Neutral Citation Number: [2021] EWHC 2596 (Pat)

Case No: HP-2021-000027

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

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 17/08/2021

Before:

MR. JUSTICE MELLOR

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Between:

(1) TEVA PHARMACEUTICAL INDUSTRIES LIMITED **(a company registered in Israel)** **(2) TEVA UK LIMITED** **(a company incorporated under the laws of England and Wales)**	**Claimants**
- and -	
JANSSEN ONCOLOGY INC **(a company registered under the laws of the State of California, USA)**	**Defendant**

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MR. MICHAEL CONWAY (instructed by **Bird & Bird LLP**) for the **Claimants**

DR. ANNA EDWARDS-STUART (instructed by **Bristows LLP**) for the **Defendant**

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Approved Judgment

(Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd.,
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MR. JUSTICE MELLOR:

1. I have an application by the claimants, Teva, against the defendant, Janssen, to list a hearing date for the trial of the action. The action is a "clearing the way" action; in other words, Teva seek to invalidate Janssen's patent EP (UK) 2,478,907. The patent relates to a combination of abiraterone acetate and prednisone for the treatment of prostate cancer. It was granted on 14th April this year and it is a divisional of EP '561, which was revoked by the Opposition Division of the EPO on 27th March 2016. Although Janssen appealed that rejection by the Opposition Division, they abandoned the appeal in February 2020, leading to the revocation of the parent patent.

2. Teva also refer to validity proceedings in the US and in Canada, considering the US and Canadian equivalents to the patent, and in both cases the patent has been held invalid over some prior art called O'Donnell which is cited in these proceedings.

3. Of course, Teva in bringing this clearing the way action are seeking to clear the way for their own abiraterone product. I will have to return a little bit later to some criticisms which Ms. Edwards-Stuart for Janssen has made of the specificity of Teva's plans.

4. This is not the CMC. It is just an application to list a hearing date and it is put forward on the basis that the parties have been informed by the listing officer that there is a slot in the Patents Court diary to list a Category 4 trial of suitable length in a five-day window beginning 27th June 2022.

5. The parties seem to be agreed that it is a Category 4 case, although my perhaps slightly uneducated assessment is that it is at the low end of Category 4. Although the parties are not completely agreed that it will require five court days, in the sense that Janssen say at least five court days, if I list this trial in that slot, I will direct that it shall only take five days in court.

6. Teva rely on the Practice Statement, which was issued back in 2015. Ms. Edwards-Stuart is right to point out there is a conflict between the way patent cases are described in the Practice Statement and the way that the listing officer now wants trials listed, in this sense, that in the Practice Statement the trial windows were divided as follows: estimated hearing time, i.e. excluding pre-reading and preparation of closing submissions, up to five days and then estimated hearing time, six to ten days and then over ten days.

7. The practice has changed since this Practice Statement was formulated, in the sense that now the listing officers want to know how many days of judge time a trial is going to occupy and, therefore, when obtaining a listing from the listing officers they want to know, first of all, how much pre-reading is included and also how much time off is built in for preparation of closing submissions, because that gives the listing officer a much better estimate of how long a judge will be occupied on that particular trial. In certain cases, if a generous period is allowed for preparation of closing submissions, it is possible for a judge to take other cases in the meantime, but, generally, if closing submissions preparation only needs one day, then it is somewhat difficult to have the judge occupied in that intervening day.

8. Be that as it may, Janssen object to the trial listing on a number of bases. First, they say that the correct listing window for a trial of five court days is October 2022 to January 2023, but this submission fails to take account of the Practice Statement.

9. The second point that Janssen take is that they say Teva have not advanced any sufficient justification for listing the trial at this point. They point out Teva are not seeking expedition, but the reason Teva have given for wanting this trial slot is because it will enable, it is hoped, a judgment to be issued either by the end of July 2022 or perhaps in August 2022 and before the market exclusivity for the Janssen product runs out on 7th September 2022.

10. The third point that Janssen take is they suggest that Teva have delayed in bringing these proceedings and they say that is a problem entirely of Teva's own making. I do not really think there is anything in this point. As I have mentioned, the patent was granted on 14th April 2021 and on 9th June 2021, Bird & Bird for Teva wrote to the patent agents for Janssen, notifying them of their intentions and warning them that if constructive progress cannot be made in a timely manner, Teva will not hesitate to start proceedings for revocation of the patent.

11. From 9th June to 30th June, that period was largely delay taken up on the defendant's side in deciding what their position was going to be and then notifying Bird & Bird of their position, which was that they considered the patent to be valid and correctly granted. From that point, the proceedings were issued on 12th July and served on 13th July. Also, on 13th July, Teva invited Janssen to agree to a trial date between April and July 2022. Therefore, I do not regard delay as really a factor in this case at all.

12. The next point that Janssen take is they criticise Teva for seeking to fix a trial date when the parties have yet to agree directions for trial. Teva have put forward a set of directions which make it clear that the parties can easily take all the steps necessary for this trial date, which is now some 10-11 months hence. I do not see any difficulty in getting ready for trial by 27th June 2022.

13. The fifth point that Janssen takes is based on some observations I made in the course of argument when I was hearing the CMC in *Sandoz v Bristol-Myers Squibb*. I am afraid the comments on the transcript have been taken somewhat out of context, because in that particular case, what I was objecting to was Sandoz obtaining a trial listing when the court was not properly informed of all the circumstances, namely that there was about to be a second action, *Teva v Bristol-Myers Squibb*, being joined to it, and the fact that it was sought and obtained on a paper application, only some seven days before the actual hearing of the CMC.

14. In context, the real import of my observation was that a trial listing should be obtained only if the court is given a proper appreciation of the scope of the trial and certainly I am satisfied on the evidence before me that I do have a sufficient appreciation of the scope of the trial. To avoid these observations being taken out of context, I point out they apply to a situation where the trial estimate is in dispute or (and this was the situation in *Sandoz*) where foreseeable events may affect even a previously agreed trial estimate.

15. Reverting to the Practice Direction, I am going to list this trial floating in a five-day window beginning 27th June 2022. I am going to list it on the basis of one day pre-reading and then five court days, roughly along the lines of half a day for openings, one and a half days for expert evidence from each side and I take into account that although it may be possible to rely on one expert each side in this case, it may also require two experts on each side, but I am satisfied that a day and a half for each side's experts is going to be sufficient, if not ample.

16. The final point to mention is that there may be a difficulty in providing a High Court judge to hear this trial on that trial listing and, therefore, I have explored with the parties whether this case might be suitable to be heard by a suitably qualified deputy judge. I am satisfied that if a suitably qualified deputy judge is available to hear this trial, it will be a suitable trial for a deputy to hear.

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