

## Enlarged Board of Appeal to Consider the Doctrine of Plausibility

It is fairly common at the EPO in the fields of chemistry and biotechnology for applicants/patentees to rely upon data that are not present in the application as filed, and that were generated after the priority/filing date, to support arguments in favour of inventive step. Such data are often referred to as “post-published data”. They are often used to evidence some technical advantage associated with the claimed invention, as compared with disclosures in the prior art. That enables the patentee or applicant to define the “objective technical problem” solved by the claimed invention as that of providing an improved product or process.

The EPO’s examination guidelines specifically endorse the use of post-published data in the context of assessing inventive step, to evidence a technical effect associated with the claimed subject matter (section G-VII-5.2, fifth paragraph). However, the case-law of the boards of appeal has introduced into EPO jurisprudence the principle that post-published data may be only taken into consideration when considering inventive step if it does not serve as the **sole** basis to establish whether the application solves the problem it purports to solve: there must be a plausible disclosure of (for example) relevant biological activity in the application as filed.

Two key board of appeal cases explaining this requirement for a plausible disclosure of activity are T1329/04 (Johns Hopkins), and T488/16 (Dasatinib) - our news item on the latter decision can be found [here](#). Both cases involved therapeutic products. In both cases, the board revoked the relevant patent for lack of inventive step, noting that the specification as filed did not contain a plausible disclosure of the relevant biological activity. The boards in T1329/04 and T488/16 thus rejected as inadmissible post-published data evidencing the efficacy of the claimed products.

In both T1329/04 and T488/16, however, it is perhaps fair to say that it is not made entirely clear whether the requirement for a plausible disclosure requires some technical information (such as experimental results) which supports an assertion of biological activity, or whether all that is required is a mere assertion of biological activity which is *prima facie* credible. Further, there are other board of appeal cases which suggest that a mere assertion of the relevant biological activity should suffice, if there is no substantiated doubt about the theoretical case made for the efficacy of the invention (see for example T578/06).

Current EPO jurisprudence is not therefore wholly clear regarding the level of support needed in a patent application which asserts that a claimed product is patentable by virtue of some technically advantageous property, such as a desirable biological activity. This issue was considered by the UK Supreme Court in [Warner Lambert v Actavis](#) in some detail (see our briefing [here](#)), where

the UK tribunal held that a mere assertion of efficacy should not suffice. The court held that a “plausible” disclosure of efficacy requires at least some credible supporting technical information. However, the Warner Lambert decision applies only in the UK.

It now seems as if questions relating to the use of post-published data to support a technical effect will be referred to the Enlarged Board of Appeal of the European Patent Office. In particular, in a recently published set of minutes from EPO Board of Appeal hearing on 22 July 2021 (appeal number T0116/18) regarding European patent EP2484209, the Board of Appeal indicated that it would be referring a number of questions to the Enlarged Board of Appeal.

European patent EP2484209 was granted with claims defining an insecticide composition comprising thiamethoxam (a known insecticide) and a compound of formula [Ia] represented by a Markush formula (also known to have insecticidal activity). Such compositions were said to “*produce a greater effect than would be expected when both of the compounds individually are applied solely, thus enabling a reduction in the rate or number of applications of agrochemicals or pesticides to be realized*”. In the patent itself, only two examples of such compositions were given.

During opposition proceedings, further data was filed by the patentee providing additional examples of compositions showing the synergistic effect, as evidence in support of inventive step. The appellant (opponent) argued that such data should not be taken into account, because the application as filed did not contain enough data to reach the “plausibility” threshold. At appeal, the decision as to whether the claims did or did not have inventive step turned on whether or not it was legitimate to rely on the additional post-published data.

During appeal proceedings, the Chairman proposed the following referral questions to the two parties involved:

*“If for acknowledgment of inventive step the patent proprietor relies on a technical effect and has submitted data or other evidence to proof [sic] such effect, such data or other evidence having been generated only after the priority or filing date of the patent (post-published data):*

- 1. Should an exception to the principle of free evaluation of evidence (see e.g. G1/12 reasons 31) be accepted in that the post-published data must be disregarded on the ground that the proof the effect rests **exclusively** on such post-published data?*
- 2. If the answer is yes (post-published data must be disregarded if the proof [sic] of the effect rests exclusively on these data): can post-published data be taken into consideration if based on*

*the information in the patent application the skilled person at the relevant date would have considered the effect plausible (ab initio plausibility)?*

3. *If the answer to the first question is yes (post-published data must be disregarded if the proof of the effect rests exclusively on these data): can post-published data be taken into consideration if based on the information in the patent application the skilled person at the relevant date would have seen no reason to consider the effect implausible (ab initio implausibility)?*

The patentee and the appellant raised a number of further points

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which may also be included in the final version of the questions referred, regarding defining the effective date more clearly (for instance, if priority is claimed), whether the effect relied upon by the patentee must concern the full scope of the claim and where the burden of proof of the presence/absence of such a technical effect lies.

The next stage is for the Board of Appeal to issue the written decision, which will set out the final versions of the questions to be referred to the Enlarged Board of Appeal. Practitioners in the chemical and biotech fields will be watching these developments with interest.

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