



The Standing Committee on Pharma and Biotechnology

## AIPPI Position Paper

### Recommendations on the use of post-filing data in support of inventive step

#### AIPPI and background to this position paper

The International Association for the Protection of Intellectual Property, generally known under the abbreviated name AIPPI, is the world's leading international organization dedicated to the development and improvement of legal regimes for the protection of intellectual property (IP).

It is a politically neutral, non-profit organization, domiciled in Switzerland, which currently has over 9000 Members representing more than 100 countries. The objective of AIPPI is to improve and promote the protection of intellectual property on both international and national bases. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and national laws relating to intellectual property. AIPPI operates by conducting studies of existing national laws and proposes measures to achieve harmonization of these laws on an international basis. Where appropriate, AIPPI intervenes with submissions before major courts and legislative bodies to advocate for strengthened IP protection.

The AIPPI Standing Committee on Pharma and Biotechnology (the 'Pharma Committee') has surveyed the current practice regarding acceptance of post-filing data in support of inventive step in 26 countries around the world, as well as in the European Patent Office (EPO). This survey revealed significant differences between jurisdictions. The Pharma Committee has agreed that adopting a common ground for the acceptance of post-filing data would be beneficial, because the current practice of varying procedures is confusing and creates diverging standards regarding patentability of the same inventive concept. In particular, the committee recommends a common position to allow consideration of post-filing data in the assessment of inventive step, in particular if the post-filing data elaborate on effects that are already apparent from the application or patent.

#### Acceptability of post-filing data to support Inventive Step

Patentability of an invention should generally be evaluated on the basis of the statements and data in the application as it was filed, taking into account the prior art. However, the Patent Cooperation Treaty allows taking into account of "*any additional documents considered to be relevant in a particular case*" (Art 33(6) PCT). In line with this provision, patent offices in many jurisdictions allow applicants to provide additional evidence during prosecution, which may help to establish the inventive character of an invention.

Although this practice may be applied in any technological field, it is of particular importance in the field of biotechnology and pharmaceuticals. In biotech and pharma, early filing is often important to

secure investment for expensive development work. Biotech and pharma products usually have long development times, e.g., from 5-10 years. As a result, important data about the invention, such as *in vivo* data, may not be discovered until after the filing date of the patent application. Another consequence of long development times is the possibility of publication of research data in another document, such as a scientific article or report of a clinical trial. Such a publication could preclude obtaining a patent if it would be published prior to filing a patent application. Patent practitioners must find the appropriate balance between filing quickly and risking rejection for lack of supporting evidence, or waiting until the data is available and risking publication of prior art.

“Post-filing data”, in this context, is defined as the provision of any evidence to national authorities after the effective filing date of a patent or patent application. Generally, post-filing data are provided to national authorities by a patent proprietor or applicant in the form of an experimental report, a declaration, or a publication of the subject matter of the invention, after the effective filing date of the patent or patent application. The present position paper is confined to the existing practices in accepting post-filing data in support of inventive step.

It is important to note that post-filing data in the context of this position paper should not be considered as an amendment or addition to the specification of the patent application, which should remain as it was prior to the submission of the post-filing data. Impermissible added matter has been defined and discussed in an AIPPI Resolution: “*Added matter: the standard for determining adequate support for amendments*” which was discussed and approved during the 2016 AIPPI World Congress.

#### *Survey of Pharma Committee Members*

The Pharma Committee surveyed its members between November 2015 and February 2016, and obtained responses from Committee members in the following countries: Argentina, Australia, Belgium, Brazil, Canada, Chile, China, Columbia, Costa Rica, Ecuador, France, Germany, Hungary, India, Israel, Italy, Japan, Korea, Mexico, Netherlands, Peru, Spain, Turkey, United Kingdom (UK), United States of America (USA) and Venezuela, as well as in the European Patent Office (EPO). The results show that an inconsistent practice has developed regarding when, and to what extent, post-filing data are taken into consideration by national authorities in assessing inventive step of an invention.

The survey distinguished between the pre-grant and the post-grant phase. The pre-grant phase includes prosecution and pre-grant oppositions, where applicable, and the post-grant phase includes post-grant oppositions as well as proceedings before a national court.

In the pre-grant phase, the general view in many jurisdictions is that post-filing data is acceptable. In most jurisdictions, such data can only be used to further support effects which are disclosed in the application, although acceptance of such data may sometimes be limited to situations where there is provided a comparison with the prior art. However, further deviations from this general view exist.

In the US, the authorities must consider the totality of the evidence of unexpected results, regardless of whether the properties are disclosed in the specification. In Columbia and Ecuador, a similar practice exists. As such, in these countries post-filing evidence may be used generally to support inventive step.

The current practice at the European Patent Office is to allow post-filing evidence in support of inventive step, but only where the post-filing evidence is used to support facts that are derivable from the specification as filed. Under EPO case law, supplementary post-published evidence may not serve as the sole basis to establish a solution to a problem, or the existence of unexpected benefit. (T 1329/04, T 415/11). Post-filing data can only be used to support a teaching derivable from the application (T 716/08, see also T 578/06).

However, the State Intellectual Property Office of China (SIPO), which handles more patent applications than any other office around the world, has a much more restrictive view.<sup>1</sup> SIPO does not generally permit the use of post-filing data to support inventive step. China's practice is of great concern to the pharma industry, given the size of China's pharmaceutical market. China is the second largest pharmaceutical market in the world, and given its average annual growth rate of 14% in drug expenditures, it is expected to be the world's largest pharma market by 2017.<sup>2</sup>

Canada is similarly restrictive. In Canada, only data present in the application can be taken into account, and all other evidence is to be discarded. Canada's standard is also of concern to the pharma industry, given that commentators have noted other areas in which the Canadian patent law is hostile to pharmaceutical inventions.<sup>3</sup> In Belgium, France, the Netherlands and Venezuela the use of post-filing data in the pre-grant phase is not applicable due to particularities in their grant procedures.

In the post-grant phase, the general picture is more divergent. In many jurisdictions, post-filing data is generally acceptable to support inventive step, as long as the post-filing data are used to support further effects which are already apparent from the application. In about as many jurisdictions however, post-filing data will not be taken into account to assess inventive step in the post-grant phase. Canada adopts the same restrictive position regarding post-filing data as it does in the pre-grant phase. The US, which is lenient in permitting the use of post-filing data pre-grant, also is open to the use of post-filing data in post-grant proceedings. Columbia and Ecuador however do not allow consideration of post-filing data in the post-grant phase, in contrast to their pre-grant phases.

### AIPPI Commentary

It is the position of AIPPI that innovation is stimulated by the protection of intellectual property, and that the protection of intellectual property benefits from clear and consistent practice in how the requirements for the grant of exclusive rights are applied. In the field of patents, the present inconsistent approach in when and how to take into account post-filing data in the assessment of inventive step creates uncertainty as to what exactly should be included in a patent application, and leads to inconsistent results in patent prosecution around the world. In particular in the pharmaceutical

---

<sup>1</sup> SIPO announced that in 2015 more than one million patent applications were filed in China. See IP5 Statistics report 2015, page 17, available at <http://www.fiveipoffices.org/statistics/statisticsreports/2015edition/IP5SR2015full.pdf>

<sup>2</sup> See J. Hu et al, "Pharmaceutical pricing and reimbursement in China: when the whole is less than the sum of its parts," Health Policy 120 (2016), 519-535.

<sup>3</sup> See, e.g., D. Kappos, "Intellectual Property: Canada: A penalty box for pharm innovation, Fortune July 2, 2014, available at <http://fortune.com/2014/07/02/canada-a-penalty-box-for-pharma-innovation/>

and biotechnology field, this uncertainty may also lead to patents which are filed too early (i.e., with too little supporting data), or too late (i.e. after disclosures of research results have already occurred). Patents in these fields require filing at an early stage before commencing clinical trials, which are necessary in order to safeguard the interest of public health, and thus more leeway should be allowed for patent applicants to provide data supporting inventive step at a later stage.

The current practice hampers innovation in the pharma and biotechnology field. Patent applications filed early with a more limited amount of supporting data may never be granted. The lack of patent protection may prevent an innovator from making the necessary financial investment to further develop the invention. Additionally, innovators wary of the status of pending applications may delay publication of additional scientific material about the invention (including clinical data) until patent grant, thereby limiting the information available to the scientific community.

In order to foster harmonization of patent laws worldwide, and lead to more consistent results, the Pharma Committee recommends that national patent offices and courts accept post-filing data in support of inventive step, in particular when the properties or effects supported by the data are already described in or apparent from the application or patent. The practice should be harmonized both internationally and within each country at the pre- and post-grant phases. The Pharma Committee favours the acceptance of post-filing data in both pre-grant patent examination and post-grant proceedings, and in patent litigations. In making this recommendation, the Pharma Committee acknowledges and reiterates the principle of the 2016 AIPPI resolution on added subject matter. In the 2016 resolution, the AIPPI recommended that added subject matter, i.e. subject matter extending beyond the content of the patent application as filed, should not be permitted in an amendment after filing.

## Conclusion

Global practice regarding the acceptability of post-filing data in support of inventive step varies considerably across the various jurisdictions. The Pharma Committee recommends adoption of a common practice. This practice should be harmonized to allow consideration of post-filing data in the assessment of inventive step, in particular if the post-filing data elaborate on effects that are already apparent from the application or patent. This practice should be adopted consistently in all countries both during prosecution and in the event of a post-grant challenge to validity.

April 13, 2017