

Resolution



Question Q202

The impact of public health issues on exclusive patent rights

Yearbook 2008/I, pages 367–369
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AIPPI

Noting that:

- 1) The focus of this resolution is exceptions to exclusive patent rights applicable to medicines and other medical products.
- 2) Access to affordable medicines and other medical products is a pressing issue but exceptions to exclusive patent rights alone cannot resolve this issue.
- 3) AIPPI has studied exceptions to exclusive patent rights in previous questions, leading in particular to:
 - i) The resolution of the Executive Committee of Barcelona in 1990 – Question Q101, Yearbook 1991/I, page 298 entitled ‘Parallel Import Of Patented Products’ (*Barcelona Parallel Import Resolution*);
 - ii) The resolution of the Executive Committee of Tokyo in 1992 – Question Q105, Yearbook 1992/III, pages 282-283 entitled ‘Experimental Use as a Defence to a Claim of Patent Infringement’ (*Tokyo Experimental Use Resolution*); and
 - iii) The resolution of the 38th Congress of Melbourne in 2001 – Question Q156, Yearbook 2001/I, pages 511-512 entitled ‘International Exhaustion of Industrial Property Rights’ (*Melbourne International Exhaustion Resolution*).
- 4) The Barcelona Parallel Import Resolution resolved that a patentee be able to invoke its patent against parallel import of a patented product, notwithstanding the circumstances under which such product has first been put on the market in a given country “B”, subject to exception by contractual agreement authorising import into another country “A”.
- 5) Paragraph 3 of the Tokyo Experimental Use Resolution resolved that each country should except acts done for experimental purposes from the rights of the patentee on the basis that experimental use:
 - i) Includes any use of the patented invention performed for academic purposes and having no commercial nature;
 - ii) Includes testing to evaluate the teaching of the patent and validity of the patent;
 - iii) 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; and

- iv) Should be subject to the overriding principle that the use must involve work on the subject of the patent; use merely to obtain the advantage of the invention disclosed by the patent is not experimental use.
- 6) The Melbourne International Exhaustion Resolution affirmed the Barcelona Parallel Import Resolution and resolved that there should be no international exhaustion of industrial property rights (patents, trademarks, designs and plant breeder's rights) notwithstanding that regional exhaustion may be applied in order to foster regional integration of different national economies under a uniform regulatory and legal framework.
- 7) The patent law in some countries provides for an exception to exclusive patent rights for an "extemporaneous" preparation of a medicine in a pharmacy for individual cases in accordance with a medical prescription issued by a medical doctor (commonly referred to as the individual prescriptions exception).
- 8) A number of WTO Members have not yet ratified Article 31bis of the TRIPs.

Considering that:

- 1) Patent law provides for a number of exceptions to exclusive patent rights which may play a role in providing access to patented medicines and other medical products.
- 2) Compulsory licensing is a more appropriate and proportionate means of providing access to patented medicines and other medical products than expropriation of patent rights.

Resolves that:

- 1.1) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorisation of the patentee, experiments relating to the subject-matter of the invention, irrespective of whether the ultimate aim of the experiments may be commercial.
- 1.2) Paragraph 3 of the Tokyo Experimental Use Resolution is affirmed insofar as it is not in conflict with paragraph 1.1.
- 2) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorisation 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.
- 3) The Barcelona Parallel Import Resolution and the Melbourne International Exhaustion Resolution are each affirmed.
- 4) To the extent that the patent law provides for an individual prescriptions exception, the exception should be limited to preparation of medicines as and when required for an individual patient and should not extend to situations where medicines are prepared on a larger scale.
- 5) To the extent that the patent law permits patentability of methods of medical treatment, the law should provide for an exception to the rights of a patentee, allowing medical personnel to use patented methods of medical treatment, without the authorisation of the patentee, in circumstances where it is not practicable to negotiate a licence before treatment.

- 6) Concerning public health:
 - a) the patent law should provide that a compulsory license can only be granted in exceptional and strictly defined circumstances.
 - b) the law should not permit expropriation of patent rights.
- 7) Article 31bis of the TRIPs should be promptly ratified by WTO Members that have not yet done so.