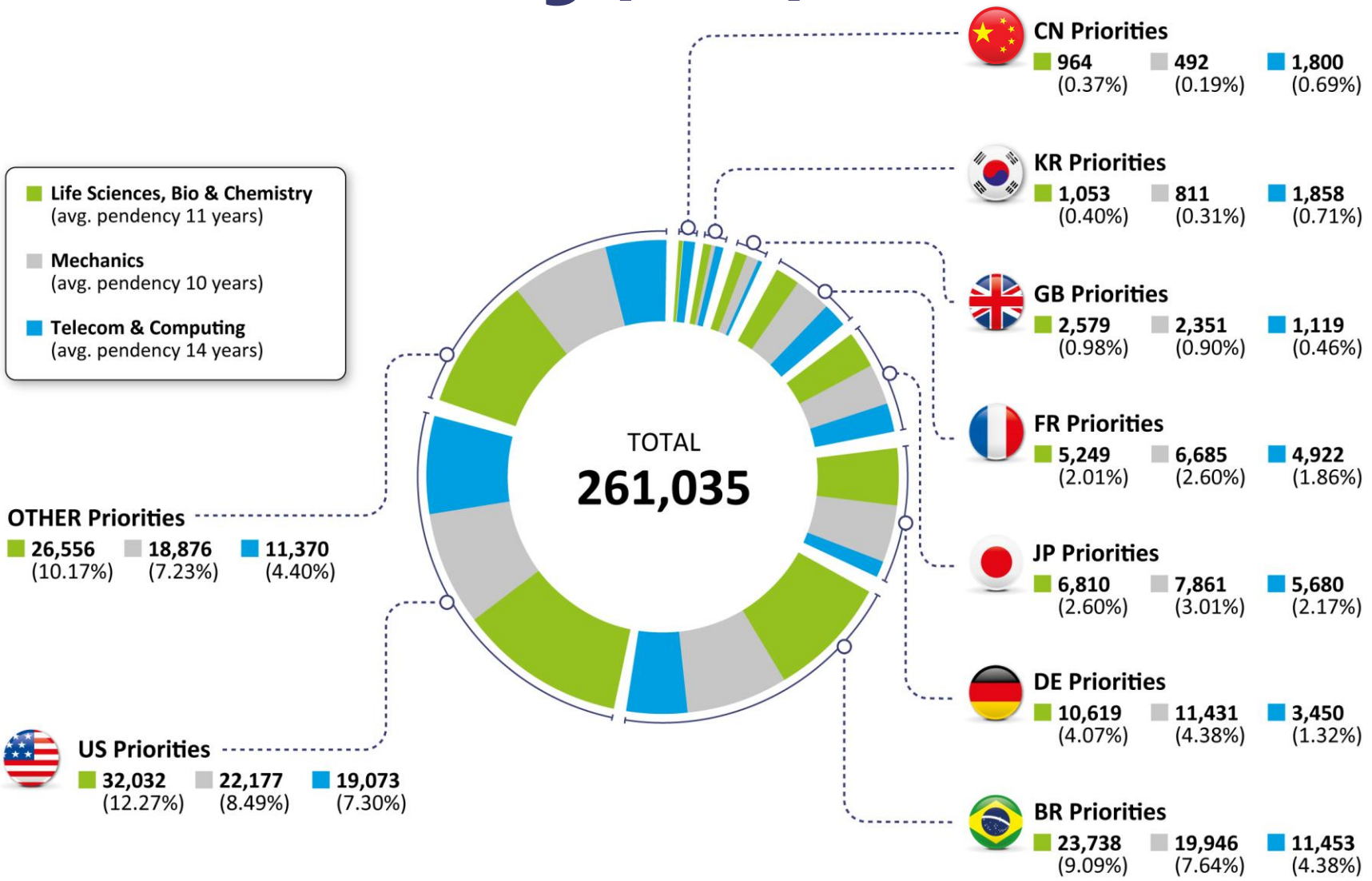
Licks
ATTORNEYS

# II Seminário sobre Propriedade Intelectual

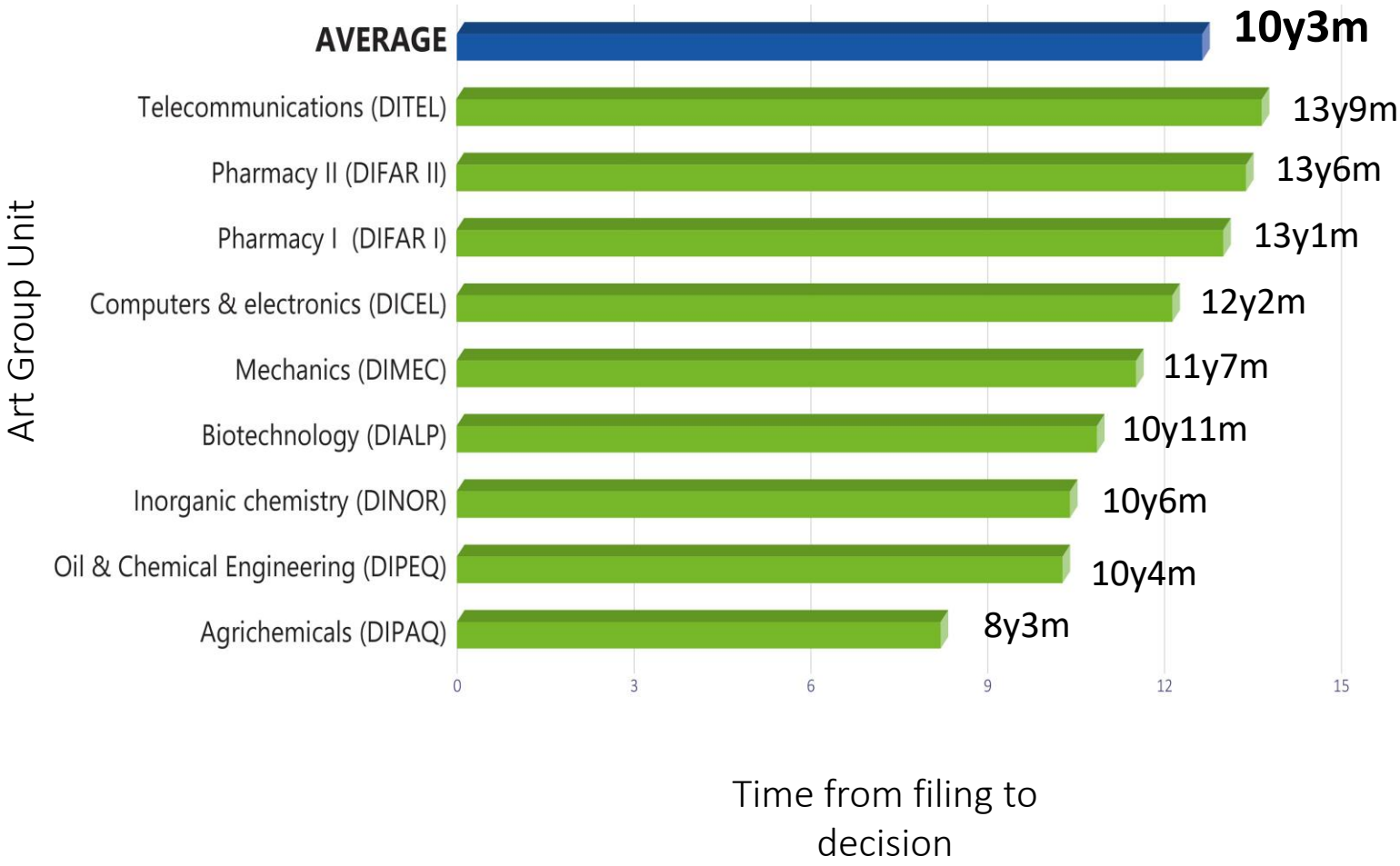
May 8th, 2018

# BRPTO's backlog (2017)



# BRPTO's pendency by division (2018)

## Over 13 years



# Administrative fast-track programs

Average pendency time for an application is of more than 10 years. Examination can be expedited at BRPTO through different programs, such as:

| Rule #217/2018 | Rule #151/2015 | Rule #175/2016 |
|---|---|---|
| Applications related to diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer, (pre-defined) neglected diseases or rare diseases | (i) if a third-party's application claims the same subject matter;<br>(ii) in case of infringement of the pending patent application. | Applications covering environmentally friendly technologies of alternative energy, transportation, energy conservation, waste management and agriculture, based but not limited to the WIPO's IPC Green Inventory. |

# Patent Prosecution Highway

## Current programs

| USPTO (Rule #154/2015) | JPO (Rule #184/2017) | EPO (Rule #202/2017) | PROSUR (Official Notice #224/MDIC) | SIPO (Rule #209/2018) |
|---|---|---|---|---|
| Oil, gas and petrochemical technologies classified under specific IPCs. | IT technologies classified under specific IPCs. | Chemistry field or related to technologies applied to medicine*, classified under specific IPCs. | Not limited to a specific technical field. Not limited to specific IPCs**. | Chemical, measurement, packaging and IT fields*, classified under specific IPCs. |
| 2-year term has been extended. It will close on May 10th, 2018) and limited to 150 applications. | 2-year term (until March 31st, 2019) limited to 200 applications. | 2-year term (until November 31st, 2019) and limited to 300 applications per year. | 1-year term (until June 31st, 2019). | 2-year term (until January 31st, 2020) and limited to 200 applications, of which 20 can be Mottainai requests |

- *Drug-related applications are not eligible
- ** AR, BR, CL, CO, CR, EQ, PY, PE or UY priority

# Patent Prosecution Highway

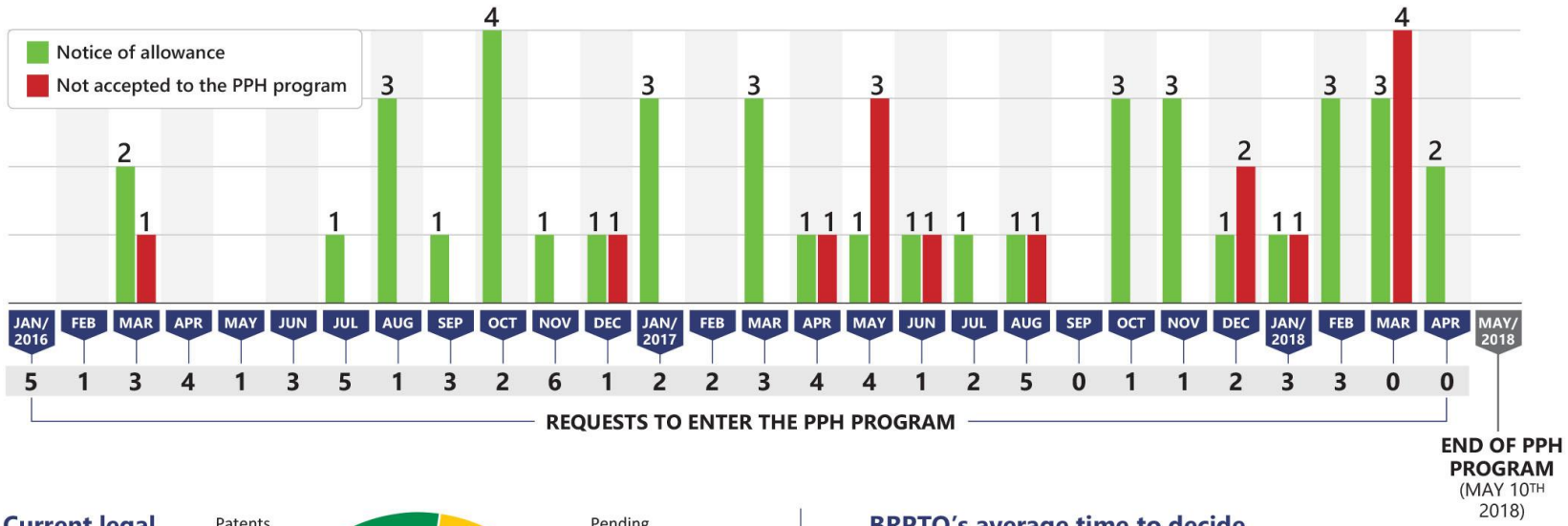
## Comparing PPH INPI –USPTO Phases I and II

| Rule #154/2015<br>In force up to May 10, 2018 | Rule#218/2018 (published today)<br>In force from May 10, 2018 to<br>April 30, 2020 |
|---|---|
| Oil, gas and petrochemical technologies and classified under specific IPCs. | Oil, gas and petrochemical technologies and classified under specific IPCs (comprising additional IPCs),<br>and<br>IT technologies and classified under specific IPCs. |
| limited to 150 applications. | limited to 200 applications, of which 50 can use results from PCT to apply for the program. 1 request per month per applicant. |

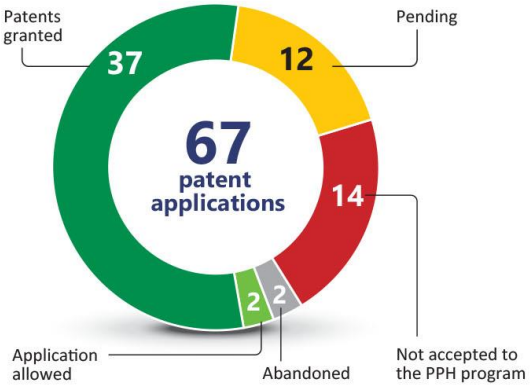
# PPH BRPTO – USPTO

## Only 67 requests and 39 allowed since December 2015

**# of PPH requests notifield by the the BRPTO per month**




**Current legal status of PPH patent applications**

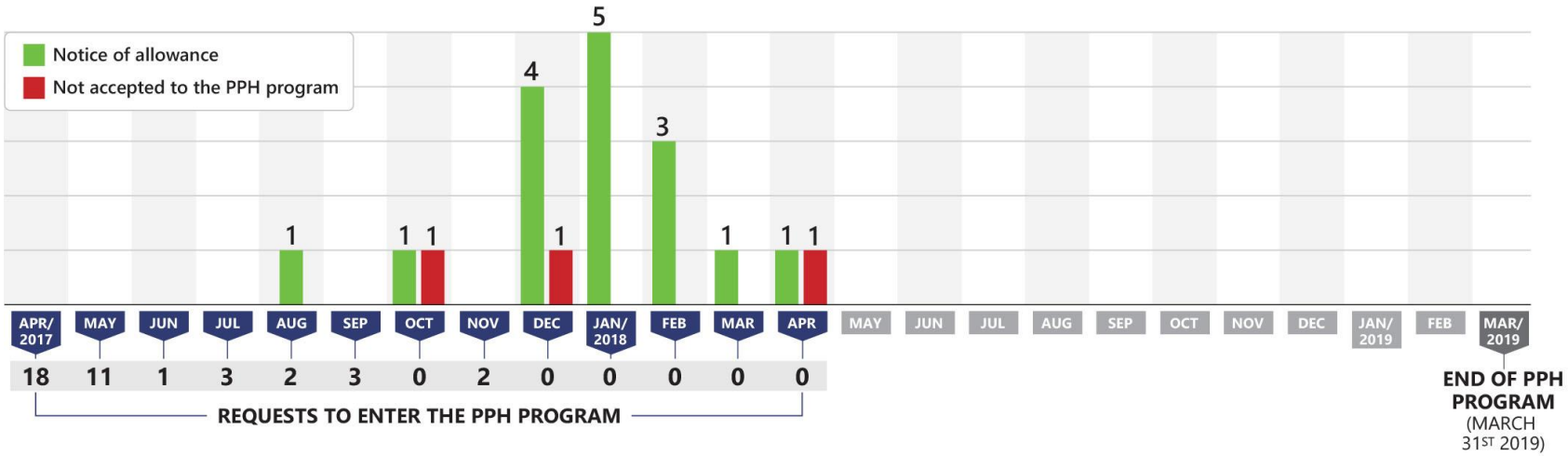



**BRPTO's average time to decide on PPH patent applications**

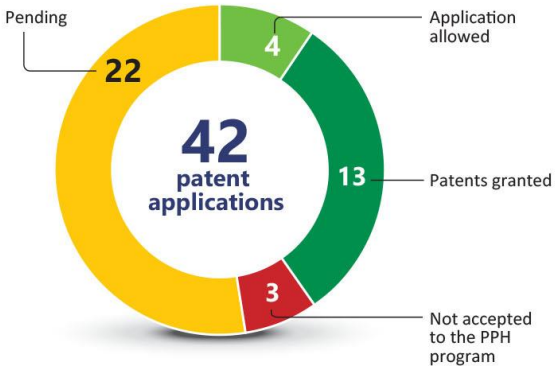
# PPH BRPTO – JPO

## Only **42** requests and **17** allowed since April 2017

**# of PPH requests notifield by the the BRPTO per month**




**Current legal status of PPH patent applications**

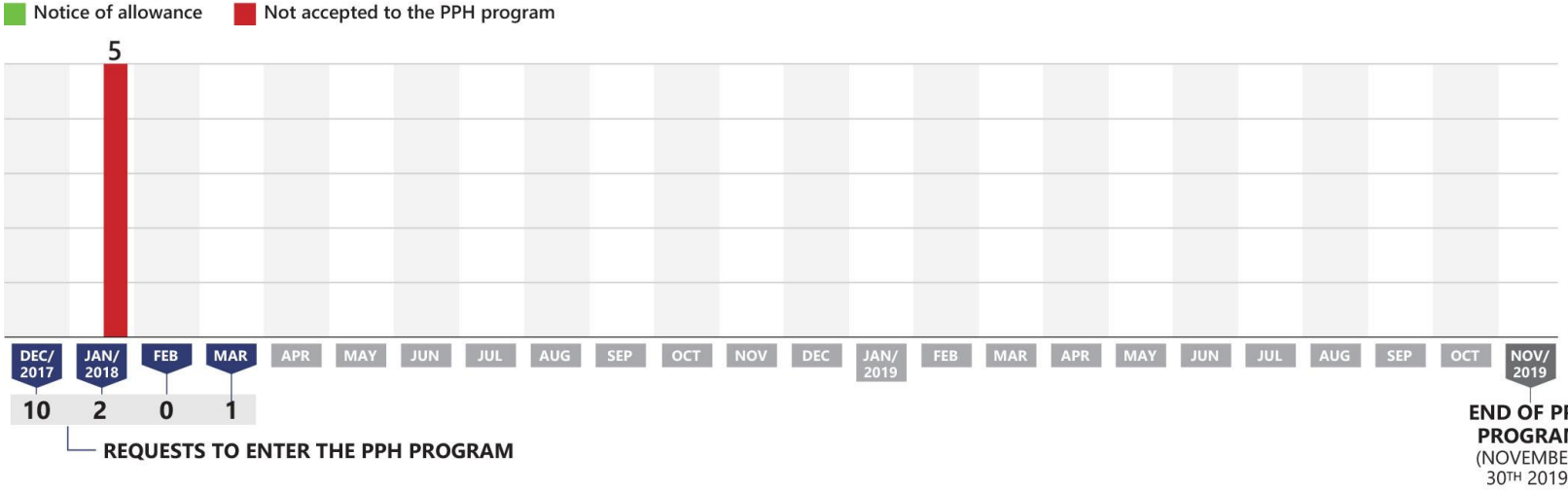



**BRPTO's average time to decide on PPH patent applications**

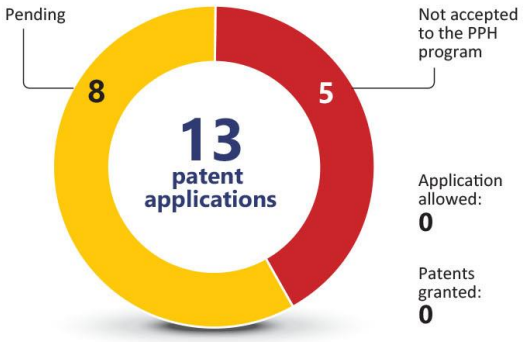
# PPH BRPTO – EPO

## Only 13 requests and 0 allowed since December 2017

### # of PPH requests notifield by the the BRPTO per month




### Current legal status of PPH patent applications

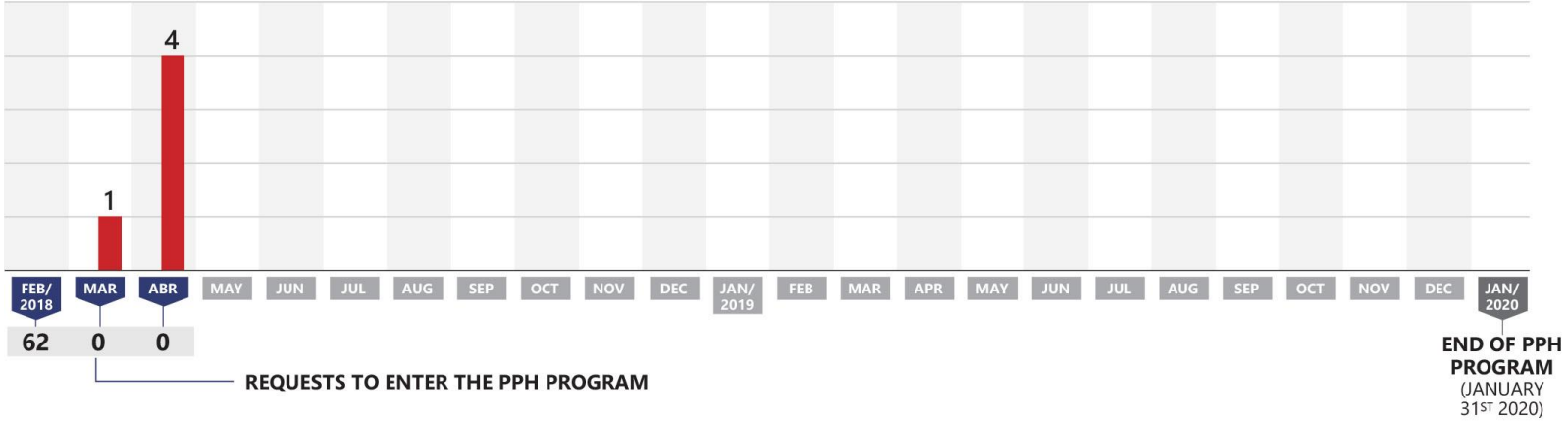



### BRPTO's average time to decide on PPH patent applications

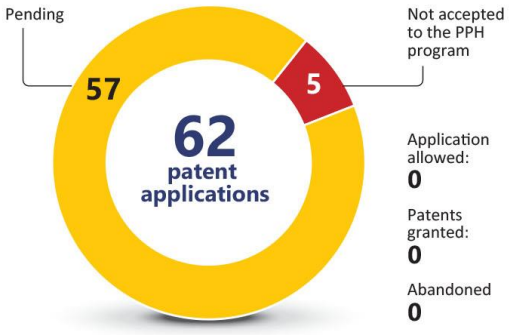
# PPH BRPTO – SIPO

## Only 62 requests and 0 allowed since February 2018

### # of PPH requests notifield by the the BRPTO per month



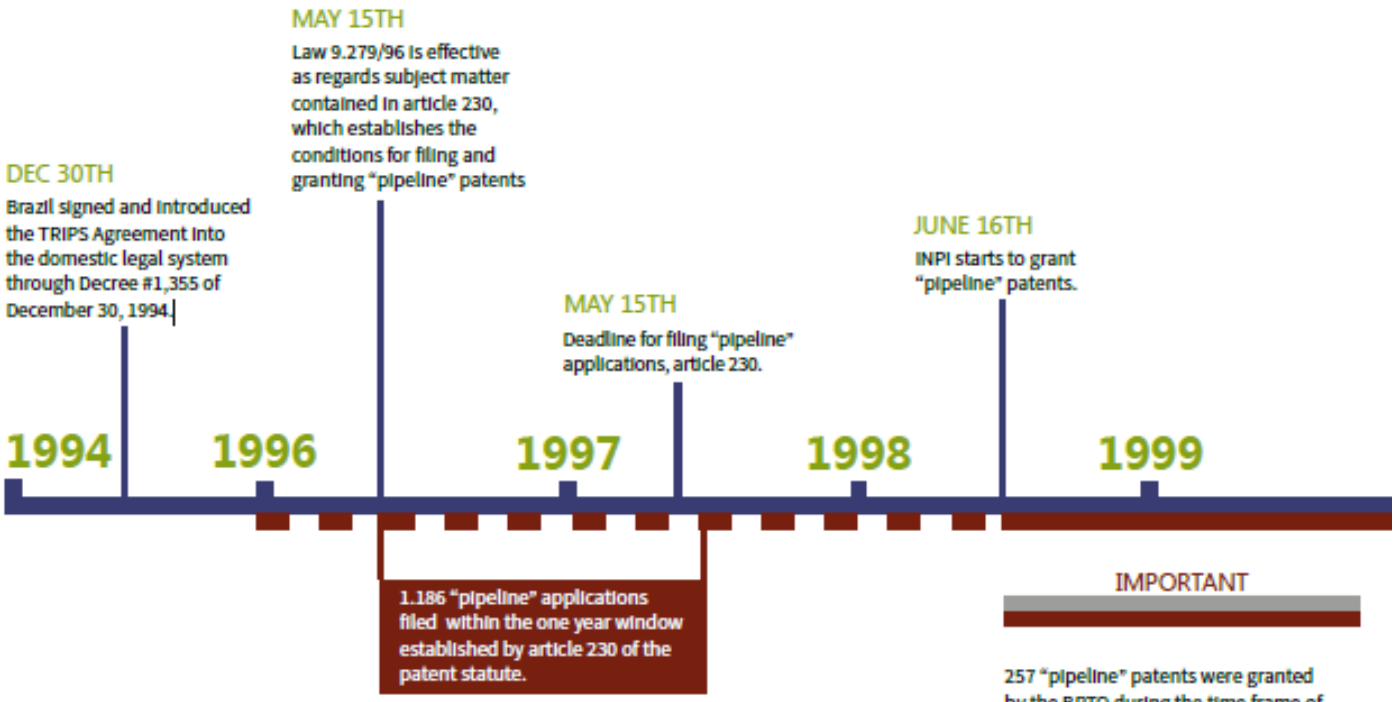

### Current legal status of PPH patent applications




### BRPTO's average time to decide on PPH patent applications

# ANVISA's Prior Approval

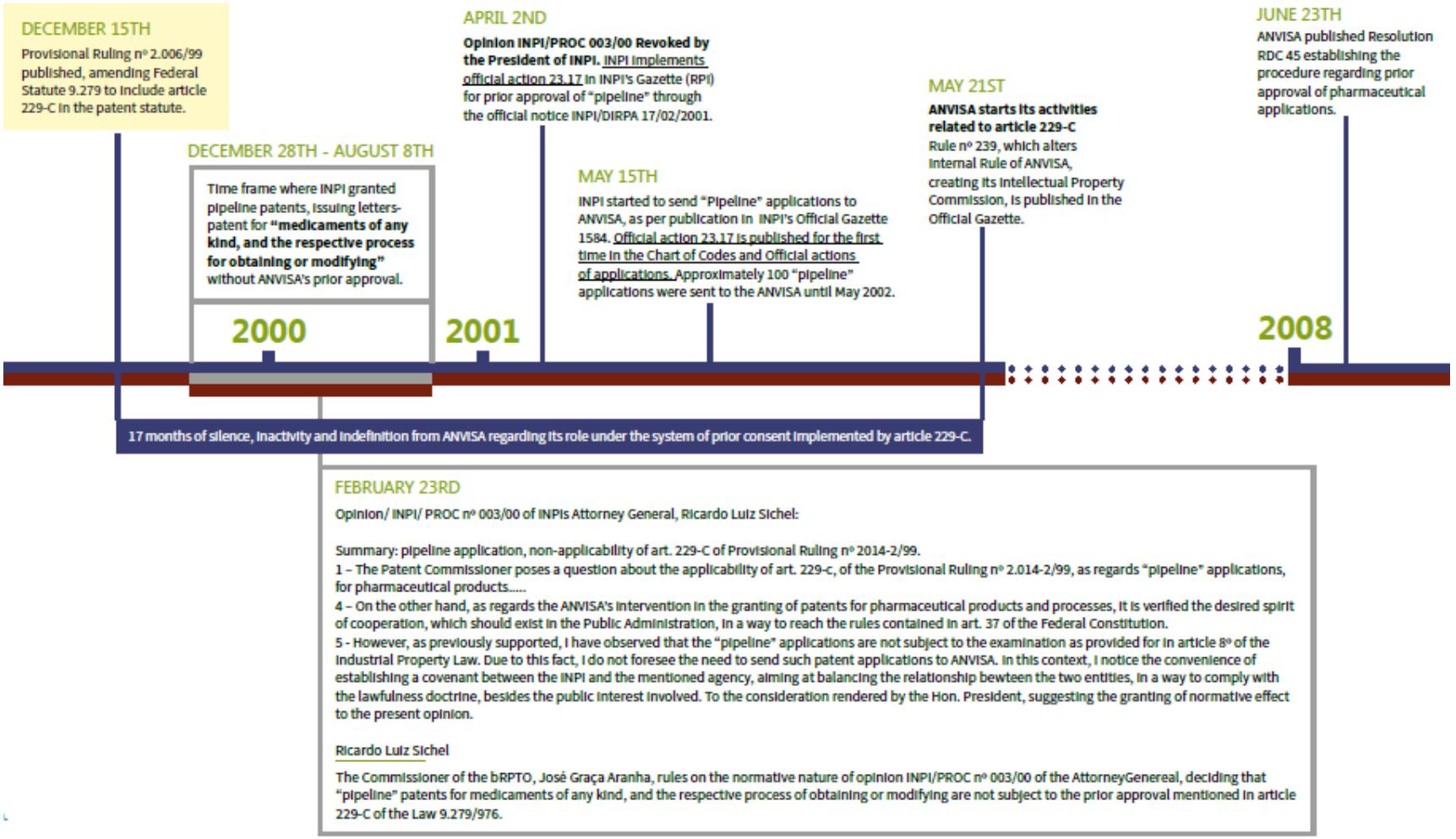
# ANVISA's prior approval:
## the early days




IMPORTANT

257 "pipeline" patents were granted by the BPTO during the time frame of 12/28/1999 until 08/08/2000. Besides the "pipeline" patents subject to ANVISA's prior approval system, in the same Official Gazettes, the BPTO also granted "pipeline" patents for the other three technologies contained in article 230 of the Law 9.279/96. Thus, all granted "pipeline" patents, that do not have as object medicaments of any kind, and the respective process for obtaining or modifying, are not subject to article 229-C (such as the "pipelines" of EMBRAPA, or the oner that have as object inventions of chemical products). Among the 257 "pipeline" patents granted, few more than one hundred may be subject to ANVISA's prior approval system.

# ANVISA's prior approval:
## the early days



# ANVISA's prior approval:
## the early days

**On October 16, 2009** the Brazilian Attorney-General's Office (AGU) published opinion #210/PGF/AE/2009 limiting ANVISA's analysis and stating that it could not perform examination of patentability requirements.

**On January 7, 2011** this position was reiteraded in AGU's opinion #337/PGF/EA/2010.

**On May 24, 2012** the government published inter-ministerial Ordinance #1065 establishing the workflow between ANVISA and INPI regarding prior approval analysis.

**On April 15, 2013** ANVISA published RDC #21 amending RDC #45 establishing standards for the analysis under art. 229-C.

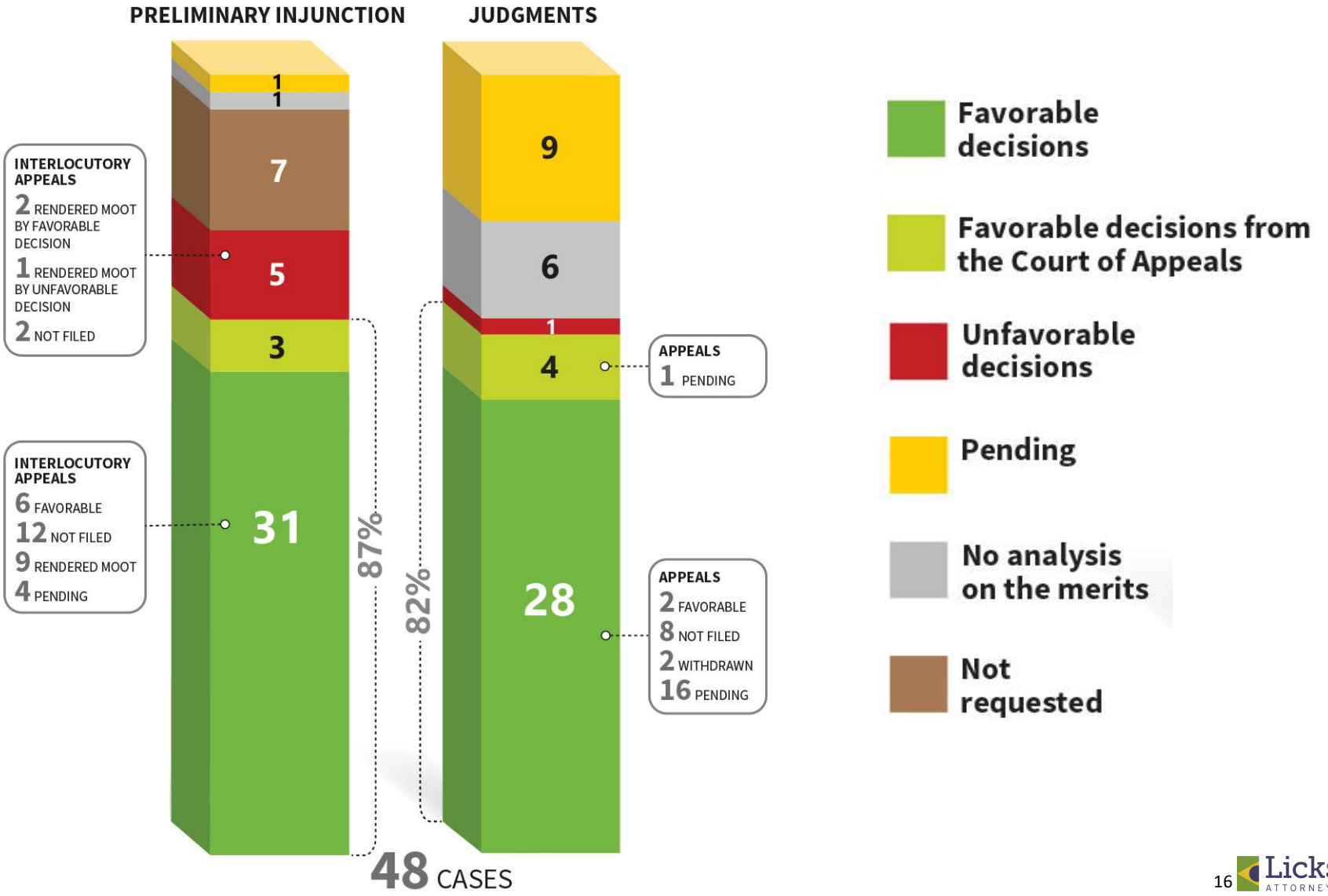
**On September 12, 2013** the Civil Class Action filed by the Federal Prosecutor's Office seeking the nullity of AGU's opinion #337/PGF/EA/2010 was rejected.

# Interfarma's class action

Interfarma sought to annul paragraph 1, item II and paragraph 3 of art. 4 of RDC #45/2008 (as amended by RDC #21/2013).

> ***Paragraph 1, item II*** *– "The patent application shall be considered against public health when: II - The patent application of pharmaceutical product or process is of interest to the public policies of access to medicines and pharmaceutical assistance of the Public Healthcare System (SUS) and does not meet patentability requirements and further criteria established by Patent Statute #9,279 of 1996".*
>
> ***Paragraph 3*** *– "The patent application for pharmaceutical product or process will be deemed as interest to the public policies of access to medicines and pharmaceutical assistance of the Public Healthcare System (SUS) when comprises, or results in, substance established in the Ordinances published by the Ministry of Health establishing the strategic products, for SUS, and your regular updates, as well as comprises, or results in, substance established to the therapeutic purpose listed in the mentioned Ordinances".*

# Prior approval litigation against ANVISA



# Interagency Ordinance #1/2017

On April 12th, 2017, BRPTO and ANVISA signed Interagency Ordinance #1/2017 establishing new procedures for the agencies interaction regarding the prior approval of patent applications under art. 229-C of the IP Statute. The new ordinance entered into force on June 12th, 2017.

Rule #168/2017, issued by ANVISA, establishes on art. 4 that after receiving the patent application, ANVISA will perform its examination in light of public health, through a decision in the technical opinion submitted by the assigned unit inside the Agency.

# Interagency Ordinance #1/2017

Art. 9 of Interagency Ordinance #1 has the potential to turn off the pharmaceutical patent system by creating an Interagency Policy Group between the agencies to “harmonize” construing and the application of the Brazilian patent law.

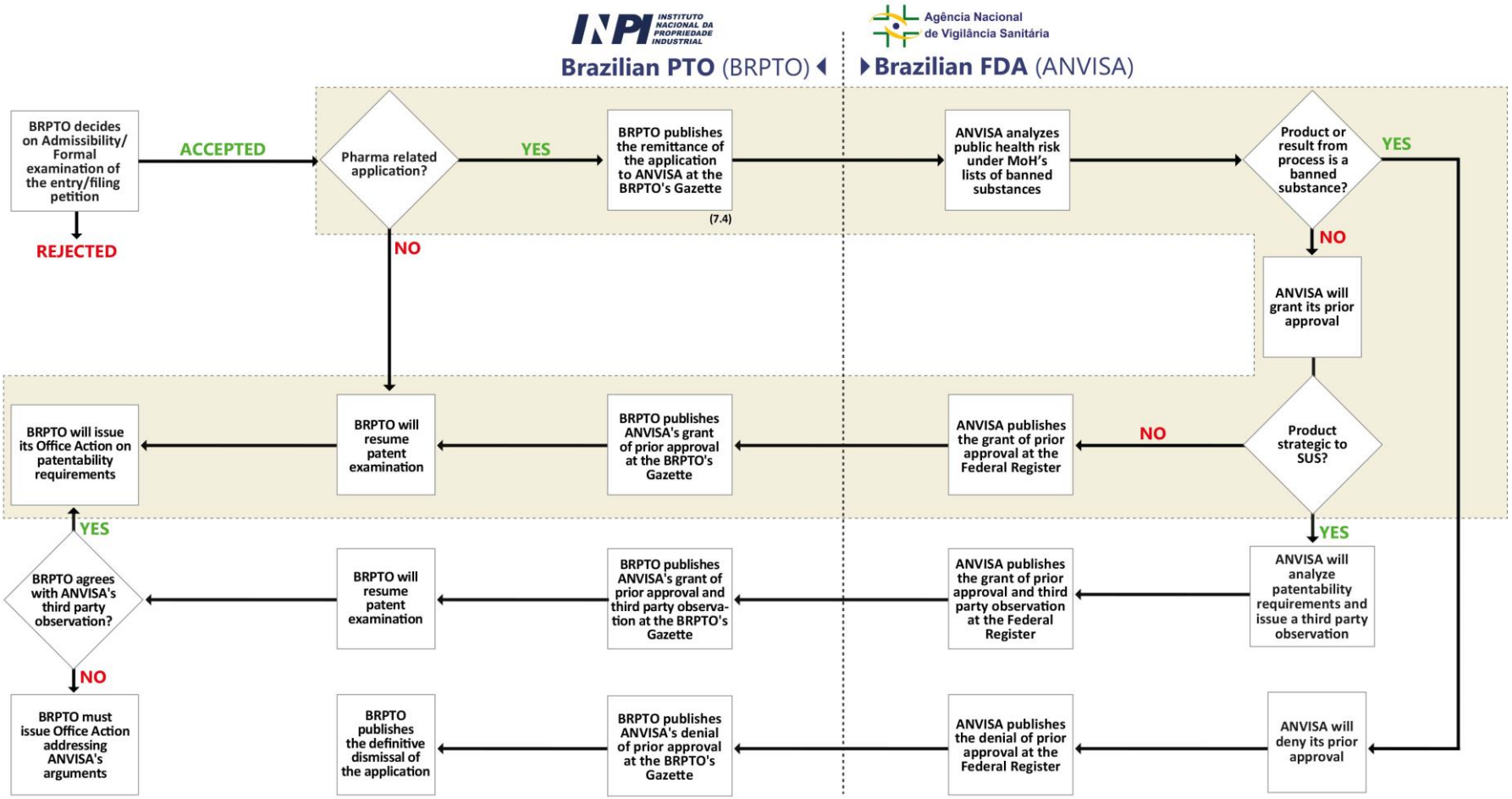
Within the Interagency Policy Group, BRPTO and ANVISA will discuss common understandings on the interpretation of patentability requirements.

Currently, the ANVISA performs a more strict analysis on the following subject matters, when compared to the BRPTO:

- Selection patents;
- Polymorphs, co-crystals and enantiomers;
- Prodrugs
- New uses

# Workflow

## ANVISA's prior approval and third-party observations proceedings



# Another class action filed by the FPO

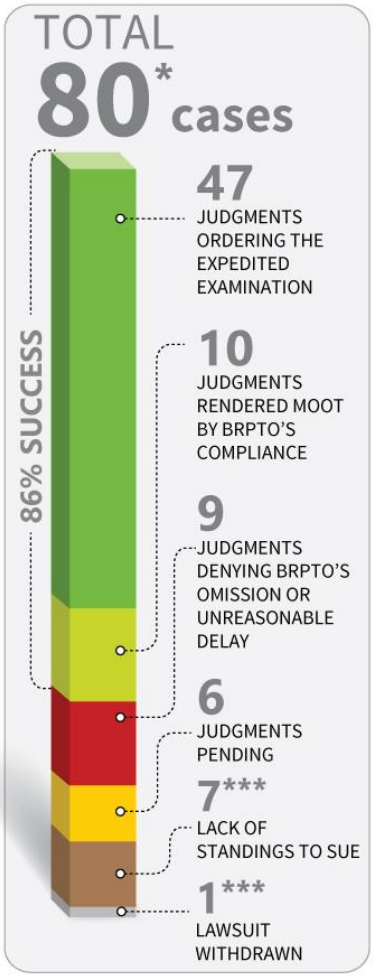
On April 17, 2018 the FPO filed a Civil Class Action, seeking to **annul art. 4 and art. 5 of Interagency Ordinance #1**.

> ***Art. 4°*** *Após recebimento dos pedidos de patente encaminhados pelo INPI, a ANVISA analisará tais pedidos à luz da saúde pública, mediante decisão consubstanciada em parecer técnico emitido pela unidade organizacional competente no âmbito da Agência.*
>
> ***Art. 5º*** *Nos pedidos de patente que contenham produto ou processo farmacêutico considerado de interesse para as políticas de medicamentos ou de assistência farmacêutica no âmbito do SUS, a ANVISA poderá emitir parecer, com fulcro em requisitos de patenteabilidade, que corresponderá a subsídios, durante o exame pelo INPI, nos termos do artigo 31 da Lei nº 9.279, de 1996.*

The FPO also seeks to establish that ANVISA has statutory authority to *"analisar os pedidos de patente de produtos e processos farmacêuticos do ponto de vista da saúde e interesse públicos e* ***também para avaliar o preenchimento dos requisitos de patenteabilidade*** *(novidade, atividade inventiva e aplicação industrial), nos termos do art. 229-c, (...) tendo seu parecer caráter vinculante perante o INPI"*

# Judicially induced fast-track prosecution

# Judicially induced fast-track prosecution - judgments




## 9th
Federal District Court of Rio de Janeiro

JUDGES: **Hon. Ana Amelia Silveira Moreira Antoun Neto [ 4 | 3 ].** Assisted by Hon. Mariza Pimenta Bueno [ 1 | 0 ], Hon. Celso Araujo Santos [ 1 | 0 ] and Hon. Daniela Pereira Madeira [ 1 | 0 ]

PATENTS: 2 | 1 | 1

TRADEMARKS: 5 | 3 | 1 | 2 | 1

TOTAL CASES BEFORE THE COURT: 16

## 13th
Federal District Court of Rio de Janeiro

JUDGE: **Hon. Marcia Maria Nunes de Barros [ 11 | 4 ] e Caroline Somesom Tauk [ 1 | 0 ]**

PATENTS: 4 | 1 | 1

TRADEMARKS: 8 | 1 | 3 | 1

TOTAL CASES BEFORE THE COURT: 19

## 25th
Federal District Court of Rio de Janeiro

JUDGES: **Hon. Eduardo André Brandão [ 9 | 1 ]** and **Hon. Guilherme Bollorini [ 1 | 0 ].** Assisted by Hon. Luciana Cunha Villar [ 1 | 0 ]

PATENTS: 4 | 1 | 1 | 1

TRADEMARKS: 7 | 1 | 1

TOTAL CASES BEFORE THE COURT: 16

## 31st
Federal District Court of Rio de Janeiro

JUDGES: **Hon. Marcelo Leonardo Tavares [ 7 | 0 ].** Assisted by Hon. Caroline Somesom Tauk [ 5 | 1 ] and Hon. Marcio Solter [ 1 | 0 ]

PATENTS: 3 | 1

TRADEMARKS: 10 | 2 | 1 | 3

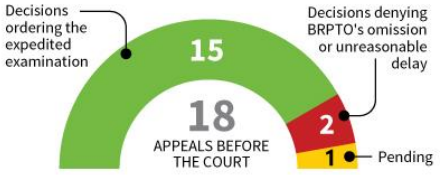
TOTAL CASES BEFORE THE COURT: 20**

- Judgments ordering the expedited examination
- Judgments rendered moot by BRPTO's compliance
- Judgments denying BRPTO's omission or unreasonable delay
- Judgments pending
- Lawsuit withdrawn
- Lack of standings to sue

## Federal Court of Appels

### 1ST SPECIALIZED PANEL


### 2ND SPECIALIZED PANEL




Includes one case that was dismissed by the 9th Federal District Court of Sao Paulo. Includes four cases that are pending judgments, four granted and one with lack of standings to sue before the 1st, 2rd, 3rd, 5th, Federal District Courts of Brasilia.

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

*** Excluded from the basis for calculating the success rate.

# The interpretation of art. 32 of the IP Statute

# The interpretation of art. 32

*Neste ponto cabe pontuar que a alteração voluntária para a redução da proteção após o pedido de exame não é inofensiva para a sistemática da proteção de patentes, tal como seria possível supor.*

*Isso porque tal possibilidade estimula a formulação de pedidos iniciais excessivamente amplos que geram impactos negativos na livre iniciativa e na livre concorrência.*

*Tal fenômeno pode ser facilmente compreendido quando se tem vista que durante o longo período que vai da formulação inicial do pedido excessivamente amplo, passando pelas restrições, até a definitiva concessão da patente, paira no mercado insegurança jurídica quanto à possibilidade/viabilidade econômica dos concorrentes explorarem invenções e modelos de utilidade similares.*

(Class Action #0513584-06.2003.4.02.5101, page 1073; **Federal Prosecutor Renato de Freitas Souza Machado**; October 10, 2017)

# The interpretation of art. 32

*(...) Em adição, a consequência imediata de tal adoção se refletiria no indeferimento quase que automático de praticamente todos os pedidos de patente apresentados ao instituto. Fato este altamente comprometedor e contrário a qualquer política industrial, política pública ou política de acesso pela sociedade brasileira dos bens de consumo hoje disponíveis no mercado.*

*(...)*

*Acreditar que a possibilidade de alteração voluntária estimula a formulação de pedidos iniciais excessivamente amplos que geram impactos negativos na livre iniciativa e na livre concorrência, demonstra desconhecimento do trabalho árduo realizado na DIRPA.*

(Class Action #0513584-06.2003.4.02.5101, page 457; **Julio Cesar Moreira**; April 12, 2018)

# EPO Validation System: An enhancing tool for efficiency

# The European Patent Organisation Validation System

Since 2010, the European Patent Organisation (EPO) has signed validation agreements.

Most of the patent applications filed in Brazil originate from a first filing abroad. It is assumed that a significant percentage of these filings are also targeting the EPO, either in the context of a direct European patent application or an international application under the PCT.

# Geographic coverage of the EPO Cooperation

**Member states (38)**

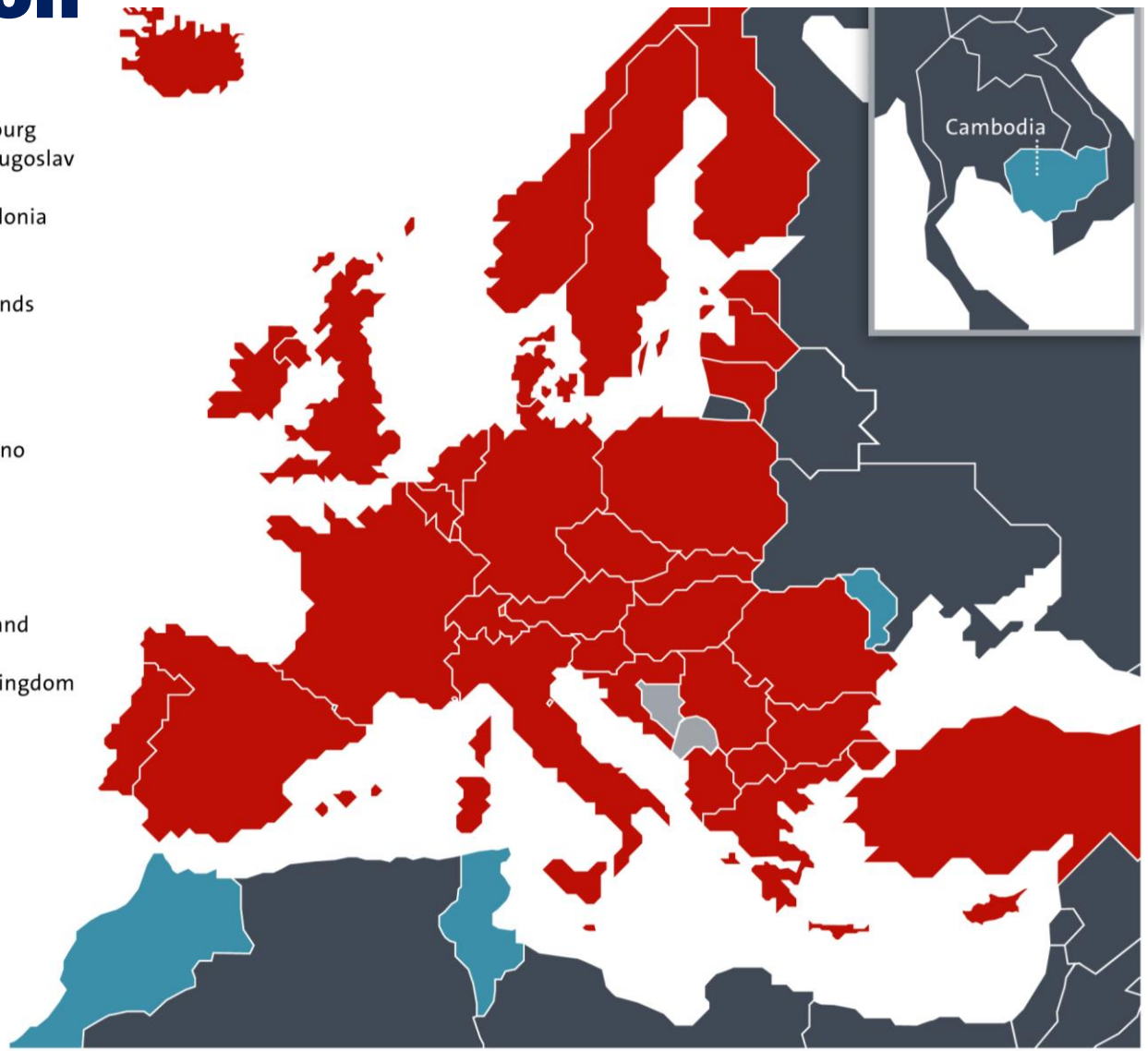
Albania
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Former Yugoslav Republic of Macedonia
Malta
Monaco
Netherlands
Norway
Poland
Portugal
Romania
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom

**Extension states (2)**

Bosnia-Herzegovina
Montenegro

**Validation states (4)**

Cambodia
Republic of Moldova
Morocco
Tunisia




Updated as of 1 March, 2018. Source: European Patent Office. Available here.

# The Benefits of Validation

Some of the benefits of the EPO Validation System include:

- Reduce duplication of search and examination work.
- Enable national patent offices to prioritize first filings from national applicants.
- High quality and multilateral examination.
- Cost-effective and strategic filing option for applicants.

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## Thanks!

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