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Brazil: TRIPS waiver and Compulsory license

Roberto Rodrigues Pinho, Felipe Mesquita (Licks Attorneys) · Wednesday, July 20th, 2022



In September 2021, Brazilian Congress passed a law changing the compulsory licensing landscape as a political answer to the impact of the Covid-19 pandemic. Initially, Congress wanted to include new possibilities to issue compulsory license and tried to create a mandatory tech transfer provision that could severely jeopardize companies doing business in Brazil. In view of the negative impact, President Bolsonaro vetoed some of the relevant provisions. Almost one year later, Congress maintained the Presidential vetoes and concluded the legislature procedure.

The compulsory license legislation amends article 71 of the Patent Statute, creating new possible ways to request compulsory license in Brazil.

Article 71 now reads: *“In cases of a declaration of national or international emergency or public interest, declared by law or an act of the Federal Executive Branch, or a state of nationwide public calamity declared by the National Congress, a temporary and non-exclusive compulsory license may be granted, ex officio, for the exploitation of a patent or patent application, without*

prejudice to the rights of the respective holder, provided that the patent or patent application holder or its licensee does not meet these needs”.

The legislation creates a list, where public entities, educational and research institutions and other representative entities of society and the industrial sector shall be consulted to include patents and applications subject to compulsory licensing. Also, any public or private institution may submit a request for listing of patents and applications.

Patentees may seek delisting if any of the following requirements are fulfilled: (i) the patent or application is subject to transfer of technology agreements for its production or voluntary licensing capable of ensuring the fulfillment of internal demand; (ii) the owner made objective commitments to fulfill domestic demand under conditions of volume, price and time-limit by direct exploitation, voluntary licensing or transparent contracts for the sale of a product associated with the patent or application.

Once the list is published, the executive branch has 30 to 60 days to evaluate it and grant non-exclusive compulsory licenses to manufacturers with proven technical and economic capacity to manufacture the subject matter of the invention. Regarding compensation, even though circumstances of each case shall be considered, the law establishes a fixed rate of 1.5% on the net selling price of the product associated with the invention until its value is effectively established, only and if after the patent is granted.

President Bolsonaro reviewed the legislation and decided to veto three provisions that were the focus of controversy (subsection 8, 9/10 and 17).

Subsection 8 establishes that the patentee must provide the necessary and sufficient information for the effective reproduction of the subject matter, as well as other technical aspects, test results and data necessary for the granting of marketing approval. Subsection 9 also establishes the obligation to provide biological material essential to the realization of the invention. Subsection 10 establishes that if the patent refuses to do so, the patent of application will be invalidated due to lack of enablement.

Lastly, subsection 17 created “jurisdiction” for the legislative power to grant compulsory licenses, an act deemed to be exclusive of the discretion of the executive power.

On the veto message, President Bolsonaro claimed the proposal was against public interested, violated due administrative process, and that the executive branch has jurisdiction over executive acts, including the grant of compulsory licenses. Congress accepted the Presidential vetoes, keeping the new CL legislation more limited.

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