

“Exceptions and limitations to Patent Rights” and patent flexibilities under “Patents and Health”

Turkey believes that exception regarding acts for obtaining regulatory approval is important for public health purposes. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twenty-sixth session, Turkey submits the following information on “Exceptions and limitations to Patent Rights on Patents and Health” in accordance with Circular No.8687:

(a) exception regarding acts for obtaining regulatory approval from authorities:

(i) the description of the exception:

Bolar exception, which is an exception for the exclusive rights granted by a patent, permitting the use of patented products in experiments for the purpose of obtaining marketing authorization for medicines, is introduced in Turkey by Law No. 5194 on 22.06.2004 by the addition of Article 75(f). This exception also took its place in Industrial Property Law No. 6769 which entered into force in 10.01.2017.

Bolar exception is described in Article 85(3)(c) of the Law No. 6769 on Industrial Property regarding Limits and Scope of Rights Conferred by a Patent as follows: “Registration of medicaments and acts involving the subject matter of the invention for experimental purposes in order to obtain marketing authorization for medicinal products, including the required tests and experiments for this purpose.” shall remain outside the scope of rights conferred by a patent.

(ii) its objectives and goals;

In the pharmaceutical industry, patents can prevent generic drugs from entering the market. The risk of patent infringement may potentially deter generics manufacturers from carrying out the tests required to obtain marketing authorization until after patent expiry, resulting in a delay of market entry of generics.

The Bolar exception provides some protection for generic drug manufacturers when preparing their products for marketing authorization. The exemption enables generic drug manufacturers to use an patented pharmaceutical drug before the patent expires, which not only aids in the early launch of generic versions of the drug once the drug’s patent term ends, but also promotes further R&D.

In consequence, this system allows generic drug producers to enter the market without any obstacle just after the expiration of patent rights of original product. This results for the public to access innovative medicines much earlier.

(iii) national implementation;

The Turkish Medicines and Medical Devices Agency is the national body responsible for marketing authorization of drugs in Turkey. Under the Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation) (Official Gazette No. 25705 of 19 January 2005), no medicinal product for human use can be marketed unless it is authorized for marketing in Turkey.

According to the Turkish legislation, the acts of generic companies for marketing authorization is not regarded as contrary to patent rights under Article 85(3)(c) of the Law No. 6769. In Turkey, a process so called the "abbreviated application" allows generic drug producers to apply for marketing authorization without submitting any information about tests and clinical trials, if the data exclusivity period has been expired, provided that certain circumstances has been fulfilled. In Turkey innovator companies enjoy the period of data exclusivity for up to 6 years.

- (iv) challenges faced by Member States in its implementation; and

Turkey is not currently facing any inherited challenges regarding the implementation of Bolar exception. However, conflicting opinions regarding the limit of the scope of the Bolar exception sometimes gives rise to discussions between parties in court cases.

- (v) results of its implementation

Both originator and generic drug industries coexist in Turkey. Although, foreign companies play an important role in the manufacture of medicines, nearly 65% of pharmaceuticals are local on Turkish pharmaceutical market and more than 75% are generics. Therefore, Turkey has a powerful generic drug manufacturing industry. Thanks to the successful implementation of the Bolar exception the marketing authorization for the generic can then be issued immediately as soon as the originator patent or marketing exclusivity expires. In Turkey there is no challenge on the access to essential medicines for public health purposes. One can say that in Turkey public can access innovative medicines at an earlier stage.

b) use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes:

Turkey provides the following patent flexibilities for public health purposes:

- Bolar exception (as mentioned in detail above)
- Compulsory licensing;

Industrial Property Law No. 6769 article 129(c) provides for compulsory licensing considering the public interest. According to this article, public health and national defense prevails over the exclusive right conferred by the patent to his owner.

- Surgery, therapy and diagnostic methods are excluded from patentability

Under 82 (3)(c) Industrial Property Law No. 6769, patents are not to be granted in respect of diagnostic methods and methods of treatment including surgery practiced on the human or animal body. According to 82 (6), the previous provision (art. 82 (3)(c)) shall not apply to products, in particular substances or compositions, for use in any of these methods.

- extemporaneous preparations of medicines in pharmacies

Industrial Property Law No. 6769 Article 85(3)(ç) provides “extemporaneous preparations of medicines in pharmacies involving no mass production and carried out solely in making up a prescription and acts related to the medicines thus prepared” shall remain outside the scope of rights conferred by a patent.