



IP Forefront Pharma Forum

Brazil Pharma Patent Protection Practices and Latest Developments
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Quick overview of the Brazilian market



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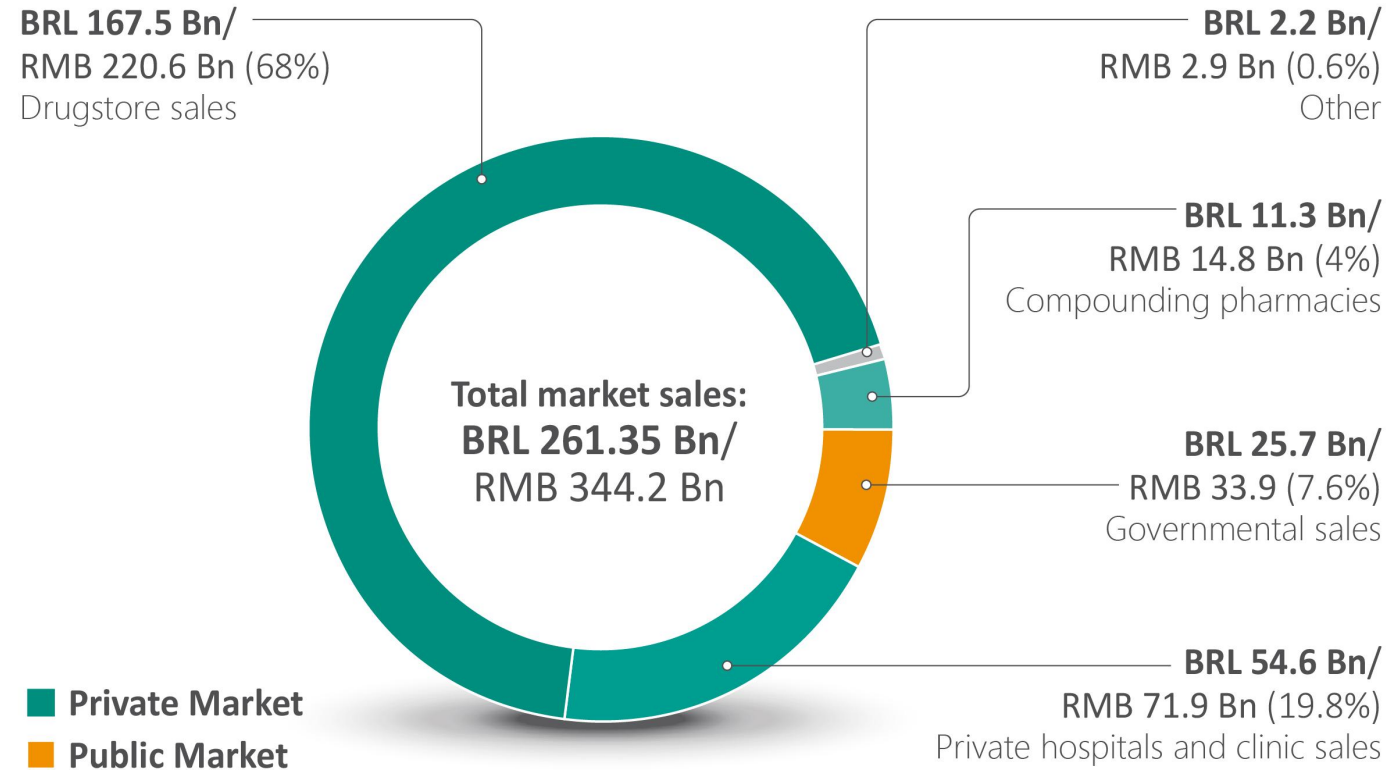


Ricardo Campello



Faça a leitura para me adicionar como amigo.

The size of the Brazilian market



Brazil is the 7th most populous country in the world (214,2 million people);
Brazil has the 6th largest pharmaceutical market worldwide

The Brazilian public market

Brazil has a 100% publicly funded free universal healthcare system (named “SUS”). As per the Constitution and Statute #8,080/1990, **SUS must procure and distribute drugs to the population for free** (no copayment nor reimbursement).

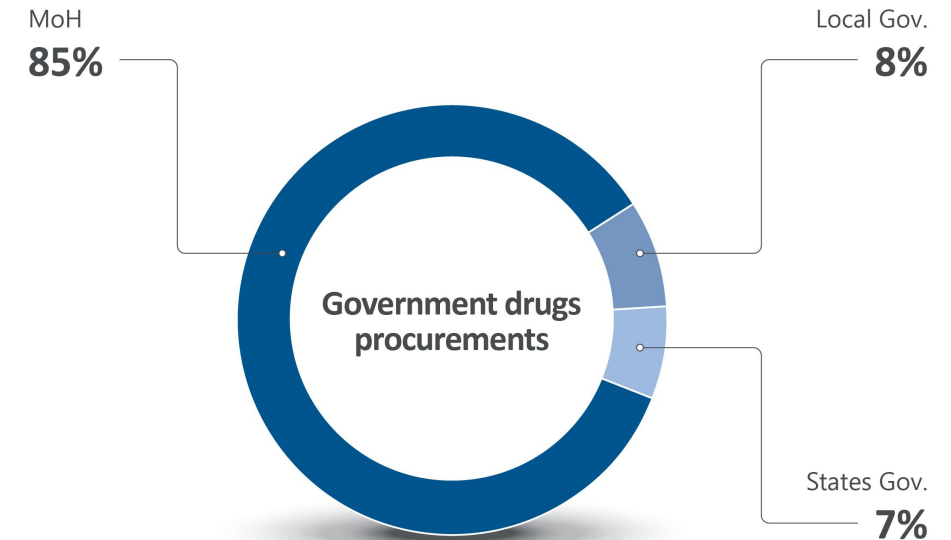
Depending on the complexity and cost of treatment, medicines are procured and distributed by local, state or Federal Government (through the Ministry of Health - MoH) or by its public hospitals (e.g. cancer medicines).

To be procured regularly, medicines must be included in SUS’ formularies. Those are procured through a lowest-price, winner-takes-all yearly bid or from a “single source” due to a single supplier (patented product).

Non-incorporated drugs can also be procured when patients file lawsuits against its local, state or the Federal Government and obtain a court-decision ordering the supply.

approx. 168,000 lawsuits were filed in 2025, 7,000 more than in 2024

approx. 3Bn (BRL)/4Bn RMB spent by the MoH to comply with court decisions in 2024



The Brazilian private market

Comprises sales mainly to private hospitals and clinics, which usually provide care based on private health insurance, and drugstores, which mostly sell self-administered drugs.

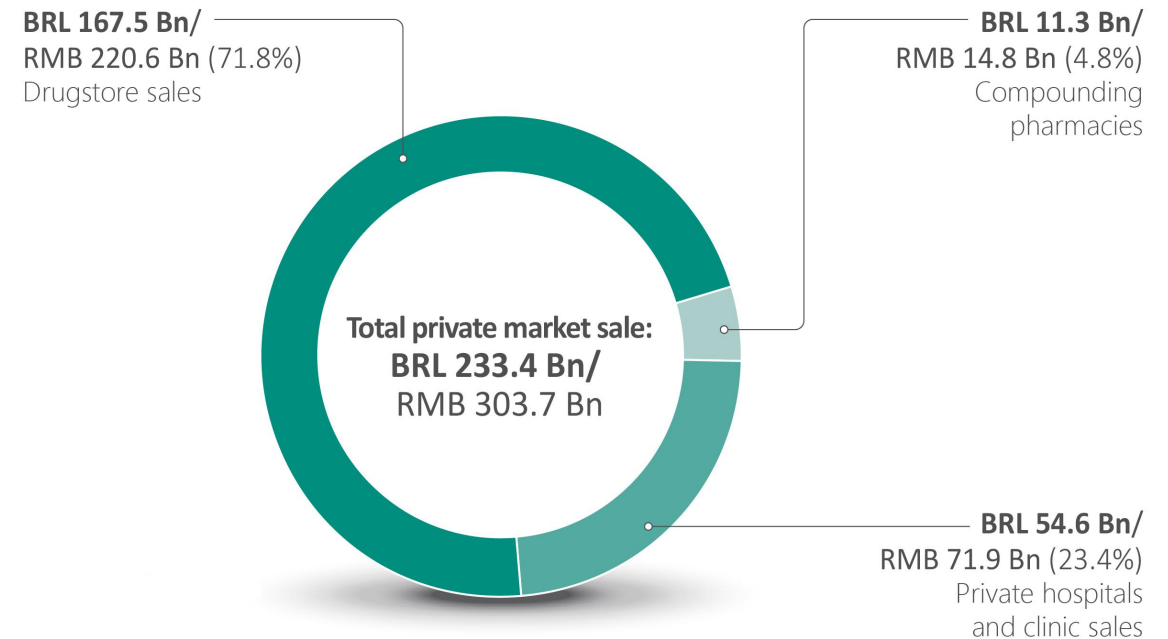
Brazil has the **3rd largest market** for health insurance worldwide: **52,96 million people (24,7% of the population)** have health insurance in Brazil, which are regulated by the federal Agency ANS under the terms of Law 9,656 of 1998.

In terms of drug coverage, Law 9,656 and ANS' regulation require health insurance companies to provide:

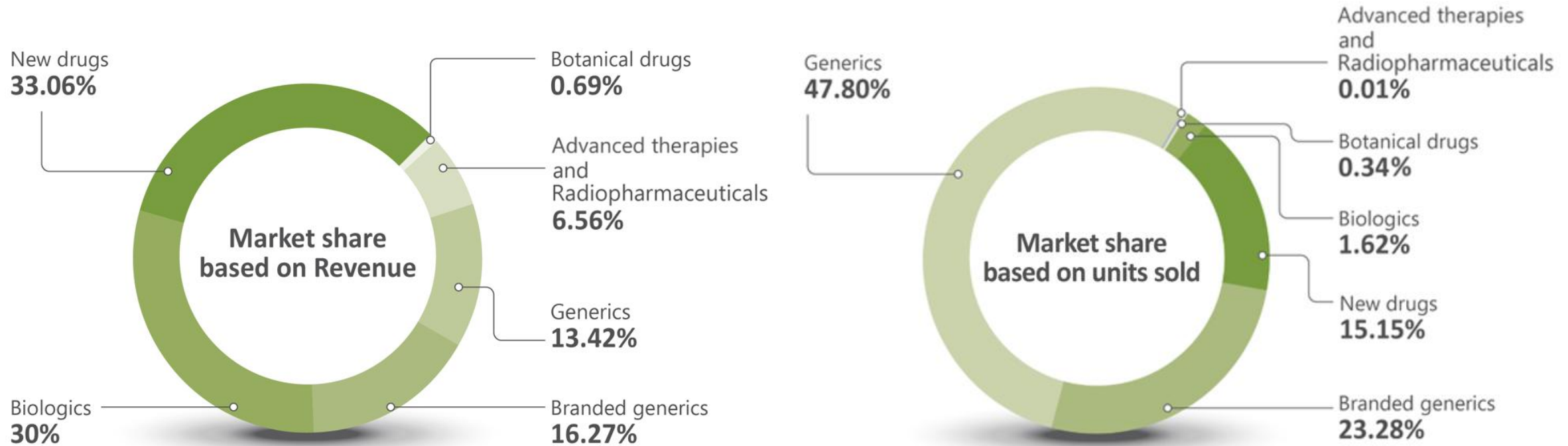
- self-administered oral antineoplastics and medicines for their adverse effects;
- all medicines used during hospitalization (including biologics); and
- medicines listed as of mandatory coverage. Since 2022, the list must comprise any medicine included in SUS' formularies (article 10, paragraph 10, of Statute #14,307/2022).

Note: litigation seeking medicines supply is also a common practice within the private market. Approx. 235,000 lawsuits filed in 2024 – more than BRL 5Bn spent by the health insurance companies.

Sources: IBGE Research (2026), Medicina S/A (2026) and Abradilan (2026).



The Brazilian market by type of products



Source: Drug Market Regulation Chamber (2025).

The Brazilian market by type of products

Leading products by revenue

1	ONCE-WEEKLY wegovy [®] semaglutide injection 2.4 mg	>	BRL 3,8 Bn	6	RYBELSUS [®] semaglutide tablets	>	BRL 924 Mn
2	forxiga [®] dapagliflozina	>	BRL 2,1 Bn	7	Torsilax [®] caféina 30mg	>	BRL 817 Mn
3	mounjaro [®]	>	BRL 1,9 Bn	8	Glyxambi [®] (empagliflozin/linagliptin) tablets 10 mg/5 mg, 25 mg/5 mg	>	BRL 683 Mn
4	OZEMPIC [®] semaglutida (injetável)	>	BRL 1,8 Bn	9	SeloZok [®] succinato de metoprolol (50 mg)	>	BRL 655,3 Mn
5	Glifage [®] KR	>	BRL 1,3 Bn	10	Jardiance [®] (empagliflozin) tablets	>	BRL 628 Mn

Source: IQVIA (2026).

Leading pharmaceutical companies by total sales in Brazil (2025)

1	 GRUPO EMS	BRL 30 billions		6	 sanofi	BRL 8,1 billions	
2	 Eurofarma	BRL 24,1 billions		7	 Lilly	BRL 7,4 billions	
3	 Hypera pharma	BRL 18,6 billions		8	 TEUTO	BRL 7,1 billions	
4	 CIMED	BRL 10,6 billions		9	 novo nordisk®	BRL 6,9 billions	
5	 achē	BRL 9,8 billions		10	 biolab	BRL 5,8 billions	

Note: Figures are based on final product sales.

Source: Close-Up (2025).

Chinese pharmaceutical companies in Brazil



Sino Biopharmaceutical

Does not operate directly in Brazil, only indirectly through its investment in CoronaVac



Shanghai Pharmaceuticals Holding

Through its subsidiary **holds multiple ANVISA GMP certifications** requested by Brazilian companies EMS, Aché, Blau and Eurofarma



Jiangsu Hengrui Pharmaceuticals

In 2021, **supplied Cisatracurium** Besylate injection to mitigate a **drug shortage** in Brazil

Also **holds multiple ANVISA GMP certifications** requested by Blau and Discovery Imp.



CSPC Pharmaceutical Group

Maintains a direct operational presence in Brazil through CSPC Latina, its regional division headquartered in the country

Also holds a Letter of Adequacy for caffeine

Chinese pharmaceutical companies in Brazil



Aurisco Pharmaceutical

Holds multiple ANVISA GMP certifications requested by Global Ativos and Syntegra

Also **participates in a PDP** with Fiocruz aimed at the tech-transfer of Nusinersen



Fosun Pharma

Operates in Brazil through its subsidiary, Shanghai Henlius Biotech, under a licensing and collaboration agreement with Eurofarma

Its subsidiary **also holds multiple ANVISA GMP certifications** requested by Eurofarma, Abbott and Organon



Sinovac

Supplied the vaccine Coronavac in a partnership with Butantan

Also **participates of two PDP** with Tecpar aimed at the tech-transfer of human rabies and varicella vaccines



Gan & Lee

Holds multiples ANVISA GMP certifications requested by Biommm, Fiocruz and Gan & Lee Pharmaceuticals do Brasil

Also **participates in a PDP** with Fiocruz aimed at the tech-transfer of insulin glargine

Why Brazil has an attractive market for Chinese pharma companies

- ① **Rapid gain of market share in the public market** due to Partnership for Productive Development (PDP) Program. PDP is a long term (usually, five or ten years) government contract involving tech transfer with guaranteed sales to SUS + local manufacturing of the medicine.

Chinese Private Partner	Public Institution	Brazilian Private Partner	Product	Year
 Aurisco Pharmaceutical	 Fiocruz Bio-Manguinhos	 Hypera Pharma	Nusinersen	2025
 SINOVAC Biotech (Singapore)*	 TECPAR	-	Human rabies vaccine (inactivated)	2025
 SINOVAC Biotech (Singapore)*	 TECPAR	 Eurofarma Laboratórios S.A.	Varicella vaccine (attenuated)	2025
 Gan & Lee	 Fiocruz Bio-Manguinhos	 Biommm S.A.	insulin glargine	2025

Examples of rapid gain of market share

Somatropin (Cristalia): 70% of market within 10 months of MA approval

Etanercept (Samsung Bioepis): 60% of market within 1,6 year of MA approval

Rituximab (Sandoz): 50% of market within 1,4 year of MA approval

*The subsidiary participating in the PDP is based in Singapore, but Sinovac is a Chinese company.

Why Brazil has an attractive market for Chinese pharma companies

- ② Price-driven bids may give advantage to Chinese pharma companies in comparison to Brazilian generic companies, considering some examples of procurement of non-approved products due to unavailability in the domestic market (ANVISA's Rule No. 203/2017).

Imunoglobulin

Nanjing Pharmacare Company Limited won a bid in 2021 to supply its **Imunoglobulin at a price approx. 30% lower** than the following contract signed by the Ministry of Health with a Brazilian company.

Epoetin alfa

Proposal to supply **Shenzhen Sciprogen Bio Pharmaceutical's SEPO™** at a price **50% lower** than the one offered by the winning company. The Chinese company did not win the bid due to judicial challenge.

Insulin

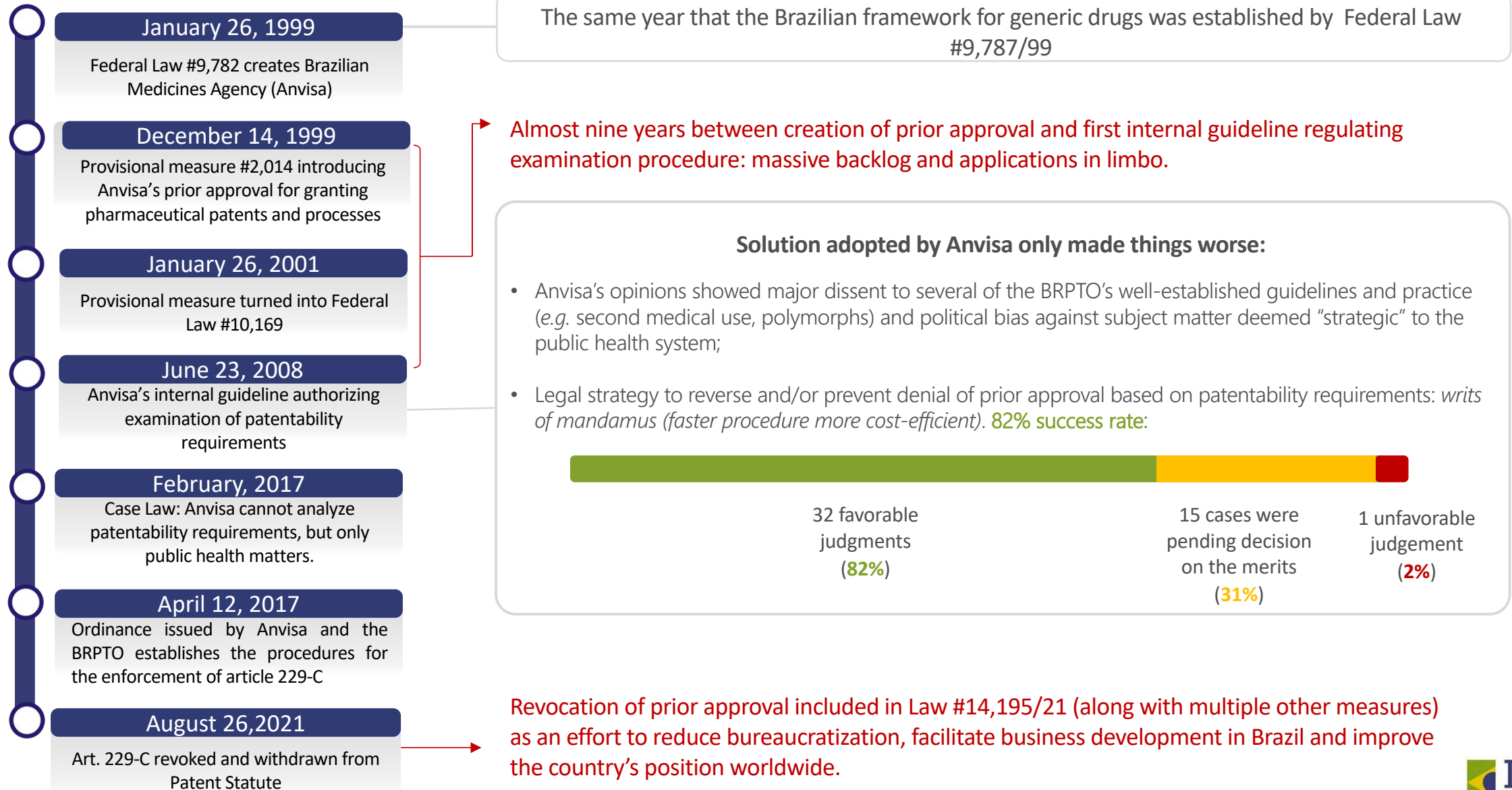
GlobalX won a bid in 2024 to **supply Zhuhai United Laboratories' USLIN™**. As a result, two supply contracts signed to meet the 2025 and 2026's demand. In this case, all proposals were to supply medicines not approved in the country.



Possible judicial challenge by the companies that hold MA in Brazil. In two opportunities, the Supreme Court has stated that the exception cannot be applied based solely on economic purposes. Unavailability in the Brazilian market shall be demonstrated by the Ministry of Health.

**Issues faced by
pharma patents
since the TRIPs
agreement and the
most recent
problem: BRPTO's
backlog.**

Dual examination: Anvisa's participation in prosecution



Causes of the backlog: increasing number of filings

The number of patent applications pending before the BRPTO (backlog) steadily increased since the agency's establishment, as it was unable to keep pace with the growing volume of filings over the years

Increase in patent filings



Insufficient examiner workforce



Chronic and exponentially growing backlog

FILINGS

+23.4%

26,718 → 32,966 (2008-2015)



EXAMINERS

-16.8%

232 → 193 (2008-2015)



BACKLOG

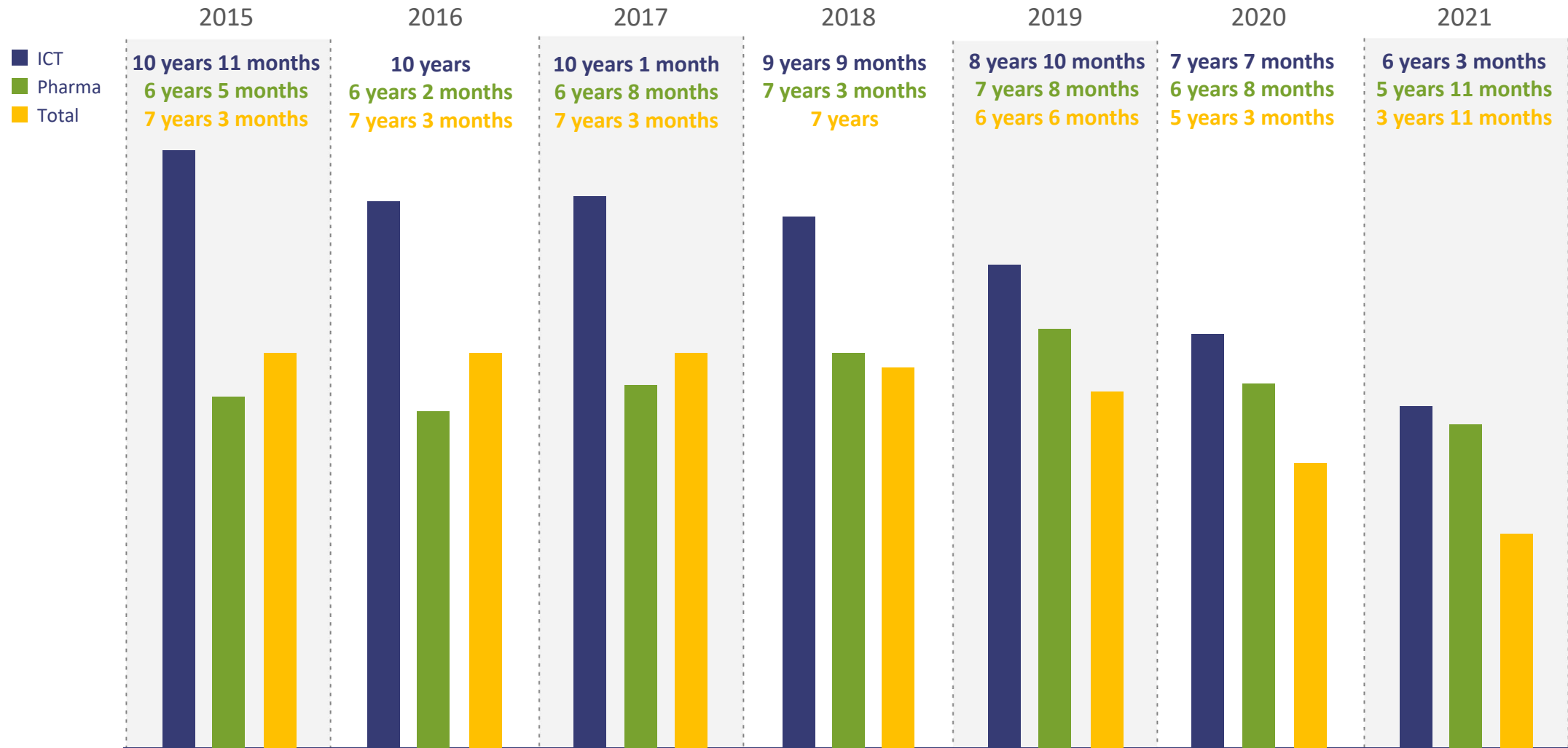
+38.4%

175,028 → 242,151 (2008-2015)

The 2008–2015 was the period which mostly contributed to the escalation of the BRPTO's backlog.

Brazilian pendency over the years

The time required for the BRPTO to complete the examination has become unreasonable, **in some cases exceeding ten years** for a purely formal procedural step that involves no substantive examination or decision-making



Institution of backlog
combat plan

Backlog led to a discussion before the Supreme Court

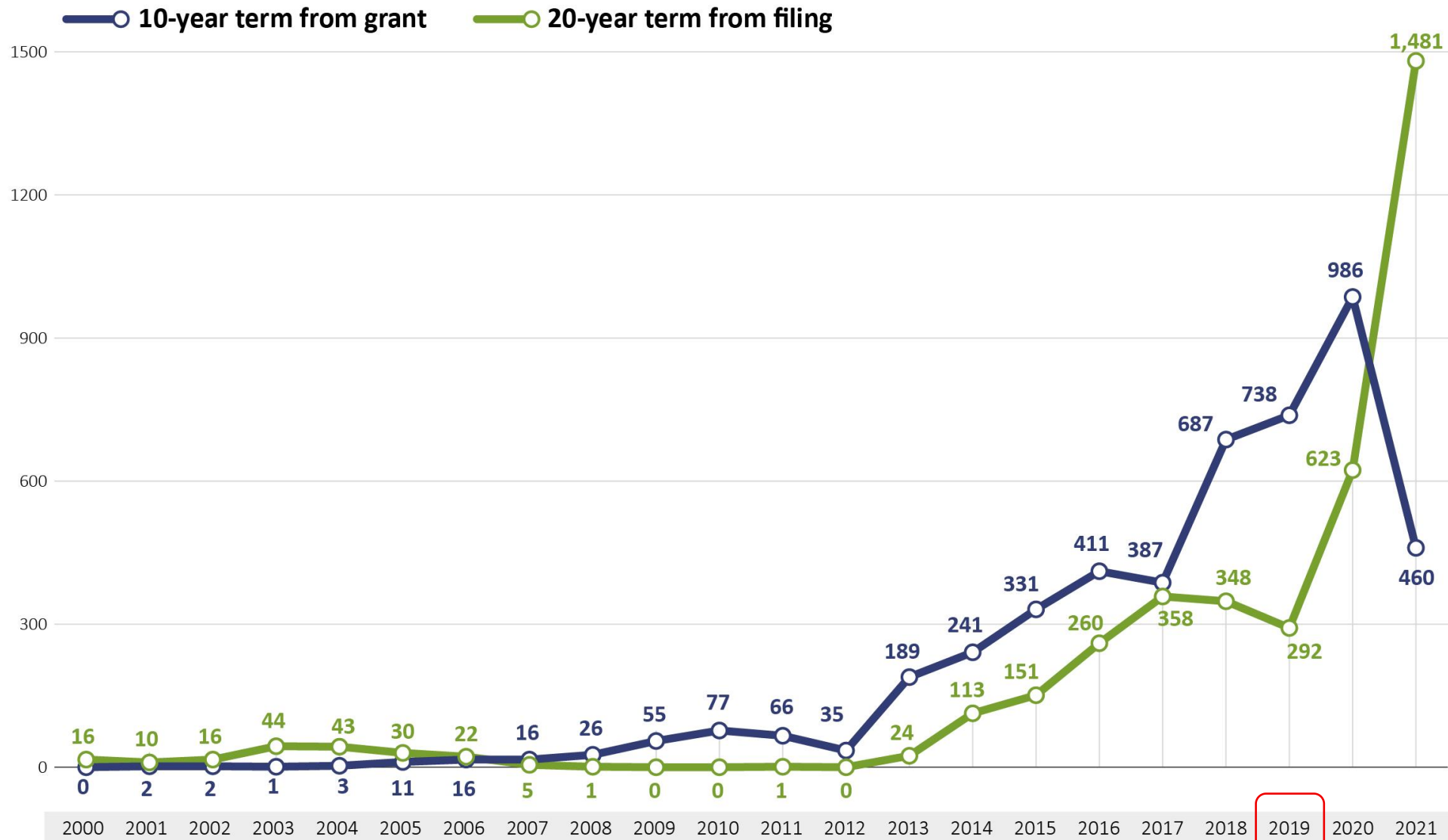
Article 40, sole paragraph of the IP Statute

Patent terms before the Supreme Court ruling: minimum term was 10 years from grant



Due to the BPTO's chronic backlog, **the 10-year term from grant**, which was intended to operate only as an **exception** became common, until the BRPTO implemented a plan to decrease backlog.

Comparison of patent terms (pharma and biopharma)



BRPTO's backlog plan

The Unconstitutionality Challenge (“ADI”) No. 5,529



Nov. 4, 2013
ABIFINA filed the Unconstitutionality Challenge No. 5,061



Jul. 28, 2014

ABIFINA requested the Federal Prosecutor to challenge the constitutionality of the sole paragraph of Article 40 of the IP Statute



May 17, 2016
The Federal Prosecutor's Office filed the Unconstitutionality Challenge No. 5,529

Oct. 31, 2017
The Reporting Justice Luiz Fux dismissed ADI No. 5,061 on admissibility grounds

Sep. 14, 2020
Justice Dias Toffoli was assigned the new Rapporteur of ADI No. 5,529

May 6, 2021

The Supreme Court ruled the sole paragraph of Article 40 unconstitutional by a 9-2 majority.

2013

2014

2015

2016

2017

2018

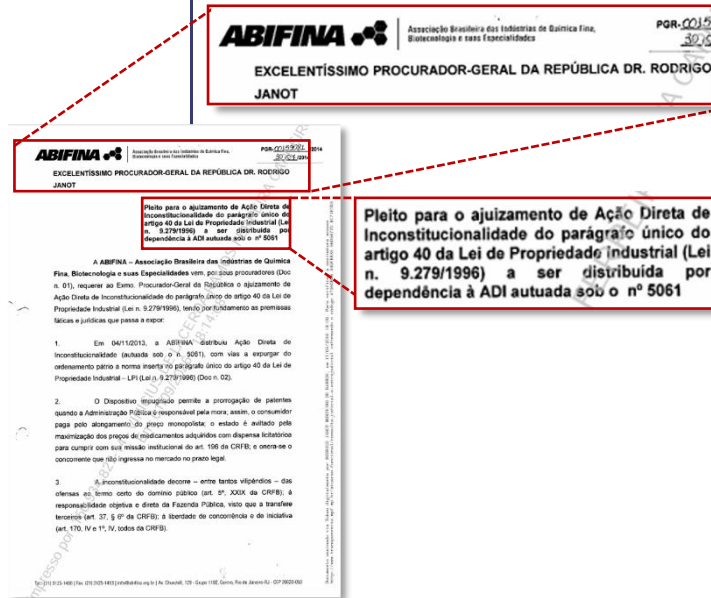
2019

2020

2021

Covid-19 Pandemic

The case remained **inactive** for years until Justice Luiz Fux was appointed Chief Justice, which led to a reassignment of the case to a new reporting Justice.



Legislative changes after the ruling

Federal Law No. 14,195/21

Revocation of the sole paragraph of Article 40 and the Article 229-C of the IP Statute.

Sole paragraph of Article 40

The term of a patent shall be at least 10 (ten) years from grant, unless the BPTO is prevented from carrying the examination of the application, due to proven court injunction or circumstances beyond its control.

Revoked and Withdrawn from IP Statute

Article 229-C

The granting of patents for pharmaceutical products and processes shall depend on the prior approval of Anvisa.

Revoked and Withdrawn from IP Statute

Consolation Prize?

The **revocation of prior approval** as an effort to reduce bureaucracy also seemed like a **consolation prize for patent applicants** following the invalidation of the 10-year term from grant provision by the Supreme Court in ADI 5,529

Aftermath of the ADI 5,529: waves of PTA litigation lawsuits

Supreme Court left an opening door for PTA

In its decision, the Brazilian Supreme Court favorably referred to other mechanisms that do not raise the same concerns associated with the sole paragraph of Article 40 of the Patent Statute.

The study concluded that the sole paragraph has no counterpart in any of the jurisdictions examined. It is true that some jurisdictions around the world provide for additional exclusivity rights, which are, however, fundamentally different from the automatic and discretionary extension established under Brazilian law.

(ADI 5529 Decision, p. 15)

In the case of PTA, the determination of the period added to the patent term stems from an assessment of the delay attributable to the patent office, minus any delay caused by the applicant itself, evidencing an analysis of each specific case in accordance with the parameters set forth by law, rather than an automatic extension. In turn, PTE requires a request from the interested party, is directed to a specific technological sector, and concerns the time taken by regulatory authorities to reach a decision, rather than the entire process before the patent office.

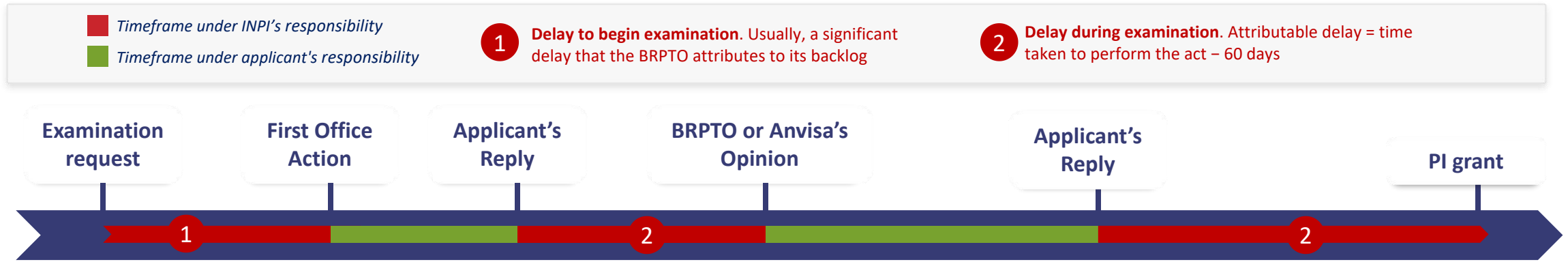
(ADI 5529 Decision, p. 17)

Against this backdrop, one must conclude that the mechanisms adopted abroad to extend periods of exclusive exploitation of inventions, in their various forms, durations, and specific rules, contain safeguards that prevent patent terms from being extended for longer than necessary.

(ADI 5529 Decision, p. 48)

PTA lawsuits and calculation methods

In the lack of specific statutory deadlines for the BRPTO to perform each act within the examination, the patentees claim a 60-day period, which is established by Article 224 of the Patent Statute and/or Articles 48 and 49 of the Federal Administrative Procedure Law.



Thesis 1

Claimed periods: **1** **2**

The claimed PTA corresponds to all periods of delay attributed to the BRPTO.

Potential issue: The long adjustments sought would result in patent terms exceeding 10 years from grant.

Thesis 2

Claimed periods: **2**

The claimed PTA corresponds to the total delay attributed to the BRPTO, calculated by subtracting the statutory 60-day period from the time taken to perform each act. The period preceding the start of the examination was excluded because it was considered backlog resulting from institutional and resource constraints, rather than case-specific delay.

Result: More proportionate adjustments.

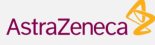
Thesis 3

The claimed PTA corresponds to the reinstatement of the patent term originally granted under the former sole paragraph of Article 40 of the Patent Statute, which was declared unconstitutional by the Supreme Court.

Result: This approach led to the filing of a constitutional complaint and ultimately had adverse repercussions for the other PTA lawsuits.

Example: Hypera's ALEKTOS® PTA lawsuit

PTA-like cases by company

 2 lawsuits	 1 lawsuit	 1 lawsuit	 1 lawsuit	 1 lawsuit	 3 lawsuits	 3 lawsuits	 1 lawsuit
 4 lawsuits	 1 lawsuit	 2 lawsuits	 1 lawsuit	 1 lawsuit	 1 lawsuit	 1 lawsuit	 1 lawsuit
 2 lawsuits	 1 lawsuit	 1 lawsuit	 3 lawsuits	 1 lawsuit	 1 lawsuit	 1 lawsuit	 1 lawsuit
 1 lawsuit	 2 lawsuits	 1 lawsuit	 5 lawsuits	 1 lawsuit	 1 lawsuit	 2 lawsuits	 1 lawsuit
 1 lawsuit	 1 lawsuit	 1 lawsuit	 14 lawsuits	 6 lawsuits	 1 lawsuit	 1 lawsuit	 1 lawsuit
 1 lawsuit	 5 lawsuits	 2 lawsuits	 3 lawsuits	 4 lawsuits	 1 lawsuit	 2 lawsuit	 1 lawsuit
 1 lawsuit	 1 lawsuit	 1 lawsuit	 14 lawsuits	 1 lawsuit	 1 lawsuit	 1 lawsuit	

PTA-like cases in numbers

106 cases

3 PI in force	3 favorable decisions on the merits	44 unfavorable decisions on the merits	47 appeals against decisions on the merits
25 interlocutory appeals regarding PI	5 complaints to Supreme Court	200 requests for third-party intervention	3 withdrawals

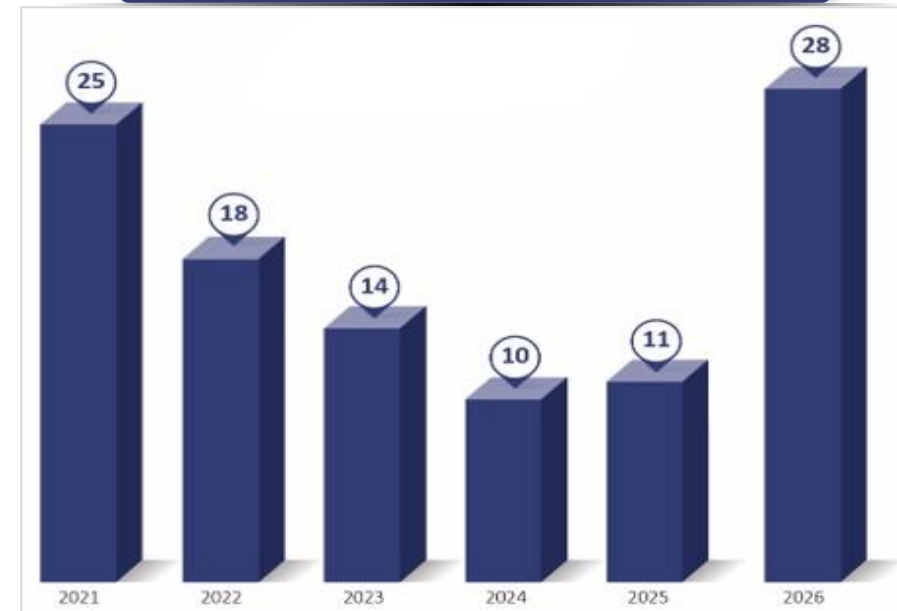
Favorable decisions to patentees

PIs in force: cases filed by Gilead ref. Vemlidy (tenofovir alafenamide), Genzyme ref. Cerdelga (eliglustat) and Novartis ref. Entresto (sacubitril valsartan)

Favorable decisions on the merits: cases filed by Gilead ref. Vemlidy (tenofovir alafenamide), Genzyme ref. Cerdelga (eliglustat), and Novo Nordisk ref. Saxenda and Victoza (liraglutide)*

*Decision stayed in a single judgment by the Reporting Appellate Judge of the appeal

Case distribution by year



Other mechanisms for establishing PTA

Amendment proposed by Hamilton Mourão(REPUBLICANOS/RS) to Bill No. 2,210/2022

Bill No. 5,810/2025

PROPOSERS

Federal Deputies Julio Lopes (PP/RJ) and Paulo Abi-Ackel (PSDB/MG).

Federal Deputies Capitão Alberto Neto (PL/AM), Dr. Zacharias Calil (UNIÃO/GO), and Mersinho Lucena (PP/PB).

SCOPE

The amendment provides for a mechanism to adjust the patent term to compensate for delays in patent examination by the BRPTO that are not attributable to the patent owner.

The Bill provides for a mechanism to adjust the patent term to compensate for delays in patent examination by the BRPTO that are not attributable to the patent owner.

REGULATION BY THE BRPTO

Provided for in the amendment.

Provided for in the Bill.

TERMS

Maximum extension of five years.
The request must be filed within 60 days of the patent grant.

Maximum extension of five years.
The request must be filed within 60 days of the patent grant.

STATUS

Awaiting the submission of a report by Senator Hiran Gonçalves (PP/PR) to the Committee on Science, Technology, Innovation, Communications and Information Technology.

Awaiting referral to the Committee on Industry, Commerce and Services.

Urgency requested

Urgency requested

Other mechanisms for establishing PTA

	Bill No. 2,056/2022	Bill No. 1,471/2023	Bill No. 32/2026
PROPOSERS	Federal Deputy Alexis Fonteyne (NOVO/SP).	Federal Deputy Kim Katagiri (MISSÃO/SP).	Federal Deputy Renata Abreu (PODE/SP).
SCOPE	The Bill provides for a mechanism to adjust the patent term to compensate for delays in patent examination by the BRPTO that exceeds a 60-day term.	The Bill provides for a mechanism to adjust the patent term to compensate for delays in cases where the period from filing to grant exceeds ten years.	The amendment provides for a mechanism to adjust the patent term to compensate for delays in patent examination by the BRPTO that are not attributable to the patent owner.
REGULATION BY THE BRPTO	Provided for in the Bill.	Not provided for in the Bill.	Provided for in the Bill.
TERMS	Maximum extension of five years. There is not a term for the adjustment request by the patent holder.	Maximum extension of five years. There is not a term for the adjustment request by the patent holder.	Maximum extension of five years. The request must be filed within 60 days of the patent grant.
STATUS	Awaiting the definition of rapporteur at the Committee on Public Administration and Civil Service.	Awaiting the definition of rapporteur at the Committee on Constitution, Justice and Citizenship. Urgency requested	Awaiting approval at the Committee on Industry, Commerce and Services.

Government's unfavorable position on PTA



Geraldo Alckmin

Vice-President and Minister of Development, Industry Trade and Services

In 2026, Alckmin stated that: *“Adjusting patents actually makes the product more expensive for consumers – it harms not only healthcare, but agribusiness as well. We need stable rules and predictability.”*



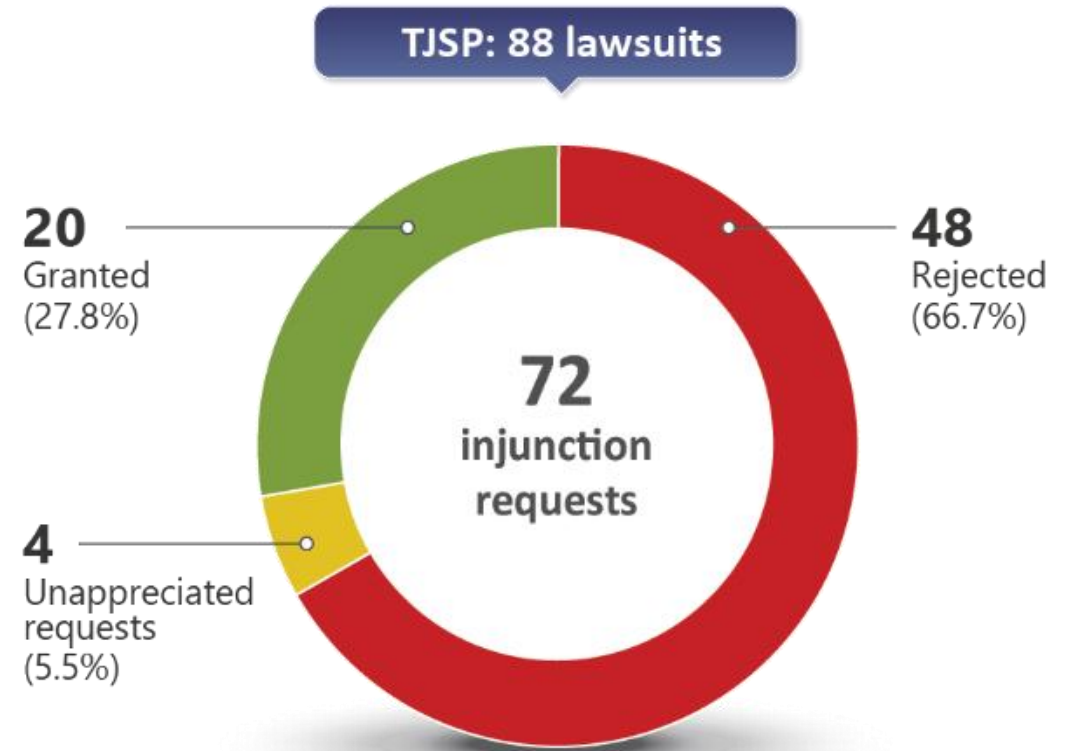
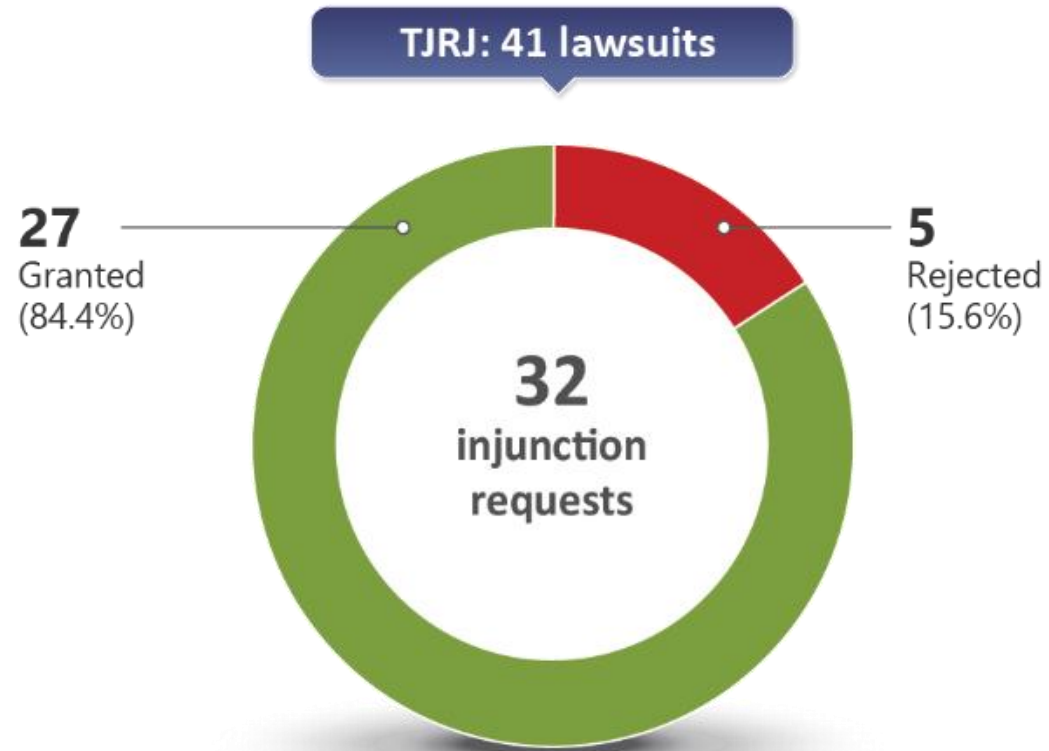
Alexandre Padilha

Minister of Health and Former Chief of the Institucional Affairs Office

Also in 2026, Padilha stated that: *“We oppose adjustments through judicial and legislative pathways. Our actions have focused on seizing the opportunities of patent expiration to make Brazil more productive and drive price reductions.”*

Practice challenges enforcement of pharma patents

PIs in patent infringement in life sciences cases



PIs in patent invalidity lawsuits related to life sciences

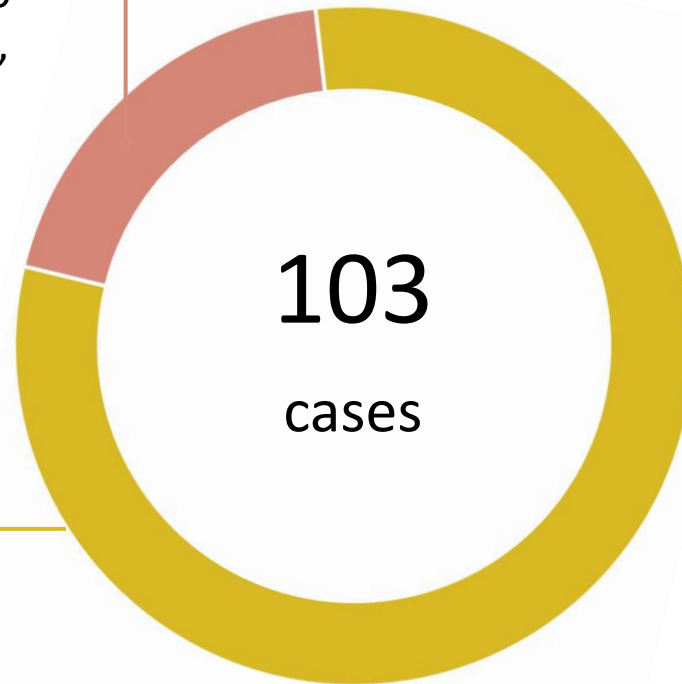
Data from Jan/2013 to Jan/2024

20 (19.42%)

Lawsuits with PI requests to suspend the patent's rights, out of which:

83 (80.58%)

Lawsuits without PI requests to suspend the patent's rights

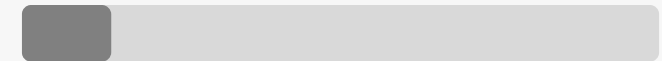


PI OUTCOMES

8 cases denied (40%)



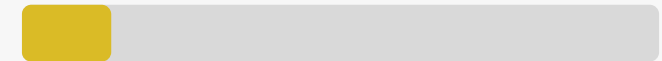
2 cases not considered (10%)



8 cases granted (40%)



2 cases pending (10%)



First challenge: who is the potential infringer?

- No patent linkage system of any kind. No Orange Book, nor Purple Book. No certification proceeding.
- ANVISA **does not disclose the applicants of pending MAAs**. The patentee may only monitor whether there is any pending MAA for a Gx or Bx and, if so, the route of administration, dosage form and strength.

<https://app.powerbi.com/view?r=eyJrIjoIMjg2Y2ZINjMtNDVhZS00YTlYwLTkzNTMtYTlYwYTQwODRiZjk5IiwidCI6ImI2N2FmMjNmLWZjZjMtNGQzNS04MGM3LWI3MDg1ZjVIZGQ4MSJ9>


ANVISA
 AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Medicamentos Pendentes de Conclusão da Análise de Registro pela Anvisa

Princípio ativo	Quantidade
semaglutida	
Novo	
solução injetável	
1,34 mg/mL	12
0,68 mg/mL	3
2,27 mg/mL	2
3,2 mg/mL	2
2,68 mg/mL	1
Biológico	
solução injetável	
1,34 mg/mL	4

Busca por Princípio ativo

Categoria Regulatória

First challenge: who is the potential infringer?

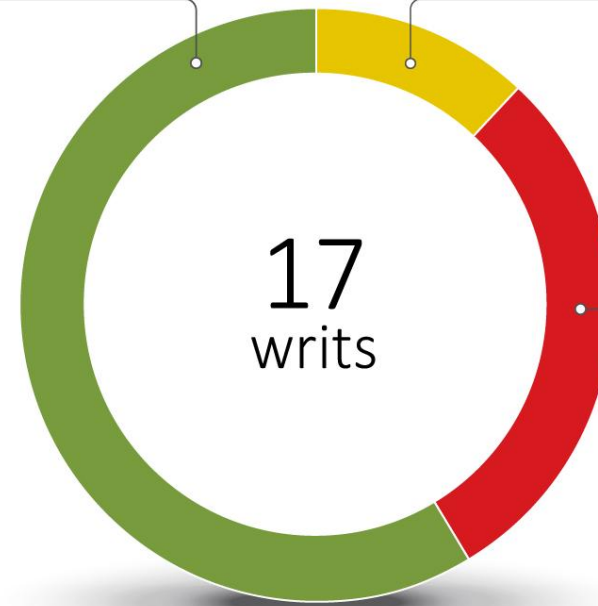
The solution: patentees file writ of mandamus against ANVISA seeking the disclosure of the MA applicants.

10

Favorable decisions:

- 1 decision at the trial level granting the PI
- 1 decision on interlocutory appeal granting the PI
- 6 trial decisions on the merits granting the writ*
- 1 appellate decision granting the writ
- 1 Anvisa voluntarily disclosed the information

*In 4 of these cases, the Appellate Court upheld the granting decision. The remaining case is under seal, so it is not possible to confirm the appeal's outcome.



2

Pending cases
(PI request still to be examined)

5

Unfavorable trial decisions:

- 2 PI rejected, but pending decision on the merits
- 1 pending review by the Appellate Court
- 1 appeal not filed
- 1 patentee withdrew the case

Second challenge: when to act

Under the prevailing interpretation, the bolar exemption allows a competitor to obtain marketing approval while the patent is still in force. As a rule, then, the patent owner must wait for the approval to be granted before it can move against the entry of the infringing product. The problem is that this gives the patent owner a narrow window to act. But there are to circumventing this.

MONITORING IMPORTS

Import records held by the Federal Revenue reveal volumes of API importation, leading to potential evidence of stockpiling which acts outside the exception.

 **Challenge:** Federal Revenue understands the records are confidential. Necessary to file writ to obtain access, but the case law is favorable to patent owners.

USING ANVISA'S REGULATION

Regulatory framework obliges the holder to place the medicine on the market: depending on the timing, it could be possible to prove that there is a clear intention to infringe, considering that the infringer would necessarily need to start commercialization before the end of the patent's expire date, under penalty of not being able to renew their marketing approval. Example from State Court of São Paulo:

Genentech v. **AMGEN**

"Urgency arising from the likelihood of the imminent granting of marketing approval [...] — demonstrating a risk of harm and a threat to the useful outcome of the proceedings, given that Article 12 of Law No. 6.360/76 mandates the actual commercialization of the medication during the final two-thirds of the granted registration period, under penalty of non-renewal of said registration".

Third challenge: enforcing secondary patents

Pharmaceutical patents not covering the compound itself face several challenges:

How to prove infringement

Challenges

COMPOSITION PATENTS

- **Compositions not characterized by quantities or concentration:** Product label;
- **Compositions characterized by quantities or concentration:** Confidential form ("FP1") submitted to Anvisa.

- Label only available after product launch, hindering early preparation;
- Confidentiality of the form hinders access to proof of infringement – early production of evidence necessary.

PROCESS PATENTS

- Documents showing that the process is implemented by the infringer;
- Art. 42, §2nd of the Patent Statute determines inversion of the burden of proof: accused party must prove non-infringement.

- Difficulty for obtention of preliminary injunction due to lack of evidence;
- Lack of standard for accused party to prove non-infringement.

SECOND MEDICAL USE PATENTS

- Therapeutic indication being inserted in the product's label.

- Skinny label hinders enforcement, due to difficulty in proving that drug will not be used for patented indication.
- There are discussions about the legality of skinny label.

DOSING REGIMES OR PATIENT GROUPS

- Product label.

- Brazilian BRPTO's position that such patents cannot be granted.
- Necessary change in guidelines for such patents to be granted or need to file lawsuit to obtain grant.



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