

A Fine to Remember: Brazilian Antitrust Authority Condemns Pharmaceutical Company to pay 11 Million Usd

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The administrative court of the Brazilian antitrust authority (Conselho Administrativo de Defesa Econômica – CADE) has very recently fined a major pharmaceutical industry in over 36 million Brazilian reais (approx. 11 million American dollars) for sham litigation involving the patent application in Brazil of a blockbuster drug used in the treatment of cancer. Although this is not the first millionaire fine imposed by CADE on a pharmaceutical company, cases like this are still rare and the case law of the bureau's administrative court, which is a federal nonjudicial instance entrusted with enforcing the constitutional economic principles, such as free enterprise and free competition, is still being built.

In the present case, the accused company has filed a patent application for a procedure to produce the abovementioned drug before the TRIPS Agreement had come into force in Brazil (later it has broadened the application's claims to include the drug itself). As it is of common knowledge, Brazilian Law did not admit the patentability of chemical and pharmaceutical compounds until the issuance of the new Industrial Property Act in 1996, which was passed by Congress in order to comply with TRIPS. Notwithstanding the foregoing, by the time the applicant has requested the examination of the invention before the Brazilian Patent Office (BPO), the TRIPS agreement had indeed come into force.

Since the BPO has dismissed the application on grounds of non-patentability of pharmaceutical inventions at the time of filing, the company has engaged itself in several lawsuits to overrule this decision and to have the patent granted based on the reasonable thesis that the applicable Law should be the one in force at the time of the request for examination and that the compound fulfilled all the legal requirements therefor. CADE has not convicted the company for sham litigation because of this particular thesis and lawsuit, but rather because of the subsequent steps thereof.

As a matter of fact, the company has been accused of forum shopping and convicted for sham litigation because of contradictory lawsuits filed before the federal courts of Rio de Janeiro and Brasília. In Rio, after the BPO has denied its application again (but this time for lack of inventive step), it has sought the suspension of the patent prosecution through a new lawsuit until the local federal court has decided on the fulfilment of this legal requirement. Meanwhile, in Brasília the company has sued ANVISA, the federal Health and Sanitary Agency, seeking the trading exclusivity of the applied compound on grounds of section 70.9 of the TRIPS agreement.

In short, by combining both decisions, the company has obtained in Rio de Janeiro the suspension of BPO's prosecution of its patent application whilst in Brasília the court has granted the trading exclusivity of the compound subject of the same application. This move has driven a previously existing generic competitor out of the market for months, thus giving rise to the complaint before CADE for anticompetitive behavior, which ended up with the mentioned 36 million fine.

The company has been denounced to CADE by a generic drugs industry class association. It is important to state that Brazilian state funded public health system, which assures free medicines to citizens, makes Brazil one of the world's largest pharmaceutical markets. Consequently, any patent case that may produce significant effects on the national Treasure and on access to medicines is dealt with as a public interest issue.

Being this the case, CADE's decision is very important to indicate what the bureau considers as an anticompetitive behavior and infringement of the economic system concerning sham litigation and the abuse of intellectual property rights.

Kasznar Leonardos follows up this important issue and is fully available to provide you further information. Please feel free to contact us, whether in written or by phone, directly to your usual contact within our office or to gabriel.leonardos@kasznarleonardos.com.