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Brazil – BPTO's acceptance decision for a patent application for Hepatitis C treatment launches a debate in Brazil

The granting of an injunction on September 24, 2018 that nullified the Brazilian Patent and Trademark Office (BPTO) publication that accepted a patent application for the treatment of Hepatitis C – the drug market name is sofosbuvir – is the latest news about this complex matter involving the pharmaceutical company Gilead Pharmasset LLC, the BPTO and Brazil's Public Health System ("SUS").

The BPTO accepted application number PI 0410846-9 ("*nucleoside and pharmaceutical composition comprising the same*", PCT US 2004/012472) on September 18, 2018. Such application was filed in 2004 by Gilead Pharmasset LLC.

The publication of the BPTO acceptance decision launched a debate among the Brazilian politicians regarding the possibility that the generic drug production related to the patent application would be halted/interrupted if the final fees for the granting of the patent-letter are paid by Gilead Pharmasset LLC (which most likely will happen). Moreover, if granted, the patent will benefit from a provision of the Brazilian IP Law which extends the validity of the patent for 10 years from the granting date, as the examination of the application took more than 10 years to happen (filing in 2014).

Generic drugs for Hepatitis C are produced by Fiocruz-Farmanguinhos (a Brazilian highly reputed public agency in the production of generic drugs), had already been registered by ANVISA (Brazilian National Health Surveillance Agency) and were offered to the Brazilian population by SUS. The production of generic sofosbuvir is said to generate an economy of BRL 1 billion to the SUS.

Following the publication of the BPTO decision, the Minister of Industry, Foreign Trade and Services, to which the BPTO is subordinated, was called for a hearing at the Brazilian Senate for further explanation about the acceptance of the patent application.

Also, a presidential candidate, Marina Silva, filed a lawsuit requesting an injunction, in which she demanded compulsory license and authorization for the non-commercial production of the generic drug of sofosbuvir, claiming that the BPTO decision is contrary to the "constitutional right to health". That is the injunction that was now granted and may be subject of appeal. The decision limited to nullify the BPTO decision and postponed the request for compulsory license.

The BPTO limited to say that it restricted its analysis as per the requirements of patentability and legal provisions of the Industrial Property Law.

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