

# DANIEL

Information for Participants of C5's  
13th Annual Forum on Pharma and  
Biotech Patent Litigation in Europe

Brazil As a Potential Venue For  
International Patent Litigation

## Meet our representative at our Booth or schedule a personal meeting!

***Roberto Ribeiro***

***Partner – Pharma Desk***

Roberto is a well-known speaker in events worldwide since many years, having dedicated the most recent lectures to Compulsory Licensing in Latin America, Patenting second medical use in pharma products, Artificial Intelligence in the pharma industry, IP essentials for doing business in Latin America (organized with UK Government representatives on IP) etc.

Roberto is essentially an IP strategist, highly experienced in most IP areas in various industry fields such as pharmaceutical, food, consumer healthcare products, mechanics and metallurgy, having successfully acted in more than 50 jurisdictions in his 33 year career. Roberto's most important achievements in patents and trademarks include prosecuting complex applications, structuring patent based strategies enabling entry into markets of biological pharmaceutical products in very densely patented technology areas in Latin America, Japan, Asia and Pacific and winning complex pharma patent litigation in Brazil Argentina and Australia, among others.

Roberto benefits from his multi-faced background as a civil engineer, post graduate in business administration (MBA) and attorney at law, accredited before the Brazilian Patents and Trademarks Office (the "INPI").]



*// As a leading firm serving clients of assorted sectors, Daniel Law has structured its services not only to ensure quality and competitive fees for what is requested from us.*

*We are mindful about the importance of being in the forefront of events that may, in some way, impact our clients activities, even if in the middle or long term.*

*Accordingly, we constantly monitor and alert our clients about proposals for bills of law, new IP regulations as well as the political vectors relating to IP and related areas.*

*In addition, with strict adherence to ethics compliance rules, we count on a network of politicians and law makers to anticipate what is about to come from Government bodies or Class entities, for example, and recommend respective actions to our clients, as the case may be.*

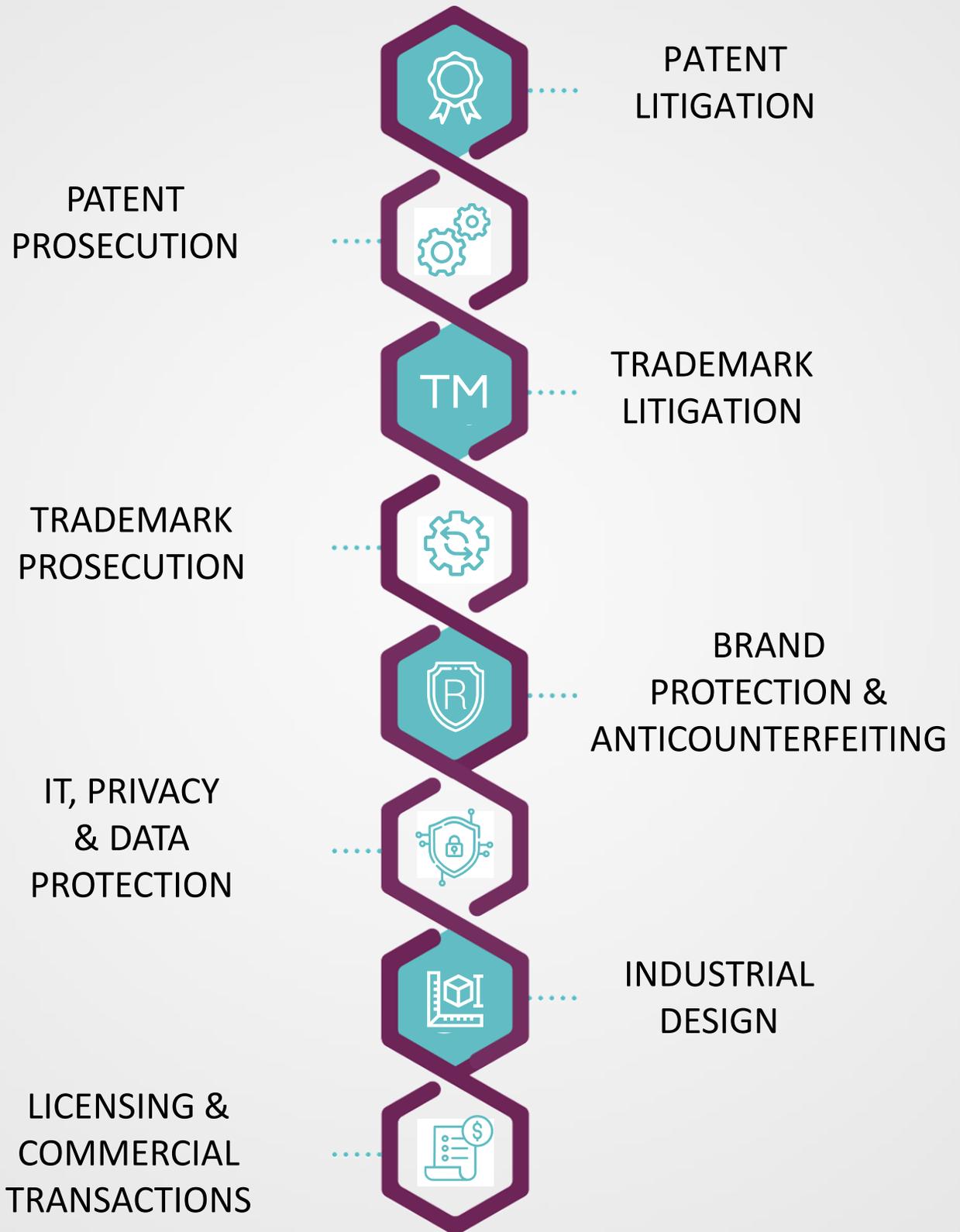
*On the top of this, we apply sophisticated business intelligence tools to ensure our prosecution practices give our clients high quality patents to face any possible litigation on a front foot.*

*We combine these tools with our broad view and experience accumulated not only in Brazil, but also in other countries across Latin America."*

**Roberto Ribeiro**



# Our Practice Areas



# Daniel Law

Daniel has carefully protected and managed Intellectual Property (IP) and other immaterial assets that give dynamic businesses their competitive edge.

Development and execution of **customized strategies** to meet **specific IP needs** of clients.



**Diverse team** of over 200 partners, attorneys, engineers and other professionals

**In-house** legal and technical **expertise**

Real-world business **experience**

Deep and native knowledge of **Brazil's** complex legal environment enables **Daniel** to:

Better anticipate the client's needs

Understand potential risks

Provide more successful management of IP assets



60 years of continuous growth and innovation



Strong regional network of affiliated law firms in South America



Offices in Rio de Janeiro and São Paulo

# Daniel Law

We are proud to be recognized by the best national and international legal rankings.



Indicated as one of the best intellectual property offices in Brazil in all editions of the publication.

*“Daniel is very active in areas related to the fight against counterfeiting in the field of technology.”*



*“They are extremely effective in their actions, while being assertive and confident in their opinions.”*



*“The best adviser and the most informed of the market. Committed and efficient, it provides excellent service.”*



# Commitment to Diversity and Inclusion



Daniel Plural came to put into practice the whole concept of equality that we want to see in the world, applied to our corporate environment. Our inclusion program is designed to recruit and retain the best candidates, seeking talented individuals from a variety of backgrounds, worldviews, and life circumstances. In addition to creating a corporate culture of inclusion, we are trying to expand these opportunities for others by working locally to close the educational gaps that prevent diverse candidates from reaching our organization in the first place.

Our diversity program is designed to enhance the level of diversity in our supply chain, ensuring that Daniel is an active participant in and contributor to this important movement. Both of these initiatives have visibility at the highest level of our leadership. Our aim with these programs is not only to create a mosaic of perspectives for our firm and our clients, but also to have an impact that goes beyond our organization.



We are proud to be the largest woman-owned and woman-led law firm in Latin America and to be certified as a WomenOwned Business by WEConnect International, guaranteeing that our firm meets the universal standards for Women's Business Enterprises (WBEs).



We are very honored to have been awarded *Most Innovative Program for Employee Mental Health and Well-being* by Chambers and Partners.



Leadership Position

45% female



55% male

Partners

51% female



49% male



JANUARY 2018  
WOMEN-OWNED  
BUSINESS CERTIFICATION



AUGUST 2018  
LATERAL HIRE: PARTNER HEAD  
OF INCLUSION AND DIVERSITY



DECEMBER 2018  
CLOSED GENDER  
WAGE GAP

# Latam Hub

Daniel's substantial technical experience and the vast network of partnerships accumulated over decades have led to the office becoming a key entry point to the region for companies worldwide.

As a result, Daniel has developed a Latam Hub, allowing our clients to access Intellectual Property services across Latin America and the Caribbean using one express service, with a single point of contact and invoicing.

We offer our clients simple and fast operations, and less bureaucracy in the management and processing of their portfolios throughout the Latam region.

We maintain a level of excellence in the provision of services in all Latam Hub countries, based on existing agreements signed with our entire network of partners and a strict quality control process monitored by the Daniel team.

## Operation of Hub

### Multi-jurisdictional representation

We simplify and streamline the process of legalizing powers of attorney to meet the specificities of all Latam Hub jurisdictions and manage all related bureaucracy on our clients' behalf.

### Single Invoice

Whether the services are performed in one jurisdiction or in ten - we can compile all services provided in a single invoice.

### Blended Rates

We offer pre-agreed fees for the similar services provided across all Latam Hub jurisdictions, leading to greater budget predictability and competitive rates for our clients.



# Jurisdictions

Through Daniel's network of partnerships, we maintain structured operations in countries across the Latin America and Caribbean region, including:



Argentina



Bolivia



Brazil



Chile



Colombia



Costa Rica



Cuba



Ecuador



El Salvador



Guatemala



Haiti



Honduras



Mexico



Nicaragua



Panama



Paraguay



Peru



Dominican Republic



Uruguay



Venezuela

# Information on Brazil as a potential venue for international patent litigation

Brazil is the largest country and economy in Latin America, and among the most important countries in the world in terms of intellectual property. Our clients often ask us how Brazil is relevant in terms of litigation in other jurisdictions, for example, in the US or Europe.

In recent times, the Brazilian Government has been making some significant changes with the objective of creating a culture of innovation, and growth of Intellectual Property and technology in the country.

As a result of recent initiatives, international companies can now process patents at a much accelerated pace, as well as count on the Brazilian judiciary to provide fast and effective solutions to international patent disputes.

## Facing multiple challenges

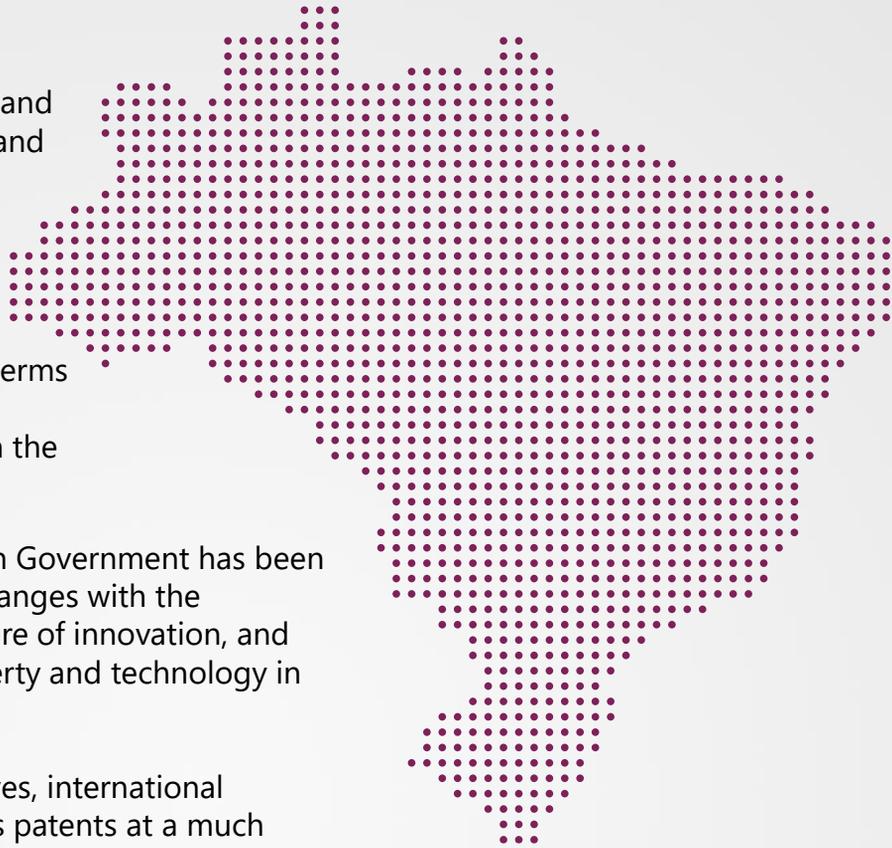
Our team caters to both the biotech and pharma markets, due to the wide overlap of expertise of these two market industries. Our pharmaceutical practice involves, protecting innovations in the fields of biologics, DNA- and RNA-based technologies, gene therapy, antibiotics, immunotherapeutics, recombinant human insulin, and vaccines, to give just a few examples.

We have also represented clients in the largest pharmaceutical patent litigation in the country and obtained important victories in cases involving "blockbuster" drugs and in sophisticated disputes regarding biosimilars.

Our knowledge of Food & Drug law helps us understand our clients' needs and are an additional tool we often use in order to achieve important goals.

We also have experience in navigating the intersection between intellectual property and antitrust regulation and are in a strong position to understand the risks and opportunities in this area.

We recognize that certain disputes will raise public health issues and policy considerations and know how to leverage these factors in our clients' favor.



# Patent Litigation in Brazil

The Brazilian courts are independent and unbiased against foreign entities in the country. This assertion is backed by the fact that many foreign entities have been bringing successful litigation in the country to secure their patent rights.

In addition, the standards for obtaining preliminary injunctions in Brazil are comparatively low, and no discussion on the balance of hardships takes place in the process of obtaining such remedies in the courts.

In fact, in Brazilian proceedings, it is possible to have ex-parte meetings with judges, without the requirement of giving prior notice to the other side in the dispute. Preliminary injunctions in patent disputes can often be obtained even before defendant is officially served with the initiating summons.

Further, NPE's (Non-Practicing Entities) have equal access to such legal recourses.

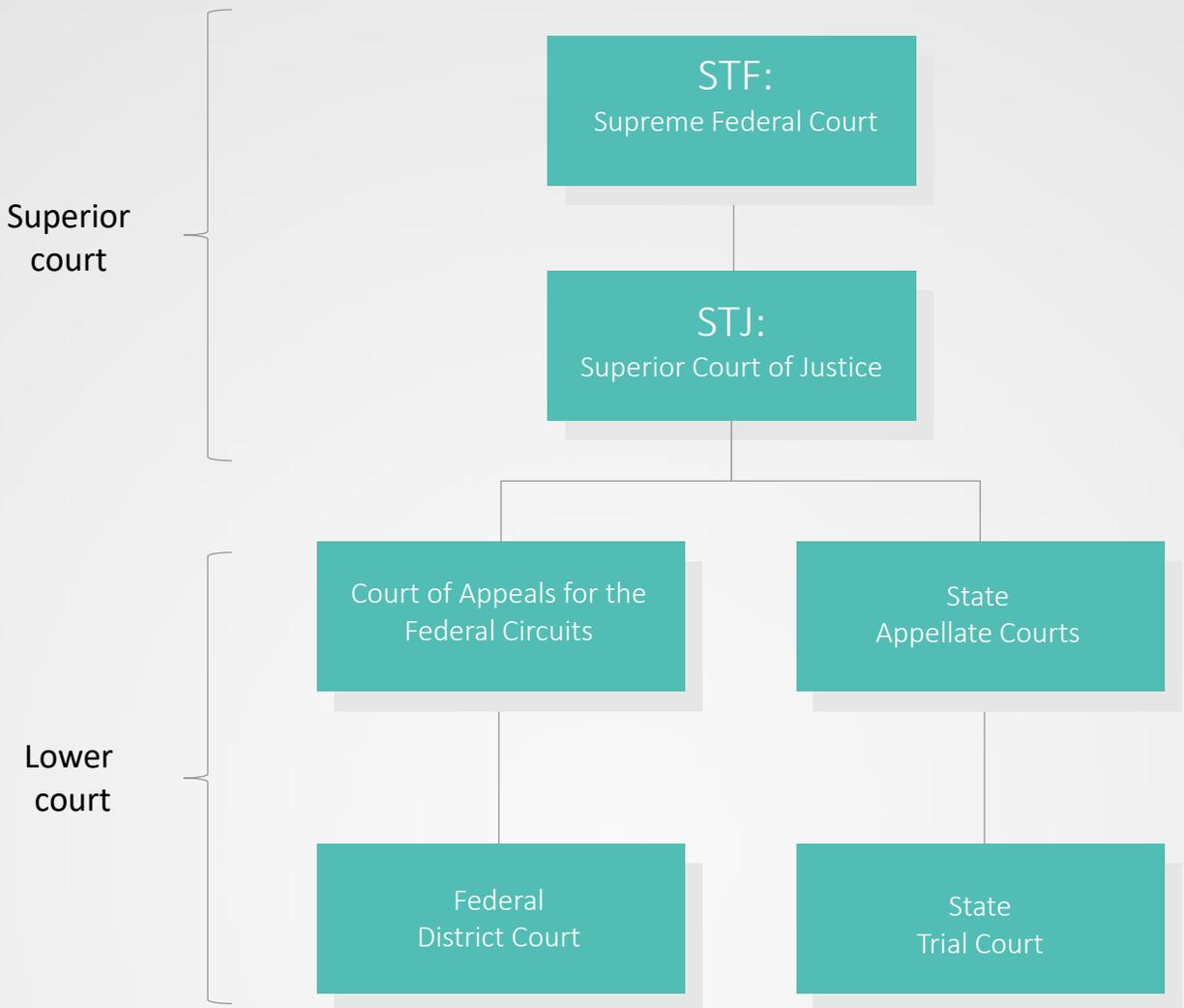
The cost of litigation is comparatively low, and there is also no requirement to post a bond or other security for such a lawsuit to be heard by the courts.

Moreover, certain courts, for example in the state of Rio de Janeiro, have a more favorable environment for patent holders, so a forum shopping strategy can be employed to benefit the plaintiff in such actions.



# Bifurcated System

Court structure



STF:  
Supreme Federal Court

- 11 justices nominated by the President;
- Highest body of the judiciary;
- Responsible for prosecution and judgment of the cases in which is a threat or a violation of constitutional provisions is claimed.

STJ:  
Superior Court of Justice

- Responsible for standardizing the interpretation of federal law throughout Brazil.
- Last instance of the Brazilian Justice for the infraconstitutional causes

Bifurcated System

- Infringement actions are brought before state trial courts;
- Invalidity challenges must be filed before federal district courts

# Patent enforcement

## Infringement topics

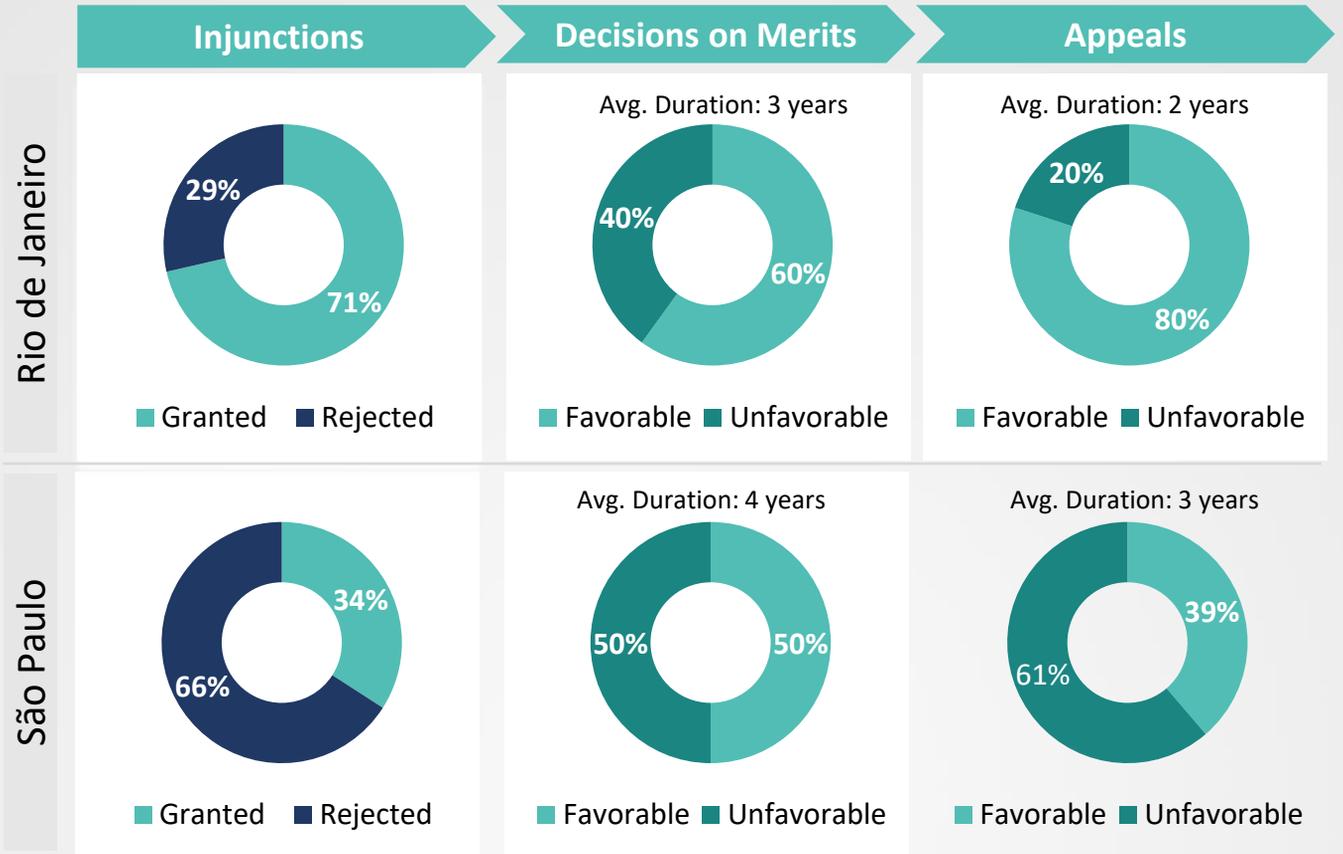
- Doctrine of equivalence, inducement and contributory infringement
- Shift in the burden of proof for cases related to process patents
- Compensation for loss profits (your losses or infringer's profits or reasonable royalties) + actual/consequential damages + moral damages
- Average amount of damages
- No Markman hearings
- Permanent injunctions are a very common remedy
- Settlements are less common, most cases go to trial

# Invalidity Lawsuits

## Invalidity lawsuits (federal district courts)

- Precedent from the Superior Court of Justice
- BRPTO is a mandatory co-defendant
- Federal Courts in Rio de Janeiro
- Hard to get an injunction
- Possibility of staying the infringement lawsuit

# Forum-shopping strategy is applicable



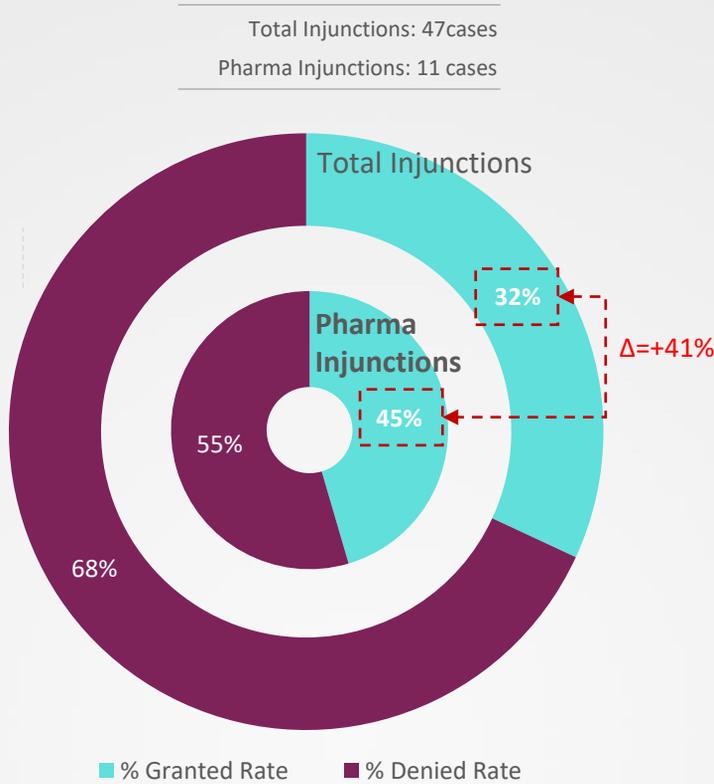
Rio de Janeiro has a more favorable environment for patent holder.

# Invalidity Lawsuits

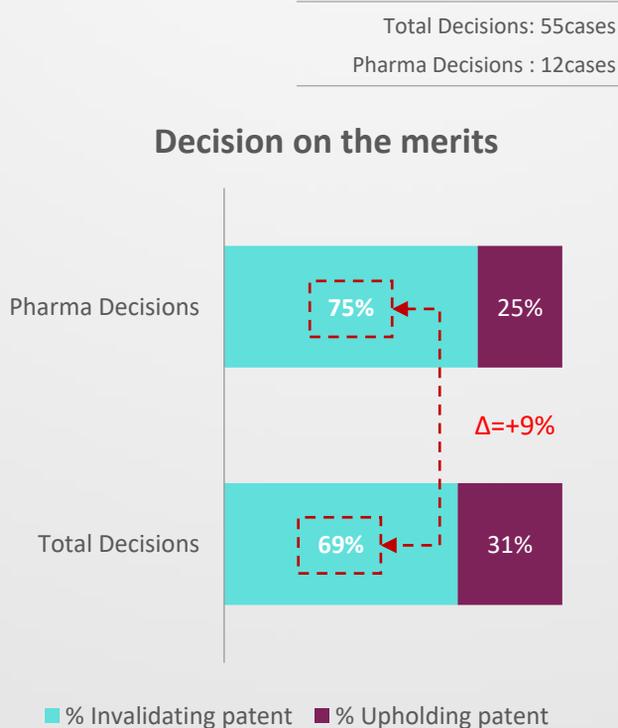
## Lawsuits Analysis: Invalidity lawsuits in Rio de Janeiro

### Comparing Pharma with the rest of the market\*:

- Pharma Injunctions are **41% more likely to be granted**.



- Although in a difficult segment, Pharma decisions on the merits **are comparable** to the rest of the market in the mid/long run.



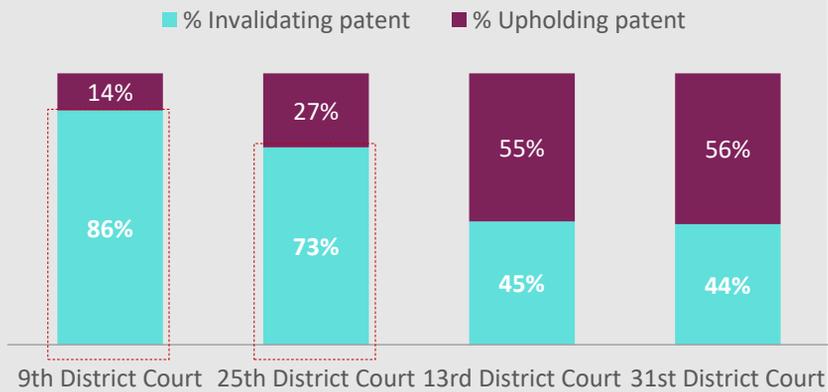
Note: [\*] Disregarding Mailbox data  
Source: Brazilian Data/ Daniel Law analysis

# Invalidity Lawsuits

## Lawsuits Analysis: Invalidity lawsuits in Rio de Janeiro

### Decision on the merits (by District Court)\*:

The **9th and 25th District Courts** of Rio de Janeiro have over 50% of probability to decide towards patent invalidation.



### Court of Appeals for the 2nd Federal Circuit (TRF2)\*:

Depending on the panel, there will be almost no chance for decision overruling.

Panels	Appeals	Decisions overruled	% Overruled Decisions
1st Panel	10	0	0%
2nd Panel	32	5	16%

Note: [\*] Disregarding Mailbox data

Source: Brazilian Data/ Daniel Law analysis

# New Initiatives in Brazil to combat patent backlog

The Plan to Combat Patent Backlog, launched in 2019, is part of a broader initiative, in which the BPTO seeks to reposition the country in terms of competitiveness and improved legal certainty.

There are also several other programs aimed at improving the quality of patent examinations, encouraging innovation and strengthening strategic sectors.

One of them is the agreement known by the acronym **PPH (or “Patent Prosecution Highway”)**, which, in general, takes advantage of the search results and previous examination in other patent offices that are members of that Agreement.

In addition to the PPH, the BPTO also created **several new programs** aimed at specific segments (at present there are more than 15 programs).

Among various technology-based industries, pharmaceutical technologies play a central role in the fast-track programs currently available by the BPTO; for instance, it is possible to accelerate examination of patent applications related to cancer, HIV/AIDS, rare and neglected diseases.

Today, in light of the global COVID-19 pandemic, a new fast-track examination program was launched by the BPTO covering technologies directed to pharmaceutical products and processes, as well as equipment and/or materials used in health for diagnosis, prophylaxis and treatment of coronavirus, aimed at stimulating development of new technologies in this area and expediting applications.

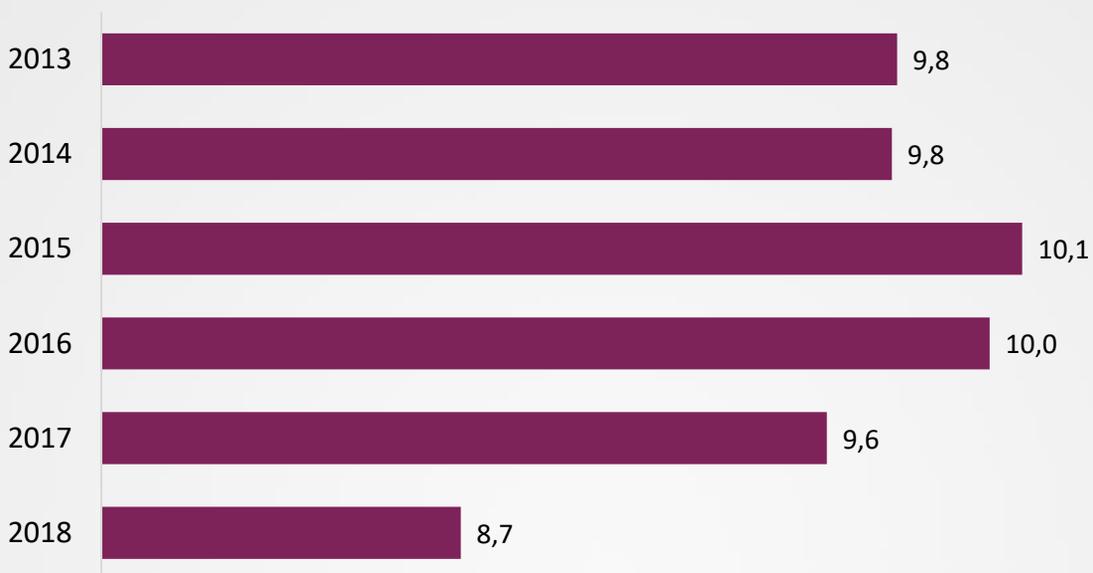
**The Plan to Combat Patent Backlog is ambitious.  
And the good news is that it is working.**

# Patent backlog situation

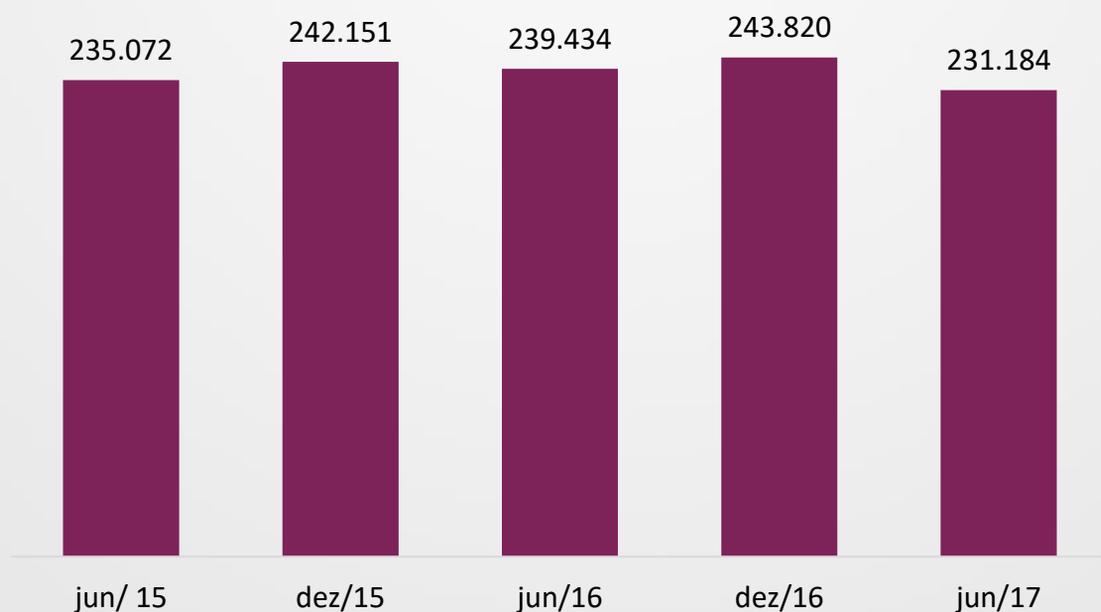
## Patent backlog situation

- In the last years, the BRPTO has not been able to process and examine patent applications in a reasonable time.
- In 2018, the BRPTO took, on average, 8.7 years to grant patents applications.

### BRPTO's average time to grant a patent<sup>1</sup> (years)



### Backlog evolution (patent applications waiting for a decision)



# Patent backlog situation

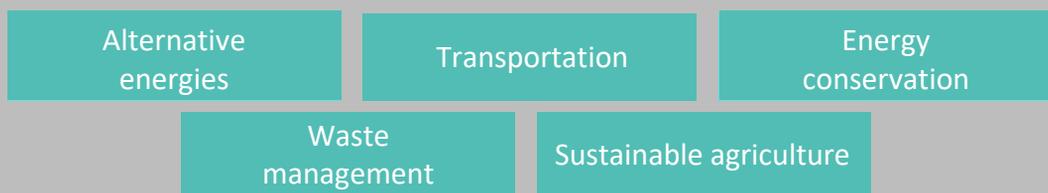
## Expedite examinations programs

BRPTO offers acceleration programs to reduce the delay to grant patents, such as:

1	Green patents
2	PPH
3	Pre-examination office action
4	Health products
5	Potential infringement
6	Senior applicant
7	Local R&D Institutes
8	Others: BR Priority, Small and medium-sized enterprises, ICTs Patents

### 1. Green patents

Program focused on environmentally friendly inventions, involving topics such as:



Green patent fast track approval rate for examination



# Patent backlog situation

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## 2. PPH



APO



KIPO



JPO



UKIPO



EPO



USPTO



CNIPA



DKPTO



IPOS



PRV

- The PPH involves International agreements between BRPTO and other Patent Offices in other countries.
- Agreements in force with offices in Austria (APO); China (CNIPA); South Korea (KIPO); Denmark (DKPTO); United States (USPTO); Europe (EPO); Japan (JPO); United Kingdom (UKIPO); Singapore (IPOS) and Sweden (PRV).
- In 2019, the BPTO has removed any limitations to specific technologies broadening the scope for foreign applicants.
- Phase II of the Patent Prosecution Highway (PPH) Program started from January 1, 2021.
- Phase II of the PPH program was anticipated, which was originally expected to start only in December 2022.
- The number of applications that can be accepted under the new PPH program, was increased from 400 to 600 per year.

# Patent backlog situation

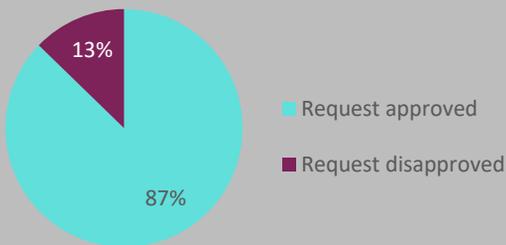
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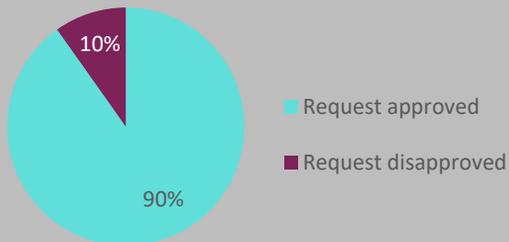
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## 2. PPH

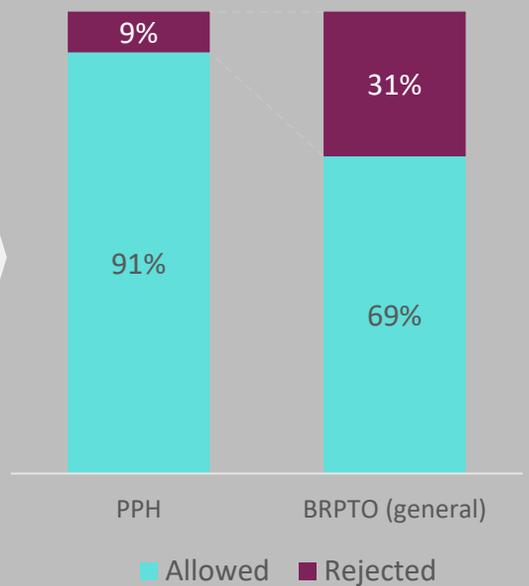
PPH fast track request approval rate



INPI-JPO PPH fast track request approval rate



Allowance rate



# Patent backlog situation

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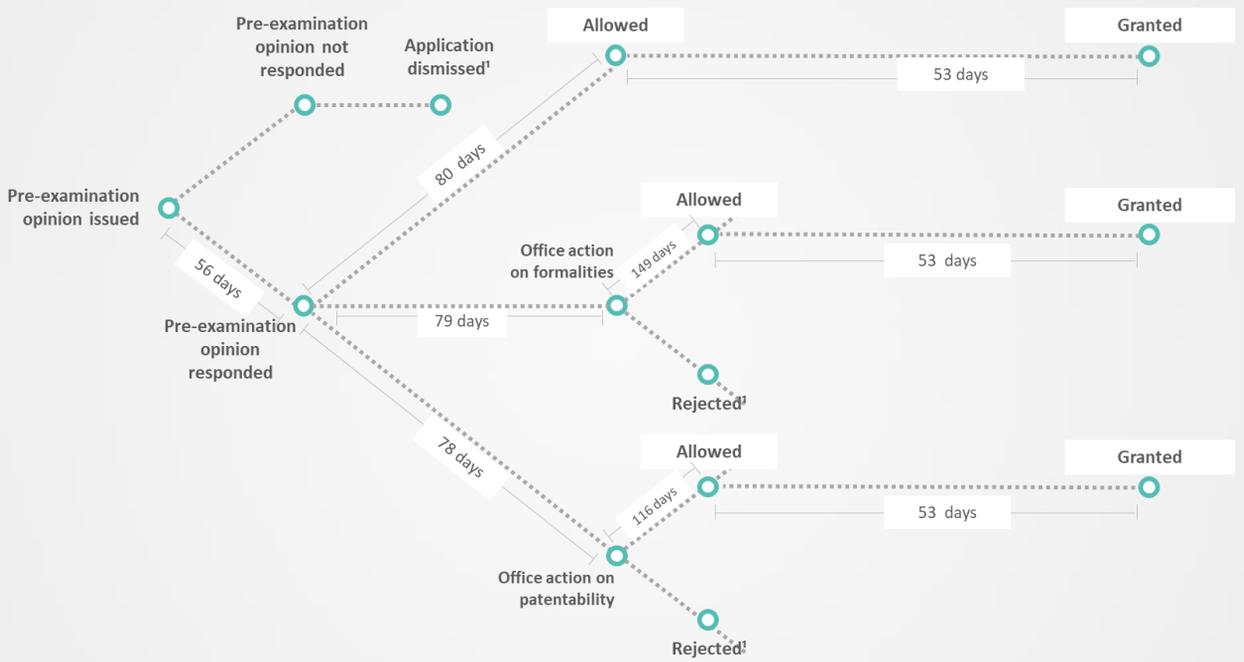
### 3. Pre-examination office action

A new kind of office action based on the indication of prior art references mentioned by foreign offices aiming at giving applicants the opportunity to amend their applications to mirror the claims granted abroad.

- An office action containing the prior art cited on counterpart applications abroad;
- No substantive opinion or formalities comments;
- 60-day deadline to respond it;
- BR application can be amended according to its counterparts filed abroad;
- Applicant can respond it by filing amendments and/or arguments;
- Once the response is filed, the substantive examination begins;
- If the pre-examination office action was properly responded, the patent can be granted, on average, 2 months from the response.

# Patent backlog situation

## 3. Pre-examination office action



Notes: [1] From the application until concession, by year of concession  
Source: BRPTO

# Patent backlog situation

## Expedite examinations programs

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### 4. Health products



#### Neglected diseases:

Chagas disease, dengue, dengue hemorrhagic fever, schistosomiasis, leprosy, leishmaniasis, malaria, tuberculosis, Buruli ulcer, neurocysticercosis, echinococcosis, boubu, fasciolose, paragonimiasis, filariasis, cholera, helminthiasis and intoxications or poisoning due to venomous or poisonous animals.

AIDS

Cancer

# Patent backlog situation

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### 5. Potential infringement

The potential infringement fast-track is applicable for situations in which a third party is exploiting the claimed invention without authorization.

#### Requirements:

- ▶ Warning letter with confirmation of receipt
- ▶ Demonstration of the potential infringement

### 6. Senior applicant

The senior applicant fast-track is applicable for applicants that are 60 years or more.

# Patent backlog situation

## Expedite examinations programs

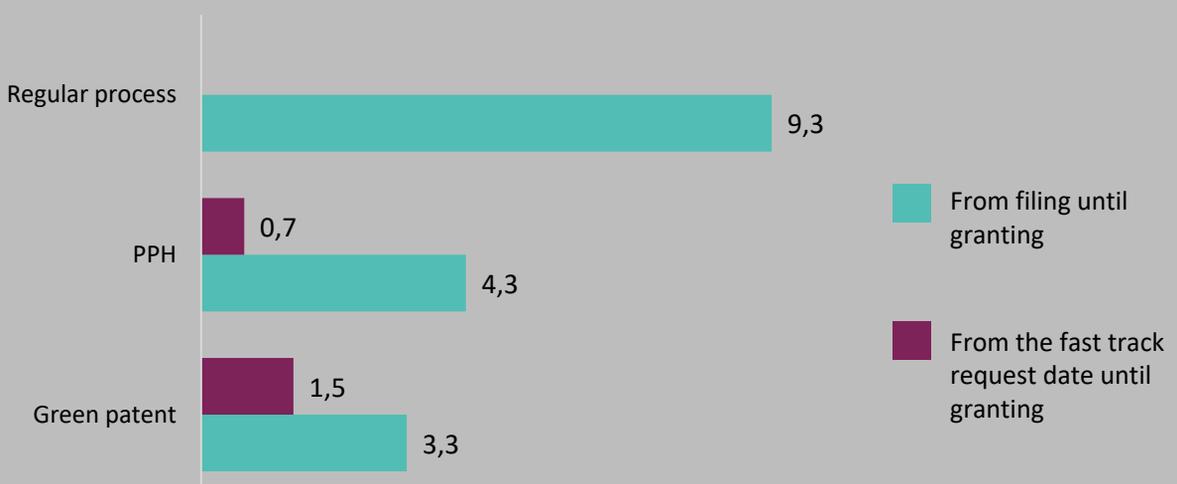
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### Program's efficiency

These acceleration programs have shown great efficiency in speeding up the application process:

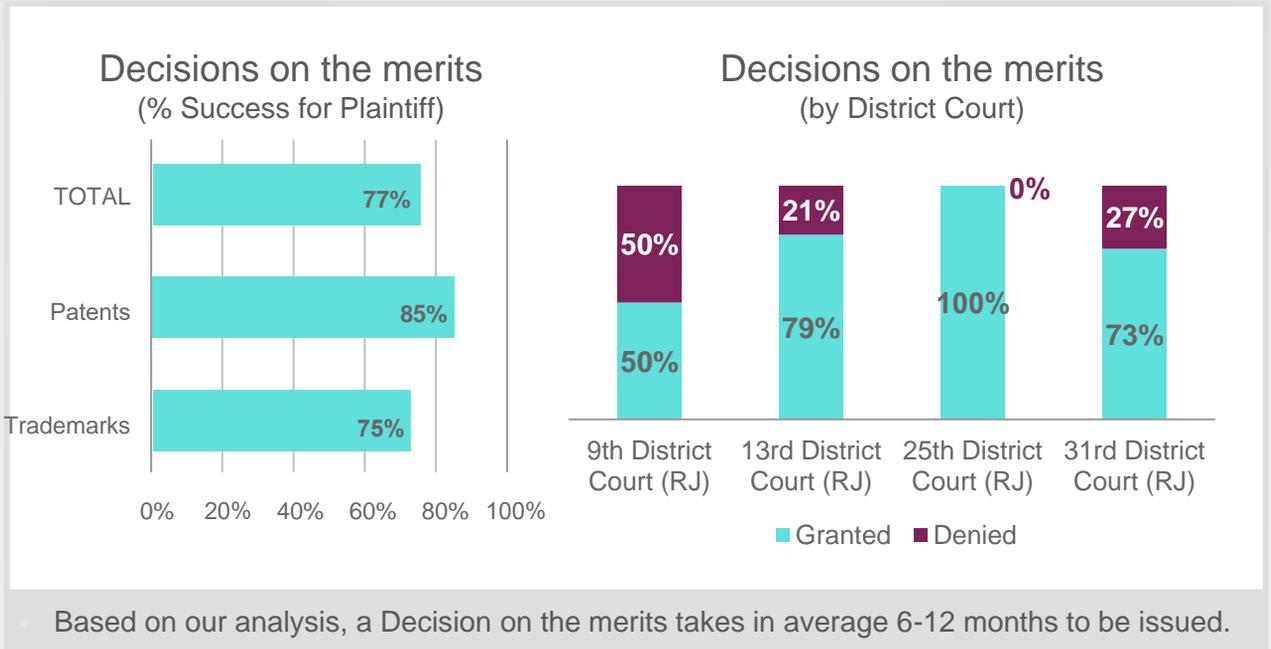
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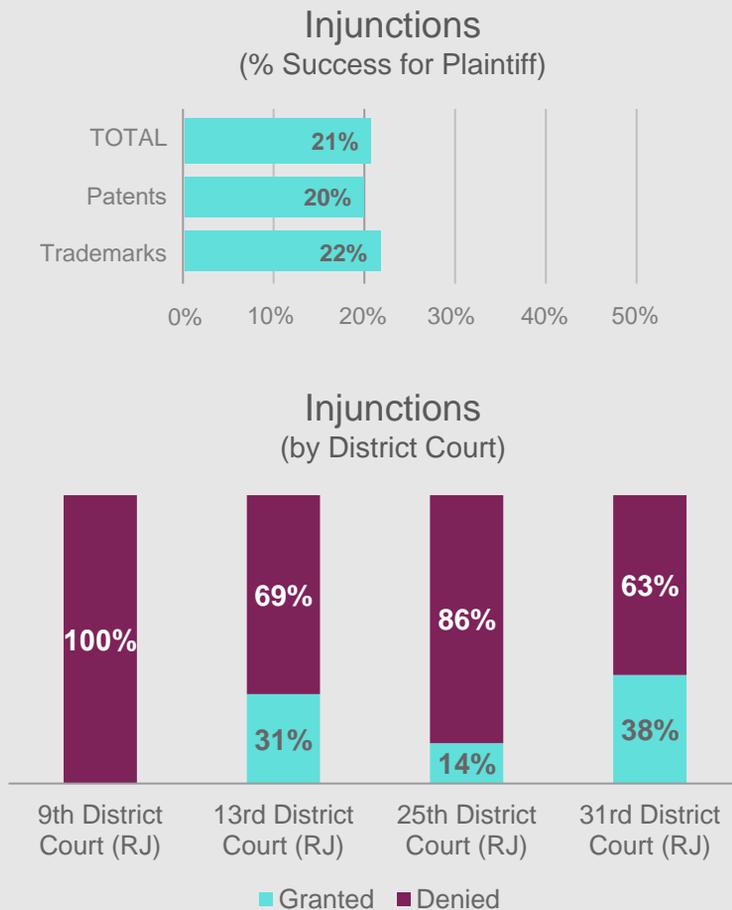
# Judicial induced fast track

## Lawsuits against the Brazilian PTO challenging delays

So far over 87 lawsuits were filed against the Brazilian PTO challenging unreasonable delays



### Injunctions Analyses:



**DANIEL**

[www.daniel-ip.com](http://www.daniel-ip.com)