2023 AIPPI World Congress – Istanbul
Adopted Resolution
25 October 2023

Standing Committee on Pharma Resolution

Experimental Use and Bolar-type Exemptions

Background:

1) This study question concerns experimental use and Bolar-type Exemptions as an exception to patent infringement.

2) Many countries provide an exception to patent infringement when the use of the patented invention is experimental. In most countries, acts that would otherwise be infringing may be exempted as experimental use, when those acts constitute experiment(s) practiced "on" the patented invention, for example, to study the claimed invention as part of the process of making an improvement invention.

3) AIPPI has previously studied experimental use as a defence to patent infringement – see Resolution on Q105 ("Experimental use as a defence to a claims of patent infringement", Tokyo, 1992) (the Tokyo Resolution). The Tokyo Resolution stated that there should be exemption from patent infringement for "acts done for experimental purposes." The Resolution defined such acts, in part, as those:
   - performed for academic purposes and having no commercial value.

- evaluating the teaching of a patent and validity of the patent; and
- using a patented invention for experimentation (as opposed to commercial use).

4) In addition to an exemption for experimental use, many countries have specific laws or rules providing an exemption from infringement when the otherwise infringing acts carried out for the purposes of developing medicines for regulatory review. These provisions are commonly known as "Bolar-type" exemptions, with reference to the 1984 decision of the United States Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858 (1984). For example, the U.S. has a statute exempting infringement "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." In the European Union, EU Directive 2004/27, Article 10(6), exempts from patent infringement any acts of "conducting the necessary studies and trials" to develop a generic or biosimilar drug.

5) In 2008, AIPPI studied Bolar-type exemptions as an exception to exclusive patent rights applicable to medicines and other medical products, in Resolution Q202 ("The impact of public health issues on exclusive patent rights", Boston, 2008) (the Public Health Resolution). The Public Health Resolution proposed an exception to the rights of a patentee, allowing a party to undertake, without the authorization of the patentee, acts necessary for the purpose of obtaining regulatory approval for medicines and other medical products such as medical devices, diagnostics, research tools and the like. The Public Health resolution also clarified the Tokyo Resolution on Q105, stating that the experimental use exemption includes experiments having commercial aim.

6) AIPPI has made no further studies of experimental use or Bolar-type exemptions since the 2008 resolution.

7) The past decade has witnessed rapid advancements in technology, and a significant increase in international collaboration in research and

development. Since the outbreak of the Covid pandemic[1], world-wide cooperation between entities has grown to an unprecedented level, affecting the way experiments are conducted. This is particularly true for medicines, which are commonly subject to pre-clinical studies and clinical trials in multiple countries. This "globalization" of research in certain areas, and in particular, in the development of medicines, coupled with the discrepancy between national laws governing patent exemptions, gives rise to increasing complexity and uncertainty of scope of patent protection and possible patent exemptions both for the patentee and others.

8) Consistent and predictable application of the experimental use and Bolar-type exemptions are therefore an important factor in advancing research in medicine and public health, providing investors, governments, and other stakeholders with certainty that the actions they take are not infringing upon the legitimate rights of patent holders.

9) The AIPPI Pharma Committee drafted a set of 19 questions and submitted them to the various AIPPI National Groups. The Committee received Reports from the following Groups and Independent Members in alphabetical order: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chinese Taipei (Independent Members), Colombia, Ecuador, El Salvador, Finland, France, Germany, Hungary, India, Israel, Italy, Japan, Korea, Malaysia, Mexico, Netherlands, Nicaragua, Panama, Peru, Philippines, Poland, South Africa, Spain, Sweden, Switzerland, Turkiye, Vietnam, the United Kingdom, the United States of America and Uruguay. 37 Reports were received in total.

10) The Committee thanks the Groups and Independent Members for their helpful and informative Reports. All Reports may be accessed in AIPPI's library at www.aippi.org. The Reports provide a comprehensive overview of national and regional laws, practices, and policies relating to experimental use and Bolar-type exemptions.

[1] C.f. AIPPI Position Paper: TRIPS Agreement and the COVID-19 Waiver - "AIPPI is not aware of evidence that intellectual property rights constitute a barrier for accessibility of COVID-19 related medicines and technologies. …"

11) At the AIPPI World Congress in Istanbul in October 2023, the subject matter of this Resolution was further discussed within a dedicated Study Committee, and again in a full Plenary Session, following which the present Resolution was adopted by the Executive Committee of AIPPI.

AIPPI resolves that:

Experimental Use and Bolar-type exemptions are different concepts, which serve different purposes.

1) The Experimental Use exemption is intrinsic to patent law, as it aims at promoting technological progress, by allowing inventors to experiment on patented technologies/subject matter. The Experimental Use exemption covers experiments on the subject matter of the invention, irrespective of whether the ultimate aim of the experiments may have some commercial value.[2] Bolar type exemptions are extrinsic to patent law by nature as they prominently serve other public interests, *inter alia* the facilitation of regulatory approval for and ultimately entry into the market of generic medicines for patients.

   While the Experimental Use exemption is applicable to all technical fields, Bolar type exemptions are prominently focused on the medical field and possibly other fields where regulatory approval is required for entering a new product to the market.

2) While the Experimental Use exemption and Bolar-type exemptions are not co-extensive, certain activities may fall within the ambit of both exemptions, such as the development of certain activities supporting regulatory approval of innovative medicines.

[2] See section 1.1 of The Public Health Resolution.

Scope of the Experimental Use exemption is limited to certain activities

3) Experiments performed on a patented invention should fall within the Experimental Use exemption. Section 3.4 of the Tokyo Resolution that "*Experimental use should be subject to the overriding principle that the use must involve work on the subject of the patent; …*" and section 3.1 of the Tokyo Resolution that "*…use of the patented invention performed for academic purposes and having no commercial value*" should be understood in this context.

4) Experiments made with a patented research tool (a device, substance or method intended for use in scientific research) for its claimed or originally intended use would not qualify for the Experimental Use exemption, even if used for experimental or non-commercial purposes. The claimed or originally intended use of the patented research tool should be determined from the patent specification.

5) Sections 3.2, 3.3 and 5 of the Tokyo Resolution are affirmed:

> "3.2: Experimental use includes testing to evaluate the teaching of the **patent** and validity of the **patent**.
>
> 3.3: Experimental use includes any use of the patented invention to an extent appropriate to experimentation (as opposed to commercial use) which is **for the purpose of improving the invention or making an advance over the invention or finding an alternative to the invention**, but not the commercial exploitation of the subject of any improvement or advance.
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> 5: As experimental use is an **exception** to the rights of the patentee; this exception should be narrowly interpreted by the Courts."

6) As a continuation of the Tokyo Resolution, Experimental Use provisions should exempt from any infringement of a patent undertaken for experimental purposes on the subject matter of the invention, to discern or discover:

   I. the validity of the patent and the scope of protection afforded under the patent;

II. features, properties, inherent characteristics or advantages of the patented subject matter;

III. alternative methods of making or using the patented subject matter for the same purpose; or

IV. improvements to the patented subject matter.

Experimental Use exemption may extend to supply and other assistance by remote parties under certain conditions:

7) Any person or entity assisting a third party in the performance of experimental activity that is within the Experimental Use exemption should not be liable for patent infringement, even if there is a commercial intent of the third party. For example, a supplier of a patented product may be exempted from infringement to the extent it can show that the patented product is supplied solely for an exempted act. According to paragraph 4, experimentation with a research tool by such entity or person assisting a third party for its originally claimed or intended use should not be an exempted act.

Burden of Proof on Experimental Use lies on Parties putting forward the exemption defence

8) Section 6 of the Tokyo Resolution that "*The **burden of proof** of an experimental use exception should lie on the third parties which put forward such an exception*" - should also apply to persons or entities assisting a third party in the performance of experimental acts, e.g. by supplying materials or equipment therefor.

Scope of Bolar-type Exemptions

9) Type of Activities Bolar-type exemptions should apply to acts necessary for the development of innovative, biosimilar, and/or generic products, which require regulatory approval.

10) Geographical Scope –Bolar-type exemptions apply when the otherwise infringing act occurs for the purposes of generating data in support of a submission for regulatory review irrespective of whether the regulatory review is in the territory where the experiments take place.

Bolar-type exemption extends to supply and other assistance by remote parties under certain conditions:

11) Supply and Other Assistance by Remote Parties - Contractors assisting in the performance of activity of a third party that is exempted by a Bolar-type exemption, should not be liable for patent infringement by reason of their acts of assistance in relation to the exempted activity. For example, a supplier of patented product should be exempted from infringement to the extent it can be shown that the patented product is supplied solely for an act to which a Bolar-type exemption applies. The burden of proof of a Bolar-type exemption should lie on the party which put forward such an exemption.

Bolar-type exemption does not include stockpiling activities:

12) "Stockpiling" is the manufacture of a product during the term of a patent covering the product, in preparation for sales after patent expiration, and at an amount exceeding what is needed to support regulatory review. Stockpiling should not be covered by Bolar-type exemptions.