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Use of Post-Filing Data to Support Patentability

The use of post-filing data to support patentability can be a mechanism to alleviate time pressures related to first-to-file patent regimes. However, the admissibility of such data is dependent on the filing jurisdiction and can be treated very differently depending on its use. The September issue of the Global Patent Prosecution Newsletter examines the role of post-filing evidence in the US, Europe, China, and Japan with respect to sufficiency of disclosure and inventiveness.

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SUBMISSION OF POST-FILING DATA – THE DICHOTOMY BETWEEN ENABLEMENT AND OBVIOUSNESS IN THE UNITED STATES, CHINA, AND JAPAN

By Paul A. Calvo, Ph.D.

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POST-FILING EXPERIMENTAL DATA AT THE EUROPEAN PATENT OFFICE

By Fei Sha and Paul A. Calvo, Ph.D.

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United States

Post-filing evidence is routinely used in applications to support prophetic examples often times in rebutting a rejection based of lack of enablement. This evidence is particularly effective when the prophetic examples describe the manner and process of making and using an embodiment of the invention, and the post-filing data is used to demonstrate what was expected. This scenario often comes into play in the life sciences where compounds may have been created, but in vivo testing may not have been performed. In cases such as this, the USPTO allows for submission of post-filing evidence that supports the prophetic disclosure.

But what about situations where post-filing data is needed to rebut an assertion of obviousness? In many cases, a US Examiner will require an affidavit or declaration containing evidence of criticality or unexpected results be submitted for consideration. To have probative value in the determination of nonobviousness, there must be a sufficient factual and legal connection between the objective evidence and the claimed invention.

China

China has a relatively strict approach to the determination of sufficiency of disclosure, especially when compared to the approach taken in other jurisdictions, such as the US and Europe. Although the patent examination guidelines were loosened in 2017, the determination of sufficiency of the disclosure, is still performed based upon the contents of the specification as originally filed. The Amended Guidelines make clear that, "*The Examiner shall examine*

supplementary experimental data submitted after the date of filing. The technical effect to be demonstrated by the supplementary experimental data should be (an effect) that can be arrived at by a person skilled in the art from the contents disclosed in the patent application." Thus, post-filing experimental data demonstrating a technical effect, should not be rejected outright, but may be considered as long as the technical effect can be understood by a person skilled in the art from the application as originally filed.

Since the China National Intellectual Property Administration (CNIPA) usually requests that technical effects to be proved by supplementary data be directed to a technical effect capable of being known by a person skilled in the art as of the filing date, the SIPO requires that there is explicit disclosure in the original data of a relevant technical effect. Absent that original data, the CNIPA generally will not allow supplementary experimental data be used to prove inventive step, even if the data is comparative relative to the prior art.

Japan

The *Examination Guidelines for Patent and Utility Model* in Japan requires that supplementary experimental results are not a substitute for a "Detailed Description of the Invention" in a patent application. Similar to China however, as long as the relevant effects are disclosed in the original patent specification, or can be speculated by a person skilled in the art from the specification or drawings, post-filing data demonstrating technical effects will be taken into consideration during prosecution.

The High Court in Japan loosened the requirements for when supplemental data is allowable for cases related to inventiveness in 2010. The Court held that since an applicant is not able to know which cited prior art will be compared with the claimed invention, it is not fair to the applicant if they have no opportunity to objectively verify any technical effects based on comparative data. Thus, the Court held that even in cases where an application does not explicitly disclose remarkable technical effects but they can be derived from the specification, it is allowable to take supplemental data into account in the context of the determination of inventive step.

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Sufficiency of Disclosure

Article 83 of the European Patent Convention ("EPC") requires European patent applications to "disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." A single example may suffice, but for claims that cover a broad field, a patent application must disclose multiple examples or describe alternative embodiments or variations extending over the technical area encompassed by the claims. If a patent specification lacks disclosure of tangible proof that the claimed concept can be put into practice, post-published documents can confirm the teachings of a patent application, but cannot be used to "cure" an insufficiency in disclosure.[1]

For example, if a patent disclosure provides no guidance as to how to perform a particular aspect of a claimed invention, post-published documents that later show how such performance is accomplished cannot "cure" the insufficiency.[2] In addition, if a patent specification provides only a vague indication of possible medical use for a yet-to-be-identified chemical compound, post-published documents containing details as to the identity and medical use of the compound cannot remedy the insufficiency of disclosure.[3] However, where an application lacks such explicit data, but discloses a technical concept that is plausible in view of common general knowledge at the relevant filing date, post-published documents may be used to support sufficiency of disclosure.[4]

Inventive Step

In view of the "problem-and-solution approach" to an inventive step analysis, which determines whether a claimed invention provides a non-obvious solution to a technical problem defined by its closest prior art, the "plausibility test" requires that the claimed invention is made plausible by the disclosure in the patent application and that its teaching indeed solves the technical problem that it purports to solve.[5] To satisfy plausibility, there must be verifiable evidence

disclosed in the initial application in the form of experimental data or a structure-activity relationship that makes the activity plausible. Mere assertion in the absence of any data is not sufficient to render plausible the teaching of the patent application.

Post-published evidence that supports the proposition that the invention solves the technical problem that it purports to solve can only be considered when it already appears plausible from the patent disclosure that the problem is indeed solved.[6] For example, claims to broad classes of chemical compounds asserted to have some common technical effect were not inventive because nothing in the patent disclosure demonstrated that the compounds would all have that common technical effect – thus the patent disclosure was found to be implausible.[7] However, absolute proof of the achievement of a technical effect through the highest quality evidence is not required for that effect to be deemed plausible.[8] Whether post-published documents may be allowed to support plausibility is ultimately decided on a case-by-case basis.

Similar to most all other jurisdictions, a plausible technical effect or surprising property of the invention must be present over the full scope of the claims. Such an effect can be demonstrated with data in a comparative test between the claimed invention and its closest prior art, where the effect is convincingly shown to have its origin in a distinguishing feature of the invention as compared to the closest prior art.[9]

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[1] Decision T 1205/07 "Adenoviral packaging system/CRUCELL" (Sep. 20, 2011).
[2] Decision T 0497/02 "Insulinotropic hormone/GENERAL HOSPITAL" (May 27, 2004), *citing* decision T 222/00 "Hemicellulose degradation/VALTION" (Jan. 15, 2003).
[3] Decision T 609/02 "AP-1 complex/SALK INSTITUTE" (Oct. 27, 2004).
[4] Decision T 0950/13 "Dasatinib in the treatment of chronic myelogenous leukemia/BRISTOL" (Feb. 03, 2017), *citing* decision T 1262/04 "Light detection in mammals/LELAND STANFORD" (Mar. 07, 2007).
[5] Decision T 1329/04 "Factor 9/JOHN HOPKINS" (June 28, 2005).
[6] Decision T 0488/16 "Dasatinib/BRISTOL-MYERS SQUIBB" (Feb. 01, 2017); *see also* CLBA I.D, 4.6.
[7] Decision T 0939/92 "Triazoles/AGREVO" (Sep. 12, 1995); *see* EPC Art. 56.
[8] Decision T 0716/08 "Infectious salmon anaemia virus vaccine/INTERVET" (Aug. 19, 2010).
[9] Decision T 1009/12 (Jan. 08, 2013); *see also* CLBA I.D, 10.9.