UNCTAD

Practical experiences on the effectiveness of, and challenges associated to, exceptions and limitations to patent rights, in particular in addressing development issues

Information provided by the UNCTAD Secretariat

In the context of its technical cooperation activities, the UNCTAD Secretariat through its Intellectual Property Unit, Division on Investment and Enterprise, has gathered some experience on the effectiveness of the use of certain exceptions and limitations to patent rights in various developing countries. This experience mainly relates to the (1) regulatory review ("Bolar") exception; (2) experimental use exception; and (3) concept of exhaustion of patent rights.

(1) The regulatory review ("Bolar") exception has not been implemented in all developing countries' patent regimes. Especially countries still relying on pre-TRIPS patent laws provide no legal possibility for generic producers to use patented substance without the patentee's authorization for marketing approval purposes. This is particularly true for those countries that have limited their domestic experimental use exception to acts solely carried out for non-commercial research (see below). UNCTAD experience shows that even in some of the countries that have enacted the regulatory review ("Bolar") exception, it is not necessarily used much by generic producers, due to their lack of awareness of patent issues or limited production capacities. It may also be observed that this exception may vary in scope, depending on national implementing legislation. Some countries limit covered activities to those that are directly related to the act of seeking regulatory approval, while other countries include certain preparatory activities even if the latter never actually result in the submission of a request for regulatory approval. Another difference in scope is territorial: while some countries limit the exception to activities undertaken for regulatory approval in their own territory, other legal systems allow preparatory acts to request regulatory approval abroad.

(2) The experimental use exception, while being implemented in the overwhelming majority of developing countries, including those that still rely on pre-TRIPS legislation, widely varies in scope. A considerable number of developing countries limit the scope of this exception to research done solely for non-commercial purposes. This is not in line with economic realities, where research undertaken for scientific purposes may at the same time be used for commercial purposes. Developing countries that recently amended their patent laws often reflect this reality by allowing research on the patented substance to enable the generation of new knowledge, even where there may be a distant commercial purpose. This follows the 2008 Resolution Q 202 by the International Association for the Protection of Intellectual Property (AIPPI), stating that

> "1.1) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorization 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]

[1] AIPPI, Resolution Question Q 202 "The impact of public health issues on exclusive patent rights", 10 September 2008 (cited in https://www.aippi.org/download/amicus/amicus30274EdwardsBRIEF.pdf on p. 23 of the electronic file; visited on 21 September 2016).

(3) There appears to be a great degree of unawareness of the issue of patent exhaustion in many developing countries. Some countries' laws on the one hand include an express exception of the rights conferred under a patent where the patented article has been commercialized in any country of the world with the consent of the patent holder. At the same time, these laws expressly include the right to prevent the importation of the patented good among the rights conferred by a patent. Another challenge is specific to the area of pharmaceuticals. Some countries that allow for parallel importation of patented medicines lack guidelines for their medicine regulatory agencies on how to authorize parallel imported pharmaceutical products. There is a need for coherence and complementarity between the areas of patent law and drug regulatory law in respect of parallel imports.

In sum, it may be stated that patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational.