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Claim No. HP-2023-000020

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: Thursday, 26th September 2024

Before:

MR. JUSTICE MEADE

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Between:

SAMSUNG BIOEPIS UK LIMITED	**Claimant**
- and -	
JANSSEN BIOTECH, INC.	**Defendant**

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- -

MR. TOM MITCHESON KC (instructed by **Simmons & Simmons LLP**) appeared for the **Claimant.**

MR. THOMAS HINCHLIFFE KC and **MS. KATHRYN PICKARD** (instructed by **Carpmaels & Ransford LLP**) appeared for the **Defendant.**

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Approved Judgment

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MR. JUSTICE MEADE :

1. This is the first instalment of the form of order hearing, following my judgment of 30th July, in which I held the patent in suit invalid for obviousness over a document called the Sands Slides, and rejected some other attacks, including an attack over prior art that I compendiously referred to as the Ochsenkühn work. This is the first instalment of the form of order hearing in the sense that I am dealing with permission to appeal today, in order to move things forwards towards the Court of Appeal (if permission is obtained) without waiting for the second instalment of the form of order hearing, which will deal with costs and other consequential matters, and which takes place next term. A procedural point was ventilated at the start of this hearing about whether the time for appealing starts to run from today, and Mr. Hinchliffe KC (who appears for the patentee, with Ms Pickard, as he did at trial) confirmed that it does, and anyway that is my understanding of the natural meaning of the draft order that is before me.

2. The substantive matter I have to deal with today is whether I should give permission to appeal, and in a very clear and concise written and oral presentation, Mr. Hinchliffe makes the following submissions. In relation to my findings on interpretation of the patent in suit, Mr. Hinchliffe accepts, and does not seek to appeal, my findings at paragraphs 214 and 215, that the therapeutic effect in question has to be a real one caused by the treatment, but that no particular measure of statistical significance is required by claim 1. As I say, there is no attempt to appeal against that.

3. In paragraphs 216-218, I dealt with the question of corticosteroid-free clinical remission ("CSFCR") and it is on that feature that the application for permission to appeal turns. It is the submission of the patentee that whilst it is not a requirement of the claim that the patients to be treated are on steroids at the beginning of treatment, it is a requirement that the drug, ustekinumab, for this patient group is *capable* of treating *both* patients who start on steroids and patients who do not. Therefore, Mr. Hinchliffe says that my statement in paragraph 218, that "claim 1 is an easier target for the prior art attacks in relation to expectation of success", because of the possibility of treating patients who are not on steroids to begin with, is wrong. That submission carries forwards into the critical discussion for the purposes of this application for permission to appeal, which focuses on paragraphs 311-313 of my judgment.

4. Mr. Hinchliffe makes clear that it is not his client's desire to appeal against my primary findings of fact that there would be an expectation of a treatment effect in the sense of achieving remission, which is what I considered in the light of the Sands Slides, down to paragraph 310. Rather, Janssen's submissions focus, as I have said already, on corticosteroid-free clinical remission, and in 311 I said: "[i]f the skilled person thought ... that ustekinumab would be an effective treatment for UC at the end of the maintenance phase then they would also think that there would be more patients in CSFCR, compared with a placebo." And I gave two reasons.

5. The first one was the fact that patients who were never on steroids to begin with would not be on steroids at the end, and if effective treatment was achieved then there would be more patients in corticosteroid-free clinical remission than there were at the start. This finding of fact, so far as it was a finding of fact (because I think it is really an inevitable truth) is not sought to be challenged on appeal either.

6. In paragraph 313, I said that I accepted Professor Bloom's evidence that if the treatment was successful during the maintenance phase, then it would also be expected that that would enable some material number of patients who started on steroids to be taken off them, and that made sense because an extra, effective mechanism of treatment would be making one of the initial treatments no longer necessary.

7. Mr. Hinchliffe, again, does not mount an attack on my primary finding (of an expectation that some material number of patients on steroids at the start would come off them) and does not advance that as a ground for permission to appeal, but he says, taken in combination with paragraph 312, that still does not render the claim obvious, or at least there is an arguable case that it does not. The fundamental point taken at that level is that Mr. Hinchliffe says that there was not adequate evidence to establish that one could combine the two patient cohorts in this way.

8. I have the gravest doubts about whether the first limb of this argument is correct; in other words, I think it is an extremely difficult argument to say my conclusion in paragraph 218, that the possibility of treating patients who were never on steroids at all does not render the claim obvious, but I can just about understand the contention that ustekinumab has to be capable, in this population, of treating both those who are on steroids and those who are not at the start of treatment. But even if that argument had a reasonable prospect of success that could found permission to appeal, I think the necessary further contention, that there can be a reasonable argument that it is not permissible to combine the two cohorts considered in paragraphs 312 and 313 of my judgment, is completely hopeless. There was no magic to what I did there; I simply found that there was the necessary expectation of achieving corticosteroid-free clinical remission for those who were not on steroids in 312, and for those who were in 313. In 313 I used the expression "material number of patients", and I think, even stepping back and considering this carefully from a distance, there is no daylight between that and what I said in 214, that the therapeutic effect has to be a real one caused by the treatment. I remind myself that no case is sought to be made on appeal that statistical significance is required. So I think it is unreal to say that I was not entitled to combine 312 and 313.

9. However, furthermore, I would say it was always clear at trial, that Samsung was attacking the patent on the basis both of what I said in 312 and what I said in 313, and I do not believe the point was ever put by Janssen, as it would have needed to be, in argument or in evidence or in cross-examination, that there was some magic or difficulty or science required to combine the conclusions arising from the two groups of patients. I think the argument has no prospect of success, and I also think it is not legitimate to raise it at this stage. If it was to have been taken, it could and should have been taken at trial. Subtle and careful though the argument is, I reject it and I refuse permission to appeal.

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