



Congress Toronto
Adopted resolution
September 17, 2014

Resolution

Question Q238

Second medical use and other second indication claims

AIPPI

Noting that:

- 1) The scope of this resolution is the permissibility of patent protection for new therapeutic uses of known compounds and substances, the protection conferred by such patents, and their interplay with regulatory frameworks governing the marketing of pharmaceuticals.
- 2) While requirements of patentability other than patent eligible subject matter – particularly requirements of novelty and inventive step – may be relevant to the permissibility of patent protection for new therapeutic uses of known compounds and substances, this resolution does not specifically address such requirements. Issues of patent term extension, compulsory licensing, entitlement and supplementary protection certificates are also outside the scope of this resolution.
- 3) AIPPI has previously studied the impact of public health issues on exclusive patent rights (Q202). That resolution focused on exceptions to exclusive patent rights applicable to medicines and other medical products.
- 4) AIPPI has further studied issues related to liability for contributory infringement of IPRs and in particular patents (Q204 and Q204P), the availability of injunctions in case of infringement of IPRs (Q219), and relief in IP proceedings other than injunctions or damages (Q236).
- 5) None of the above-mentioned resolutions is affected by the present resolution.

Considering that:

- 1) In this resolution, the term "second medical use(s)" refers to new therapeutic use(s) of known compounds and substances. A "second medical use" may be the second or any subsequent new therapeutic use of a known compound or substance.
- 2) Second medical uses may provide solutions to unmet medical needs and significant benefits to patients. They may require significant investment in research and development and represent socially, medically and economically valuable innovations.
- 3) Pursuant to Article 27 of the TRIPS Agreement, patents may be obtained for any inventions in all fields of technology.
- 4) Pursuant to Article 41 of the TRIPS Agreement, members shall ensure that enforcement procedures are available to permit effective action against any act of infringement.
- 5) Second medical uses qualify as patent eligible subject matter in many, but not all, jurisdictions.
- 6) Of those jurisdictions that permit patent protection for second medical uses, there is variation as to the types of second medical uses that may be protected, and as to permissible claim formats. Typically, one or more of the following claim formats are permissible: method of treatment claims; claims in the form "use of substance X in the manufacture of a medicament for the treatment of condition Y" (Swiss-type claim); use claims in the form "use of substance X for the treatment of condition Y"; and purpose-limited product claims in the form "substance X for use in the treatment of condition Y".
- 7) Even where the permissible claim format is consistent between jurisdictions, the actual protection conferred by a patent granted for a second medical use may vary, e.g. due to different claim constructions; different requirements for direct or indirect (contributory) infringement; and any exemptions from infringement or liability for infringement.
- 8) In some jurisdictions that permit patent protection for second medical uses, regulatory frameworks allow a generic applicant for marketing authorization to exclude from the product information (e.g. product label, package inserts etc., collectively referred to as "label instructions") references to patented second medical uses. This is often referred to as "skinny labelling", or "carving-out" patent protected indications.
- 9) In many jurisdictions, the regulatory framework provides incentives for generic substitution of a branded pharmaceutical without preventing such substitution if the generic pharmaceutical has not been authorized for the prescribed, patented second medical use.

- 10) Lack of harmonized laws relating to patent protection for second medical uses and associated regulatory frameworks create uncertainty for all stakeholders, and in particular for originator and generic pharmaceutical companies.
- 11) The present resolution strives to harmonize patent eligibility of second medical uses and the available protection, independent of any specific claim format.

Resolves that:

- 1) As a matter of principle clearly reflected in the TRIPS Agreement, patents should be granted without discrimination for any inventions in all fields of technology, including inventions relating to second medical uses.
- 2) A second medical use should be patentable if it meets the patentability requirements of novelty, inventive step (non-obviousness), and utility or industrial applicability.
- 3) Exceptions to patent eligibility for methods of medical treatment of the human or animal body should not preclude the patentability of second medical uses. Where such exceptions exist, claim formats for the protection of second medical uses that are compatible with those exceptions should be available.
- 4) Exclusions from patentability should not depend on the type of second medical use. Patent eligible second medical uses may include, but are not limited to, the use of a known compound or substance for the treatment of a disease or condition not previously treated by that compound or substance; the use of a known compound or substance for the treatment of a new patient class; a different mode of administration of a known compound or substance; the use of a known compound or substance in a new dosage regimen; and a new therapeutic application of a known compound or substance based on a different technical effect.
- 5) Second medical uses that qualify for patent protection should not be limited to uses that treat disease but should include uses directed at alleviating or preventing disease or otherwise improving health.
- 6) Each jurisdiction should recognize at least one claim format that provides patent protection for second medical uses, commensurate with this resolution.
- 7) In principle, every unauthorized act that constitutes a commercial exploitation of a patented second medical use, and acts that contribute thereto, should constitute an act of infringement and give rise to liability for infringement.
- 8) The unauthorized making, storing, offering, promoting, marketing, distributing, dispensing, selling, importing and exporting of a pharmaceutical with label instructions specifying the patented second medical use should constitute acts of infringement.

9) The fact that a pharmaceutical does not contain label instructions specifying the patented second medical use should not *per se* exclude the finding of infringement of a patent for the second medical use. In particular:

a) Offering, selling, or promoting a pharmaceutical for a patented second medical use, but without label instructions for such use, as well as placing such pharmaceutical on the market with concomitant references to such second medical use by means other than the label instructions, should constitute infringement;

b) Whether or not other acts directed to putting a pharmaceutical without label instructions for a patented second medical use to such use amount to infringement should be assessed on a case-by-case basis, taking into account factors such as:

- i. the intent of the alleged infringer;
- ii. knowledge of the uses of the pharmaceutical by the alleged infringer, or whether such uses are obvious in the circumstances;
- iii. the ability to identify the uses to which the pharmaceutical is put;
- iv. the labelling of the pharmaceutical, including whether the label is mandated to include any reference to carved out indications;
- v. any marketing or promotional activity carried out by the alleged infringer;
- vi. any steps taken by the alleged infringer to discourage/encourage infringing use;
- vii. economic conditions of the relevant market, including the relative sizes of the markets for the different uses and the volume of the allegedly infringing pharmaceutical;
- viii. prescription practices of relevant professionals, including whether the prescribed use is conveyed to the person who chooses the particular pharmaceutical to be administered; and
- ix. dispensing practices, including regulatory provisions aimed at generic substitution.

10) If there is a finding of infringement of a patent claim for a second medical use, liability should be determined in the same manner as liability is determined for infringement of any other type of patent claim, and the same relief should be available as for infringement of any other type of patent claim.

11) However, private acts for non-commercial purposes, including use by patients, should not give rise to liability for infringement of a second medical use claim, provided that such exemption should not extend to any party contributing to such use in a non-private capacity or for commercial purposes.

- 12) Injunctive relief for infringement of a patented second medical use should not be denied solely because such relief could prevent a pharmaceutical from being commercialized for non-patented uses. Consideration should be given to all circumstances of the case, including the interests of the involved parties.
- 13) The regulatory frameworks governing the importation and marketing of pharmaceuticals, their labelling, prescription, distribution, dispensing and reimbursement should facilitate transparency as to whether such pharmaceuticals are being dispensed for patented medical uses, and, while not preventing the legitimate commercialization of pharmaceuticals for non-patented medical uses, facilitate enforcement of patent protection for second medical use.
- 14) AIPPI urges the relevant authorities to implement the necessary measures so that effective protection of second medical uses is not jeopardized by regulatory frameworks.