



Neutral Citation Number: [2021] EWHC 1123 (Pat)

Case No: HP-2020-000048  
HP-2021-000009

**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: Friday, 23<sup>rd</sup> April 2021

**MR. JUSTICE MELLOR**  
Remotely via Microsoft Teams

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Between (HP-2020-00004):

**SANDOZ LIMITED**

- and -

**Claimant**

**(1) BRISTOL-MEYERS SQUIBB HOLDINGS  
IRELAND UNLIMITED COMPANY**  
**(a company incorporated under the laws of Ireland)**  
**(2) PFIZER INC.**  
**(a corporation incorporated under the laws of the  
state of Delaware)**

**Defendants**

And Between (HP-2021-000009)

**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

- and -

**Claimant**

**(1) BRISTOL-MEYERS SQUIBB HOLDINGS  
IRELAND UNLIMITED COMPANY**  
**(2) PFIZER INC.**

**Defendants**

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**MR. JAMES ABRAHAMS QC and MS. ALICE HART** (instructed by **Bristows LLP**) for  
**Sandoz**

**DR. ANNA EDWARDS-STUART** (instructed by **Hogam Lovells International LLP and  
Wilmer Cutler Pickering Hale and Dorr LLP**) for **Bristol-Meyers Squibb**

**DR. JUSTIN TURNER QC and MS. BETH COLLETT** (instructed by **Pinsent Masons**) for  
**Teva**

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## **Approved Judgment**

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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THE HON MR JUSTICE MELLOR

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

1. This is the first CMC in two related actions which it has been agreed should be case managed and heard together. They are concerned with various Formulation Patents relating to the drug apixaban. The first action, HP 2020-00048 is between Sandoz and BMS and Pfizer (for convenience, I will refer to BMS and Pfizer collectively as "BMS"). That first action was commenced on 15th December 2020. The second action was brought by Teva against BMS on 16th February 2021, that is HP 2021-000009. Both these actions ('the Formulation Actions') originally sought revocation of five Formulation Patents held by BMS, namely EP (UK) 2 538 925, EP (UK) 3 017 811, EP (UK) 3 246 021, EP (UK) 3 251 660, and EP (UK) 3 257 500. Although on 16th April 2021 Sandoz reached a Settlement Agreement with BMS with the result that the Sandoz revocation action now only relates to claims 1 to 7 of EP 021 alone, the Teva action continues in full, seeking revocation of all five patents.
2. The parent patent is EP925, with the other four being divisionals. Mr. Sharp in his witness statement for Teva has given a very useful analysis of the various sets of claims in these five patents. As he illustrates in his annex 1, the patents collectively seem to relate to eight different features of different formulations of apixaban (e.g. various particle size thresholds termed D<sub>90</sub>, the method for measuring D<sub>90</sub>, a particular dissolution profile, the method for testing dissolution, the formulation process (wet or dry granulation and air-jet milling) along with claims to the amount of apixaban contained in the tablets/capsules, addition of standard excipients and the use of these pharmaceutical formulations to treat thromboembolic disorders). One is left with the strong impression that the parent, these divisionals and all 59 claims in them are simply there to give every possible combination, or at least as many possible combinations of those eight features as possible. The combinations seem to give rise to considerable overlap.
3. So far BMS have served defences which I am told amount to a bare denial, although at this CMC they are introducing by agreement counterclaims for infringement against both Sandoz and Teva.
4. In terms of the invalidity cases that each of Sandoz and Teva are running, Sandoz, as I understand it, are continuing to run the same invalidity case even though its case has narrowed in the way I have described. They have got three pieces of prior art pleaded as obviousness attacks and Teva have also pleaded two of those three pieces of prior art. Sandoz also include a lack of plausibility plea based on their point that if the patentee alleges that a particular particle size is alleged to have a particular technical significance that is not plausible. Teva have a similar point, although it is characterised slightly differently as an arbitrary selection argument. Sandoz also have an uncertainty/insufficiency case, although Teva do not run that case.
5. The parties have agreed that each side should have permission to call two experts, one in the field of pharmaceutical formulation and the second being either a clinician or a pharmacologist. These actions to revoke the Formulation Patents

take place against the backdrop of other clearing-the-way actions. The first action was started by Sandoz in November 2020 seeking to revoke EP 415 and its related SPC which cover the compound apixaban. That has been characterised as the Compound Patent action. Teva has brought its own similar claim. I recently gave directions down to the trial of that action. As in this Formulation Action, the two cases run by Sandoz and Teva were case managed together and will be heard together at a single trial.

6. The trial for the Compound Patent action has been set to start on, or float from 31st January 2022 and it is listed for five days in court.
7. As for the two issues that have arisen for my determination at this CMC, the first one relates to the trial date for the trial of these formulation actions. There were three possible candidates. The first one was a five-day trial starting on 21 February 2022, and I think all parties agree that that is uncomfortably close to the trial of the compound action and therefore that trial date has been ruled out. That leaves the alternatives, which are either a five-day trial floating from 26th April 2022 or the other candidate is a five-day trial starting or floating from 4th July 2022. Sandoz argue for the July date principally on the basis that it is convenient for counsel and various other members of the team.
8. I understand that BMS's preference is also for July, with April in second place. Teva argue for April, relying on the practice direction that patent actions can, in appropriate circumstances, be listed within 12 months of the start of the claim. Bearing in mind the Teva formulation action started in February 2021, I decided it was appropriate that Teva should be entitled to clear the way and clear away the commercial uncertainty as quickly as reasonably possible and it is for those reasons that I directed this trial to start or float from 26th April 2022.
9. The second issue I have to determine relates to independent validity. The parties have agreed that Sandoz and Teva should serve their PPDs as soon as practicable but in any event within ten weeks of the date of the order resulting from this CMC. The parties have also agreed that BMS should give details of the claims alleged to be independently valid within a certain period after both PPDs have been served.
10. In the circumstances of its Formulation Action, Teva suggest that a limitation on the number of independently valid claims is appropriate and seek a direction that BMS should be permitted to rely on no more than 6 claims as independently valid, with those 6 claims identified within, I think, eight weeks after receipt of the PPDs.
11. In response, Ms Edwards-Stuart for BMS offered to identify 15 independently valid claims within eight weeks of service of the PPDs by Sandoz and Teva.
12. As counsel for Teva pointed out, in his trial judgment in *Conversant v Huawei* [2020] EWHC 14, Birss J at [6] mentioned that at the CMC in that case he had limited the patentee to no more than nine independently valid claims. Counsel also points out that if, on service of their expert evidence, BMS really can justify a greater number of independently valid claims, then they can apply.

13. There are and will be some cases where, at the CMC, the Court does not have sufficient information or a sufficient understanding of the issues to be confident enough to impose a limitation on the number of independent valid claims that the patentee can assert. In other cases, the Court will be able to develop a sufficient understanding
14. Turning back to this case, I am conscious of the fact that as trial approaches in patent actions, the number of independently valid claims does tend to decrease so that at trial, even if Ms. Edwards-Stuart identifies 15 claims alleged to be independently valid in the course of this action, I very much doubt that there will be 15 independently valid claims in issue at trial.
15. I bear in mind that although there is a total of 59 claims in the five patents which Teva are seeking to invalidate, in view of their subject-matter it is extremely unlikely that these patents contain 15 separate inventions. I entirely accept that one more claims and/or one or more of these patents may well be valid, but at the moment the 59 claims seem to represent very much a scattergun approach of simply different combinations of the eight features identified in Mr Sharp's annex.
16. In the particular circumstances of this action and these five patents, I will accede to Teva's application in part. However, I will require the patentees to identify no more than ten independently valid claims within 28 days of service of both PPDs. By that time, the patentees will have had ample opportunity to analyse the validity attacks but will also have a clear idea of the alleged infringements. I emphasise that the patentees should expect to limit themselves to fewer than those ten claims, certainly by the time of trial, if not by the time of service of experts' reports. In that regard all sides have liberty to apply so that if the patentees really can justify having more than ten claims in issue as being alleged to be independently valid, they can apply. If the Claimants wish to say that the ten claims that have been identified remains an excessive number, they also have liberty to apply.

*(For continuation of proceedings: please see separate transcript)*

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