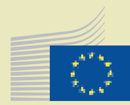

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Drug Patents and the Bolar Exemption in Madagascar

Background

A pharmaceutical company A from the European Union operates in the industrial city of Ansirabe, Madagascar. Company A sought to obtain marketing approval for its own generic drug made from the active pharmaceutical ingredients, prior to the expiration of the drug patent. Company A's decision was influenced by the Bolar exemption which its parent company in Europe has leveraged in their market strategy.

Action undertaken

Company A engaged the services of a local patent attorney, who then advised on the applicability of the Bolar exemption in Madagascar. According to the attorney, the Bolar exemption allows a potential generic drug manufacturer to obtain marketing approval on a drug that has been patented by another person before the expiration of the drug patent and without liability for infringement.

A generic drug is an alternative drug product that copies the active pharmaceutical ingredients or novel chemical compositions of the originally patented drug. The purpose of the exemption is to address the delay in approving generic (and usually much cheaper) drugs, which typically enter the market long after the expiration of the patent covering the original drug. Though the generic drug may be approved for marketing, it does not enter the market until the patent on the original drug has expired.

The exemption began in the United States and applies in the European Union through the Article 10(6) of the Directive 2001/83/EC of the European Parliament. Influenced by the applicability of the exemption in its headquarters in Europe, Company A had sought marketing approval for its generic equivalent of a drug patented by a local company, ahead of the patent expiration. However, the attorney advised that the Bolar exemption is not recognised in Madagascar. Therefore, a marketing approval for the drug would wait until the expiration of the patent.

Lessons learned

1. Companies looking to expand business operations into African countries are advised to apprise themselves of the extant laws of the target African countries. Company A's business strategy partly relied on maximising the Bolar exemption, which was found to be inapplicable in Madagascar, and incurred losses as a result.

2. Company A had to wait until the drug patent expired before applying to the Madagascar Drug Agency for marketing approval, thereby delaying the entry of their drugs into the market than anticipated. This impacted their finances and slowed down business growth.