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Dasatinib – post-filing data in Europe

Additional post-filing data is often crucial to confirm the technical effect of pharmaceutical patents. On 1 February 2017 the Board of Appeal of the European Patent Office will be deciding the fate of Bristol-Myers Squibb's (BMS) patent directed to dasatinib. The decision could have far-reaching implications on patentability of pharmaceuticals in Europe and the usefulness of post-filing data.

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Background to the case

The original patent application filed by BMS identified a range of compounds by means of a general formula and include dasatinib in a list of example compounds. Assays for the identification of protein kinase (PTK) inhibitors were described and it was stated that the example compounds had shown activity in one or more of those assays, but no data for individual example compounds was provided. In the opposition proceedings, prior art documents were cited disclosing that other compounds falling within the general formula are PTK inhibitors, and the claims were narrowed to focus solely on dasatinib as a single compound and its use in treating cancer. BMS argued that the application made it plausible that dasatinib is a PTK inhibitor useful in the treatment of cancer and referred to post-filing evidence verifying that fact.

First Instance Findings

The novelty of dasatinib as a single compound was never in doubt. However, in revoking the Patent, the Opposition Division decided that as the original application did not include data demonstrating the activity of dasatinib, its utility was not sufficiently disclosed and no technical effect could be attributed to the compound. The post-filing data could not remedy that defect and was not admitted. Thus, the medical use claims were found insufficient and the compound *per se* claims found to be directed to an obvious arbitrary selection that could have been arrived at by trial and error and so lack an inventive step.

Admissibility of Post-filing data

It is generally accepted that supplemental post-filing data is admissible in support of a technical effect when the application as filed goes beyond mere speculation and instead makes it plausible that a problem has been solved. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has commented that in this case "*the application most certainly renders it plausible or credible that the problem of providing alternative anti-cancer agents or alternative PTK inhibitors has been solved.*" Thus, the Opposition Division's decision not to admit the post-filing data undermines established practice for the patenting of pharmaceutical compounds.

Implications

If the Opposition Division's findings are upheld and become widely adopted, there could be profound implications for the patentability of pharmaceutical inventions in Europe. Should the ability of an applicant to file additional supporting data later be substantially curbed, it will become essential to include comprehensive data at the time

of filing in order for the patentability of novel compounds to be established. While, some corporations may have the ability to delay filing patent applications until data on all potential lead compounds has been obtained, many others including SMEs and universities may not be in a position to do so: it may be necessary for them to file patent applications and publish at an early stage, i.e. as soon as the activity of a group of compounds has been rendered credible, in order to secure the funding for further investigations that verify the initial findings. Also, any delay in the filing of patent applications risks relevant information being published that renders the innovation non-patentable. For all parties, the risks associated with conducting research into pharmaceutical innovations will be increased, having a knock-on effect on the availability and price of new medicines.

What next?

The outcome of the Appeal hearing on 1 February 2017 is awaited with bated breath by the pharmaceutical industry. We will report on the outcome as soon as it is known.

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