Neutral Citation Number: [2020] EWHC 3157 (Pat)

Case No: HP-2020-000021

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: Monday, 16th November 2020

Before:

THE HON. MR. JUSTICE FANCOURT
Remotely via Teams

- -

Between:

TEVA UK LIMITED	**Claimant**
- and -	
JANSSEN PHARMACEUTICA N.A.	**Defendant**

- -
- -

MR. JEREMY HEALD (instructed by **Pinsent Masons LLP**) for the **Claimant**

MR. JOE DELANEY (instructed by **Bristows LLP**) for the **Defendant**

Hearing date: 16 November 2020

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Approved Judgment

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THE HON. MR JUSTICE FANCOURT

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MR. JUSTICE FANCOURT:

1. This is the first case management conference in a claim by Teva UK Limited against Janssen Pharmaceutica NV for a declaration that a Supplementary Protection Certificate, that came into force on 12th May 2017 and is due to expire on 11th May 2022, is invalid and should be revoked. The SPC was for an anti-psychotic drug. I refer to the SPC in question by its number, SPC 044.

2. The grounds of alleged invalidity are that SPC 044 was granted contrary to Articles 3(c) and 3(d) of the Supplementary Protection Certificate Regulation 2009, first, because the active ingredient of Xeplion, protected by SPC 044, is said to be paliperidone, which was already the subject of an earlier SPC, granted to the defendant, for a drug marketed as Invega. That SPC is number 065. Alternatively, the claimant pleads that SPC 065 also conferred protection on paliperidone palmitate, which the defendant contends is the active ingredient of Xeplion.

3. The second basis of infringement of the Regulation is that the marketing authorisations relied upon for the grant of SPC 044 were dated March 2011, whereas the first authorisation to place paliperidone on the market was in June 2007. So it is said that the authorisations of March 2011 for Xeplion were not the first authorisations.

4. At trial, the principal issue in dispute will be whether the active ingredient of Xeplion is paliperidone or paliperidone palmitate. This may raise for decision, apparently for the first time, the question of whether a salt ester prodrug of an active ingredient of an existing approved product is the same or a different active ingredient.

5. The relevant pleaded statements of case are the claimant's grounds of invalidity and the defendant's defence. The relevant particulars in the grounds of invalidity in support of SPC 044 being invalid are the following,

> "(b) Paliperidone palmitate is a salt ester prodrug of paliperidone. Paliperidone is the major active metabolite of risperidone which is a widely used atypical antipsychotic approved for the treatment of schizophrenia and other psychiatric disorders.
>
> "(c) Following intramuscular injection, the paliperidone palmitate salt ester prodrug is hydrolysed in the body to form paliperidone and palmitic acid. Paliperidone is the active ingredient of paliperidone palmitate. Palmitic acid has no therapeutic effect of its own.
>
> "(d) In the premises, the product the subject of the 044 SPC within the meaning of Article 1(b) of the SPC Regulation is paliperidone."

6. The relevant paragraphs of the defence are first paragraph 5, which pleads to paragraph 1(b) of the grounds of invalidity, in the following terms:

> "(a) Paliperidone palmitate is the palmitate ester of paliperidone;

> "(b) Paliperidone is the major active metabolite of risperidone. Risperidone is an atypical antipsychotic used in the treatment of schizophrenia and certain other psychiatric disorders;
>
> "(c) Save as aforesaid, paragraph 1(b) is not admitted."

7. Paragraph 6 of the defence, which pleads to paragraph 1(c) of the grounds of invalidity states:

> "(a) As to the first sentence, paragraph 5(a) above is repeated. It is admitted that paliperidone palmitate is hydrolysed in the body to paliperidone and palmitic acid;
>
> "(b) Paliperidone palmitate is the active ingredient of the defendant's Xeplion medicinal product protected by the 044 SPC and the subject of the marketing authorisations relied on therein and is not the same active ingredient as paliperidone;
>
> "(c) Save as aforesaid, paragraph 1(c) is not admitted."

8. The particular matters in issue are, accordingly, whether paliperidone palmitate is a salt ester prodrug of paliperidone and whether palmitic acid has any therapeutic effect on its own. Depending on the answers to those questions and the law, the active ingredient of paliperidone palmitate either will or will not be paliperidone.

9. The only issue in dispute at this case management conference is whether there should be an order for extended disclosure against one or both parties. The parties have now agreed that there may be expert evidence at trial in medicinal chemistry and also expert clinical medical opinion evidence.

10. The first point of dispute is whether there properly exists any "issue for disclosure" within the meaning of CPR PD51U at all. The claimant contends that there is one and the defendant says there is none. It follows that the defendant is saying that the issues for trial do not, for a fair resolution, need to be determined with some reference to contemporaneous documents, as provided in para 7.3 of PD51U.

11. The claimant says that the issue for disclosure is whether paliperidone or paliperidone palmitate is the active ingredient of Xeplion.

12. The defendant says that is an entirely objective question for the court to determine, with the benefit of expert evidence. However, it is common ground that the summary of product characteristics and the European Public Assessment Report (EPAR) are material documentary evidence and relevant to that issue, so it cannot be right that there will be no reference to contemporaneous documents at trial.

13. I agree with the claimant that the issue that it has identified is properly characterised as an issue for disclosure, but that only really raises the question of what, if any, model for extended disclosure for either party is appropriate.

14. The claimant submits there should be extended disclosure by the defendant under Model C in relation to two requests. It formulates those as follows:

> "1. Correspondence and/or communications between the European Medicines Agency, EMA, and Janssen-Cilag, or any Janssen group company or agent on behalf of Janssen-Cilag, relating to the active ingredient of the medicinal product, the subject of the marketing authorisation applications for Xeplion, the Xeplion MA applications.
>
> "2. Any written submissions, results of studies and/or data submitted to the EMA by Janssen-Cilag or any Janssen group company or agent on behalf of Janssen-Cilag, in relation to the active ingredient of the medicinal product, the subject of the Xeplion MA applications."

It accepts that it should give Model B disclosure on that issue

15. Following a challenge by the defendant in correspondence and in skeleton arguments to the broadness of those classes of document, which would require the defendant to assess relevance and materiality against a generally pleaded case, the claimant now accepts -- but without expressly withdrawing any application for Model C disclosure -- that the extended disclosure should be Model D, but in terms limited to the categories of documents previously identified. The effect of that would leave the defendant to assess, against the generality of the pleaded case of the claimant, whether a document that relates to an active ingredient would be capable of assisting the claimant's case or harming its own case, which is the appropriate test under Model D for disclosure.

16. The claimant says that communications between the European Medicines Agency and Janssen Cilag (which is evident from the public documents) relating to the active ingredient of the product that was the subject of the application will be of materiality. It says that the statements in the public documents are not entirely clear and that such documents are not conclusive. It also points out that the defendant does not accept that, as the EPAR arguably shows, the active ingredient was an ingredient already known to the European Medicines Agency because of its approval of Invega in 2007.

17. The defendant submits the claimant cannot properly seek to go behind the public documents, either for the purpose of interpreting them, or to see what test information or data was given to the EMA, unless it makes out a specific case as to why any document or class of documents is material to an issue to be decided at trial.

18. The claimant says that what Janssen was telling the EMA about the active ingredient and its therapeutic effect, in communications or in reports or data submitted in support of their application, and anything the EMA asked about the active ingredient or its effect, will be material to resolve the issue at trial. It points out that, in the EPAR, the EMA is recorded as having sent a list of questions to Janssen Cilag, which were then responded to, and later a list of outstanding issues was sent and responded to. The claimant does not know what those were about. They may have been about the active ingredient of the product, or not, but the claimant says it is unable to be more focused in its application at this stage, because it simply does not have sufficient knowledge of what was discussed or what was said by Janssen in support of its application.

19. I need to ask myself, first, what potential relevance and materiality any of the documents sought may have at trial. This is not an easy exercise, because the classes of document sought are relatively wide. They are sufficiently wide that the claimant now seems to accept they are not properly the subject of a Model C disclosure request. I asked Mr. Heald, who appeared on behalf of the claimant, whether there was arguably a distinction between the two different classes of requested document, in that the class 2 data or reports would be likely to be the basis for any assertion or opinion made in a class 1 document. He did not accept that there was such a simple distinction. He said that a letter falling within class 1 might give detailed reasons based on underlying data.

20. I am not persuaded that anything that Janssen might itself have said to the EMA is information or a statement likely to be of any assistance to the claimant or materiality at trial in deciding the issues that need to be decided. These are issues that will be decided based, essentially, on the contents of the public documents and the expert opinion evidence that the court will hear. Even if the documents sought did contain some subjective assertion by Janssen Cilag (which is not the defendant), that, in my judgment, would carry little, if any, weight against the expert evidence and the public statements, even if it might be a little embarrassing to the defendant in advancing its case. In any event, if there were such a document in correspondence with the EMA, it would be a known adverse document and disclosable as such, if it appears to be asserting something that is contrary to the defendant's case.

21. There is also no reason to think that the applicant company would have said anything material to the EMA that was not reflected in some way in the EPAR, which of course must be interpreted according to its own terms as a public document.

22. As originally drafted as a Model C request, and the more so as the basis for seeking broader Model D disclosure, I am not persuaded that general disclosure of all communications and correspondence with the EMA that relate to the active ingredient is appropriate or necessary. There may be further much more specific questions that the claimant can properly ask, either as a request for further information or as a notice to admit, or even as a request for specific disclosure, but they have not yet been formulated with the requisite degree of specificity.

23. Notably, to my mind, Mr. Heald did not seem to embrace with any enthusiasm my suggestion at an early stage of the argument that some or all of this disclosure might be necessary for the experts to prepare their evidence. I had assumed that this might be the true basis for at least the second class of documents that were being requested. Mr. Heald's skeleton argument says that the experts will need information about Xeplion and what its properties are, in order to opine on what its active substance is, but nowhere was it said that the disclosure sought is necessary or even desirable for the experts to be able to perform their work.

24. The reason, possibly, and as suggested by Mr. Delaney for the defendant, why the claimant was not able to go that far, is that in the EPAR for the claimant's own generic paliperidone palmitate product, the following statement occurs:

> "The pharmacodynamic, pharmacokinetic and toxicological properties of paliperidone palmitate are well known and have been adequately summarised based on publicly available literature."

25. Further, the claimant is not proposing, at least until after it sees what the defendant's expert evidence is, to call clinical evidence in this case.

26. I am, therefore, left with the feeling that this is a somewhat unfocused application for disclosure in support of an as yet unparticularised case, where the original terms of the request for Model C disclosure were too broad, since they identify documents that relate to a general issue, and where Model D disclosure is unjustified.

27. I did, initially, consider that a reformulated and more limited Model C request might be appropriate, but Mr. Delaney has persuaded me that the answer is not at this stage, at least. What may be justified, though of course I make no decision in that regard, is a much more focused application for specific documents in due course, which needs to be preceded with a proper request and explanation in correspondence between the solicitors.

28. One of the reasons why I consider that extended disclosure as sought is not yet appropriate or necessary is that the defendant has offered, admittedly rather belatedly, in the afternoon of 12th November, to provide (subject to some limitations) the underlying evidence and documentations that were no doubt the focus of the second class of disclosure that the claimant seeks. The letter says:

> "Our client would in principle be prepared to provide your client with copies of the evidence (i.e. the data and/or results of studies) submitted to the EMA by Janssen Cilag as part of the Xeplion MA Applications on the basis set out below.
>
> Following the inter-solicitor conference call on 5 November 2020, the correspondence to date and the DRD, we do not understand your client to be suggesting that all data and/or results of studies submitted to the EMA might be relevant to your case. However, it remains unclear which data and/or results of studies your client does consider to be relevant to the Issue for Disclosure identified by your client. Absent any explanation of your client's case, this makes it impossible for our client to understand how to comply with your client's Extended Disclosure Requests under either Model C or D. In circumstances where the EPAR is a public document that your client has access to, we therefore invite your client in the first instance to identify which particular tests and/or studies referred to in the Xeplion EPAR it considers to be relevant to your client's Issue for Disclosure. Subject to the reasonableness and proportionality of your client's request, our client is in principle prepared to provide your client with copies of any non-privileged documents containing the data and/or results underlying those tests and/or studies (suitably redacted to remove obviously irrelevant but confidential material and disclosed under the terms of an agreed confidentiality club)."

29. The claimant rejected that offer by its skeleton argument, saying that it was wrong to offer only objective documents and not subjective documents, by which was meant communications or correspondence in which Janssen Cilag may have expressed its own views or asserted opinions about the active ingredient. This was explained on the basis

of possible overlap in material in correspondence or communications, but it seems to me that any objective data referred to in such letters will be found elsewhere, in the underlying results or data.

30. In my judgment, therefore, the offer from the defendant to deal with data and reports in that way is more appropriate than ordering otherwise unjustified Model D disclosure and the claimant and the defendant should co-operate to deal with any limited disclosure in that way.

31. What I am going to do is make an order for extended disclosure, but only on the basis of Model B disclosure for both sides, which requires disclosure - to the extent it is not already complied with in initial disclosure - of the key documents relied upon in support of the pleaded cases and the key documents that are necessary to enable each side to understand the case that they have to meet.

32. I apprehend that that may largely already have been dealt with in initial disclosure, but there may, on reflection, be further material on both sides that falls into that category.

(For continuation of proceedings: please see separate transcript)

33. I shall not make an order in the defendant's favour for the costs of the application, for two reasons. First, it was an application for general directions at the case management conference, which was needed in any event, and which covered other matters that were not agreed at the time when the application was made. Second, it was only at a relatively late stage that the defendant moved itself to a position where it had offered what I consider to be appropriate relief, effectively, in favour of the claimant.

34. But on the other hand the costs of the hearing itself, the costs of everyone attending today, seem to me to have been incurred because the claimant did not accept the offer that was made in 12th November letter. That could have been done and the costs of today could have been saved.

35. It may not be easy to identify what are the costs of the hearing today, as opposed to other costs of considering and preparing for a case management conference generally, but in principle I consider that the claimant should pay the defendant's costs incurred in attending and arguing the matter today.

36. The remainder of the costs of the application should be costs in the case.

(For continuation of proceedings: please see separate transcript)

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