

# New bill about compulsory license sanctioned in Brazil

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On September 02, Bill no. 12/21 was sanctioned in Brazil, aiming to amend the provisions of compulsory licenses set forth by the Brazilian IP Law in cases of national or international emergency, and in case of public interest or recognition of public calamity nationwide, as well.

Although a lot has been said about this amendment, the provisions are quite similar to what is already provided in the IP Law, specially considering that the controversial mandatory technology transfer plea of said Bill has not been approved by the president.

According to the text included by Law no. 14,200/2021, the compulsory license will be analyzed on a case-by-case basis, and it will only be implemented if the patentee is not able or refuses to meet the local demand.

The main differences from what was already provided by the IP Law are that (i) patent applications are also subject of compulsory license and (ii) the royalties are fixed as 1,5% of the net selling price of the product associated with the patent until its value is effectively established.

However, the new provisions clarify that such mechanisms shall be applied only for patents and patent applications which are not subject of technology transfer agreements with third parties, or subject of voluntary licensing capable of ensuring the national demand. In this case, it will be analyzed if the amount of supplies, the price and deadline are compatible with the emergency situation, public interest or public calamity.

Thus, the patentee will be excluded from a potential compulsory license request on the following cases:

1. If the patent/patent application technology is being duly and directly explored in the country;
2. If the patent/patent application is already subject of a voluntary license;
3. If there are transparent agreements for the sale of the product subject of the patent/patent application.

Another amendment inserted on article 71 of the Brazilian IP Law comprises the possibility of the compulsory license for humanitarian reasons. If a country has insufficient or no capacity of manufacturing a certain product in the pharmaceutical industry to attend its own demand, the compulsory license of the product's patent shall be granted in Brazil, in order to be manufactured in the country and exported right after.

Nevertheless, as mentioned above, the provision that required a mandatory technology transfer to the third party was vetoed, since, apart from being a measure of difficult enforcement, this provision could jeopardize commercial relationships and future external investments in technology in Brazil.

In a statement, the government highlighted that, for now, the COVID-19 vaccines are being duly provided by international partners though, and the compulsory licensing will not be used, unless in case of any shortage in the local market in the future, when the legal provision may be applied[1]. According to the government, *“such measures would be of difficult implementation and could be able to promote a legal uncertainty on the international trade sector, besides of being able to discourage investments in technology and to discourage strategic commercial partnership, existing other measures much less shocking to ensure the solution of this type of crisis.”*[2]