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

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A sole paragraph of Article 40 of the Brazilian Industrial Property Law has been revoked by the Brazilian Supreme Court, doing away with a 10-year minimum patent protection.*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

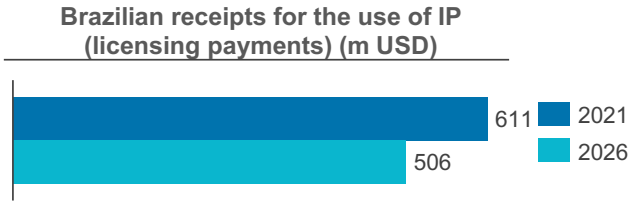
We quantify the effects of the Article 40 sole paragraph revocation.

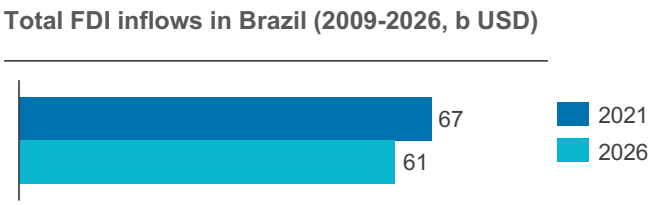
* ABPI's subsequent lawsuit against the federal government seeking greater funding for the Brazilian Patent Office (INPI) received an initial favorable result, requiring certain actions by and funding for INPI, but may yet be appealed.

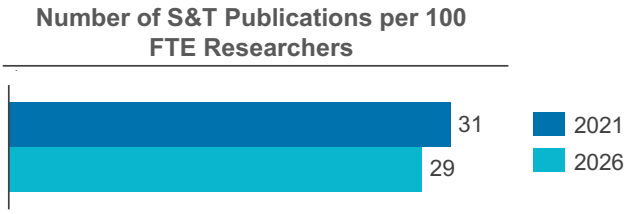
EXECUTIVE SUMMARY: QUANTIFICATION OF THE EFFECTS OF THE COMPULSORY LICENSING LAW AND THE ARTICLE 40 SOLE PARAGRAPH REVOCATION SUGGESTS A WORSENING FUTURE FOR BRAZILIAN INNOVATION

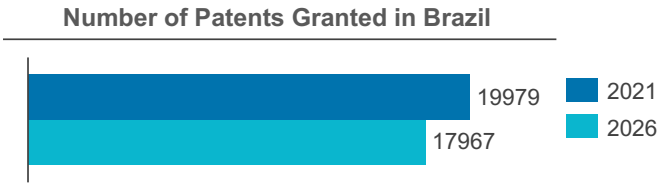
COMPULSORY LICENSING LAW

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





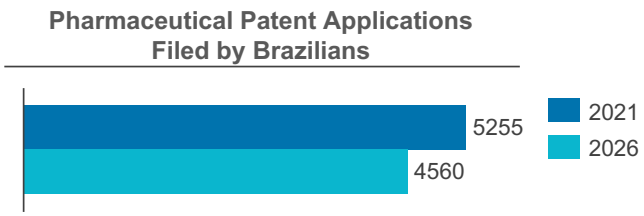


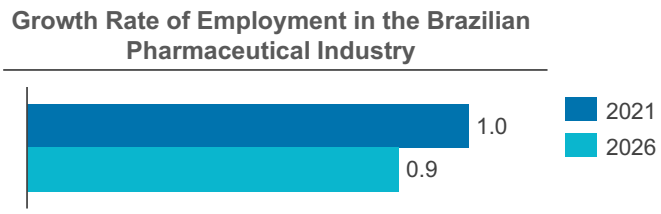


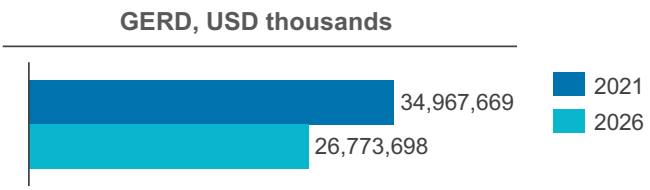
ARTICLE 40 SOLE PARAGRAPH REVOCATION

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.







1. Project overview

THE CONSEQUENCES OF CHANGES IN THE INTELLECTUAL PROPERTY RULES IN BRAZIL WILL BE ANALYSED OVER FOUR STEPS

	1 →	2 →	3 →	4 →
	BRAZIL INNOVATION POLICY FRAMEWORK	**QUANTIFICATION OF THE NET IMPACT OF CHANGES**	**LONGER-TERM IMPACT ON CHANGES IN THE ENVIRONMENT**	**DEVELOPMENT OF THE REPORT**
ACTIVITIES	• Review the recent literature of expert opinions on the changes in Brazilian IP law – Changes that have occurred since 2019 in the regime and changes to enforcement – Academic, grey literature on how it works in practice – The existing policy debate	• An in-depth analysis and critique of recent changes and the net impact on environment for innovation • Case studies from other countries which have implemented similar policies	• An interview series with industry and external stakeholders to understand the impact of the changes in terms of confidence and uncertainty	• Draft INTERPAT white paper – Incorporate comments • Participate in meeting to disseminate findings
DELIVERABLES	• A description of the changes in the IP regime including challenges and opportunities	• Quantification of the net impact of the IP changes on key metrics	• A qualitative description of the longer-term impact on changes in the IP regime	• White paper report with policy implications

WE HAVE CONDUCTED 15 INTERVIEWS, SPLIT BETWEEN INTERNAL AND EXTERNAL STAKEHOLDERS

INTERNAL:

abbvie · interfarma · janssen · Lilly · NOVARTIS · PhRMA RESEARCH • PROGRESS • HOPE · Pfizer · ucb

EXTERNAL:

abpi ASSOCIAÇÃO BRASILEIRA DA PROPRIEDADE INTELECTUAL · achē mais vida para você · AXONAL · DANNEMANN SIEMSEN · INOVA AGÊNCIA DE INOVAÇÃO DA UNICAMP · ipea Instituto de Pesquisa Econômica Aplicada · SINDUSFARMA

2.

An overview of Brazil's changes in the IP framework

CHANGES TO THE INNOVATION ENVIRONMENT THAT HAVE EMERGED SINCE 2019

In 2019, CRA conducted an analysis on behalf of INTERPAT and Interfarma that looked at the benefits of addressing existing challenges (patent backlogs, lack of regulatory data protection for pharmaceutical products, lack of sustained policy on innovation).

SINCE THEN...

- The Supreme Court revoked the sole paragraph of Article 40 of the Brazilian Industrial Property Law, doing away with a 10-year minimum of patent protection.[2]
- New legislation allows the Brazilian government to grant compulsory licenses more easily. Compulsory licenses were already legal in Brazil, but versions of this new law could compel transfer of technology and know-how.[3,4]
- With the revocation of Article 229-C, pharmaceutical patent applications no longer require prior approval from ANVISA.[5]
- Brazil is examining its current IP law as part of a new National IP Strategy.[6]

Sources:

[1] Pharmaceutical Research and Manufacturers of America Special 301 Submission 2021. (2021.) PhRMA. Retrieved from https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf.

[2] Boclin, Ricardo. The end of the Minimum Patent Term in Brazil: Implications of the Brazilian Supreme Court's Decision. (2021). Clarke + Modet. Retrieved from https://www.clarkemodet.com/en/news-posts/the-end-of-the-minimum-patent-term-in-brazil-implications-of-the-brazilian-supreme-courts-decision/.

[3] Leonardos, Gabriel Francisco. The Covid-19 pandemic triggered the issuance of new compulsory license rules for patents in Brazil. (2021). Kasznar & Leonardos. Retrieved from https://www.kasznarleonardos.com/news-and-publications/newsletters/the-covid-19-pandemic-triggered-the-issuance-of-new-compulsory-license-rules-for-patents-in-brazil.

[4] Lozouet, Louis. Brazil: New Compulsory Licensing Rules For Patents In Brazil. (2021). Mondaq. Retrieved from https://www.mondaq.com/brazil/patent/1111706/new-compulsory-licensing-rules-for-patents-in-brazil.

[5] Salerno, Gabriela. Law that accelerates prosecution of patent applications in the pharmaceutical field is sanctioned in Brazil. (2021). Montaury Pimenta Machado & Vieira de Mello. Retrieved from https://www.montaury.com.br/en/articles/512-law-that-accelerates-prosecution-of-patent-applications-in-the-pharmaceutical-field-is-sanctioned-in-brazil.

[6] Lozouet, Louis. National IP Strategy aims to make Brazil a world-class hub for innovation. (2021). IAM Media. Retrieved from https://www.iam-media.com/brazils-national-strategy-of-ip-further-step-towards-the-leap-of-innovation.

THE REVOCATION OF THE SOLE PARAGRAPH OF ARTICLE 40 AND THE COMPULSORY LICENSING LAW

UPDATE

COMPULSORY LICENSING LAW

- Brazil's new CL bill was passed in September 2021 and builds on Brazil's current CL law.[4]
- Key sections were vetoed by the president.[4,5]
- – The presidential version recently confirmed by the congress[6,7] could compel public institutions to share data.

POTENTIAL IMPACT

- The new CL law may **hinder public-private partnerships** with companies in Brazil, as public institutions could be compelled to hand over confidential information.[3]
- Collaboration and direct investment in Brazilian companies and institutions may suffer.[3]

REVOCATION OF THE SOLE PARAGRAPH OF ARTICLE 40

- In May 2021, the Brazilian Supreme Court ruled that a sole paragraph in Article 40 of Brazil's IP law was unconstitutional, **removing the ten-year minimum term granted to patents.**[1]
- This decision had **retroactive effects for the pharmaceutical industry,** meaning that many drugs lost years of exclusivity with almost no warning.[1,2]

- The loss of patent exclusivity may further **delay launch of much-needed products.**[3]
- The loss of a minimum patent term adds to the **instability and uncertainty of the IP environment** in Brazil, which may lead to further decreased investment.[3]

Sources:

[1] Boclin, Ricardo. The end of the Minimum Patent Term in Brazil: Implications of the Brazilian Supreme Court's Decision. (2021). Clarke + Modet. Retrieved from https://www.clarkemodet.com/en/news-posts/the-end-of-the-minimum-patent-term-in-brazil-implications-of-the-brazilian-supreme-courts-decision/.

[2] Calil, Ana Luiza, Alysson Farias and rob Rodrigues. Supreme Court patent term decision. (2021). IAM Media. https://www.iam-media.com/supreme-court-patent-term-decision.

[3] CRA interviews with external and internal stakeholders, December 2021-January 2022.

[4] Leonardos, Gabriel Francisco. The Covid-19 pandemic triggered the issuance of new compulsory license rules for patents in Brazil. (2021). Kasznar & Leonardos. Retrieved from https://www.kasznarleonardos.com/news-and-publications/newsletters/the-covid-19-pandemic-triggered-the-issuance-of-new-compulsory-license-rules-for-patents-in-brazil.

[5] Lozouet, Louis. Brazil: New Compulsory Licensing Rules For Patents In Brazil. (2021). Mondaq. Retrieved from https://www.mondaq.com/brazil/patent/1111706/new-compulsory-licensing-rules-for-patents-in-brazil.

[6] Pinho, Rodrigues, Felipe Mesquita. Brazil: TRIPS waiver and Compulsory license. (2022). Kluwer Patent Blog. Retrieved from http://patentblog.kluweriplaw.com/2022/07/20/brazil-trips-waiver-and-compulsory-license/.

[7] Brazilian Congress maintains Presidential Veto on Compulsory Licensing of Patents. (2022). Daniel Law. Retrieved from https://mailchi.mp/6753a383571b/brazilian-congress-maintains-presidential-veto-on-compulsory-licensing-of-patents?e=b32b737c18.

THE REVOCATION OF ARTICLE 229-C AND THE DEVELOPMENT OF A NATIONAL IP STRATEGY

UPDATE

REVOCATION OF ARTICLE 229-C

- In August 2021, Brazil passed a law **eliminating the requirement for prior consent from ANVISA** for pharmaceutical products and processes before the technical examination performed by INPI.[1]
  - This step in the patent application process has long been seen as one of the problems **contributing to Brazil's patent backlog** and uncertainty around patent terms.[1,2]

NATIONAL IP STRATEGY

- Brazil's new National IP Strategy (ENPI) was introduced for public consideration in August 2020 and is **intended to create significant improvements to the national IP system.**[4,5]
  - The ENPI is intended to span the next ten years, with implementation renewals every two years.[4,5]

POTENTIAL IMPACT

- The revocation of Article 229-C will help **reduce the patent backlog and increase confidence** in the patent application process.[1,2,3]
  - The backlog is much improved, though there are still delays for certain pharmaceutical products.[3]
- A bill has already been filed to reintroduce ANVISA into the patent application process (Bill 2713/2021), though it is unclear how likely it is to be passed.[3]

- The national strategy will include **a government review of the Brazilian IP law,** which will create opportunities for the laws to change in positive or negative ways.[3]
- The government review may be impacted by the **overall political atmosphere in Brazil,** including the 2022 elections and public perception of IP issues.[3]

Sources:

[1] Salerno, Gabriela. Law that accelerates prosecution of patent applications in the pharmaceutical field is sanctioned in Brazil. (2021). Montaury Pimenta Machado & Vieira de Mello. Retrieved from https://www.montaury.com.br/en/articles/512-law-that-accelerates-prosecution-of-patent-applications-in-the-pharmaceutical-field-is-sanctioned-in-brazil.

[2] Leonardos, Kasznar. Text of the Business Environment Bill is approved by the Chamber of Representatives, and it ends the prior approval for pharmaceutical patents, in addition to bringing relevant changes to trade names. (2021). Lexology. Retrieved from https://www.lexology.com/library/detail.aspx?g=e947cd6a-2dc8-4344-bce8-f301f4b6218c.

[3] CRA interviews with external and internal stakeholders, December 2021-January 2022.

[4] Lozouet, Louis. National IP Strategy aims to make Brazil a world-class hub for innovation. (2021). IAM Media. Retrieved from https://www.iam-media.com/brazils-national-strategy-of-ip-further-step-towards-the-leap-of-innovation.

[5] Brazil publishes pathway for accelerating innovation: the National Strategy of Intellectual Property. Generics and Biosimilars Initiative. Retrieved from https://www.gabionline.net/policies-legislation/Brazil-publishes-pathway-for-accelerating-innovation-the-National-Strategy-of-Intellectual-Property.

3.
Different perspectives on the impact on innovation

INTERNAL AND EXTERNAL* INTERVIEWEES HAVE HAD DIFFERENT AND SOMETIMES CONTRADICTORY REACTIONS TO SOME OF THE CHANGES TO BRAZIL'S IP SYSTEM

COMPULSORY LICENSING LAW

INTERNAL INTERVIEWS

- International pharma companies are concerned by the potential for compelled transfer of know-how or technology in the case of compulsory licenses and warn that this threat may make it more difficult for them to partner with domestic organizations or companies.

EXTERNAL INTERVIEWS

- National companies are not particularly concerned about the compulsory licensing law, as they have little interest in tech transfer from international companies.
- External interviewees also doubt that compulsory licenses would be able to create many changes if implemented.

ARTICLE 40 SOLE PARAGRAPH REVOCATION

INTERNAL INTERVIEWS

- The ten-year minimum patent term from the sole paragraph of Article 40 was really compensation for the backlog, and now the compensation is gone but the backlog remains, though it is improving.
- The revocation can only be offset by other policies such as patent term adjustments.

EXTERNAL INTERVIEWS

- The revocation of the sole paragraph of Article 40 provides important opportunities for national companies and standardizes the patent expiration across countries, as the sole paragraph was leading to longer patent exclusivity in Brazil than in other countries.

*External interviews took place with interviewees at national generics companies and local networks of pharmaceutical industry players within Brazil as well as with law firms and organizations dealing with IP in Brazil.

REVOCATION OF ARTICLE 229-C

INTERNAL INTERVIEWS

- This revocation is generally seen as a positive step for the pharmaceutical industry.
- Part of the motivation for the revocation was to put Brazil closer to international regulations and standards for the patent process.

EXTERNAL INTERVIEWS

- The involvement of ANVISA had been lessened in recent years, but it is still helpful to have them removed from the process entirely, as their involvement was logistically difficult.
- It is likely that more pharmaceutical patents will be granted as a result of the revocation.

NATIONAL IP STRATEGY

INTERNAL INTERVIEWS

- The fact that the national strategy forces communication between the many ministries involved in IP is a good sign.
- It is hoped that the national strategy will give independence to INPI, which has historically lacked the necessary resources and authority to carry out its duties.

EXTERNAL INTERVIEWS

- The national IP strategy is the first of its kind, but it has not yet been demonstrated that there is a real commitment of resources to its activities.
- The strategy's inclusion of an inter-ministerial group (GIPI) is promising, as it should incorporate different stakeholders.

*External interviews took place with interviewees at national generics companies and local networks of pharmaceutical industry players within Brazil as well as with law firms and organizations dealing with IP in Brazil.

INTERNAL AND EXTERNAL INTERVIEWS ALSO NOTED THAT THE COMBINATION OF MANY OF THESE CHANGES LED TO UNCERTAINTY WITHIN THE PHARMA INDUSTRY

MANY OF THE CHANGES SINCE 2019 HAVE CREATED MORE UNCERTAINTY IN THE IP ENVIRONMENT

THE RESULTING UNCERTAINTY MAY HAVE NEGATIVE CONSEQUENCES FOR BRAZIL

REVOCATION OF SOLE PARAGRAPH OF ARTICLE 40

- The revocation of the sole paragraph of Article 40 and the new compulsory licensing law have introduced uncertainty around the predictability of the IP regime in Brazil

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- Companies cannot tell what IP environment they're launching new products in
- This may play a factor in decision-making around (dis)investments and product launches in Brazil

COMPULSORY LICENSING LAW

- The threat of compulsory licensing has increased
- Additionally, there are political uncertainties regarding potential uses of the law

→

- Partnerships with public institutions in Brazil may bring the risk of being compelled to share trade secrets
- In the long-term, the law may disincentivize the industry from investing in Brazil

LACK OF CLARITY ON THE NATIONAL IP STRATEGY

- It is uncertain whether the review of the IP regime in Brazil mandated by the National IP Strategy will result in improvements or setbacks to the IP regime

→

- The influence of the generic industry in the inter-ministerial group on IP (GIPI) may result in Brazil's IP regime deteriorating further, such as through the reintroduction of ANVISA to the patent review process

Another cause of uncertainty is the very **negative public and political perception of the pharma industry in Brazil,** possibly as a result of a lack of understanding of the benefits of IP. This negative perception has existed for many years and has contributed to existing issues such as the patent backlog, lack of RDP, and difficulty obtaining damages for infringement, all of which also contribute to the uncertain environment in Brazil.

Sao Paulo skyline, Brazil, shutterstock.com

4.

Potential impact of Brazil's changes in the IP framework

IN THIS STUDY, WE AIM TO QUANTIFY THE IMPACT OF THE KEY RISKS EMERGING FROM THE LATEST IP DEVELOPMENTS IN BRAZIL

COMPULSORY LICENSING LAW

1

COMPULSORY LICENSING QUANTIFICATION

We quantify the effects of the compulsory licensing law through comparisons to countries with no trade secret protections or with new and aggressive compulsory licensing laws.

ARTICLE 40 SOLE PARAGRAPH REVOCATION

2

ARTICLE 40 SOLE PARAGRAPH REVOCATION QUANTIFICATION – PATENT BACKLOGS

We quantify the effects of the Article 40 sole paragraph revocation in part by evaluating patent backlogs across countries, as the revocation has similar effects as a longer patent backlog due to inefficiencies in INPI.*

3

ARTICLE 40 SOLE PARAGRAPH REVOCATION QUANTIFICATION – PATENT TERM ADJUSTMENTS

We also quantify the effects of the Article 40 sole paragraph revocation by looking at studies on the effects of the lack of patent term adjustments, as patent term adjustments would mitigate the effects of the revocation.

THE INCREASED RISK OF COMPULSORY LICENSING AND FORCED TECHNOLOGY TRANSFER NEGATIVELY IMPACTS LOCAL INNOVATION, FDI, ACCESS AND RESEARCH ACTIVITY

IMPACT ON LOCAL INNOVATION

- The risk of pharmaceutical patents or trade secrets not being protected has a negative impact on local innovation, as there would be less knowledge transfer between international and local companies.[1]
- For example, one study analysing R&D offshore outsourcing to foreign vendor firms in India found that there is a transfer of knowledge from the client to the vendor firm, with vendors having a higher innovation performance compared to non-vendor firms.[2]

The risk to pharmaceutical patents or the risk of trade secrets not being protected can result in a 53% decrease in knowledge transfer.*[1]

IMPACT ON FDI

- In the future, pharmaceutical companies may mistrust compulsory licensing nations' promises to protect and enforce patent rights. As a result, the pharmaceutical industry may avoid engaging in foreign direct investment in nations that grant compulsory licenses and instead invest in countries which better protect their IP.[3,4]
- For example, in 2001, PhRMA informed Egypt that its weak intellectual property laws, primarily attributed to the risk of compulsory licensing, deterred PhRMA from investing $300 million in Egypt's pharmaceutical sector. FDI flows declined from $948 million in 1987 to $598 million in 1995 to $428.2 million in 2001-02.[3]

There are case studies where FDI was reduced by 54.8% over a 15 year period.[3]

*Knowledge transfer is defined as the value of IP licensing receipts per 1,000 population.

IMPACT ON ACCESS TO INNOVATIVE PRODUCTS

- One study found despite some emerging countries using compulsory licensing to improve access to antiretroviral therapy (ART), the level of ART coverage is not correlated with the use of compulsory licensing.[5]
- Furthermore, given that counties that have used compulsory licensing are perceived as being more likely to use it again in the future, access to innovative products may be hindered.[5]

Countries with strong price regulations wait an average 2 years longer for the launch of 25% of drugs launched in other countries than countries with no/weak price regulations.*[6]

IMPACT ON SCIENTIFIC OUTPUT

- The risk of lack of protection to pharmaceutical patents or the risk of trade secrets not being protected have a negative impact on basic research.[1]

The risk to pharmaceutical patents or the risk of trade secrets not being protected can result in a 18% decrease in basic research.**[1]

IMPACT ON COMMERCIAL RESEARCH

- The risk of lack of protection to pharmaceutical patents or the risk of trade secrets not being protected have a negative impact on the number of patents granted.[1]

The risk to pharmaceutical patents or the risk of trade secrets not being protected can result in a 30% decrease in the number of patents granted per 1,000 population.[1]

*Brazil has used threats of compulsory licensing to negotiate and control prices in the past
**Basic research is defined as the number of novel scientific and medical articles published per 1,000 population

A SUMMARY OF THE IMPACT OF THE INCREASED RISK OF COMPULSORY LICENSING AND FORCED TECHNOLOGY TRANSFER

IMPACT ON LOCAL INNOVATION

A **reduction of 3.7% per year in knowledge transfer,** defined as the value of IP licensing receipts per 1,000 population*[1]

IMPACT ON FDI

A reduction of 1.8% per year in FDI**[2]

IMPACT ON ACCESS TO INNOVATIVE PRODUCTS

International products launched in Brazil are likely to face **an additional delay of at least 2 years**[6]

IMPACT ON SCIENTIFIC OUTPUT

A **reduction of 1.3% per year in basic research,** defined as the number of novel scientific and medical articles published per 1,000 population*[1]

IMPACT ON COMMERCIAL RESEARCH

A **reduction of 2.1% per year in the number of patents granted** per 1,000 population*[1]

Assumptions:

*We assume that the growth defined in the paper is the average growth over a 14.2-year period, based on a weighted average of 2 countries implementing TRIPS in 1995, 12 implementing in 2000, and 23 implementing in 2005, as TRIPS implementation deadlines were based on development level.[1]

**We assume that CL accounts for only some portion of the FDI change reported in the paper due to the number of changes occurring in Egypt at the time.[3] We estimate this portion at 50%, as the CL law was one of several significant issues at the time (other issues included parallel imports, a narrow patent definition, and difficulty enforcing patent infringement).[7]

Sources:

[1] Cockburn, I.M., Wilsdon, T., Pistollato, M., Jayasuriya, R. and Watson, T., 2021. The Role of TRIPS in Encouraging Diffusion of Pharmaceutical Technology to Developing Countries. *Available at SSRN.*

[2] Thakur-Wernz, Pooja and Christian Wernz, "Does R&D Offshore Outsourcing Improve Innovation in Vendor Firms from Emerging Economies? A Study of Bio-pharmaceutical Industry in India," *International Journal of Emerging Markets.*

[3] Bird, R. and Cahoy, D.R., 2008. The impact of compulsory licensing on foreign direct investment: a collective bargaining approach. *American Business Law Journal, 45*(2), pp.283-330.

[4] Lee, M., Alba, J.D. and Park, D., 2018. Intellectual property rights, informal economy, and FDI into developing countries. Journal of Policy Modeling, 40(5), pp.1067-1081.

[5] Wilsdon, T. and Li, L., 2016. The Evolution of Access to Essential Medicines for the Treatment of HIV/AIDS–Evidence from 2000 to 2015. Accessible at: https://www.ifpma.org/wp-content/uploads/2016/06/2016-The-Evolution-of-Access-to-Essential-Medicines-CRA.pdf

[6] Cockburn, I.M., Lanjouw, J.O., and Schankerman, M. (2014). Patents and the Global Diffusion of New Drugs. NBER Working Paper No. 20492.

[7] Aziz, S., 2003. Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry. *ILSA J. Int'l & Comp. L., 10,* p.1. https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1121&context=facscholar.

THE SIGNIFICANT PATENT BACKLOG DETERS LOCAL AND INTERNATIONAL PATENT FILINGS AND HINDERS LOCAL INNOVATION

IMPACT ON PATENT FILINGS

- One study comparing INPI to another 8 patent offices, found that Brazil ranked 8th out of 9 in terms of the number of patents filed and had the biggest backlog per examiner and the slowest review process, mostly due to the very low number of examiners in comparison to the number of pending applications.[1]
- Thus, the patent backlog discourages companies from filing patents.[1] Despite INPI efforts, there is still significant lag in the pipeline.

Brazil had significantly fewer patent applications than the other BRICS markets and 95% fewer than IP5.*[1]

IMPACT ON LOCAL INNOVATION

- The patent backlog could discourage locals from filing patents, for example, only 8.6% of patents filed in Brazil were filed by Brazilians.[1]
- Additionally, patent backlogs reduce the probability of commercialisation and the number of subsequent patents the firm is granted.[2,3]

Patent delays can reduce the number of subsequent patents the firm is granted by 14% per year delayed.**[2]

IMPACT ON LOCAL START-UPS

- Processing delays in patents can impair the ability of start-ups to grow sales, be innovative, and gain a stock market listing.[2]
- Additionally, it can impair start-ups collaborating with other stakeholders for fear of expropriation and uncertainty for competitors due to information asymmetry.[4,5]
- Each year of delay in reviewing a firm's first patent application (that is eventually approved) reduces the firm's employment growth by 21% and sales growth by 28% over the five years following approval.[2]

When focusing on start-ups, each year of patent delay results in a reduction in employment growth by 21% over the five years following the patent approval.[2]

*BRICS calculation excludes South Africa (due to lack of data) and IP5 includes US, Japan, Korea, China and EPO
**We are assuming that local innovation will behave similarly to local start-ups as measured in the US

A SUMMARY OF THE IMPACT OF UNPREDICTABLE PATENT TERMS DUE TO THE PATENT BACKLOG

IMPACT ON PATENT FILINGS

A reduction of 4% in the number of total patents filed per year*[1]

IMPACT ON LOCAL INNOVATION

A reduction of 2.8% in the number of patents filed in Brazil by Brazilians**[2]

IMPACT ON LOCAL START-UPS

An average yearly reduction of 4.2% in the number of employees employed by local start-ups**[2]

Assumptions:

*We are assuming that Brazil will converge to having similar patent filing as Mexico over a 10 year period due to the unpredictable patent term[1]

**We are assuming that local innovation will behave similarly to local start-ups as measured in the US and that the observed 14% reduction will take place over a 5 year period[2]

Sources:

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

[2] Farre-Mensa, Joan, Deepak Hegde, and Alexander Ljungqvist, "The Bright Side of Patents," USPTO Economic Working Paper No. 2015-5, December 2015, http://tld-documents.llnassets.com.s3.amazonaws.com/0016000/16446/harvard%20study%20-%20patents%20and%20start%20ups.pdf.

[3] Hrendash, T., 2019. Prioritized Examination and its Impact on Commercialization of Patents. CERGE-EI Working Paper Series, (638).

[4] Gans, Joshua S. and David H. Hsu, "The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays," Management Science, 54:5, 2008, pp. 982-997.

[5] Zaby, Alexandra Karin and Gaétan de Rassenfosse, "The Economics of Patent Backlog," July 2016, https://www.econstor.eu/bitstream/10419/145673/1/VfS_2016_pid_6628.pdf.

UNPREDICTABLE PATENT TERMS AND LACK OF PATENT TERM ADJUSTMENTS RESULT IN A REDUCED ACCESS TO INNOVATIVE PRODUCTS

IMPACT ACCESS OF INNOVATIVE PRODUCTS

- The unpredictable patent term may deter pharmaceutical companies from seeking marketing authorisation of their innovative products in Brazil.
- Launch of new products is faster in the presence of patents,[4] and a 2014 study found that increased length of patent terms sped up product launch.[5]

Countries with short patent terms wait an average 0.6 and 3.4 years longer for the launch of 25% of drugs launched in other countries than countries with medium and long patent terms, respectively.[5]

DECREASE R&D SPENDING

- When patent terms for inventions are unpredictable, incentives for research and development, especially research focused on commercial ends, are low.

R&D spending in India increased by 470% from 2005 to 2014 (an average of 52% a year) and R&D expenditure as a % of sales increased by 46.6% (5.2% a year) after product inventions started being protected in 2005.[3]

*Basic research is defined as the number of novel scientific and medical articles published per 1,000 population

A SUMMARY OF THE IMPACT OF UNPREDICTABLE PATENT TERMS DUE TO THE LACK OF PATENT TERM ADJUSTMENTS

IMPACT ACCESS OF INNOVATIVE PRODUCTS

- It is estimated that it will take **0.57 years longer for the launch** of 25% of drugs launched in other countries with medium patent terms*[5]

DECREASE R&D SPENDING

- **A reduction in R&D spending (as a percentage of sales) of 5.2% per year**[3]

Assumptions:

*We assume that the unpredictable patent term will result in Brazil being classified as having a Short Patent Regime, instead of the current Medium Patent Regime[5]

Sources:

[1] "Global Medicines Use in 2020," IMS Institute for Healthcare Informatics, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020.

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

[3] Basant, Rakesh and Shuchi Srinivasan, "Intellectual property protection in India and implications for health innovation: emerging perspectives," *Innovation and Entrepreneurship in Health,* 2016, 3, pp. 57-68.

[4] Kyle, M., and Qian, Y. (2014). Intellectual Property Rights and Access to Innovation: Evidence from TRIPS. NBER Working Paper No. 20799.

[5] Cockburn, I.M., Lanjouw, J.O., and Schankerman, M. (2014). Patents and the Global Diffusion of New Drugs. NBER Working Paper No. 20492.

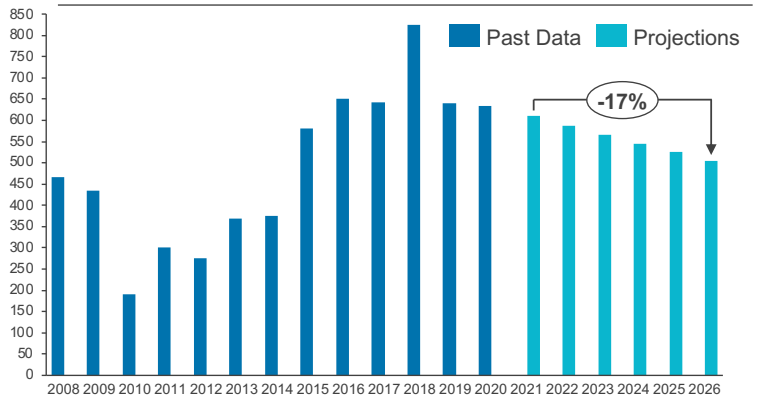
[6] "2020 profile of the pharmaceutical industry," Sindusfarma, https://sindusfarma.org.br/uploads/Publicacoes/Perfil_IF2020_ING.pdf.

5. Quantifying the impact of Brazil's changes in the IP framework

COMPULSORY LICENSING: REDUCED FDI AND KNOWLEDGE TRANSFER

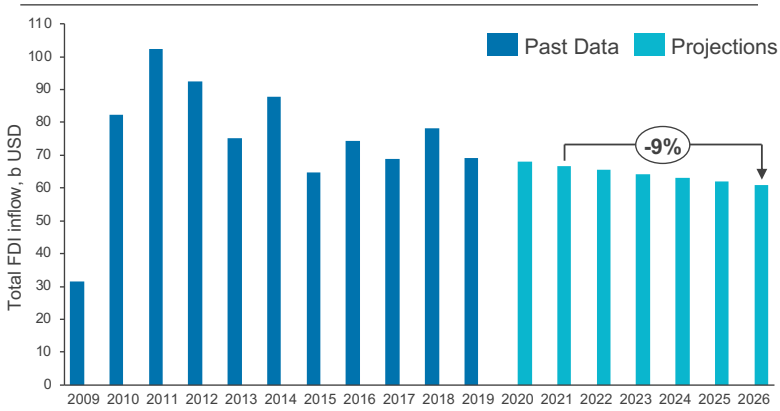
- We apply a reduction of 3.7% per year to the value of IP licensing receipts per 1,000 population as an indicator of knowledge transfer.
  - In interviews, some companies expressed concern with sharing knowledge with local institutions with the risk of forced technology or knowledge transfer from compulsory licensing.
- We apply a 1.8% reduction to FDI inflows per year.
  - Interviews with multinational pharma companies indicated that compulsory licensing could de-incentivize further investment in the country.

Brazilian receipts for the use of intellectual property (licensing payments) (2008-2026, m USD)



Source: World Bank, 2008-2020

Total FDI inflows in Brazil (2009-2026, b USD)

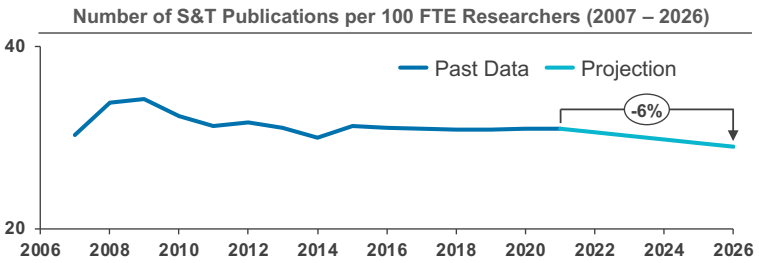


Source: World Bank, 2009-2019

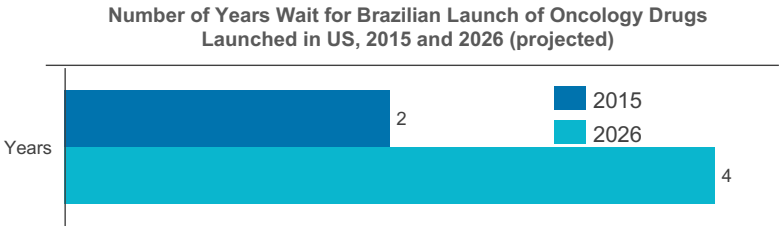
For "receipts for the use of intellectual property," OECD average for 2020 is OECD total from World Bank website (https://data.worldbank.org/indicator/BX.GSR.ROYL.CD?locations=BR) divided by 37 (OECD currently has 38 members, but Costa Rice joined in 2021)
Balance = exports – imports, millions USD
Sources: World Bank data on Brazil.

COMPULSORY LICENSING: REDUCTION IN RESEARCH AND FEWER PATENTS

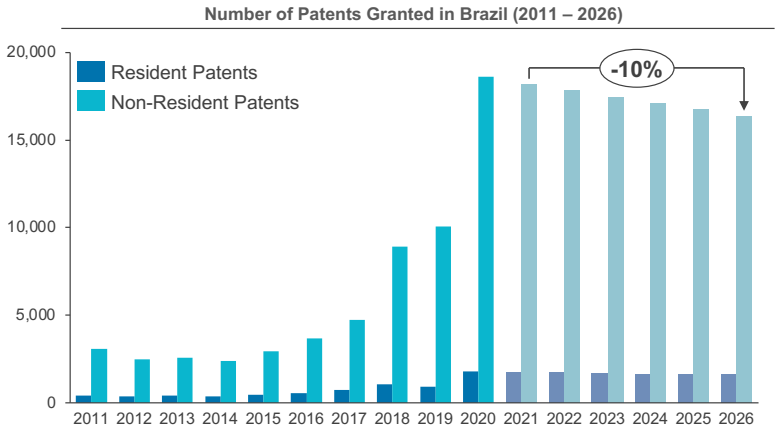
- We apply a reduction of 1.3% to the number of S&T publications per 100 FTE researchers below.
  - We also apply this reduction to the total number of researchers in R&D across all institutions (the 1.3% reduction is applied to each individual institution)
  - Where data is not present between 2014 and 2021 we take five-year moving averages.
- We apply a reduction of 2.1% per year in the number of patents granted per 1,000 population to the number of patents granted to residents and non-residents. The large increase between 2019 and 2020 can be attributed to INPI's work to decrease the patent backlog.
- We apply a launch delay of 2 years to the current wait time of 2 years for oncology products launched in the US to be launched in Brazil.



Source: Ministry of Science, Technology, Innovations and Communications (MCTIC), 2005-2014



Source: Journal of Clinical Oncology, "Approval of new drugs in Brazil"



Source: WIPO Statistical Country Profile for Brazil.
Numbers after 2020 are projections.

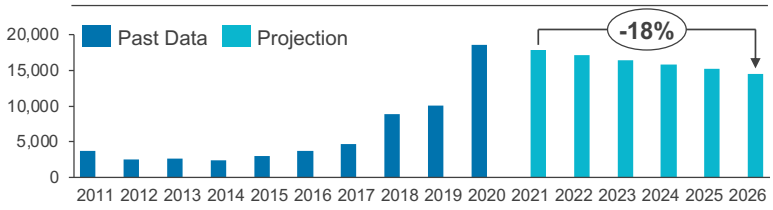
Graph Sources:

WIPO Statistical Country Profile for Brazil.
"Approval of new drugs in Brazil," Journal of Clinical Oncology, https://ascopubs.org/doi/abs/10.1200/jco.2015.33.15_suppl.e17513.
Source: Ministry of Science, Technology, Innovations and Communications (MCTIC), 2005-2014.

UNCERTAINTY FROM PATENT BACKLOGS: FEWER PATENTS AND LOWER EMPLOYEE GROWTH RATES

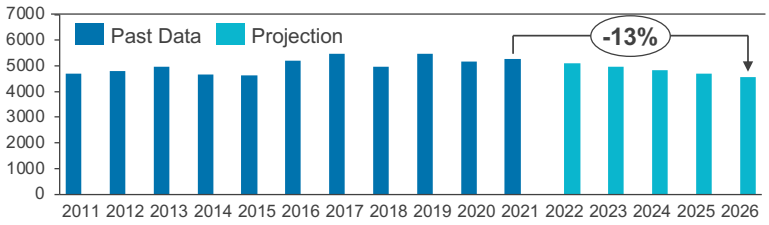
- We apply a reduction of 4% to the number of non-resident patents granted in Brazil starting in 2021.
  - Interviews indicated that the revocation of the sole paragraph in Article 40 could result in a decrease in patents filed due to increased uncertainty about the IP climate in Brazil.
- We apply a reduction of 2.8% to the absolute number of pharmaceutical patent applications filed by Brazilians in Brazil.
  - Local innovators are likely to suffer as much as multinational companies from an extended wait time and uncertain patent protection periods.
- We apply an average yearly reduction of 4.2% in the employee growth in the pharmaceutical industry.

Number of Non-Resident Patents Granted in Brazil (2011-2026)



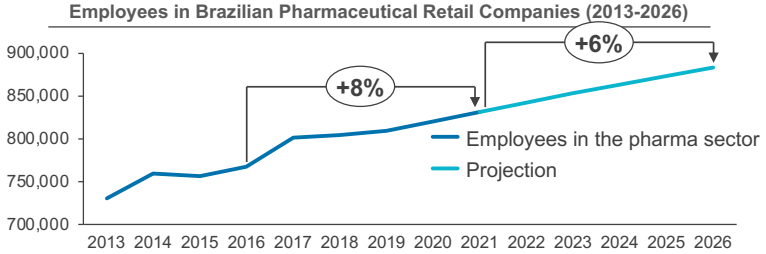
WIPO Statistical Country Profile, Brazil.

Pharmaceutical Patent Applications Filed by Brazilians (2011-2026)

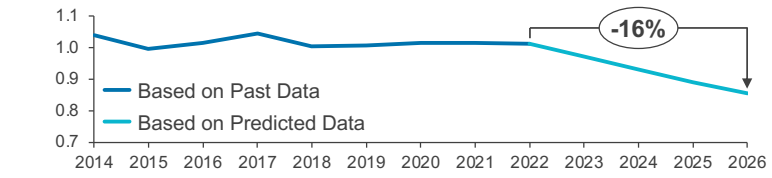


Patent applications, residents – Brazil, World Bank data.

Employees in Brazilian Pharmaceutical Retail Companies (2013-2026)



Growth Rate of Employment in Brazilian Pharmaceutical Industry (2014-2026)



Source: Statista.com, Number of employees in the cosmetics, pharmaceutical and medical retail sector in Brazil from 2013 to 2019

Graph Sources:

Statista.com "Number of employees in the cosmetics, pharmaceutical and medical retail sector in Brazil from 2013 to 2019," https://www.statista.com/statistics/1072286/brazil-employment-retail-pharmaceutical-industry/.

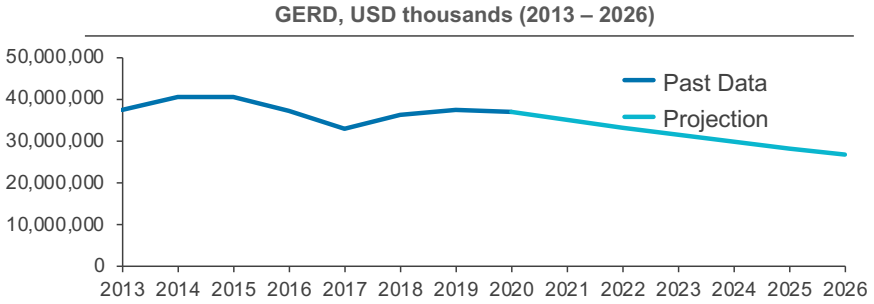
The reduction of 4.2% in the growth of start-up employees is applied to the pharmaceutical retail sector by taking the average growth rate of the five years before 2021 and applying a 4.2% reduction to it through 2026. So, for example, 2022 employees=((((2019 employees/2014 employees)-1)/5)+1)*((1-.042)^1)*2021 employees.

WIPO Statistical Country Profile, Brazil.

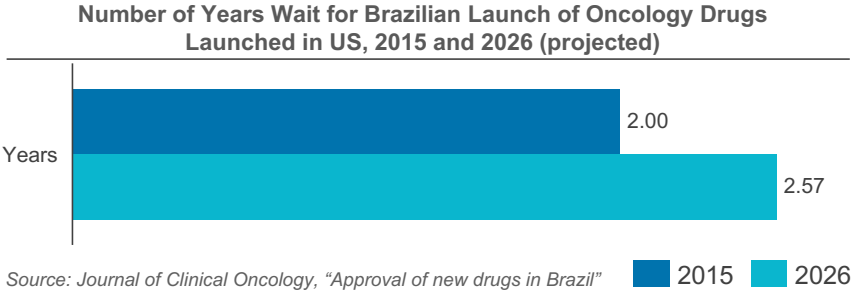
Patent applications, residents – Brazil, World Bank data.

UNCERTAINTY FROM LACK OF PATENT TERM ADJUSTMENTS: LOWER INVESTMENT IN R&D AND WAIT TIMES

- We apply a reduction of R&D spending as a percentage of sales of 5.2% per year to Gross Expenditure on R&D (GERD) in Brazil.
- We apply a launch delay of .57 years to the current wait time of 2 years for oncology products launched in the US to be launched in Brazil.
  - Interviews indicated that some companies are likely to delay launch as a result of patent term uncertainty stemming from the lack of patent term adjustments and the resulting uncertainty of IP protection.



Source: R&D Spending by Country, Gross Expenditure on R&D (GERD), UNESCO Institute for Statistics.



Source: Journal of Clinical Oncology, "Approval of new drugs in Brazil"

Graph Sources:

R&D expenditure compared to other markets (2018) - http://uis.unesco.org/apps/visualisations/research-and-development-spending/
Gross Expenditure on R&D (GERD) (in '000 US$ PPP) - http://data.uis.unesco.org/Index.aspx?DataSetCode=SCN_DS&lang=en
Science, technology and innovation--> Research and experimental development --> Gross domestic expenditure on R&D (GERD)
"Approval of new drugs in Brazil," Journal of Clinical Oncology, https://ascopubs.org/doi/abs/10.1200/jco.2015.33.15_suppl.e17513.
"2020 profile of the pharmaceutical industry," Sindusfarma, https://sindusfarma.org.br/uploads/Publicacoes/Perfil_IF2020_ING.pdf.
"2019 profile of the pharmaceutical industry," Sindusfarma, https://sindusfarma.org.br/uploads/Publicacoes/Perfil_IF2020_ING.pdf.
"Global Medicines Use in 2020," IMS Institute for Healthcare Informatics, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020.

6. Conclusions

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.

Appendix

RECENT CHANGES TO BRAZIL'S IP REGIME

THE SUPREME COURT DECISION ON THE SOLE PARAGRAPH IN ARTICLE 40 PRESENTS NEW CHALLENGES BUT MAY ALSO PROVIDE NEW OPPORTUNITIES FOR LEGISLATIVE ACTION ON PATENT BACKLOGS AND WAIT TIMES

BACKGROUND

- A May 2021 Brazilian Supreme Court decision struck down a sole paragraph in Article 40 of the Brazilian Industrial Property Law that stated that patents would be in force for at least 10 years from the issuance date, on top of the 20 years granted from filing.[3]
- The decision comes from a charge filed by the Federal Prosecutor's Office in 2016, which argued that this paragraph in Article 40 was used as a tool to unduly extend patent terms in Brazil. They made the following arguments, among others:[2]
  - The provision increased the backlog
  - The delay was harmful to the primary public interest
  - INPI's inefficiency transferred the burden from the state or public administration to society[2]
- Article 40 now limits the patent term to 20 years from the filing date for patents of invention[3]
  - This paragraph alleviated patent term issues brought about by INPI's delays and backlog, as it guaranteed that even if INPI took over 10 years from filing to grant a patent, there was still a minimum term of 10 years[1,2]

CHALLENGES/ IMPLICATIONS

- The decision only applies to future patents, except for two types of patents:
  - Patents with pending lawsuits based on the in-validity of the sole paragraph
  - Patents relating to pharmaceutical products and processes and materials for use in healthcare[2]
- Around 4,000 patents previously granted with a 10-year term will have their terms adjusted[1]

OTHER TAKEAWAYS

- This decision puts pressure on the Congress to solve issues at INPI in other ways and to pass another patent term adjustment bill, but no proposals have been introduced yet[2,4]

Sources:

[1] Montaury Pimenta, Luiz Edgard and Gabriela Salerno. Brazilian Supreme Court has finally put an end on the constitutionality judgement of the patent extended term provision. (2021.) Lexology. Retrieved from https://www.lexology.com/library/detail.aspx?g=44a932d4-0926-418b-ad52-5938f572fc15.

[2] Calil, Ana Luiza, Alysson Farias and rob Rodrigues. Supreme Court patent term decision. (2021). IAM Media. https://www.iam-media.com/supreme-court-patent-term-decision.

[3] Boclin, Ricardo. The end of the Minimum Patent Term in Brazil: Implications of the Brazilian Supreme Court's Decision. (2021). Clarke + Modet. Retrieved from https://www.clarkemodet.com/en/news-posts/the-end-of-the-minimum-patent-term-in-brazil-implications-of-the-brazilian-supreme-courts-decision/.

[4] Rodrigues, Rob, Karlo Tinoco, and Alysson Farias. Brazil's patent term decision: impact and practical tips. (2021). IP Stars. Retrieved from https://www.ipstars.com/NewsAndAnalysis/Brazils-patent-term-decision-impact-and-practical-tips/Index/7017.

BRAZIL'S NEW COMPULSORY LICENSING LAW IS LESS DRASTIC THAN EARLIER VERSIONS OF THE BILL AND IS INTENDED FOR EMERGENCIES

• BACKGROUND

- In September 2021, President Bolsonaro signed a bill on compulsory licensing into Law 14.200/2021 with at least one notable veto[3]
  - Early versions of the bill in the Senate included mandates that patent holders to disclose or hand over information and biological materials to licensees – with potential revocation of the patent if they refused – but the president vetoed this portion of the bill[1,2,3]
- The law allows the Brazilian Executive Branch to list patents or patent applications related to essential products and processes related to an emergency or public good situation and then grant licenses specifically to face the situation[3]
  - Patents and patent applications can be excluded from this list if their subject matter is already being explored in Brazil, if they are already subject to a voluntary license, or if there are transparent agreements for the sale of the product covered[3]
- Compulsory licenses are **non-exclusive and royalty-bearing**
  - The royalty has been set at **1.5% of net sales price,** but this may be fixed at a different rate[2,3]

CHALLENGES/ IMPLICATIONS

- The 1.5% royalties will only be paid **after a patent is granted,** which may present a problem in the case of compulsory licenses for patent applications[3]
- Compulsory licenses can be granted to meet the needs of other countries with insufficient manufacturing in the pharmaceutical sector, though Brazil has not specified any countries[3]

OTHER TAKEAWAYS

- The Brazilian government has noted that COVID-19 vaccines are being provided by international partners, so compulsory licensing will not be used unless a shortage occurs[4]
- Only one compulsory license has been granted in the past, for an HIV/AIDS drug in 2007[2]

Sources:

[1] Castro de Figueiredo, Roberto. Brazilian Senate Approves Bill on the Compulsory Licensing of COVID-19 Vaccines' Patents. (2021). Kluwer Patent Blog. Retrieved from http://patentblog.kluweriplaw.com/2021/05/12/brazilian-senate-approves-bill-on-the-compulsory-licensing-of-covid-19-vaccines-patents/.

[2] Leonardos, Gabriel Francisco. The Covid-19 pandemic triggered the issuance of new compulsory license rules for patents in Brazil. (2021). Kasznar & Leonardos. Retrieved from https://www.kasznarleonardos.com/news-and-publications/newsletters/the-covid-19-pandemic-triggered-the-issuance-of-new-compulsory-license-rules-for-patents-in-brazil.

[3] Lozouet, Louis. Brazil: New Compulsory Licensing Rules For Patents In Brazil. (2021). Mondaq. Retrieved from https://www.mondaq.com/brazil/patent/1111706/new-compulsory-licensing-rules-for-patents-in-brazil.

[4] Gurvitz, Monica and Maria Eduarda de Oliveira Borrelli Junqueira. New bill about compulsory license sanctioned in Brazil. (2021). Lexology. Retrieved from https://www.lexology.com/library/detail.aspx?g=ed4922e6-357f-47de-bff5-9e1463eaec28.

A JULY REVOCATION OF ARTICLE 229-C OF THE BRAZILIAN INDUSTRIAL PROPERTY LAW IS EXPECTED TO MAKE THE PATENT APPLICATION PROCESS MORE EFFICIENT

BACKGROUND

- In August 2021, a bill to improve the business environment was approved as Ordinary Law 14,195/2021[1,4]
  - This bill included the revocation of Article 229-C of the Brazilian Industrial Property Law, thus ending the requirement of prior consent from ANVISA for the registration of drug patents in the country[4]
  - ANVISA's approval is still required for marketing of pharmaceutical products regardless of patent registration[4]
- The flow of patent applications between ANVISA and INPI stopped on August 27, 2021[5]
  - Applications returned by ANVISA with no prior examination will follow normal INPI procedure with a note on the revocation of article 229-C[5]
  - Applications where prior approval examination from ANVISA already occurred have been sent back to the patent office, and INPI published ANVISA's decision[5]

CHALLENGES/ IMPLICATIONS

- It remains unclear whether the revocation of Article 229-C will have the expected decrease on patent backlogs
  - PhRMA notes that (as of early 2021) there are still 100,000 patent applications pending at INPI, and the patent backlog exceeds 10 years[6]

OTHER TAKEAWAYS

- According to one source, INPI is likely to attain its objectives related to its patent backlog (reducing grant time from 10 years on average to between 3 and 4 years) by the end of 2021[5]

Sources:

[1] Salerno, Gabriela. Law that accelerates prosecution of patent applications in the pharmaceutical field is sanctioned in Brazil. (2021). Montaury Pimenta Machado & Vieira de Mello. Retrieved from https://www.montaury.com.br/en/articles/512-law-that-accelerates-prosecution-of-patent-applications-in-the-pharmaceutical-field-is-sanctioned-in-brazil.

[2] Leonardos, Kasznar. Brazilian National Health Surveillance Agency (ANVISA) decides not to comment on a bill that proposes changes to the Industrial Property Act. (2021). Lexology. Retrieved from https://www.lexology.com/library/detail.aspx?g=dadb05da-c7ff-43a2-bb7b-fe348ef022a6.

[3] New rules governing ANVISA's interaction on pharmaceutical patent applications in Brazil. (2017). Dannemann Siemsen. Retrieved from http://www.dannemann.com.br/dsbim/uploads/imgFCKUpload/file/Ultimas_Not%C3%ADcias_04_2017_Exterior.pdf.

[4] Mattos, Rafaela. Previous consent of the National Health Surveillance Agency – Anvisa for granting of patents revoked. 2021. H&A. Retrieved from https://www.hyaip.com/en/news/previous-consent-of-the-national-health-surveillance-agency-anvisa-for-granting-of-patents-revoked/.

[5] Lozouet, Louis. INPI introduces new proceedings now that ANVISA's prior approval for pharma patents is over. (2021). IAM Media. Retrieved from https://www.iam-media.com/inpi-introduces-new-proceedings-now-anvisas-prior-approval-pharma-patents-over.

[6] Pharmaceutical Research and Manufacturers of America Special 301 Submission 2021. (2021.) PhRMA. Retrieved from https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf.

BRAZIL'S INTER-MINISTERIAL GROUP HAS CREATED A NATIONAL IP STRATEGY (ENPI) THAT THEY HOPE WILL IMPROVE THE NATIONAL IP SYSTEM

BACKGROUND

- Brazil's Intellectual Property Inter-Ministerial Group (GIPI), which includes INPI, has worked with the WIPO to create the ENPI to improve the national IP system[1,2,3]
- The strategy includes 210 actions under 7 main strategic areas[1,2]
  - Intellectual property for competition and development
  - IP dissemination, training, and qualification
  - Governance and institutional strengthening
  - The modernization of legal frameworks and non-statutory instruments
  - Compliance and legal certainty
  - Intelligence and perspectives for the future
  - Plans to integrate Brazil into the global IP system
- A draft of the ENPI was published for public feedback in August 2020; the first action plan was approved in June 2021[1]
  - GIPI is responsible for the governance and implementation of the ENPI, which is expected to continue for about 10 years, with renewal every two years[1,2]

CHALLENGES/ IMPLICATIONS

- Proposed changes that may impact the pharmaceutical industry include:
  - Development of an IP policy within the Ministry of Health
  - Measures to adjust patents on drugs considered strategic to the Brazilian Health System
  - Creation of a technical group at GIPI to evaluate IP legal landmarks around public health[2]

OTHER TAKEAWAYS

- Some action is already being taken around the ENPI[1]
  - 73% of the planned actions have been further developed or implemented since the approval of the first action plan
  - GIPI has approved 10 civil society entities to support implementations plans over the next 12 months

Sources:

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CRA International
8 Finsbury Circus
London, EC2M 7EA
United Kingdom

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