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Description	一般講演要旨

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Analysis of the Impact of Revoked Article 40 Solo Paragraph and Article 229-c (ANVISA) of the Brazilian Patent Law on Patent Enforcement and Implementation in Brazil

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1. Introduction

Brazil has been taking on the role of leader of the Third World. The country had been playing a leadership role on behalf of Third World countries during the negotiations for the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Just after TRIPS' enforcement in 1995, Brazil revised its patent law in 1996 and introduced product patents in the pharmaceutical field. However, the patent examination process is very slow in the country, and the country has a pile of backlog.

According to reports, at said point in time, it took 14 years to complete the entire patent examination procedure and obtain a patent in Brazil. Recently, two events profoundly impacted the Brazilian patent system: One of them was the Supreme Court in Brazil, which judged the sole paragraph of Article 40 of the Brazilian Patent Law unconstitutional. The other one was the abolition of Article 229-C. This study will carefully examine the impact of these two significant changes on the Brazilian patent system.

2. Brazil at a Glance

As the largest and most influential country in Latin America, Brazil has long served as a regional leader, lending its economic and diplomatic strength to hemispheric integration efforts. The country has also increasingly sought a bigger voice for developing countries on the international stage. Besides its active participation in the United Nations and other major multilateral institutions, Brazil has worked closely with China, India, and Russia to develop alternative forums [1].

Table 1 General Information on Brazil

Official Name	Federative Republic of Brazil
Total area	8,502,728 km ²
Population	215 mil.
Capital	Brasilia
Race	Europeans 48%, Africans 8%, Asians 1.1%
Official Language	Portuguese
Religion	Catholic 65%, Protestant 22%, non-religious person 8%
Literacy rate	Male: 94% • Female: 95%

Source: Ministry of Foreign Affairs, The Govt. of Japan [2]

3. Economic Status of Brazil

Brazil has a moderately free market and an export-oriented economy. The country's GDP surpasses a trillion dollars, making it the tenth largest in the world and the third largest in the Americas. Measured by purchasing power parity, it is \$3.8 trillion, making the country the eighth largest economy in the world and the second largest in the Americas after the United States [3].

Table 2 shows the basic economic indicators of Brazil compiled by JETRO [4].

Table 2. Basic Economic Indicators of Brazil [4]

item	2020	2021	2022
Real GDP Growth Rate	△3.3 (%)	5.0 (%)	2.9 (%)
Nominal GDP	7,610 (bil. BRL)	8,899 (bil. BRL)	9,915 (bil. BRL)
GDP per capita	6,794 (\$)	7,507 (\$)	n.a.
Industrial Production Index	△4.5 (%)	3.9 (%)	△0.7 (%)
CPI	4.5 (%)	10.1 (%)	5.8 (%)
Unemployment Rate	14.2 (%)	11.1 (%)	7.9 (%)
Export	209,180 (\$100 mil.)	280,815 (\$100 mil.)	334,136 (\$100 mil.)
Import	158,787 (\$100 mil.)	219,408 (\$100 mil.)	272,611 (\$100 mil.)
Current Account	△28,208 (\$100mil.)	△46,358 (\$100 mil.)	△56,997 (\$100 mil.)
Trade Account	50,393 (\$100 mil.)	61,407 (\$100 mil.)	61,525 (\$100 mil.)
Financial Account	△16,260 (\$100 mil.)	△50,168 (\$100 mil.)	△58,280 (\$100 mil.)

Source: JETRO

The World Bank expects Brazilian economic growth to slow to 0.8% in 2023, after growing 2.9% in 2022, before moving to 2.0% in 2024 [5].

On the other hand, the IMF predicted that Brazil’s economy would increase by 2.9% in 2022, 2.1% in 2023, and 1.2% in 2024. It suggested strong agricultural output supported growth in early 2023; however, slowing private consumption and falling investment would check further growth [6].

4. Pharmaceutical Industry of Brazil

4.1 The Current Brazilian Pharmaceutical Market

The pharmaceutical industry is one of the major industries in Brazil. According to “the Pharmaceutical Industry Vision 2021,” compiled by the Ministry of Health, Welfare, and Labor in 2021, Brazilian pharmaceutical sales revenues were the 7th highest in the world after the U.S., China, Japan, Germany, France, and Italy [7].

In 2022, the pharmaceutical market in Brazil generated more than R\$131.2 bil. (around US\$27 bil.) with the sale of more than 5.7 billion packs of medicines [8]. The market is estimated to grow constantly over the coming years and is expected to reach US\$33.9 bil. by 2024 [9].

4.2. Trade in the Brazilian Pharmaceutical Market

MNEs export many pharmaceutical products from their own countries and sell them in Brazil, while Brazilian pharmaceutical companies import active pharmaceutical ingredients (APIs) from other countries, such as China and India, and produce final products (drugs) in Brazil. On the other hand, Brazilian pharmaceutical exports are still limited [10].

4.3. Brazilian Pharmaceutical Market by Segment

When the Brazilian pharmaceutical market is divided by segment, patented drugs occupy the majority. For instance, in 2018, sales of patented drugs were US\$11 bil., while those of OTC and generic drugs were US\$7.2 bil. and US\$ 5.0 bil., respectively [11].

One of the reasons for this trend is that the country has the unified health system (Sistema Único de Saúde [SUS]), and most of the medicines are purchased by the SUS [NOTE 1].

Figure 3 shows the Brazilian pharmaceutical market by segment.

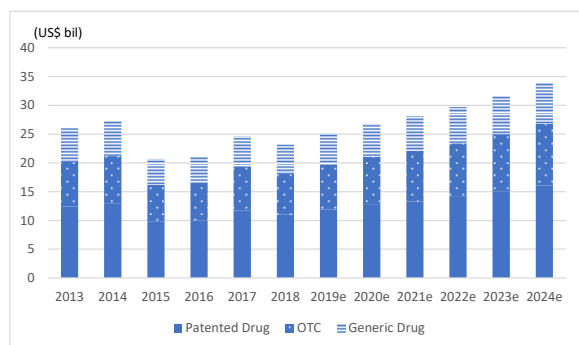


Fig. 3 Brazilian Pharmaceutical Market by Segment

Source: METI

4.4 Top 10 Pharmaceutical Companies in Brazil

Table 3 shows top 10 Brazilian pharmaceutical companies. The top 10 pharmaceutical companies occupy 44% of the total market. Among the 10 companies on the list, there are four Brazilian companies [12].

Table 3 Top 10 Pharmaceutical Companies in Brazil

ranking	company name	country	type of medicines
1	EMS Pharma	Brazil	Generic
2	Sanofi-Aventis	France	Brandname, OTC
3	Medley*	Brazil	Generic
4	Ache	Brazil	Brandname
5	Novartis	Switzerland	Brandname
6	Euro Farma	Brazil	Brandname
7	Pfizer	USA	Brandname
8	Bayer Schering PH	Germany	Brandname, OTC
9	Astrazeneca Brazil	USA	Brandname
10	Nycomed Pharma Ltd	Switzerland	OTC

Source: METI

As mentioned above, most of these Brazilian pharmaceutical companies import APIs from other countries, such as China and India, and produce final products in Brazil.

5. IPR Enforcement and Implementation in Brazil

5.1 Introduction to the Product Patent

Brazil, a developing country, did not have product patents in the pharmaceutical field until the enforcement of TRIPS. Due to TRIPS, the country revised its patent law in 1996 and introduced product patents in the pharmaceutical field. The new revised patent law came into effect in May 1996, and the country began receiving patent applications in the pharmaceutical field in May 1997 [13].

5.2 Patent Application and Grant in Brazil

The Brazilian National Institute of Industrial Property (INPI) is in charge of the prosecution and implementation of intellectual property rights in Brazil. The number of patent applications in Brazil had increased since around 2000. Due to COVID-19 pandemic, the number of patent applications in Brazil dropped in 2020.

When the number of patent applications is divided into two, one for being submitted by residents and the other one for by non-residents, the number of non-residents exceeded that of by residents. For instance, in 2022, 82% of the patent applications were submitted by non-residents. Table 4 shows patent applications in Brazil between 2018 and 2022.

Table 4 No. of Patent Applications in Brazil

applicants	2018	2019	2020	2021	2022
resident	4,980	5,465	5,281	4,671	4,398
non-resident	19,877	19,931	19,058	19,567	20,361
(Japanese)	1,688	1,602	1,559	1,257	1,066
total	24,857	25,396	24,339	24,238	24,759

Source: INPI

6. Major Changes in IPR Enforcement

6-1 Brazilian Supreme Court's Decision on the Sole Paragraph of Article 40

In Brazil, as a general rule, patents of invention are valid for a 20-year term, counting from the filing date before the Brazilian National Institute of Industrial Property (INPI). However, aiming to guarantee a minimum term of protection in cases where there was an excessive delay in the examination by the INPI, the sole paragraph of Article 40 of the Brazilian Patent Law allowed a minimum term of 10 years of protection for patents of invention, counted from the granting date.

In 2016, a Direct Plea of Unconstitutionality (ADI 5529) was filed by the Federal Public Prosecutor's Office (FPP), aiming to declare the unconstitutionality of the sole paragraph of Article 40 based on the allegation that the provision would cause legal uncertainty. On May 6th, 2021, the Brazilian Supreme Court declared the sole paragraph of Article

40 unconstitutional, considering that automatically extending the patent term for all applications that had its examination lasting over 10 years violated the principles of legal certainty and freedom of competition, among others [14]. According to data provided by the Brazilian National Institute of Industrial Property (INPI), there are approximately 36,000 patents in force in Brazil that were granted with the benefit of the sole paragraph of Article 40 of the Brazilian Patent Law. Among them, around 32,000 patents that were granted with the benefits of such an extended term will have their term safely maintained in Brazil [15].

6-2. Abolition of Article 229-C (abolition of pre-examination by ANVISA)

The second major change in the rules and regulations was the abolition of Article 229-C. Before the abolition of Article 229-C, all patent applications for pharmaceutical products and processes should have the prior approval of ANVISA before the granting of the patent by INPI [16]. Article 229-C of the Brazilian IP Law stated that “the granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the ANVISA.” Since the system was introduced in 2001, patent applicants of pharmaceutical-related products and processes have received examination by 2 different government entities using 2 different standards. It is considered that the dual examination system was one of the most important reasons why the INPI experienced significant backlogs regarding inventions on the pharmaceutical field [17].

7. Discussion

One of the most serious problems at the INPI is a pile of backlog. According to a report compiled by Licks Law Firm, most of the patents granted by INPI took more than 10 years in prosecution between 2014 and 2018, and by art, telecommunications, computer, electronics, pharmacy, mechanics, physics, electricity, and molecular biology patents historically take more than 10 years to be granted by INPI [18].

As one of the solutions to the problem, the Brazilian government has introduced the Patent Prosecution Highway (PPH) scheme. As of September 17, 2023, INPI had concluded an agreement over the PPH program with 13 authorities (Austria, China, Denmark, Europe, France, Japan, Portugal, Spain, Singapore, South Korea, Sweden, the United Kingdom, and the United States). More than 200 patent applications have been processed through the PPH program since 2018. Using the PPH scheme, patents were granted within 318 days on average, and 88% of the total patent applications were eventually granted a patent [19].

Furthermore, as another key strategy to end the backlog, INPI released in 2019 the “plan to combat the patent backlog”. The main feature of the plan was issuing “preliminary office actions,” based on the usage of search reports and technical opinions issued by foreign patent offices. The office action per se is very simple and mostly aims to request the applicant to amend the application according to what was done abroad or to submit arguments against the listed prior art. As of September 2023, 142,455 patent applications received a “preliminary office action” and 77,646 applications are still considered eligible for the program [20].

8. Conclusion

Brazil, a leading country in the Third World, has the seventh-largest pharmaceutical market in the world. Just one year after TRIPS enforcement, the country introduced the protection for product patents in the pharmaceutical field. The Brazilian pharmaceutical market today is a brand-name drug dominant market.

Over the past couple of years, the country’s patent system has experienced two significant changes: the first was the abolition of the patent extended term provision (the sole paragraph of Article 40), and the other was the abolition of Patent Law Article 229. The first issue comes from the country’s huge backlog, while the second one worsens it.

As a solution for eliminating or reducing the backlog, the Brazilian government recently introduced the PPH program and the “plan to combat the patent backlog,” and this study found that it has worked so far.

Thus, to activate IPR activities, the government also needs to implement some other measures, such as encouraging small to medium firms and public institutes to apply for a patent and encouraging domestic firms to file more patent applications.

9. Acknowledgements

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NOTE 1: Unified Health System (SUS): Brazil’s decentralized, universal public health system which is funded with tax revenues and contributions from federal, state, and municipal governments.

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