopt the Main Judgment, or otherwise to make a different decision, or give different reasons.

ii)

As to (c) - refusing permission to appeal - Mylan submits that it has never had an effective chance to seek permission to appeal against the Main Judgment when it was possible for the judge to whom the application was made to take into account that the TBA reached a different conclusion.

184.

Following Mylan's written submissions in the light of the draft judgment I directed that Neurim should reply, and I directed that Mylan should indicate what it specifically envisaged the judge deciding this action should consider. This was done.

185.

On reviewing the transcript of the trial in the light of Mylan's written submissions, I came to the clear conclusion (as I indicated in the course of oral argument on 19 January 2022) that Mr. Acland did not concede - whatever might have been said about the nature of any further trial - that permission to appeal need not be considered again at first instance. Having now understood Mylan's stance on point (c) above and thought further, I think it ought to be considered, even if the result is simply that permission to appeal is, again, refused. The fact that the TBA reached an opposite conclusion to that of Marcus Smith J is potentially material. Of course, Neurim will say that the findings on the evidence in the Main Judgment fully explain the difference in the conclusions and mean that any appeal by Mylan must fail, but that does not mean that Mylan ought not to be entitled to make an application. Mr Waugh did not, to my mind, identify any reason of principle that Mylan should not have the opportunity at least to apply. I record that Mr Waugh said his clients would rely on the fact that the Examining Division has now granted the Divisional. They may of course do so, but again it is no reason to deny Mylan the opportunity to apply.

186.

It is in the light of the fact that I think Mylan ought to be put in a position to apply for permission to appeal that I consider the submissions that Mylan says that it wants to put forward in relation to a trial of the substance of this action, i.e. the lay-patient argument. Those submissions are, as Mr Acland recognised, uncomfortably half way between the basis for an appeal against the decision of Marcus Smith J in the Main Judgment (which is not a function for another judge to undertake) and arguing for a fresh assessment of what was before him, including an assessment of the evidence of Professor Morgan, whom Marcus Smith J criticised in strong terms.

187.

By contrast with the position about permission to appeal, I was in no doubt, at the time or after subsequent review of the transcript, about what Mr. Acland said at trial about my power to adopt, in its entirety, the decision of Marcus Smith J. He accepted that I did.

188.

It may be that Mr. Acland did not intend to express himself the way that he did. If he had expressed it differently, including with a caveat in the terms that he does now on point (b) above by reference to Crehan, then I would have dealt with the argument I am dealing with now in my original reserved judgment. Only two weeks have passed since my draft judgment so I do not think that the fact that Mylan is changing its position somewhat prejudices Neurim materially. I think I should take seriously Mylan's submission that this is a question that goes to proper judicial function (although I think Crehan is a very distant analogy). I do still think it would be better and quicker if Mylan simply accepted that I should adopt the Main Judgment, but it is not willing to do that and it says that it would be wrong for me to, without scrutiny, adopt a judgment that is not my own.

189.

In the unusual circumstances of this situation, I think I must tread especially carefully. Mr. Acland accepts today – there can be no ambiguity about this, and Mylan will be held to it – that this can go back to Marcus Smith J. That seems to me to be a fair, proportionate and judicially appropriate way to proceed because if he decides, it being a decision for him and after he receives submissions, to adopt what he did before, he will be adopting his own findings, his own words and his own judgment. It will also eliminate the possibility of another judge having to deal with something uncomfortably halfway between an appeal and a fresh trial, and it best addresses the problem, which Mr Acland acknowledges, that the materials to which Mylan wants to refer include evidence from Professor Morgan, whom Marcus Smith J has the unique advantage of having heard at the first trial.

190.

That is what I am going to do. It is unfortunate that this was not better canvassed by Mylan at the trial in December, but as I have said, by now too many times, this is a very unusual situation. A short delay while Marcus Smith J considers matters is worth it to ensure that Mylan has had a fair say.

191.

Mr. Waugh, again, points to the fact that Neurim wants things moved along quickly, given the pending expiry of the patent. I understand and acknowledge that. I consider that if Marcus Smith J has the time then this can be moved along extremely briskly, and it will be for him to decide whether to have a hearing or to deal with it on the papers; following further argument at the hearing on 19 January I gave directions for page-limited submissions in writing in the first instance, in the next two weeks.

## **CONCLUSIONS**

192.

My conclusions are:

i)

Neurim's issue estoppel arguments fail.

ii)

Mylan's abuse of process argument fails.

iii)

I decline to decide the competition law issues which in any event do not affect the result.

iv)

I propose to manage the case as set out above. Hereafter, it will be managed and heard by Marcus Smith J.

193.

I will hear Counsel as to the form of Order if it cannot be agreed. I direct that time for seeking permission to appeal shall not run until after the hearing on the form of Order (or the making of such Order if it is agreed).

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<sup>1</sup> Mylan pointed out in its corrections to the draft of this Judgment, as it did in its corrections to the Consequentials Judgment, that its skeleton for the PTR of 5 October 2020 mentioned the 17-18 December 2020 hearing. Marcus Smith J explained at footnote 9 of the Consequentials Judgment that this was not an adequate substitute for raising the matter specifically.