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Brazilian Senate Approves Bill on the Compulsory Licensing of COVID-19 Vaccines' Patents

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While pressure is building up on TRIPS Council for the suspension of certain obligations under the TRIPS Agreement during the COVID-19 pandemic, the Brazilian Senate approved on 29 April 2021 a bill facilitating the compulsory licensing of COVID-19 vaccines' patents. The bill will be voted by the Brazilian House of Representatives and, if approved, it will be submitted to the Brazilian President for approval and publication. If the House of Representatives amends the bill, the bill will be remitted to the Senate before it is submitted to the Brazilian President. The Brazilian President may veto the whole bill or part of it, but the veto can be defeated by the majority of the two houses of the Brazilian Congress.

The bill approved by the Brazilian Senate amends the provisions of the Brazilian Industrial Property Act 1996 on compulsory licensing of patents in cases of national emergency or public interest. In its current version, Article 71 of the Brazilian Industrial Property Act 1996 allows the temporary and non-exclusive compulsory licensing of patents where the patent proprietor is unable to meet national emergency and public interest's needs. According to the regulation of Article 71 adopted in the Presidential Decree 3.201 of 1999, cases of public interest include matters related to public health, environmental protection, food security as well as matters concerning Brazil's technological and socio-economic development. In addition to stating that the COVID-19 pandemic is a case of national emergency, the bill approved by the Brazilian Senate amends the wording of Article 71, introducing new rules on the compulsory licensing of patents.

In the amended wording of Article 71, after the declaration of state of national emergency, public interest or calamity, the Brazilian Federal Government, in consultation with public and educational institutions, as well as with representatives of the civil society, must publish within thirty days a list of patents or patent applications that would meet its needs. Once the list is published, any public or private entity may request the inclusion of other patents or patent applications. Before the compulsory licence is granted, the Brazilian Federal Government can exclude any patent or patent application from the list upon the request of the patent proprietor or applicant, if it considers that the patent proprietor or applicant is able to meet the domestic demand and that the price and time frame are consistent with the national

emergency and public interest's needs through (i) direct use of the patent or patent application in Brazil; (ii) voluntary licensing of the patent or patent application; or (iii) transparent sales agreement of the product protected by the patent or patent application.

The amended wording of Article 71 provides for the remuneration of the patent proprietor or patent applicant, which must take into the economic value of the licence, the duration of the licence, the investments required for its exploitation, production costs, and the sales price of the product in the domestic market. Pending a decision on the remuneration, the remuneration is provisionally fixed in 1.5% of the net sales price of the product protected by the patent or patent application.

The bill 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. The amendment introduced by the bill 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. If the patent proprietor or patent applicant does not comply with these obligations, the patent will be subject to revocation and the patent application may be denied. In addition, governmental authorities may also supply to the licensees the information and data not disclosed by the patent proprietor or patent applicant, as well as supply the biological material not supplied by the patent proprietor or patent applicant. The bill 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.

The unqualified authorisation conferred on governmental authorities to disclose undisclosed information is certainly one of the controversial points of the bill approved by the Brazilian Senate, as it can be argued that such disclosures 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. Another potential conflict with the TRIPS Agreement is the amendment introduced by the bill approved by the Brazilian Senate pertaining to the export of products to other countries. While Article 31*bis* of the TRIPS Agreement creates an exception to the obligation under Article 31(f), according to which the use without authorisation of a patent 'shall be authorized predominantly for the supply of the domestic market', the amendment introduced by the bill does not reproduce or refer to the conditions set forth in the Annex to the TRIPS Agreement for Article 31(f) not to apply. The bill provides only that, for humanitarian reasons, products produced using the subject-matter of a patent or patent application subject to a compulsory licence may be exported to countries in sanitary emergency aggravated by the lack of such products. There are no further requirements concerning the eligibility of the importing country and the conditions for the issuance of the compulsory licence in this circumstance, as

required in paragraph 2 of the Annex to the TRIPS Agreement.

The Brazilian Federal Government has not announced yet whether the Brazilian President will exercise its veto power in case the bill is approved by the Brazilian House of Representatives. In 2020, the Brazilian Federal Government was aligned with Trump's administration and opposed South Africa's and India's proposal on the waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 at the TRIPS Council. However, due to the growing pressures from the Brazilian Congress and Supreme Court motivated by the increasing number of deaths in Brazil caused by COVID-19, the Brazilian Federal Government may be forced to change its policy on the compulsory licensing of COVID-19 vaccines. On 6 May 2021, the Brazilian Supreme Court ruled that the second part of Article 40 of the Brazilian Industrial Property Act 1996 was unconstitutional, confirming an earlier interim decision. Article 40 establishes a term of protection of twenty years for invention patents and of fifteen years for utility model patents from the date of filing of the application. The second part of Article 40 provides, however, that the term of protection cannot be less than ten years for invention patents and seven years for utility model patents from the date that registration is granted by the Brazilian national office. In the decision, the Brazilian Supreme Court considered that the extension of the term of protection beyond twenty years from the date of filing is arbitrary and disproportionate.

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