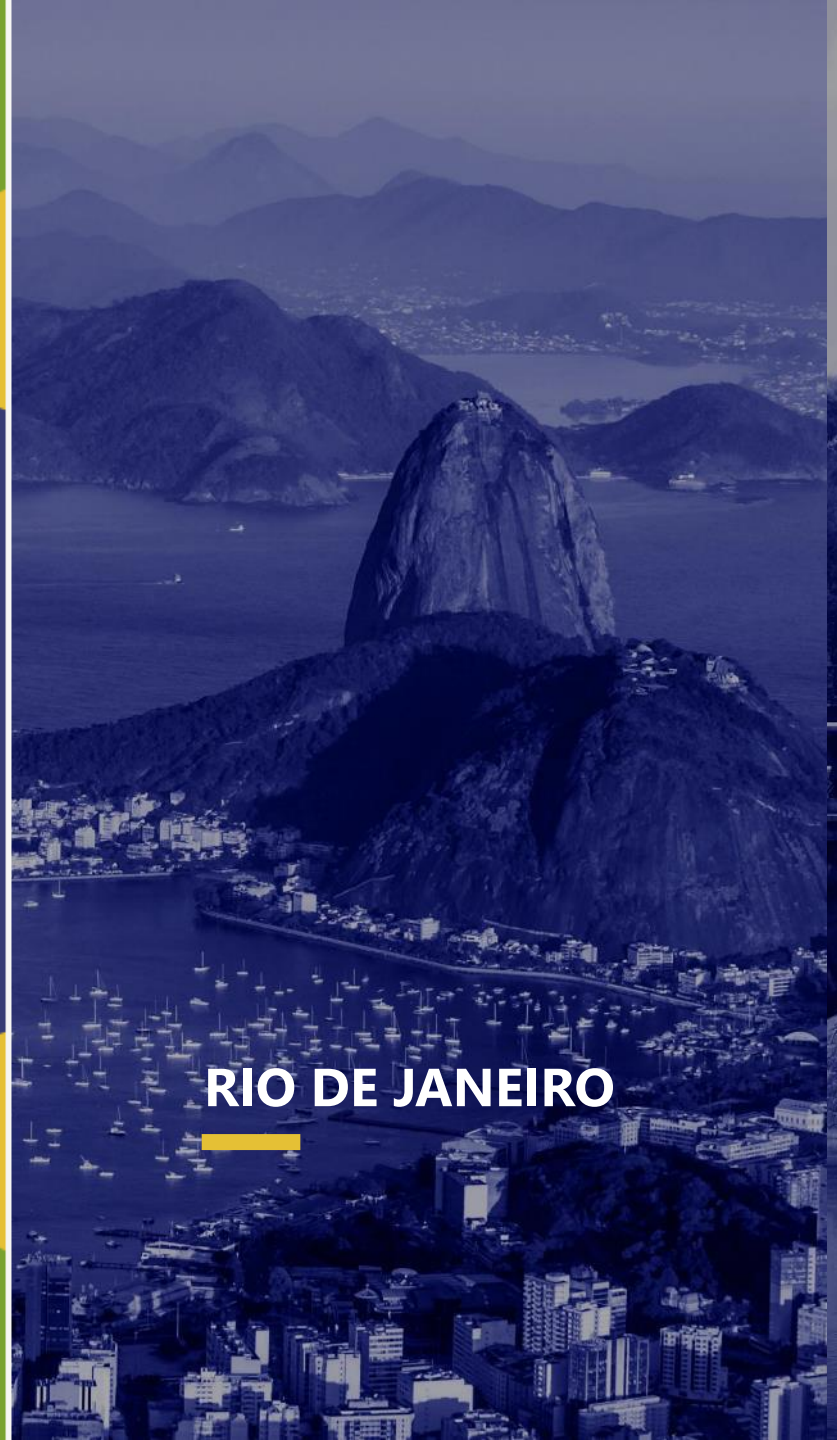
Licks ATTORNEYS

New opportunities for Canadian life sciences products and services in Brazil:

Regulatory, Corporate and IP hot topics

BCCC Healthcare Forum | 2016


RIO DE JANEIRO


東京


SAO PAULO

BRAZIL

Time for a change

- A shift in power impacting patent law
- Pharma business affecting patent practice
- Compulsory license, PAHO, WHO, BRICS
- Efforts to improve the patent system
- Judicially induced Fast-track prosecution
- Judicial review of BRPTO's decisions

A shift in power after 14 years of Worker's Party (PT) Rule

Michel Temer is the new president of Brazil

PT rose to power in 2002 with Lula (two 4-years terms) and his protegée Dilma Rousseff twice (2010 and 2014) for 4-years terms. However:

Dilma was impeached on August 31st 2016.

PT is **anti-patent, anti-free trade** and **protective of the national industry**.
PT representatives and senators never voted pro-patent, ever (as minority or government since 1995).

Michel Temer took office as President on August 31st 2016

He was Dilma Rousseff's Vice-President during her presidency and took over as Interim President on May 12th, 2016 after the Senate removed Roussef due to the Impeachment proceedings.

PMDB, on the other hand, **is in line with economic liberalism and has shown no sign of anti-patent policies**.

Eduardo Cunha was removed as Speaker of the House of Representatives by the Supreme Court on May 5th.

Why sell drugs in Brazil?

The 6th largest pharmaceutical market in the world

The **private market is approximately USD 33 billion** (2014). Retail amounts to USD 16 billions (2015), with a 67% share of national companies.

The Public Healthcare System (SUS) provides free drug distribution. **Approx. 90% of the population (180 million) makes use of SUS** to some extent (World Bank 2013). In 2014 the government spent **USD 87 billions in healthcare** (CFM).

While biological products represent only 5% of all drugs distributed by the government, they represent 43% of the total spent annually by the Ministry of Health on drugs (2014).

The **government procures drugs by the INN** and does not make any differentiation between new drugs and generics. Biologicals follow the same rules.

The government can **concentrate the acquisition** of the entire national demand of a drug **in one simple bid:** this can seize 100% of the market for a certain drug for an entire year or longer.

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

ANVISA as a regulatory Member at ICH

ANVISA became an observer at the ICH in December 2015, together with the Pan American Health Organization (PAHO) the Gulf Cooperation Council (GCC) and Asia-Pacific Economic Cooperation (APEC).

ANVISA
Agência Nacional de Vigilância Sanitária

The 2016 meeting of the ICH was held in Osaka, Japan from November 5th to 10th and **formalized the admission of both ANVISA and South Korea's Ministry of Food and Drug Safety (MFDS) as new regulatory Members.**

Regulatory Members have the right to appoint specialists to form Working Groups and play a more significant role in development and approval of new guidelines.

ANVISA will now have a 5-year term to comply with the ICH`s five guidelines: Pharmacovigilance, clinical research, implementing the Common Technical Document (CTD) and the MedDRA.

Name-based sales

Importing drugs without MA for personal use

As a Rule, **only MA holders** (or a third party on its behalf) **can import** drugs. A importing license issued by the ANVISA for the product it's also required.

Upon a prescription, **patients can import** drugs without MA nor the ANVISA's import license **for personal use only**. (ANVISA's Rule 81 of 2008)

The "personal use" requirement is determined by the comparison of the overall amount imported with the amount required for the patient's treatment.

Hospitals can **also use this procedure** on behalf of its patients, justifying the diagnostic or therapeutic indication, to be signed by the responsible physician.

Important note: Procedure is not applicable for HIV drugs and some controlled substances-based drugs.

Selling drugs without MA

PAHO Special Fund and Mercosur

Statute #9,782 (art. 8th §5) allows the MoH to procure drugs not approved in Brazil through international organizations. Decree 8.077 (art. 7th §4) does too.

In November 2015, the MoH procured through Mercosur and PAHO's Strategic Fund non approved Darunavir-based products from Hetero Drugs (USD 40 million). Janssen's Prezista was available in Brazil.

ANVISA is preparing to issue new legislation to regulate this proceeding.

To sell drugs to PAHO, the company must apply for **prequalification before WHO and PAHO**.

Information concerning the company and the drug are required (e.g. equivalence, bioequivalence and stability studies). Physical inspections in the company's facilities are also required.

When PAHO has interest in purchasing drugs, it will send **Requests for Proposals through the UNGM** (United Nations Global Marketplace) system to prequalified companies.

Complying with court orders

Access to **healthcare is a Constitutional right** to any person in Brazil (even non-resident). All levels of government are jointly responsible for SUS.

Recently there has been an **increase in "judicial activism"** seeking the supply of drugs by the government: a **727% growth** in five years. 14,940 new lawsuits were filed against the MoH in 2015 while 16,301 were filed only from January to July 2016.

Current case law holds that SUS's free drug distribution obligation **also includes products without MA** in Brazil. MoH's **expenditures has grown 220 times** in recent years: from USD 707,000 (2010) to USD 160 million (2015).

E.g.: Alexion's Soliris (eculizumab), amounting to USD 62 millions (2014).

Brazilian Supreme Court is reviewing this issue and will soon establish binding guidelines for all courts.

"Judicial activism" involving drugs without MA has **also hit healthcare insurers**. Recent case law surpasses limitations imposed by regulations and insurance policies.

Available shortcuts

Signing PDP agreements with the government

PDPs are partnerships between a government owned pharmaceutical industry and private companies (per se or consortium).

The goal is to enable the manufacturing of pharmaceutical products (small molecule drugs, biological products or medical devices) considered strategic for the SUS.

The company agrees to transfer the manufacturing technology to the government. In exchange, it becomes the **MoH's product supplier** to address SUS' needs for a **5 to 10-year** term (exclusive or non-exclusive basis).

MA is not required for signing a PDP agreement. It can be obtained at a later stage (required for the first sale).

The **government is now reviewing** the PDP program. Several of the 86 PDPs in force can be cancelled. The government is yet to issue the new list of strategic products for 2017.

No Marketing Authorization (MA) is granted directly to foreign companies

ANVISA's MA is required to sell drugs in Brazil

A Brazilian Pharma Subsidiary from Scratch (corporate aspects)

Choice of corporate type: wholly controlled subsidiary (ltda.) or multiple investor corporation (S.A.). Minimum 2 shareholders	Foreign investors should appoint attorneys-in-fact (Brazilian permanent resident); obtain Federal Taxpayer Roll (CNPJ or CPF) and Central Bank Enrollment (CADEMP/BACEN)	Drafting of articles of association (ltda.) or bylaws (S.A.): choice of appropriate headquarters (local zoning rules); appointment of officers (Brazilian permanent resident); initial capitalization rules (no minimum capital requirement)	Enrolling Company with Federal, State and Municipal Tax Authorities (CNPJ/IE/IM); local license to operate (alvará); worker's severance fund (FGTS) and social security (INSS)	Opening bank account and registering foreign investment with the Brazilian Central Bank	If importing goods: application for an import license (SISCOMEX/RADAR)

No preexisting restrictions of time or amount for remittance of dividends abroad.

Not all steps are a pre-condition to the next

Regulatory steps take approximately 18 months

A Brazilian Pharma Subsidiary from Scratch (regulatory aspects)

Appointment of a responsible pharmacist and enrollment of the company with the State Pharmacy Council (CRF).	Clearance of Fire Department and Environmental Licensing (where applicable).	Enrollment with ANVISA: establishing the size of the company, based upon earnings.	Application for a Local Sanitary License (physical inspection is mandatory), which may require a quality control lab and warehouse when applicable.	Application for ANVISA's Operating License (AFE).	Application for ANVISA's GMP Certificate (CBPF). See special rules for medical devices (MDSAP).	Application for ANVISA's MA.	Application for the product's price (CMED).

Available shortcuts

Investing in a fully operational local company or acquiring authorized pharmaceutical product

Acquisition of a 100% or majority stake in a ltda. (majority quorum of 75%) or S.A. (majority quorum of 50%+1); negotiation of shareholders' agreement with management and capitalization rules.

- Skips the regulatory steps directly to the submission of the MA application;
- The remittance of dividends is not subject to withholding taxes.

Distribution agreements with local companies holding GMP Certificate for Storage and Distribution and importing license

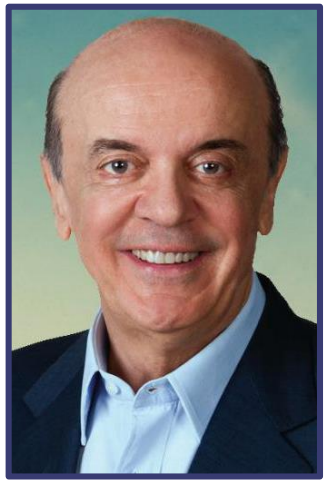
- Skips the regulatory steps directly to the submission of the MA application;
- tax effects should be carefully evaluated.

ANVISA's **updated guidelines** regarding **transfer of marketing authorization**, operation licenses and GMP Certificates arising from equity-based deals now also applicable to business transactions.

Important note: technical and sanitary conditions and characteristics of the companies and products must remain unchanged.

A shift in power after 14 years of Worker's Party (PT) Rule

New faces on the administration



José Serra is Temer's Minister of Foreign Affairs/Secretary of State.

He was Minister of Health from 1998 to 2002 and sponsored the Generic Drugs Act of 1999 and introduced the 229-C article of the Patent Statute (ANVISA's prior approval)

Marcos Pereira was appointed **Minister of Industry** by President Temer on the same day he took over as Interim President.

Luiz Otávio Pimentel is the President of the Brazilian Patent and Trademark Office (BRPTO). He was appointed by Dilma Rousseff on July 28th, 2015.

There are talks of changes in the BRPTO and in the pharmaceutical patent system:

The BRPTO is about to sign an agreement with ANVISA to address the controversy over ANVISA's authority to deny the prior approval of patent applications under article 229-C (prior approval of patent applications).

BRPTO's New guideline for pharmaceutical patent applications should be open for public consultation in early 2017.

BRPTO's Normative Instruction 01/07 establishes that the request for prioritized examination shall be analyzed 24 months after the application filing date. **The BRPTO is wrongly considering the National Phase entry date as the application filling date**.

Efforts to improve the patent system

PPH and BRPTO's new organizational structure

Brazil signed its first PPH program with the US in Nov. 2015. It was launched in Jan. 2016 (Rule 154/2015).

The program has **a two-year term** (until January 10th, 2018), and it's scope is limited to **oil and gas** applications filed from 2013 and limited to a maximum of 150 applications.

Only 20 patent applications have been accepted in the program and 5 have been granted by the BRPTO.

On September 23rd president Temer issued **Decree #8,854 restructuring the BRPTO** reducing intermediate management positions, eliminating two Director positions and opening the Executive Officer position.

License and technology transfer agreements are now directly under the supervision of the **BRPTO's Presidency**.

Registration and granting of intellectual property rights that were carried out by the eliminated directors will now be relocated to the **directors of trademarks and patents**.

Function of recording computer programs and topography of integrated circuits, is now a responsibility of the **Patent Board Director**.

Industrial Designs and Geographical Indications, is now overseen by the **Trademark Director**.

Avoiding pitfalls: Limitations raised from the filing of the Request for examination

According to Article 32 of the Patent Statute, the applicant may voluntarily submit amendments until the request for examination, provided that they are limited to the subject matter **initially disclosed in the application**.

The BRPTO's Rule #93/2013 establishes that amendments to claims, voluntarily submitted after the request for examination of the application or resulting from technical examination, will not be accepted if implicates on the "broadening of the protection scope of claims".

According to Article 26 of the Patent Statute, a patent application may, **until the end of examination**, be divided, ex officio or on request of the applicant, into two or more applications, provided that the divisional application (1) makes specific reference to the original application and (2) does not exceed the matter disclosed in the original application.

The BRPTO's Rule #93/2013 establishes that the claim chart of a divisional application must be restricted to the subject matter of the parent application as claimed before the request for examination.

Diagnostic and Therapeutic Methods

Diagnostic or therapeutic methods, for use on the human or animal body **are not considered inventions** (Art. 10, item VIII of the Patent Statute)

Therapeutic Methods: Although Therapeutic Methods are not acceptable, second medical use may be protected with Swiss-type claims.

Swiss-type claim:

> *"Use of a compound X for the manufacture of a medicament for treatment of the disease Z"*

Diagnostic Methods: *In vitro* tests, using blood samples or other body samples, are acceptable since they are not applied to the animal or human body and do not conclude the clinical state of the patient.

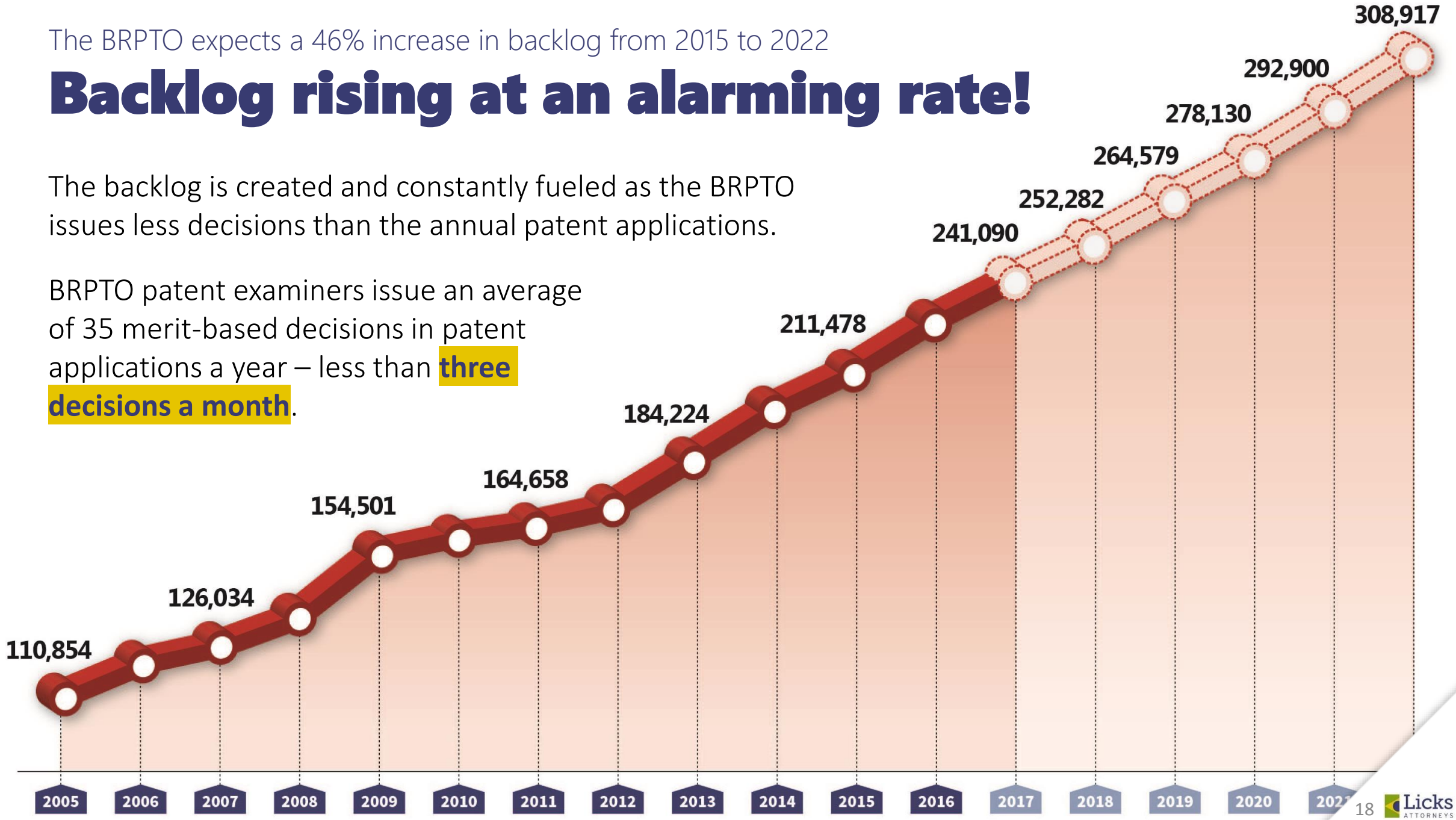
Dosage Regimen: Although there is no bar in the Patent Statute against of such type of claim, and no reference is made in the BRPTO's guidelines, the BRPTO rejects it based on the provisions of Article 10 (VIII) of the Patent Statute.

The BRPTO expects a 46% increase in backlog from 2015 to 2022

Backlog rising at an alarming rate!

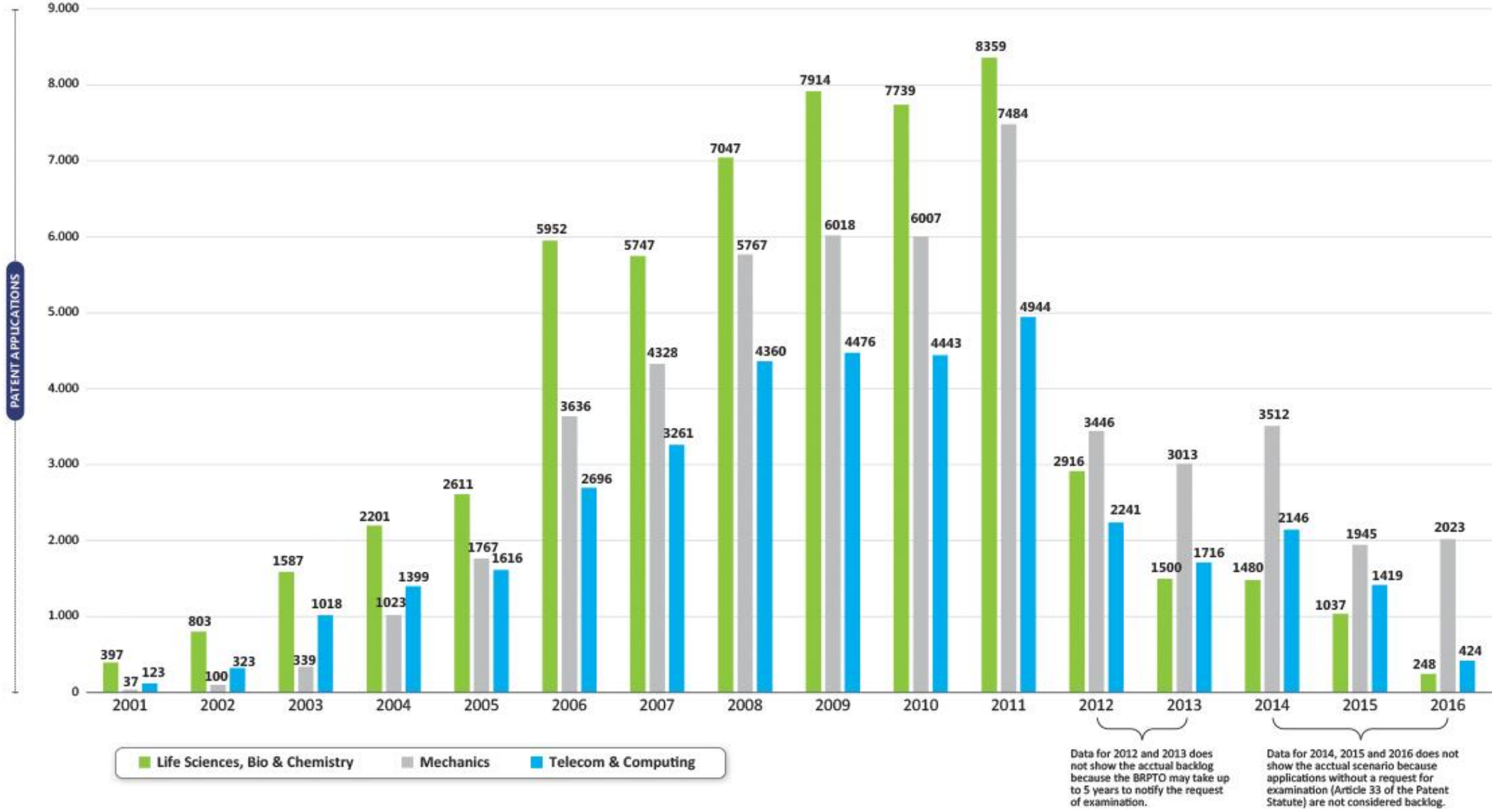
The backlog is created and constantly fueled as the BRPTO issues less decisions than the annual patent applications.

BRPTO patent examiners issue an average of 35 merit-based decisions in patent applications a year – less than **three decisions a month**.



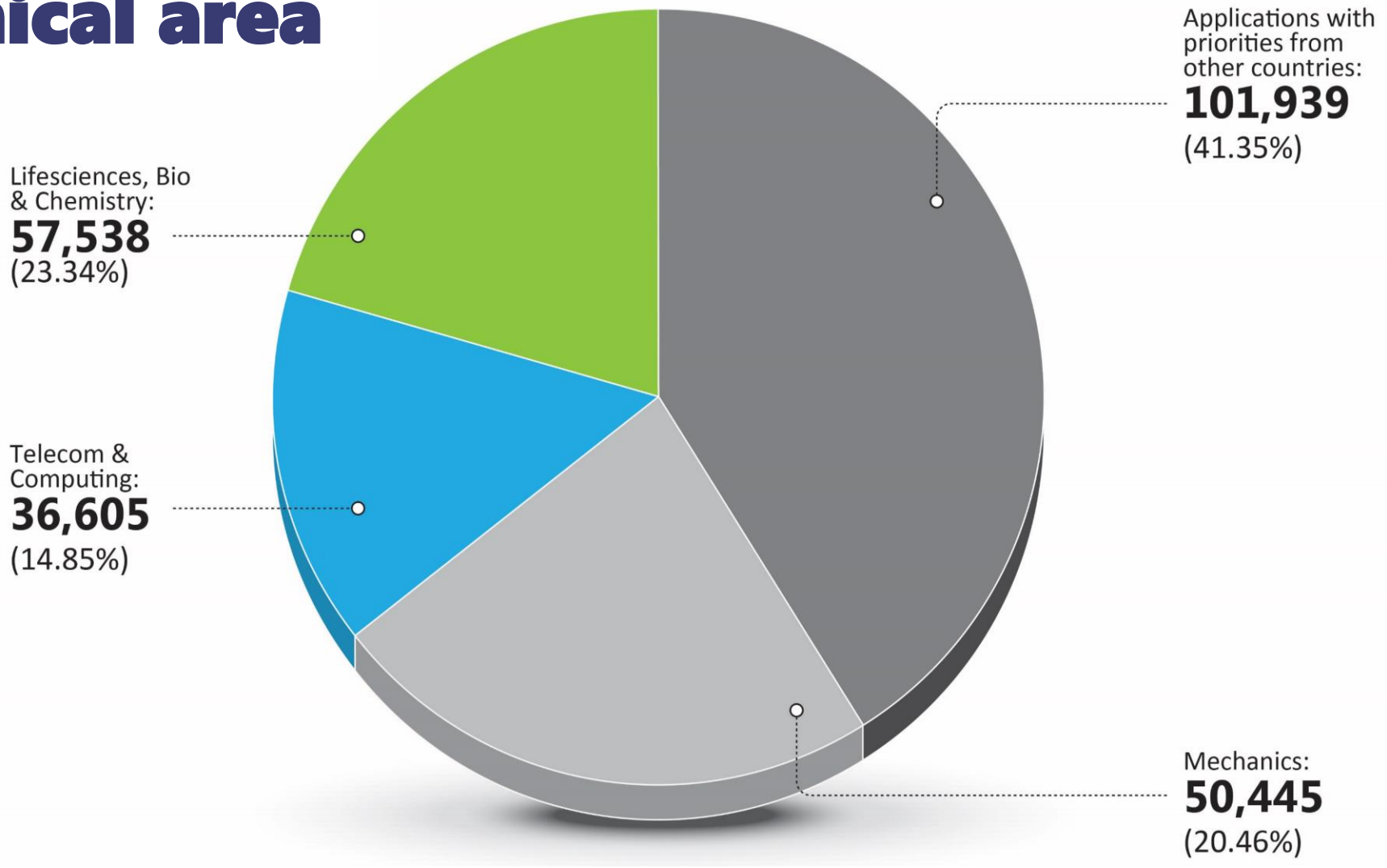
Applications having CN, FR, DE, GB, JP KR and US priorities filed between 2001 and 2016

Backlog of patent applications by technical area



Applications having CN, FR, DE, GB, JP, KR and US priorities filed between 2001 and 2016

Backlog of patent applications by technical area



BRPTO creates working groups to discuss the programs with the EPO and the JPO

Moving towards new pilot PPH programs

The BRPTO is moving forward with new pilot PPH programs with the EPO and the JPO.

On October 6th, 2016 Brazil signed a cooperation agreement with Japan for the creation of a working group to discuss a future pilot PPH program.

The first meeting was held on November 10th in Brazil and **our firm hosted JPO's delegation on the 11th to discuss the project for the Brazil-Japan PPH.**

On October 17th 2016, Brazil signed a statement with the EU to start the discussion on future implementation of a pilot PPH program.

The National Confederation of Industry (CNI) has shown support to future negotiations with the German Patent Office (DPMA) to reach a similar agreement.

BRPTO set of rules for prioritized examination

A Not-So-Fast Track for patent prosecution

The BRPTO has 4 rules currently in force for prioritized examination of patent applications.

Rule 80 of 2013	Rule 123 of 2013	Rule 151 of 2015	Rule 154 of 2015
Prioritized examination of applications related to the diagnosis, prevention or treatment of HIV-AIDS, cancer or neglected diseases.	Applications first filed in Brazil are eligible for a preliminar opinion (similar to PCT's WOISA)	Prioritized examination in specific circumstances, such as: (i) if subject matter has been declared relevant for national emergency or public interest, (ii) if a third party's application claims the same subject matter (iii) in case of infringement of the pending patent application.	Limited PPH for US oil and gas applications filed in Brazil from January 1st 2013.

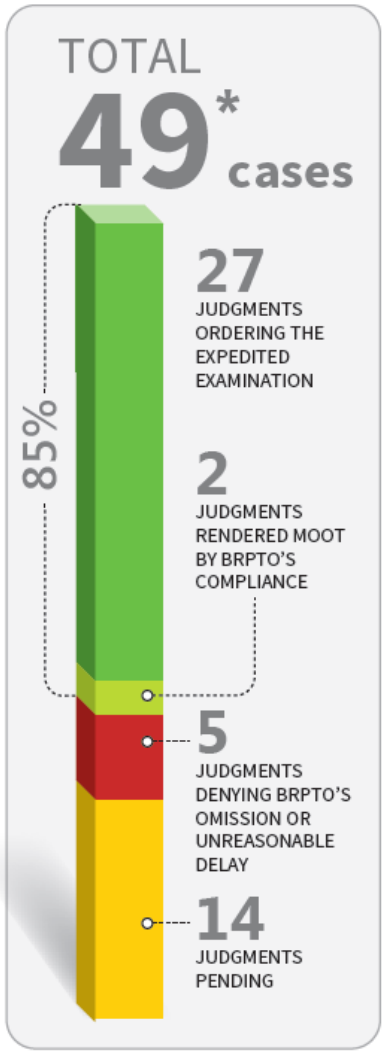
Prioritized examination average processing time

Better than nothing, but **not so fast.**

The BRPTO takes **on average 22 months to grant or reject a patent application** under these Rules.

Getting the job done

Judicially induced Fast-track prosecution



Due to BRPTO's backlog and pendency it is becoming common to seek expedited examination before Courts.

Most judgments rendered to this date have been **favorable** to the applicants.

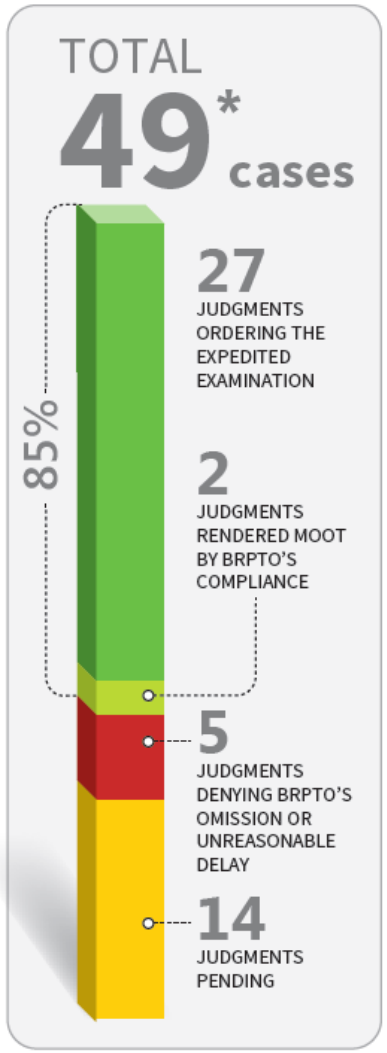
In **85% of the cases the judges ordered the BRPTO to render a merit-based decision within a 30 to 60 days term**.

Even though there are few decisions granting preliminary injunctions, **the procedure is faster than the prioritized examination obtained under the BRPTO rules**.

The average time for the trial court to render a judgment is of approx. six months.

Getting the job done

Judicially induced Fast-track prosecution



9th
Federal District Court of Rio de Janeiro

JUDGES:
Hon. Ana Amelia Silveira Moreira Antoun Neto [2 | 0]. Assisted by Hon. Mariza Pimenta Bueno [1 | 0] and Hon. Daniela Pereira Madeira [1 | 0]

PATENTS: 1 1
TRADEMARKS: 4 3

TOTAL CASES BEFORE THE COURT: 9

25th
Federal District Court of Rio de Janeiro

JUDGES:
Hon. Eduardo André Brandão [6 | 0] and **Hon. Guilherme Bollorini** [1 | 0]. Assisted by Hon. Luciana Cunha Villar [1 | 0]

PATENTS: 1 1
TRADEMARKS: 7 1

TOTAL CASES BEFORE THE COURT: 10

13th
Federal District Court of Rio de Janeiro

JUDGE:
Hon. Marcia Maria Nunes de Barros [7 | 4]

PATENTS: 2 1 2
TRADEMARKS: 5 3 3

TOTAL CASES BEFORE THE COURT: 16

31st
Federal District Court of Rio de Janeiro

JUDGES:
Hon. Marcelo Leonardo Tavares [2 | 0]. Assisted by Hon. Caroline Somesom Tauk [5 | 1] and Hon. Marcio Solter [1 | 0]

PATENTS: 1
TRADEMARKS: 8 1 3

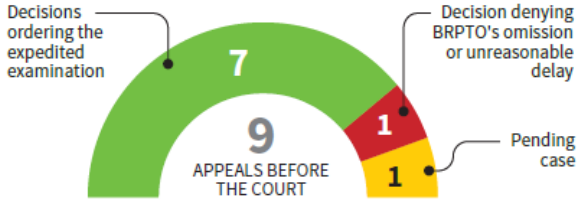
TOTAL CASES BEFORE THE COURT: 13**

*One case is pending judgment before the 9th Federal District Court of Sao Paulo.

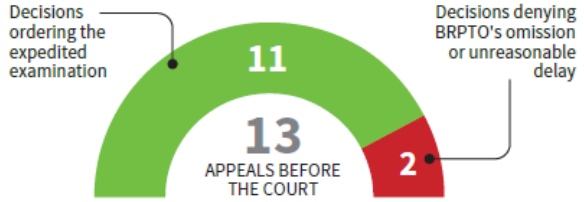
**Includes the case filed by Floatec against the BRPTO seeking the copies of a post-grant review proceeding.

Federal Court of Appels

1ST SPECIALIZED PANEL



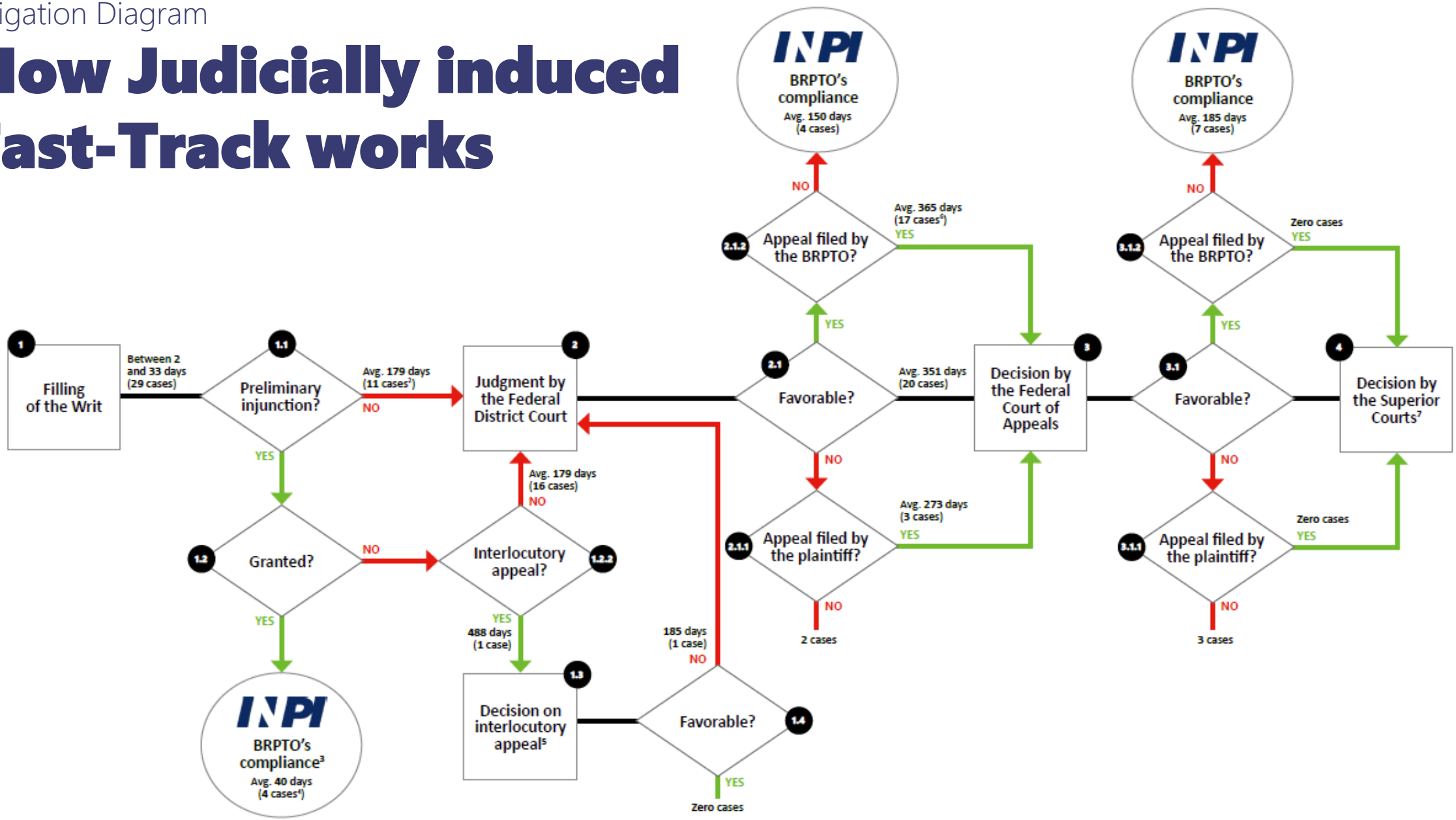
2ND SPECIALIZED PANEL



- **Judgments ordering the expedited examination**
- **Judgments rendered moot by BRPTO's compliance**
- **Judgments denying BRPTO's omission or unreasonable delay**
- **Judgments pending**

Litigation Diagram

How Judicially induced Fast-Track works



Challenging administrative decisions from the government and its agencies

Judicial review of BRPTO's decisions

Brazil adopts a broad judicial review of administrative decisions and the Government is by far the most frequent defendant in Brazil.

Judicial review is so common that Brazil has a special court system mainly to decide such cases, called **Federal Courts.**

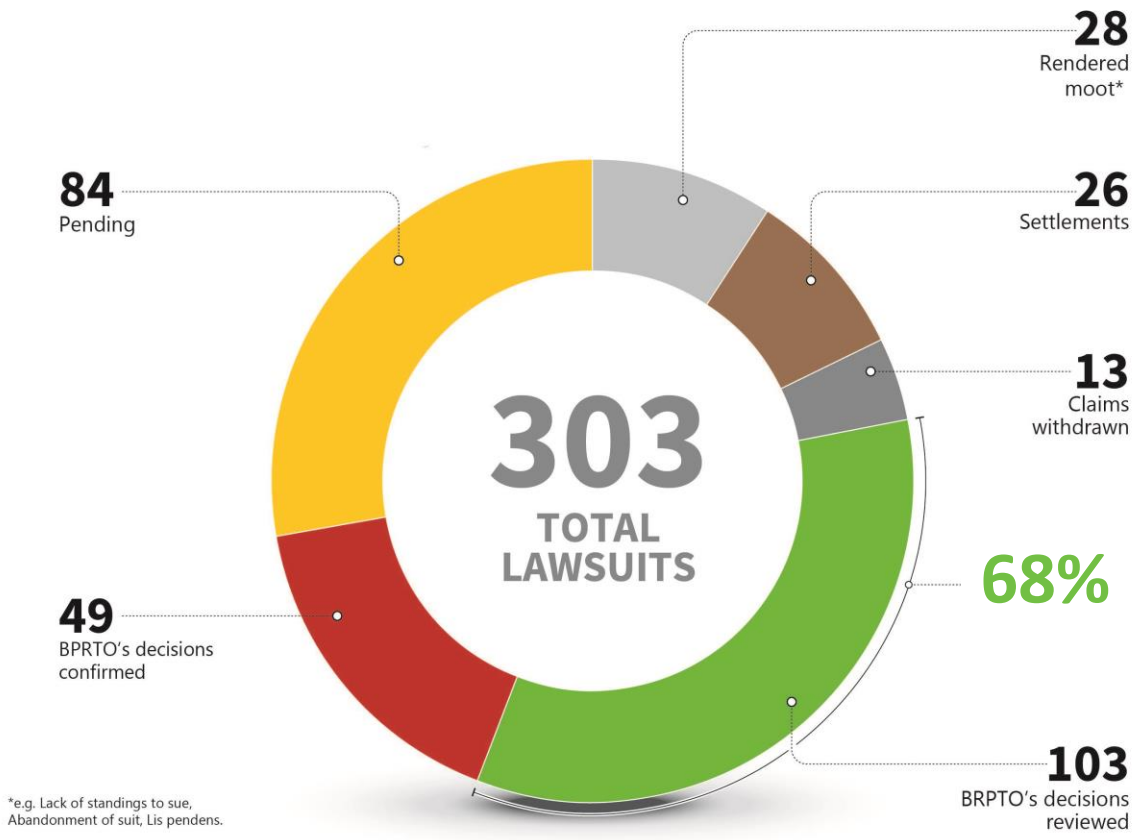
All decisions rendered by government entities such as the BRPTO are challengeable before Brazilian courts.

Brazilian federal judges review whether administrative decision and procedures followed **due process;**

The Court also reviews if the decisions complied with **formal requirements** and if they agree with the government entity on the **interpretation of the law.**

Challenging administrative decisions from the government and its agencies

Judicial review of BRPTO's decisions



There is no special deference to the BRPTO.

The judges always appoint an unbiased court expert to assist the court, and usually adhere to the expert's conclusions in the judgment.

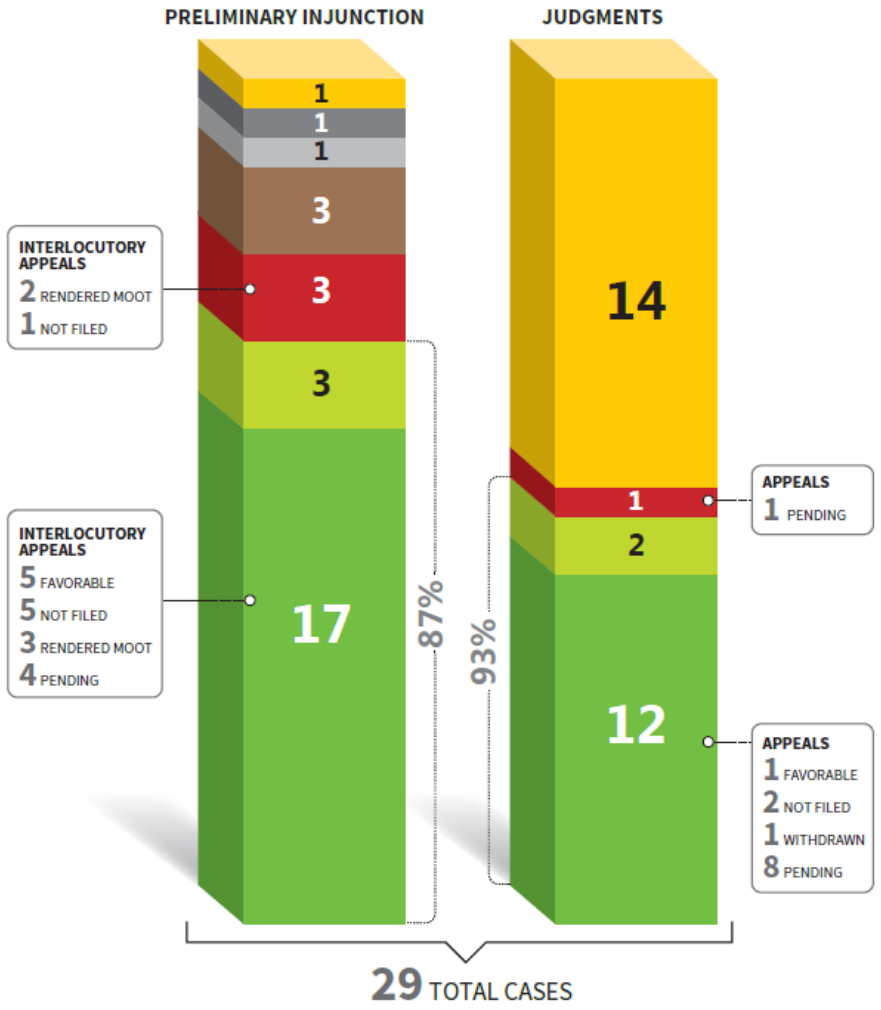
During judicial review it is possible to present new arguments and evidence that were not addressed at the administrative procedure.

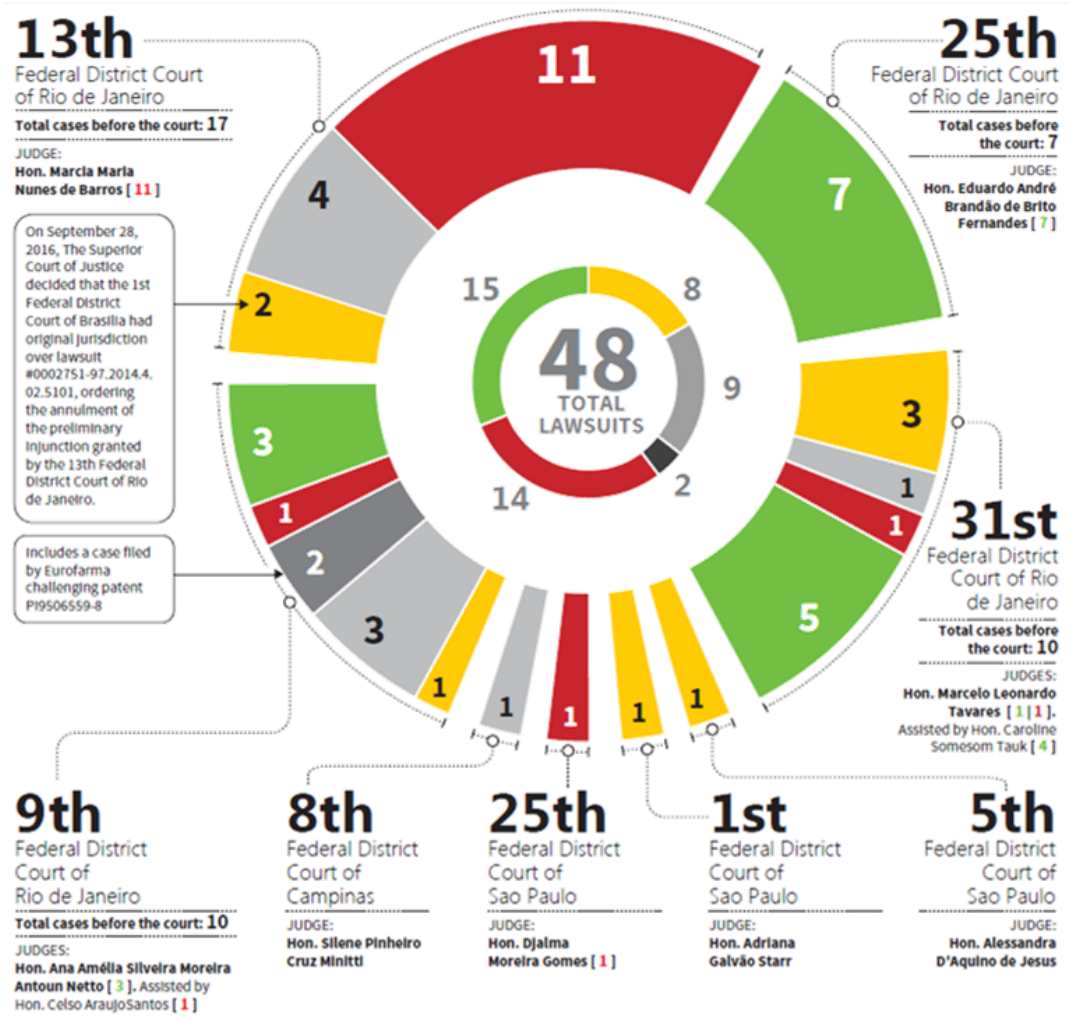
Lawsuits seeking to overcome the BRPTO final rejection of patent applications are **successful in 48% of the cases**.

68% of the judgments in cases filed in the last 11 years **reversed the BRPTO's grant of a patent.**

Administrative decisions are only final after judicial review

ANVISA's Prior Approval and Mailbox litigation





Licks
ATTORNEYS

Thank you!

Otto Licks
otto.licks@lickslegal.com
T +55-21-3550-3702
M +55-21-99792-5232