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Brazilian President's Assent to the Bill on the Compulsory Licensing of COVID-19 Vaccines' Patents

Roberto Castro de Figueiredo (Tribe Arbitration and St Mary's University) · Tuesday, September 14th, 2021

The Brazilian President gave his assent to the bill introducing [new rules on the compulsory licensing of patents](#), which facilitates the compulsory licensing of COVID-19 vaccines' patents. The Brazilian President vetoed, however, certain key provisions of the bill, including paragraphs 8, 9 and 10 of the amended Article 71 of the Brazilian Industrial Property Act 1996.

Paragraph 8 places on patent proprietors and patent applicants the obligation to disclose to licensees the information and data necessary and sufficient for the use of subject-matter of the patent or patent application, including the test results and data required to obtain the approval for use by the competent authority. Paragraph 9 also creates the obligation of the patent proprietor or patent applicant to supply to the licensees the biological material necessary for the use of the subject-matter. And pursuant to paragraph 10, if the patent proprietor or patent applicant does not comply with these obligations, the patent is subject to revocation and the patent application may be denied.

The Brazilian President did not veto, however, paragraph 11 of the amended Article 71, which places on governmental authorities the obligation to disclose the information and data necessary for the use of subject-matter of the patent or patent application. The same provision provides that disclosures made by governmental authorities do not fall within Article 195(XIV) of the Brazilian Industrial Property Act 1996, according to which it is a criminal offence to disclose, exploit or use, without authorisation, undisclosed test results and other data, the origination of which involves a considerable effort, which was submitted to public authorities as a condition of approving the marketing of a product. As noted in a [previous post](#), the disclosure of information and data necessary for the use of subject-matter of the patent or patent application is certainly one of the controversial points of the bill, as it can be argued that disclosures of undisclosed information are inconsistent with the obligation to protect undisclosed information under Article 39 of the TRIPS Agreement. In particular, paragraph 3 of Article 39 requires WTO Members to provide protection against the disclosure of data the submission of which is required for the approval of marketing of pharmaceutical or agricultural chemical products.

The amendments introduced by the bill entered into force on 2 September 2021. However, the Brazilian President's vetoes can still be rejected by the Brazilian Congress.

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