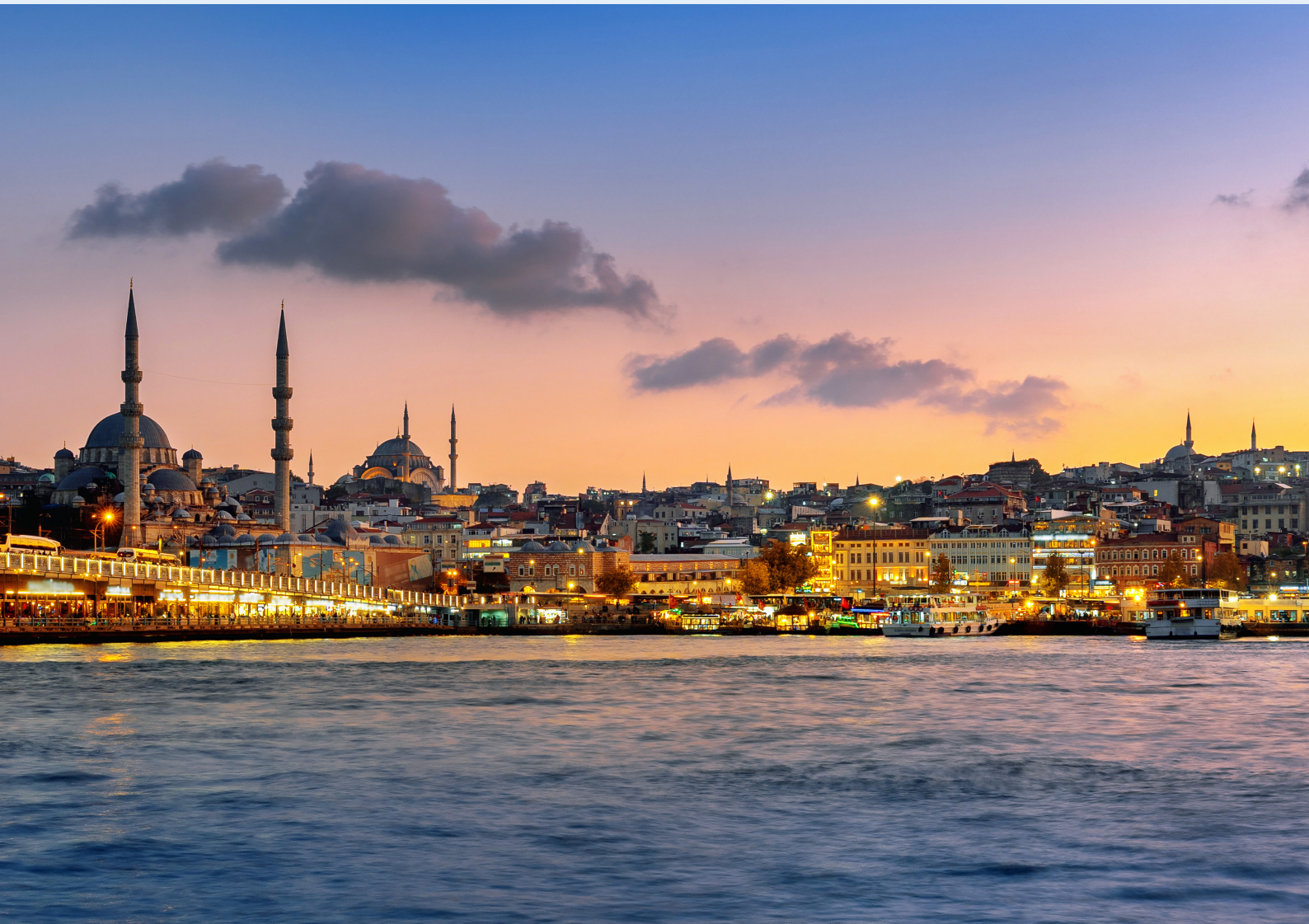
AIPPI

2023 AIPPI World Congress

Istanbul

22-25 October 2023

AIPPI Resolutions



About AIPPI

The International Association for the Protection of Intellectual Property, known as AIPPI (Association Internationale pour la Protection de la Propriété Intellectuelle), is the world's leading non-profit association dedicated to the development and improvement of laws for the protection of intellectual property. It is a politically neutral, non-profit organisation, based in Switzerland with over 8000 members worldwide from over 110 countries.

2023 AIPPI World Congress - Istanbul
Adopted Resolutions
22-25 October 2023

Content

Study Question Q284 - Patents

Doctrine of equivalents

Background:

1) The doctrine of equivalents was previously considered by AIPPI in resolutions Q175, *The role of equivalents and prosecution history in defining the scope of patent protection* (Lucerne 2003), and Q229, *The use of prosecution history in post-grant patent proceedings* (Seoul 2012). This resolution addresses issues that are not considered by resolutions Q175 and Q229.

2) In Q175, AIPPI resolved that an "*element shall be regarded as equivalent to an element in a claim, if: 4.a) the element under consideration performs substantially the same function to produce substantially the same result as the claimed element; and 4.b) the difference between the claimed element and the element under consideration is not substantial according to the understanding of the claim by a person skilled in the art at the time of the infringement*."

3) In contrast, an element shall not be regarded as equivalent to an element in a claim, if 5.a) "*a person skilled in the art would at the filing date have understood it to be excluded from the scope of protection, or 5.b) as a result the claim covers the prior art or that which is obvious over the prior art, or 5.c) the patentee expressly and unambiguously excluded it from the claim during prosecution of that patent to overcome a prior art objection*." Resolution Q229 re-affirmed the 5c exclusion.

4) This Resolution concerns the issue of infringement under the doctrine of equivalents in patent law, and in particular the lack of symmetry between infringement and validity, and the role of (unclaimed) alternative embodiments disclosed in the specification in the assessment of infringement by equivalence.

5) 40 Reports were received from AIPPI's National and Regional Groups and Independent Members, providing detailed information and analysis regarding national and regional laws relating to this Resolution. These Reports were reviewed by the Reporter General Team of AIPPI and distilled into a Summary Report (see links below). These Reports indicate a broad consensus that harmonization is desirable.

6) 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:

1) There continues to be a need for a doctrine of equivalents. The doctrine of equivalents should take into consideration legal certainty for third parties.

2) Resolution Q175 is confirmed, with the exception that 4.a is to be amended so that: *"an element shall be regarded as equivalent to an element in a claim, if:*

4.a) "the element under consideration performs substantially the same function in substantially the same way to produce substantially the same result as the claimed element."

3) Equivalent infringement should not necessarily exclude embodiments disclosed in the patent specification as possible alternatives of the corresponding element literally mentioned in the granted claims, unless the patentee expressly and unambiguously excluded them from the claims in order to overcome a prior art objection.

4) The doctrine of equivalents shall not be applied in the assessment of patentability during either examination of a patent application before grant, or post-grant re-examination of a patent by a patent granting authority.

5) The doctrine of equivalents shall not be applied in the assessment of validity of a granted claim by a competent authority.

6) An embodiment cannot infringe a claim under the doctrine of equivalents if the embodiment is disclosed in the prior art or is obvious over the prior art.

Study Question Q285 - Trade Marks

Proving trade mark use

Background:

1) This Resolution concerns proving trade mark use. It focuses on proving use in the context of the genuine use requirement of a trade mark to maintain trade mark registration and does not address proving use to acquire reputation or distinctiveness of a trade mark or proving infringing use.

2) The subject of trade mark use was studied in several AIPPI Resolutions, such as Q218 "The requirement of genuine use of trade marks for maintaining protection (2011)", Resolution Q70 "Impact of Use on Maintenance and Renewal (1978)" and Resolution Q168 "Use of a Mark as a Mark as a Legal Requirement (2002)". AIPPI also published its Law Series Book "Genuine Use of Trademarks" in 2018 and 2021 introducing the legal provisions and practice about trade mark use in various jurisdictions. Due to its high practical relevance and the emergence of new challenges and questions, for instance use in virtual worlds, more extensive study and this Resolution are justified.

3) 41 Reports were received from AIPPI's National and Regional Groups and Independent Members providing detailed information and analysis regarding national and regional laws relating to this Resolution. These Reports were reviewed by the Reporter General Team of AIPPI and distilled into a Summary Report (which can be found at www.aippi.org).

4) At the AIPPI World Congress in Istanbul in 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:

1) There should be no quantitative minimum level or duration threshold for the evidence required to prove genuine use of a trade mark in the relevant period.

2) There should be no restrictions on the type of acceptable evidence to demonstrate genuine use. All such evidence should be given appropriate weight according to the circumstances of the case, based on the overall assessment of the entire evidence submitted.

3) Reputable/well-known/famous/historical trade marks should be subject to the same evidential requirements for proof of genuine use as any other trade mark.

4) The evidence of use should indicate the place, time, extent and nature of such use. Nevertheless, it should not be required to demonstrate such specific information for every single piece of evidence, and the evidence should be considered and assessed as a whole.

5) The law and practice relating to the evidential requirements for proving genuine use of a trade mark should be consistent before courts and before IP offices/administrative tribunals. The law and practice relating to the evidential requirements for proving genuine use of a trade mark should not impose undue or excessive burdens on trade mark owners in proving genuine use.

6) The use of a trade mark in a form differing from the form as registered, in elements which do not alter the distinctive character of the trade mark as registered, should be accepted as use of the trade mark as registered. This assessment should be carried out on a case-by-case basis. In particular, the following factors should be considered when judging whether the use of the variation should be accepted as genuine use of the registered trade mark:

   a) whether the relevant public perceives them as the same mark;

   b) the degree of distinctiveness of the registered trade mark and of the variation;

   c) the features of the industry in which the trade mark is used and the business customs of the industry in relation to trade mark use.

7) Subject to paragraph 6 above, in general, the following variations should be viewed as not altering the distinctive character of the registered trade mark:

   a) non-distinctive elements are added to or omitted, partially or wholly, from the registered trade mark;

   b) the font, size, and/or colour of the registered trade mark is changed, partially or wholly:

      i. in case of a word trade mark, as long as the word remains identifiable in the form used;

      ii. in case of a figurative trade mark, as long as the variation consists of characteristics which are not essential to the distinctive character of the registered trade mark;

   c) the layout of the different elements in the registered mark is changed, for instance, changing the up-and-down arrangement into a left-and-right arrangement;

   d) the registered trade mark is used in conjunction with another trade mark or in conjunction with its transliteration.

8) Online use of a trade mark, e.g. on the internet, on a website or in social media except as provided in paragraphs 10 and 11, may constitute genuine use. The criteria for assessing such use should generally be the same as for non-online use, and applied on a case-by-case basis.

9) In particular, the following factors should be taken into account when assessing whether the online use of a trade mark should be accepted as genuine use in a particular jurisdiction in which the trade mark is registered:

a) whether there is a sale of goods or provision of services made to the relevant public from that jurisdiction;

b) whether there is content targeting the relevant public in that jurisdiction, including:

i. whether there is use of a local language of the jurisdiction;

ii. whether payment in the local currency of that jurisdiction is allowed;

iii. whether local contact details such as telephone numbers, addresses etc. are provided;

c) whether a trade mark owner conducts economic activity or has an economic connection in that jurisdiction in connection with the goods or services.

10) The determination of whether the use of a trade mark in a virtual world/metaverse also counts as the genuine use of the trade mark in relation to non-virtual goods/ services should be made according to the circumstances of each case. Among other things, the purpose of using the trade mark in the virtual world/metaverse, and its relationship with the non-virtual goods/services, as well as the perception of the relevant public, should be taken into account.

11) In particular, the following factors should be taken into account when assessing whether the use of a trade mark in a virtual world/metaverse should be accepted as genuine use in a particular jurisdiction:

a) whether the relevant public in the jurisdiction has access to and participates in the virtual world/metaverse;

b) whether there are any promotional activities targeting the relevant public in the jurisdiction by the user of the trade mark or the provider of the virtual world/ metaverse;

c) whether the virtual world/metaverse provides the option of using a local currency of the jurisdiction;

d) whether the virtual world/metaverse provides the option of using a local language of the jurisdiction.

12) Circumstances beyond the control of the trade mark owner should be a valid justification for non-use, and such reasons should be considered on a case-by-case basis. In particular, the following reasons should be considered as valid justifications for non-use of the trade mark within the territory or part of the territory in which the trade mark is registered:

a) force majeure;

b) policy restriction or prohibition;

c) requirement of a mandatory licence or marketing authorization, which takes a long time to obtain.

13) The burden of proof to justify non-use in the case of a widely known event, such as the COVID-19 pandemic, should be the same as otherwise, except that there should be no need to prove the fact of such an event widely known in the relevant jurisdiction. Nevertheless, it should still be necessary to prove proper reasons for non-use beyond the control of the trade mark owner, and beyond the mere fact of the widely-known event.

Study Question Q286 - Copyright

Collecting Societies

Background:

1) This Resolution concerns the rules under which collecting societies operate in various jurisdictions and aims to harmonise certain aspects of those rules. This Resolution concerns the collective administration of both copyright and related – or neighbouring – rights.

2) This Resolution is the first by AIPPI in studying collecting societies. A harmonised framework is important when, as is the case with collecting societies, not all jurisdictions have an existing framework and there is no harmonised framework in international law.

3) This Resolution does not aim to re-examine certain exceptions to copyright laws already considered in Q246 – "Exceptions and Limitations to Copyright Protection for Libraries, Archives, and Educational Research" (Rio de Janeiro, 2015), or those considered in Q216B and Q216A – "Exceptions to Copyright Protection and the Permitted Uses of Copyright Works in the Hi-tech and Digital Sectors" (Hyderabad, 2011; Paris, 2010) nor any other exceptions.

4) This Resolution does not address the issue of mandatory collective administration. It has become clear from discussions within the Study Committee at the AIPPI World Congress in Istanbul in 2023 that mandatory collective administration would engage a range of further factors, including competition law and constitutional considerations, which would require a more detailed review than that conducted to-date. It is therefore proposed that mandatory collective administration be considered as a further, standalone topic in a further AIPPI Study Question.

5) In this Resolution:

   a) "Collecting Society" means an organisation that facilitates the collective administration of copyright and/or related rights on behalf of one or more categories of Rightholders for their collective benefit. Such organisations grant licences to use Protected Material, collect royalties from users, distribute revenues to Rightholders and, if necessary, enforce the copyright and/or related rights in the Protected Material.

   b) "Protected Material" shall mean the material subject to copyright protection and/or protection by related rights.

   c) "Rightholder" shall mean any person, other than a Collecting Society, who holds a copyright or related right or is otherwise entitled to receive a royalty in respect of use of Protected Material.

6) This Resolution addresses:

   a) the interaction of Rightholders and users of Protected Material with Collecting Societies; and

   b) the regulation of Collecting Societies, including accountability, transparency, the setting of royalty rates, distribution of revenue and enforcement by Collecting Societies.

7) More than 36 Reports were received from AIPPI's National and Regional Groups and Independent Members providing detailed information and analysis regarding national and regional laws relating to this Resolution. Thirty-six Reports were reviewed by the Reporter General Team of AIPPI and distilled into a Summary Report (see link below).

8) At the AIPPI World Congress in Istanbul in 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:

Legal Framework for Collecting Societies

1) National law shall allow for the existence of and provide a framework for the operation of Collecting Societies.

Scope of Regulation of Collecting Societies

2) Rules and regulations on Collecting Societies shall, to the greatest extent possible under national laws, be harmonised to provide an efficient and fair remuneration for Rightholders, to enhance predictability, reasonableness of terms and ease of obtaining a licence for users and to ensure transparency, equal access and fair distribution to Rightholders, and to improve governance.

Selection of Collecting Societies

3) If more than one Collecting Society is available, Rightholders shall be free to select a Collecting Society of their own choosing.

Royalty Rates

4) Collecting Societies shall provide a framework for setting royalty rates that is fair, reasonable and transparent and enables Rightholders and users to calculate the royalty rates that apply to a particular use. Controversies over the fairness of a royalty rate should be heard before an impartial entity. To the extent possible, the entity shall be specialised in the field of royalty rate setting.

Periodic Review

5) Collecting Societies shall periodically review and, where appropriate, adjust licensing terms, including royalty rates for users and remuneration to Rightholders. The time intervals for review shall be set considering the type and sector of the licensed Protected Material.

Enforcement

6) Collectively administered and non-collectively administered copyright and related rights shall be enforced according to the same procedures.

7) To enforce a collectively administered copyright or related right, Collecting Societies shall be:

   a) contractually authorised by the Rightholder; or

   b) authorised by statute.

8) The Rightholder shall not need to be joined as a party to enforcement proceedings. If necessary, evidence required to prove originality and ownership of the copyright and / or related rights may be obtained from the Rightholder.

9) Collecting Societies shall not be entitled to collect royalties where the application of copyright exceptions does not require the payment of royalties. However, where the application of certain copyright exceptions is contingent on the payment of a royalty, a Collecting Society may be designated as the organisation collecting that payment.

Study Question Q287 - General

Responsibility of online marketplaces for online infringement of industrial property rights

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Background:

1) This Resolution concerns the civil responsibility (liability) of online marketplaces for online infringement of industrial property rights, and, in particular, trade marks, patents and industrial designs. The infringement of copyrights is outside the scope of this Resolution.

2) For the purposes of this Resolution, the term "online marketplace" (OM) includes all types of online platforms which offer for sale third parties' goods and services, by connecting or facilitating the connection between third-party sellers and buyers, or facilitating the execution of the contract, even if the OM also offers products and services for sale in its own name. This Resolution does not address offers for sale of products and services by OMs in their own name.

3) This Resolution does not concern criminal liability, the liability of marketplaces before consumers in general, or international private law issues.

4) 38 Reports were received from AIPPI's National and Regional Groups and Independent Members providing detailed information and analysis regarding national and regional laws relating to this Resolution. These Reports were reviewed by the Reporter General Team of AIPPI and distilled into a Summary Report (which can be found at www.aippi.org).

5) There is a general consensus on the need for a Special Digital Law regime aiming to ensure a balance between the interests of OMs, which role is essential for the development of e-commerce, and of the IPRs holders, who must be able to benefit effective protection.

6) At the AIPPI World Congress in Istanbul in 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:

1) Countries should adopt a Special Digital Law regime offering online marketplaces (OMs) safe harbours from responsibility (liability) from the General IP Law and the General Law regimes, taking into account the factors listed in item 2 and provided that the conditions listed in item 3 are met.

General factors to be taken into account for the Special Digital Law regime to be applicable to OMs

2) For the Special Digital Law regime to be applicable, the OM should keep a neutral or passive role regarding the offers for sale displayed in its platform. To assess the neutral or passive role, the following non-exhaustive factors should be taken into account and should be examined on a case-by-case basis:

   - The OM provides to third-party sellers only services of hosting their offers for sale.
   - The OM does not implement control over activities of third-party sellers.
   - The OM does not:
     - offer services of promotion of the offers for sale.
     - offer services of optimization of the presentation of the offers for sale.
     - offer services of storage and/or shipping of the products.
   - The user is not given the impression that the OM is providing or selling, in its own name or on its own account, the infringing products or services. Such impression could be caused, for instance, if the OM does not sufficiently differentiate its own offers for sale from those of third-party sellers where it also offers products for sale in its own name.

Requirements for OMs to benefit from the safe harbour from responsibility (liability) provided by the Special Digital Law regime

3) In order for an OM to benefit from the safe harbours from responsibility (liability), the following cumulative conditions should be complied with:

   - OM does not have knowledge of the infringing character of the product offered for sale on its marketplace.
   - Upon obtaining knowledge of the infringing character of the product, OM acts expeditiously to remove the access to the infringing product offers.
   - OM provides the following:
     - Online notice and take-down and stay-down procedure. Such notice provided by the IPR holder should be a qualified notice, and the alleged infringer should have the possibility to file a qualified counternotice.
     - Exclusion of third-party sellers in case of repeated offers for sale of infringing products.
   - OM monitors to a minimum standard the offers provided by third parties, and this standard should vary according to the technology reasonably available to the OM under consideration.

- OM collects the name, address and contact information of third-party sellers and verifies that this information is accurate and up to date. The OM provides the third-party sellers' information to the IPR holder diligently.

Remedies

4) If the Special Digital Law regime applies on the basis of the assessment described in item 2 and the OM does not comply with all the cumulative conditions set under item 3, it should be subject to the General IP Law and to the General Law regime, including the remedies for infringement offered under those regimes.

5) Regardless of the liability of the OM under the General IP Law and/or the General Law regimes and/or whether it is able to benefit from the safe harbours under the Special Digital Law regime, the OM may be required by the Court or competent authorities to take measures (e.g. injunction to cease, to inform purchasers of counterfeit products) to put an end to an infringement caused by a third party on its platform.

Standing Committee on Pharma Resolution Q288

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.

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

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. …"

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.

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.

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;

2 See section 1.1 of The Public Health Resolution.

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.

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