Note C. 8728

Additional inputs for the preparation of the second draft reference document on exception regarding acts for obtaining regulatory approval from authorities

Challenges faced by Member States in implementing the regarding acts for obtaining regulatory approval from authorities

Brazil

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In Brazil, the exception related to the acts practiced for obtaining regulatory approval from authorities, known as the “Bolar exception”, has been incorporated into Brazilian industrial property system in 2001, through Law No. 10.196/01, which added a new clause to Article 43 of Law No. 9.279/96 (IP Law):

Article 43

(...)

VII – to acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing tests results, information and data in order to obtain the commercialization registration in Brazil or abroad for the exploitation and commercialization of the product that is the subject matter of the patent, after expiration of the terms set forth in Article 40."

This amendment allows generic medicines industries to start testing for the purpose of obtaining regulatory approval prior to the expiration of the patent

for the reference medicinal product without the consent of the patent holder. As a result, generic medicines can be made available on the market immediately after patent expiration, increasing competition and access to lower-cost drugs.

Although the legal text makes it clear that the Bolar exception provision does not allow the commercialization of a patented product, there is a concern on the part of patent holders that the generic manufacturers will market the generic product as soon as they receive regulatory approval. As a consequence, some innovative companies have taken administrative and/or judicial measures against generic industries that require regulatory approval before the expiration of the patent term on the basis of counterfeit claims, which in turn hinders the full use of this exception.

Relying on the claim that the regulatory approval of generic products during the patent term would indicate a potential imminent risk of infringement of their industrial property rights, some patent holders request in court the production of documents and tangible grounds to prove the similarity between the generic and the patented products. Thereafter, the patent holders file a lawsuit to compel the generic industries to cease the presumed violation. In practice, on the basis of this kind of argument, some judges have granted temporary injunctions in order to prevent an infringement of the holder's patent rights, often because there is not enough time to conduct a deeper analysis of the issue. In some cases, this preliminary understanding is later reversed in a second more detailed analysis, but the damages have already been caused to the generic industries.

The measures taken by patent holders are not limited to the judicial sphere. In INPI, the request for fast track examination of patent applications of the pharmaceutical field, on the basis of allegations of counterfeit, has been verified. As a proof of violation, applicants present documents related to the regulatory approval of the generic products obtained by unauthorized third parties.

Another barrier to the implementation of the Bolar exception in Brazil is related to the internal rules that regulate the regulatory approval of generic drugs. In order to demonstrate the therapeutic equivalence of the generic medicine to the reference medicine, the Brazilian legislation - Law No. 6.360/76 - only requires the presentation of bioequivalence and bioavailability tests, exempting the generic industry from the presentation of data from pre-clinical

and clinical trials, which reduce the analysis time of the regulatory approval request and the final product costs. This simplified procedure is in line with the provisions of Article 39.3 of the TRIPS Agreement, internalized through Article 195, Section XIV and Paragraph 2 of Law No. 9.279/96, which allows undisclosed test data to be reused by the regulatory authority in its internal procedures for medicine registration, provided that measures are taken to protect against acts of unfair competition.

In spite of this law provision, some innovative companies have been filing lawsuits to prevent the Brazilian Health Agency - ANVISA - from granting generic drug registrations to unauthorized third parties using information from undisclosed tests, which have been submitted to the same agency to obtain the regulatory approval of the reference medicine. As a result, some generic drug registrations have been judicially canceled on allegations of unfair competition. The issue is controversial and has been raising long debates in the Brazilian judiciary, culminating in postponing the entry of generic drugs into the market.

The foregoing clearly shows that, although the exception regarding acts for obtaining regulatory approval from authorities was incorporated into national legislation almost 18 (eighteen) years ago, the registration of a generic drug during the patent term is still associated with an immediate commercialization risk or a violation of industrial property rights, evidencing the challenges faced by Brazil in implementing this exception.