CRA Charles River Associates

Value of IP for health and growth

The consequences of recent changes in the Intellectual Property rules in Brazil

JULY 2023

EXECUTIVE SUMMARY: WE IDENTIFY FOUR MAJOR CHANGES TO BRAZIL'S IP ENVIRONMENT SINCE 2019 AND QUANTIFY SOME OF THEIR POTENTIAL EFFECTS

MAJOR CHANGES SINCE 2019

COMPULSORY LICENSING LAW

New legislation allows the Brazilian government to grant compulsory licenses more easily and may compel the transfer of technology and/or know-how.

REVOCATION OF ARTICLE 40 SOLE PARAGRAPH

A sole paragraph of Article 40 of the Brazilian Industrial Property Law has been revoked by the Brazilian Supreme Court, doing away with a 10-year minimum patent protection.*

REVOCATION OF ARTICLE 229-C

Brazil has revoked Article 229-C, which means that pharmaceutical patent applications no longer require prior approval from ANVISA.

NATIONAL IP STRATEGY

Brazil is implementing a new National IP Strategy, which could have positive or negative effects.

QUANTIFYING THE IMPACT

We quantify the effects of the compulsory licensing law by evaluating analogue countries and the academic literature.

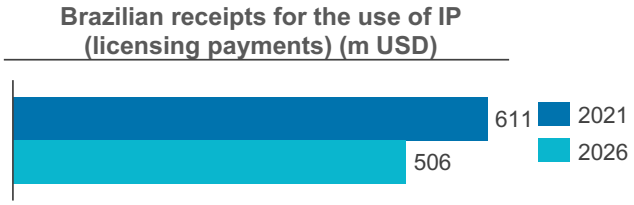
We quantify the effects of the Article 40 sole paragraph revocation.

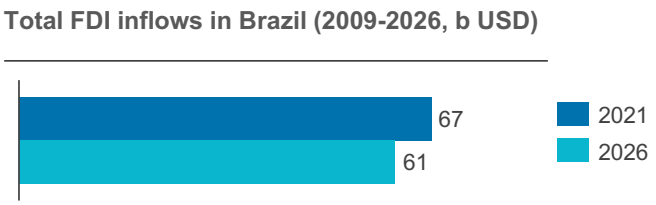
* ABPI's subsequent lawsuit against the federal government seeking greater funding for the Brazilian Patent Office (INPI) received an initial favorable result, requiring certain actions by and funding for INPI, but may yet be appealed.

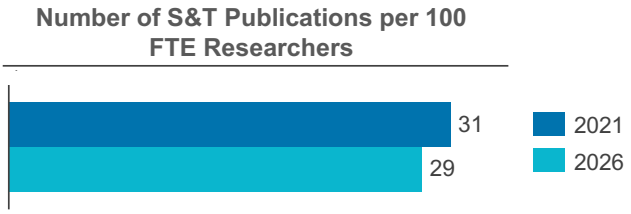
EXECUTIVE SUMMARY: QUANTIFICATION OF THE EFFECTS OF THE COMPULSORY LICENSING LAW AND THE ARTICLE 40 SOLE PARAGRAPH REVOCATION SUGGESTS A WORSENING FUTURE FOR BRAZILIAN INNOVATION

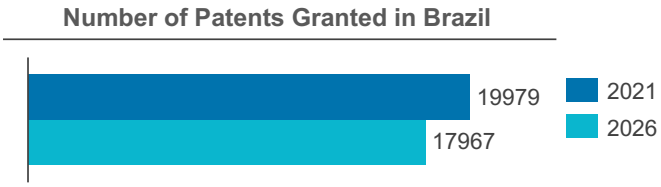
COMPULSORY LICENSING LAW

Brazil's new compulsory licensing law may reduce knowledge transfer, FDI, research, and patent applications.





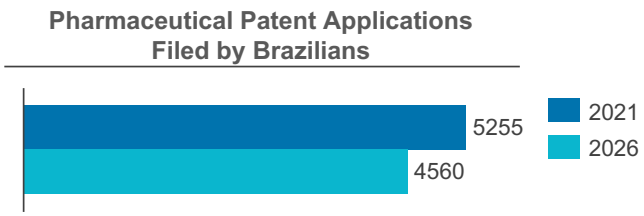


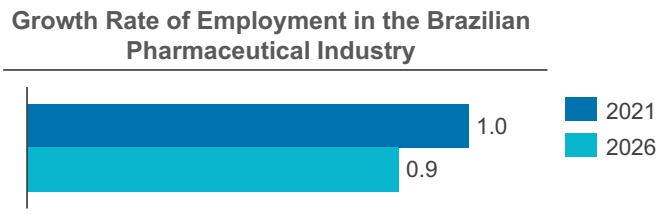


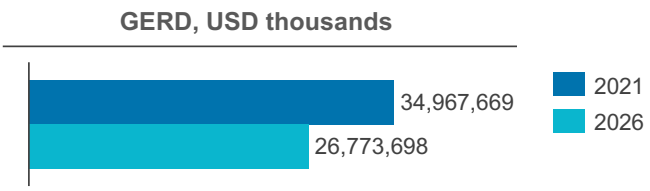
ARTICLE 40 SOLE PARAGRAPH REVOCATION

Uncertainty from patent backlogs may lead to fewer patents and lower employee growth rates.

Uncertainty from lack of patent term adjustments may lead to lower investment in R&D.







KEY POLICY RECOMMENDATIONS TO ACHIEVE A MORE PREDICTABLE AND STABLE IP FRAMEWORK IN BRAZIL

TO ADDRESS THE CL THREAT

IMPROVING THE PREDICTABILITY OF THE IP REGIME IN BRAZIL

Policymakers need to provide more predictability of the IP regime in Brazil to gain the pharmaceutical industry's confidence and attract the industry on doing long-term plans.

IMPROVING AWARENESS ON THE VALUE OF IP

Introducing educational campaigns targeted at politicians, policymakers, judges, academics, and the general population to improve the perception of the value of IP.

Advocate for private and public universities to introduce IP courses to increase awareness amongst professionals.

TO ADDRESS PATENT BACKLOG AND LACK OF PTA

INTRODUCING PATENT TERM ADJUSTMENT

The revocation of the sole paragraph Article 40 shed light on the need for a regulation for patent term adjustment.[3,4] For example, it is estimated that prior the revocation of the sole paragraph, 76.5% of the US patents filed in Brazil and granted by INPI had their term extended due to this provision.[1]

IMPROVING INPI'S EFFICIENCY

Advocating for INPI to be financially and administratively autonomous (e.g., to improve the ratio between the pharmaceutical patent application backlog and the number of examiners and to have control over the recruitment of its staff). In turn, this would result in improvements in the patent backlog.[2]

INTRODUCING REGULATORY DATA PROTECTION*

Advocate for the introduction of regulatory data protection, which complies with the TRIPS agreement.

* This policy recommendation addresses gaps present since 2019

Sources:

[1] Paes, T.D., Aguiar, L.F. and Martins, T.D.,. Identification of US-pharmaceutical patents expiring between 2018 and 2022 and their effect on the Brazilian domestic market. (2020). World Patent Information, 63, p.101999.

[2] Mercadante, Eduardo and Julia Paranhos, "Pharmaceutical patent term extension and patent prosecution in Brazil (1997-2018). (2022). Reports in Public Health, 38:1, pp. 1-13.

[3] Aziz, Anjam. The time is now to address Brazil's notorious patent backlog. (2022). PhRMA. Retrieved from https://catalyst.phrma.org/the-time-is-now-to-address-brazils-notorious-patent-backlog.

[4] Building a predictable, stable patent system in Brazil. (2022). Geneva Network. Retrieved from https://geneva-network.com/research/building-a-predictable-stable-patent-system-in-brazil/.

ADDITIONAL POLICIES COULD BE INTRODUCED TO FOSTER INNOVATION AND TECH TRANSFER, AND IN TURN REDUCE IP AND COMPULSORY LICENSING THREATS

FOSTER PRODUCTIVE DEVELOPMENT PARTNERSHIPS

Brazil has Productive Development Partnerships in place, which involve international pharmaceutical companies being given priority to sell to the public health system in exchange for doing a tech transfer agreement with local companies and/or government research organisations. However, such partnerships have not been strongly encouraged recently.

If such partnerships are fostered, Brazil will benefit from tech transfer and improved R&D know how.

EXPAND THE TECH TRANSFER OFFICES IN UNIVERSITIES

Many universities have a tech transfer office, but the majority have limited operations and do not have the necessary expertise to commercialise patents.

More funds and resources need to be allocated to tech transfer offices, which in turn will result in more tech transfer and an improved perception of the value of IP amongst graduates and academics.

INCENTIVISE ACADEMICS TO BE INVOLVED IN ENTREPRENEURIAL ACTIVITIES

Academics in Brazil are not allowed to have managerial positions within private companies, which makes it difficult to commercialise inventions or launch start-ups.

If such regulations are removed and aacademics are provided with the necessary incentives, Brazil would benefit in patent commercialisation activities and from the launch of new start-ups.

STREAMLINE REGULATORY PROCESSES FOR CLINICAL TRIALS

Regulatory processes and timelines were highlighted as key barriers in conducting clinical trials in Brazil, resulting in Brazil having very limited Phase I and Phase II clinical trials.

Brazil has an ethnically diverse and large population with treatment-naïve patients, and thus Brazil would be an attractive place to conduct clinical trials if the regulatory processes to approve a clinical trial were efficient.

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July 2023