Licks
ATTORNEYS

Strategic patent prosecution in Brazil
Judicial review of the Brazilian PTO decisions

Overcoming delays, the backlog and rejections
before Brazilian Federal Courts

Current as of December, 2016

SUMMARY

INTRODUCTION

The opportunity to obtain patent protection in Brazil is not limited to the prosecution of applications before the Brazilian PTO (BRPTO or INPI). Despite being known for its large backlog, long pendency and politically motivated decisions, the BRPTO is not the last word for granting patents in Brazil. The country´s Judiciary is the final instance of any application for both process and substance.

Differently from other jurisdictions, Brazil adopts an open model of judicial review of administrative decisions. All decisions rendered by government entities, such as the BRPTO, the Brazilian FDA (ANVISA or BRFDA) or antitrust authorities (CADE) are challengeable before Brazilian courts, as a matter of constitutional right established by Article 5, XXXV: "The law shall not exclude any injury or threat to a right from the review of the Judiciary."

Politically unbiased and independent from the Executive Power, the Brazilian Judiciary has proved to be pro-patent, with a neutral assessment of the patent system and new technologies.

Judicial review of administrative decisions is so common that Brazil has a special court system, called "Federal Courts", which exists mainly to decide such cases. The Brazilian Federal Court system should not be compared to the US Federal Courts system. There is no private adjudication of disputes before the Brazilian Federal Courts, only cases against the Brazilian government and its agencies, such as the BRPTO, ANVISA and CADE. Currently, there are more than 12 million cases pending before Federal Courts, relating to review of administrative decisions, claims for money damages and federal felonies.

Brazilian Federal Courts have 1,775 judges: 1,642 (95,2%) Trial Judges and 133 (7,5%) Appellate Judges. In 2015 Trial Judges were assigned 1,823 new cases while Appellate Judges were assigned 3,612 cases among new cases and appeals. The Brazilian Federal Court system spent R$10 billion in 2015, 0,17% of the Brazilian GDP.

The applicable standards of review are very different in Brazil, deriving from Article 37 of the Constitution: "The governmental entities and entities owned by the Government in any of the powers of the Union, the States, the Federal District and the Municipalities shall obey the principles of lawfulness, impersonality, morality, publicity, and efficiency, [...]"
There is no deference from Brazilian Federal Courts to the administration. The standard of review adopted by the Brazilian legal system applies to all agencies' fact-findings, well beyond "clearly erroneous"; "substantial evidence"; "de novo"; "abuse of discretion", and "plain error". There are no requirements of "standing" or "injury of fact" either.

As a further illustration of its broad powers, Brazilian Federal Courts have proven conscious of the ever-worsening situation of the backlog and pendency times at the BRPTO. Federal judges are now playing an important role in ordering the BRPTO to expedite examination on 85% of the cases brought before the courts, instructing the BRPTO to render a merit-based decision on the applications within a 30 to 60 days' term. As a recent example, after eight years of prosecution before the BRPTO, the 13th Federal District Court of Rio de Janeiro ordered the Agency to exam patent application PI0406674-0 within 60 days. It took 31 days for the BRPTO to proceed with the examination.

This booklet demonstrates that in Brazil it is possible and common to challenge administrative decisions. BRPTO's decision to reject of a patent application or specific claims can be reviewed.

As per recent data made available by the BRPTO, there are more than 10,000 lawsuits pending against the Office. Our research shows more than 7,000 lawsuits only in the Federal District Court of Rio de Janeiro, 267 filed in the last 12 months

In addition to the busiest and most effective patent litigation group, our firm has over 20 years of experience in adjudicating patent disputes against the Brazilian government and its agencies. We have successfully challenged compulsory licenses, illegal procurement of drugs and PDPs partnerships.

Our success in patent litigation is well-know, as our leading cases against the BRPTO and the ANVISA.

We have established the criteria for non-obviousness review; enforcement of foreign invalidity decisions; self-implementation of treaties; SEP enforcement; patent term restoration; review of denials based on added matter, lack of patentable subject matter and non-statutory claim language . We were the first to file a lawsuit against the ANVISA in the same year the agency was created and the first to revert the ANVISA's denial of prior approval of a patent under article 229-C of the Patent Statute.

JUDICIAL REVIEW OF THE BRPTO DECISIONS

The opportunities to obtain patent protection in Brazil are not limited to the prosecution of an application before the BRPTO. Differently from several jurisdictions, Brazil adopts broad judicial review of administrative decisions. All decisions rendered by government entities are challengeable before Brazilian courts, as a matter of constitutional right (art. 5, XXXV).

It is common in Brazil to seek the judicial review of administrative decisions, including of the BRPTO. Such lawsuits are filed before the Federal District Courts, which have jurisdiction to try cases where one of the parties is a federal government entity (as is the case of the BRPTO and of the ANVISA).

The applicable standards of review are also very different. First, there is no deference from Brazilian courts to the administration. The standard of review adopted by the Brazilian legal system applies to all agencies' fact-findings, well beyond "clearly erroneous"; "substantial evidence"; "de novo"; "abuse of discretion", or "plain error". There are no requirements of "standing" or "injury of fact" either.

Brazilian federal judges review whether administrative decision and procedures followed due process; if they complied with formal requirements; and if they agree with the government entity on the interpretation of the law. They also review the conclusions of fact that the administrative decision was based on.

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.

Furthermore, in the judicial review before Brazilian court it is possible to present new arguments and evidence that were not adduced at the administrative procedure.

In the lawsuits seeking the judicial review of the BRPTO's administrative decision that rejected a patent application, the judges see the BRPTO not as an uninterested entity, but as a party that is defending its act. There is no special deference to the BRPTO. The federal judges usually appoint unbiased court experts and patent masters to assist the court. When the masters and experts' reports are in direct contradiction to the BRPTO's position and policies, the federal judges give more weight to the reports produced during the litigation than to the BRPTO's opinion.

Lawsuits filed before the Federal District Courts of Rio de Janeiro seeking to overcome the BRPTO final rejection of patent applications are successful in 48% of the cases see (graph 1 on the following page).

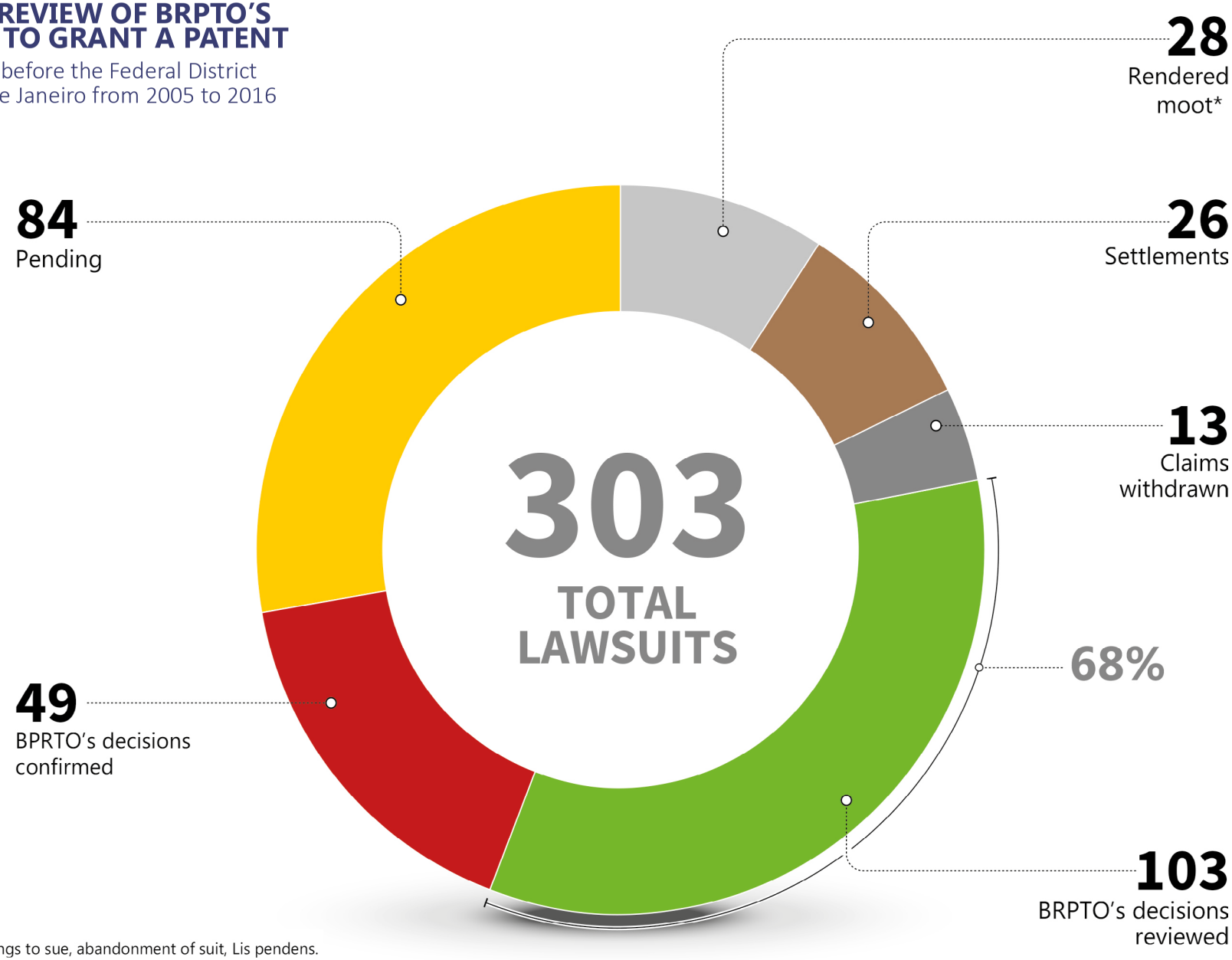
Lawsuits filed before the Federal District Courts of Rio de Janeiro seeking to overcome the BRPTO final rejection of patent applications are successful in 48% of the cases.

The same applies to lawsuits seeking the annulment of a patent, where the BRPTO will defend its act as an interested party. 68% of the judgments in the cases filed before the Federal District Court of Rio de Janeiro in the last 11 years have reversed the BRPTO's grant of a patent in violation of the Patent statutory provisions.

The same applies to lawsuits seeking the annulment of a patent, where the BRPTO will defend its act as an interested party. 68% of the judgments in the cases filed before the Federal District Court of Rio de Janeiro in the last 11 years have reversed the BRPTO's patent grant.

JUDICIAL REVIEW OF BRPTO'S DECISION TO GRANT A PATENT

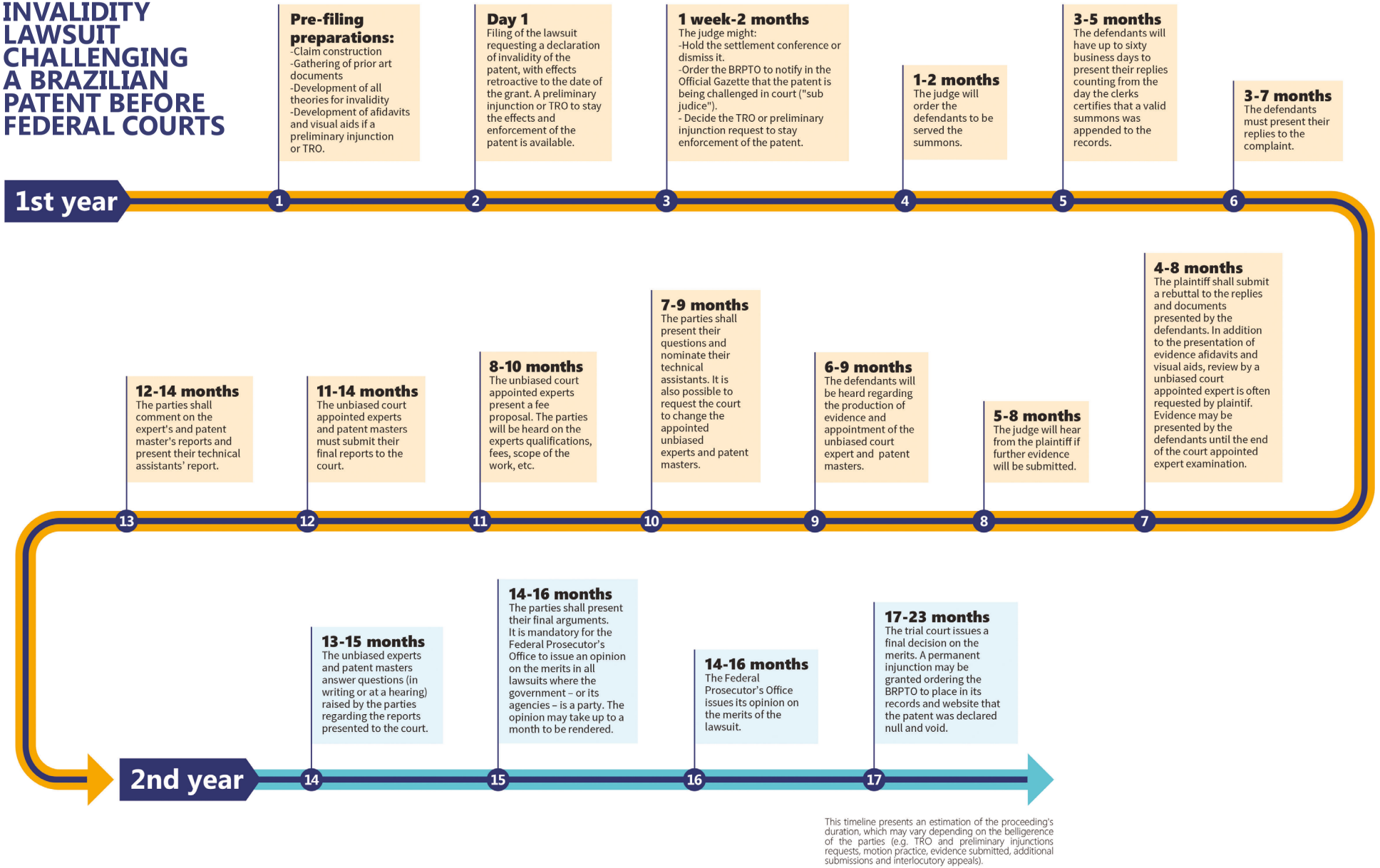
Lawsuits filed before the Federal District Court of Rio de Janeiro from 2005 to 2016



*e.g. Lack of standings to sue, abandonment of suit, Lis pendens.

Graph 1

INVALIDITY LAWSUIT CHALLENGING A BRAZILIAN PATENT BEFORE FEDERAL COURTS



This timeline presents an estimation of the proceeding's duration, which may vary depending on the belligerence of the parties (e.g. TRO and preliminary injunctions requests, motion practice, evidence submitted, additional submissions and interlocutory appeals).

Graph 2

LAWSUITS CHALLENGING ANVISA'S STATUTORY AUTHORITY UNDER ARTICLE 229-C OF THE PATENT STATUTE

The Brazilian Patent statute was amended almost 16 years ago, on December 14, 1999, by Provisional Measure 2,006/1999 issued by former President Cardoso. Congress ratified the Provisional Measure, turning it into Law 10,196/2001, which, in addition to the Article 229-C, included the regulatory review exception into the Brazilian Patent System.

The applicability of article 229-C by ANVISA and the agency´s relationship with the BRPTO have never been simple. ANVISA took a year and a half to start activities related to Article 229-C. It was only on May 21, 2001, with the implementation of Rule #239 that the agency created its Intellectual Property Commission (COOPI) to implement Article 229-C. The patent workflow developed by us portraits the proceeding for ANVISA's prior approval, which can be accessed in the link here.

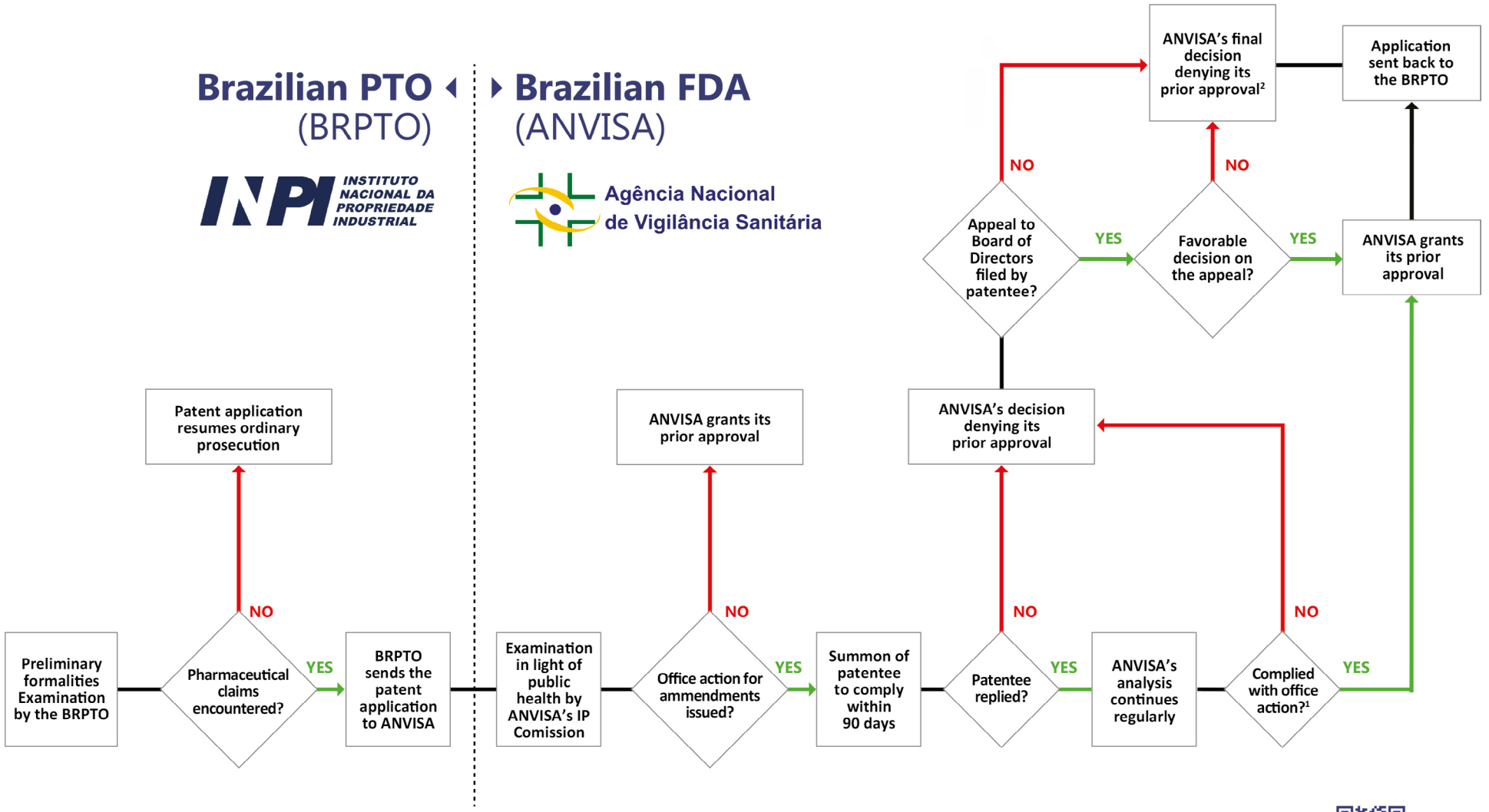
The ANVISA statutory duty, according to article 6 of Law # 9782/2001, is to provide sanitary and health controls to the population. But once the BRPTO began submitting patent applications to the ANVISA's prior approval, the agency started to examine patent claims and issue opinions declining its approval based on lack of patentability statutory requirements or patentable subject matter.

It is now common for pharmaceutical companies to challenge ANVISA's authority under Article 229-C of the Patent statute before courts. Most cases were filed before the Federal District Courts in Brasilia (24), and additional 16 before Federal District Courts in Rio de Janeiro. Most judgments rendered to this date in Brasilia have been favorable to the applicants. The judges in Brasilia Federal District Courts order the ANVISA to grant prior approval in 80% of the cases.

On the other hand, judgments rendered to this date in Rio de Janeiro have varied. The judges in Rio de Janeiro Federal District Courts order the ANVISA to grant prior approval in 57% of the cases.

The judges in Brasilia Federal District Courts order the ANVISA to grant prior approval in 80% of the cases.

WORKFLOW OF ANVISA'S PRIOR APPROVAL PROCEEDINGS



[1] Even if the applicant complies with ANVISA's office action, the Agency might still deny its prior approval.
[2] If ANVISA denies its prior approval the decision is subject to judicial review before Federal District Courts.

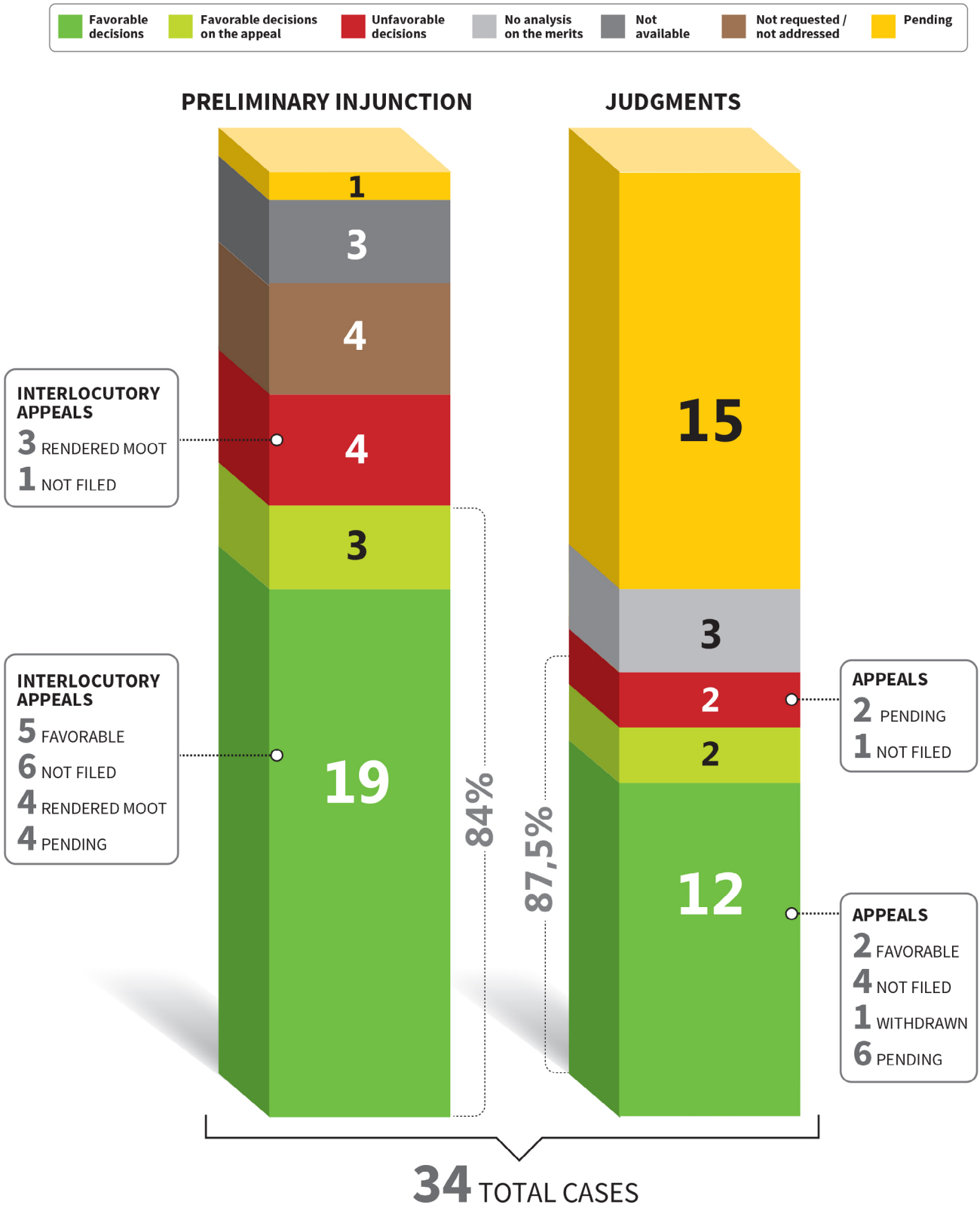
To access the complete patent prosecution workflow read the following QR Code

Graph 3

BRASILIA: LITIGATION OVERVIEW

Challenging the limits of Brazilian FDA's (ANVISA) authority under Article 229-C of the Patent Statute

The Brazilian FDA statutory duty, according to article 6 of Law # 9,782/1999, is to provide sanitary and health controls to the population. Under article 229-C of the Patent Statute (Law #9,279/1996) the BRPTO must submit pharmaceutical patent applications to the Brazilian FDA for prior approval. Disregarding the limits of its authority the agency decided to deny prior approvals based on patentability requirements. Several pharmaceutical companies filed lawsuits questioning the BRFDA's authority to analyze patentability requirements.

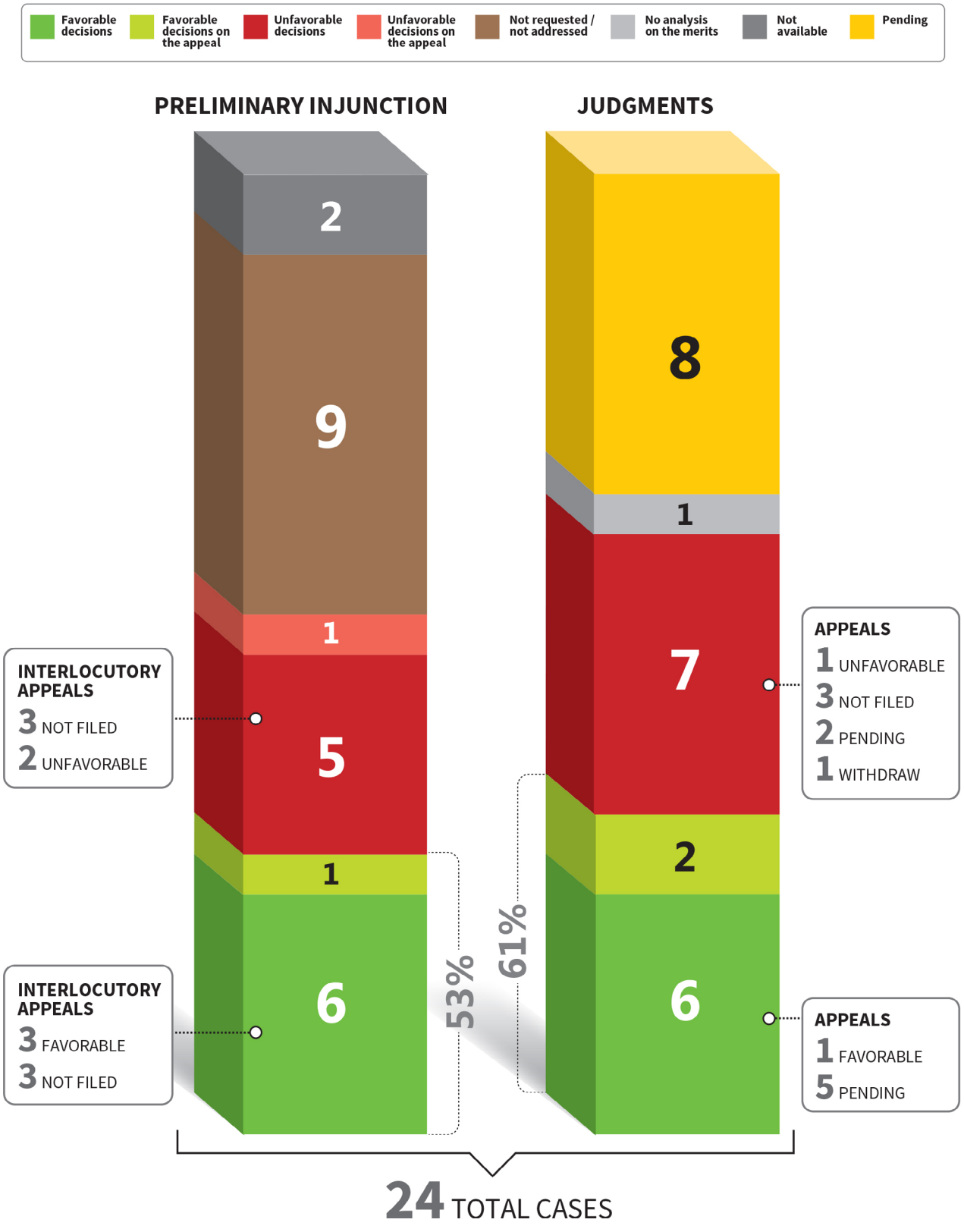


Graph 4

RIO DE JANEIRO: LITIGATION OVERVIEW

Challenging the limits of Brazilian FDA's (ANVISA) statutory authority under Article 229-C of the Patent Statute

The Brazilian FDA statutory duty, according to article 6 of Law # 9,782/1999, is to provide sanitary and health controls to the population. Under article 229-C of the Patent Statute (Law #9,279/1996) the BRPTO must submit pharmaceutical patent applications to the Brazilian FDA for prior approval. Disregarding the limits of its authority the agency decided to deny prior approvals based on patentability requirements. Several pharmaceutical companies filed lawsuits questioning the BRFDA's authority to analyze patentability requirements.

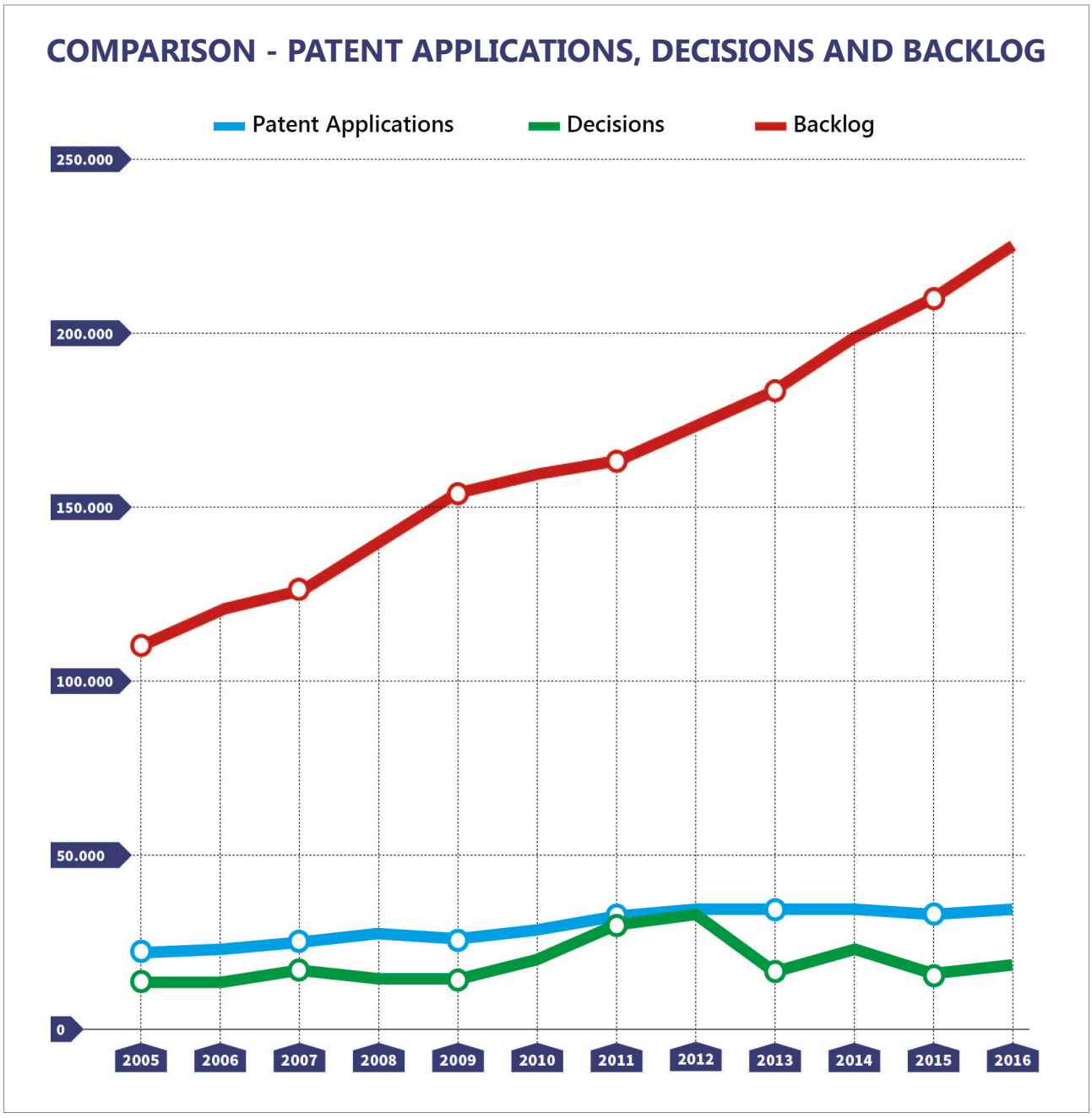


Graph 5

BRPTO'S BACKLOG

Backlog is the term used by patent system users and the BRPTO itself to designate the build-up of filed patent applications awaiting decisions on the initial examination.

As shown in graph 6 bellow the backlog (red line) is created and constantly fuelled as the BRPTO works on less applications than the annual fillings (green and blue lines).

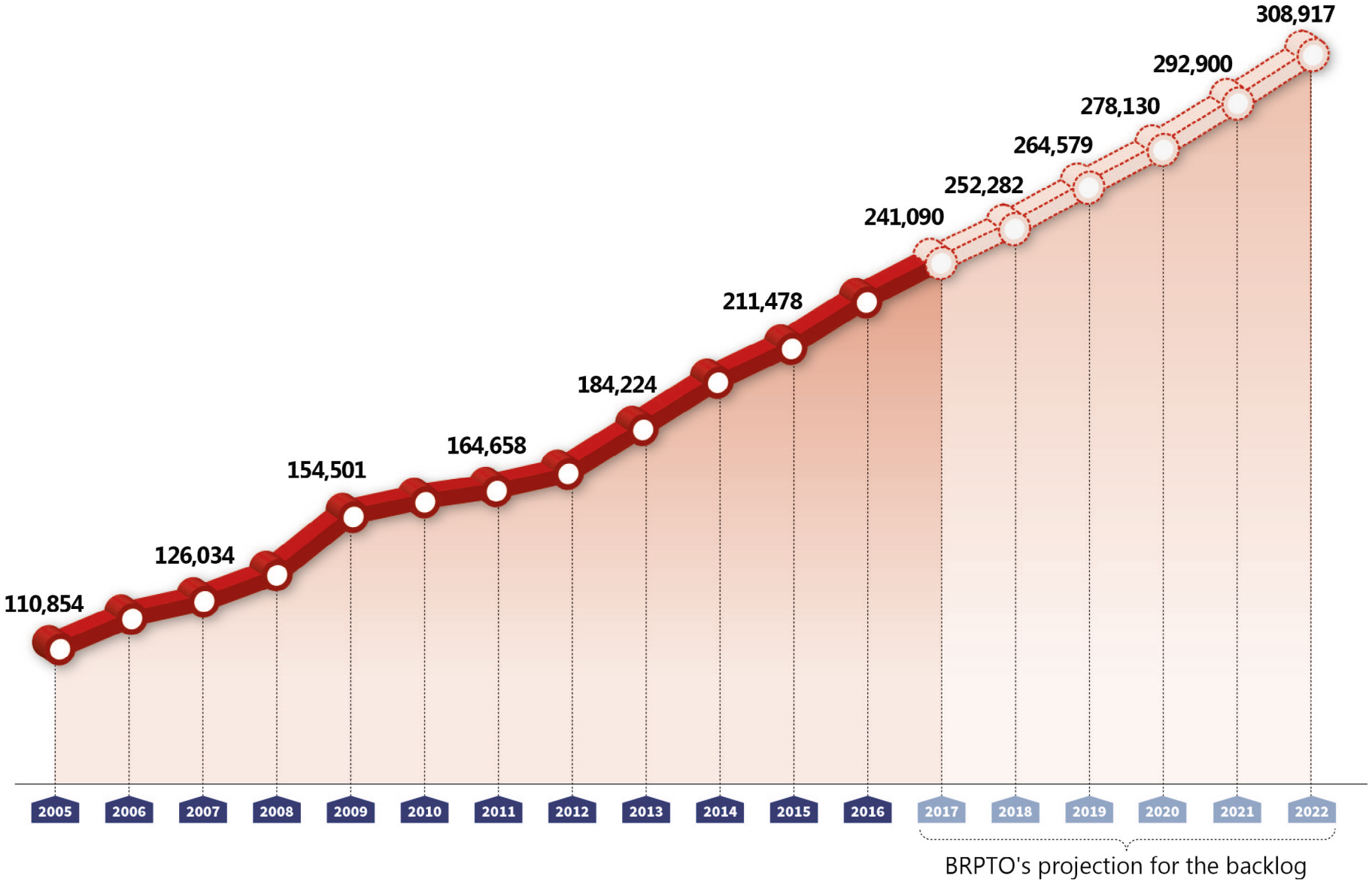


Graph 6

In 2015, the backlog reached 211,478 applications, with the BRPTO predicting that the situation will worsen during the next few years, with the backlog rising by 46% between 2015 and 2022.

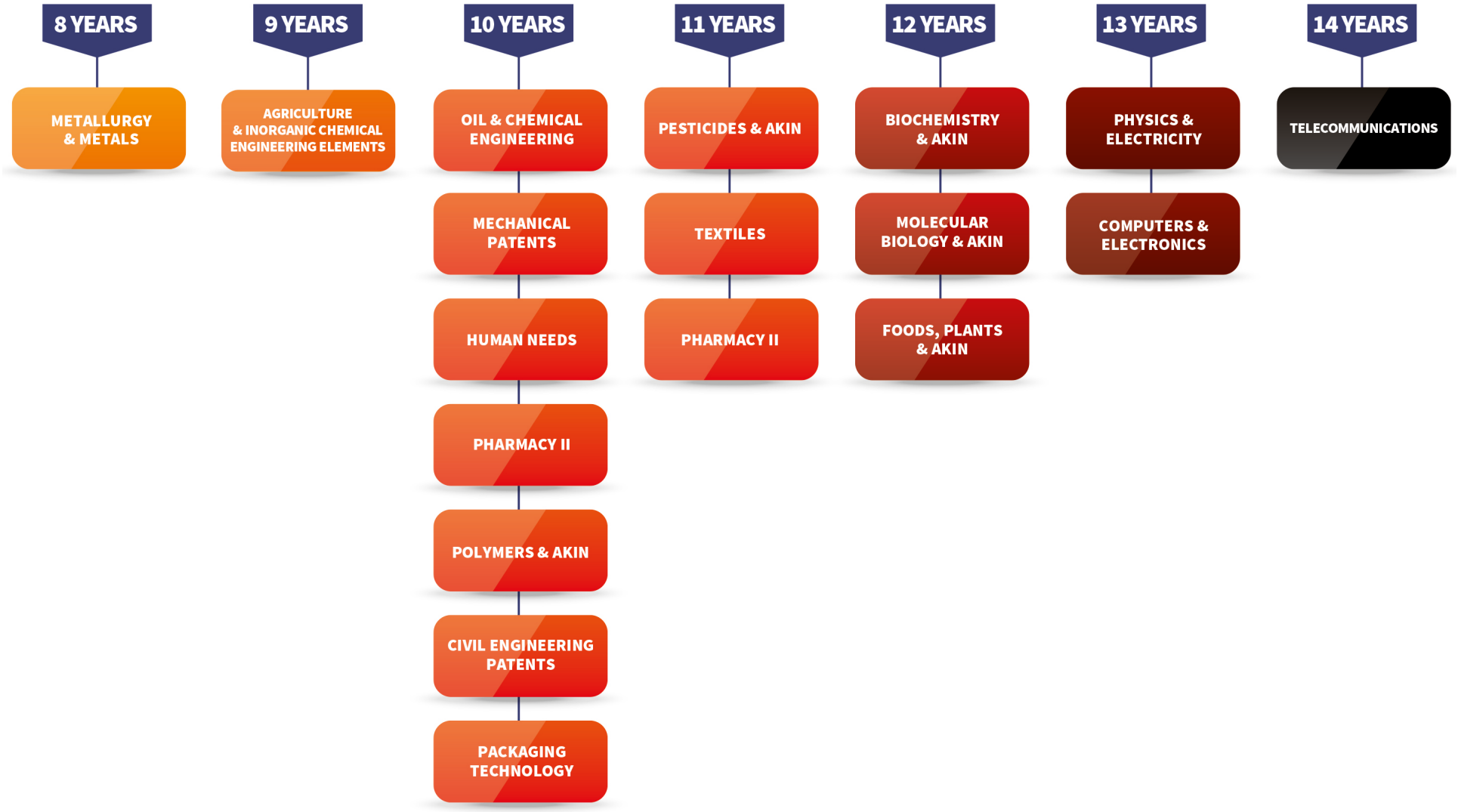
The BRPTO forecasts that the situation will worsen during the next few years, with a 46% upsurge in the backlog between 2015 and 2022

PROGRESSION OF BRPTO'S PATENT BACKLOG



Graph 7

AVERAGE PATENT APPLICATION PROCESSING TIME AT THE BRPTO BY FIELD OF TECHNOLOGY



Graph 8

JUDICIALLY INDUCED FAST-TRACK PROSECUTION

Due to the BRPTO's backlog and pendency, Brazilian Federal Courts have proven conscious of the ever-worsening situation of the backlog and pendency times of the BRPTO. Federal judges are now playing an important role in ordering the BRPTO to expedite examination on 85% of the cases brought before the courts, instructing the BRPTO to render a merit-based decision on the applications within a 30 to 60 days' term.

It is now becoming common in Brazil for patent and trademark applicants to seek expedite examination of their applications before the Brazilian Courts. Over 15 lawsuits have already been filed during 2016.

Federal judges are now playing an important role in ordering the BRPTO to expedite examination on 85% of the cases brought before the courts, instructing the BRPTO to render a merit-based decision on the applications within a 30 to 60 days' term.

Despite acknowledging the BRPTO's massive workload, the Federal Judges rule in 85% of the cases that the delays are unreasonable and disproportionate. Efficiency and productivity of government agencies are required by the Brazilian Constitution. The BRPTO breaches the Constitution when failing to provide the applicants with a reasonable waiting time until the grant of a patent or any other office action.

Even though there are few decisions granting preliminary injunctions in those cases, the procedure ends up being faster than the fast-track obtained administratively, under the BRPTO resolutions. The reason is that the average time for the trial court to render a judgment with an perment injunction on the merits is about six months, as opposed to the average one to two years of BRPTO's prioritized examination procedures.

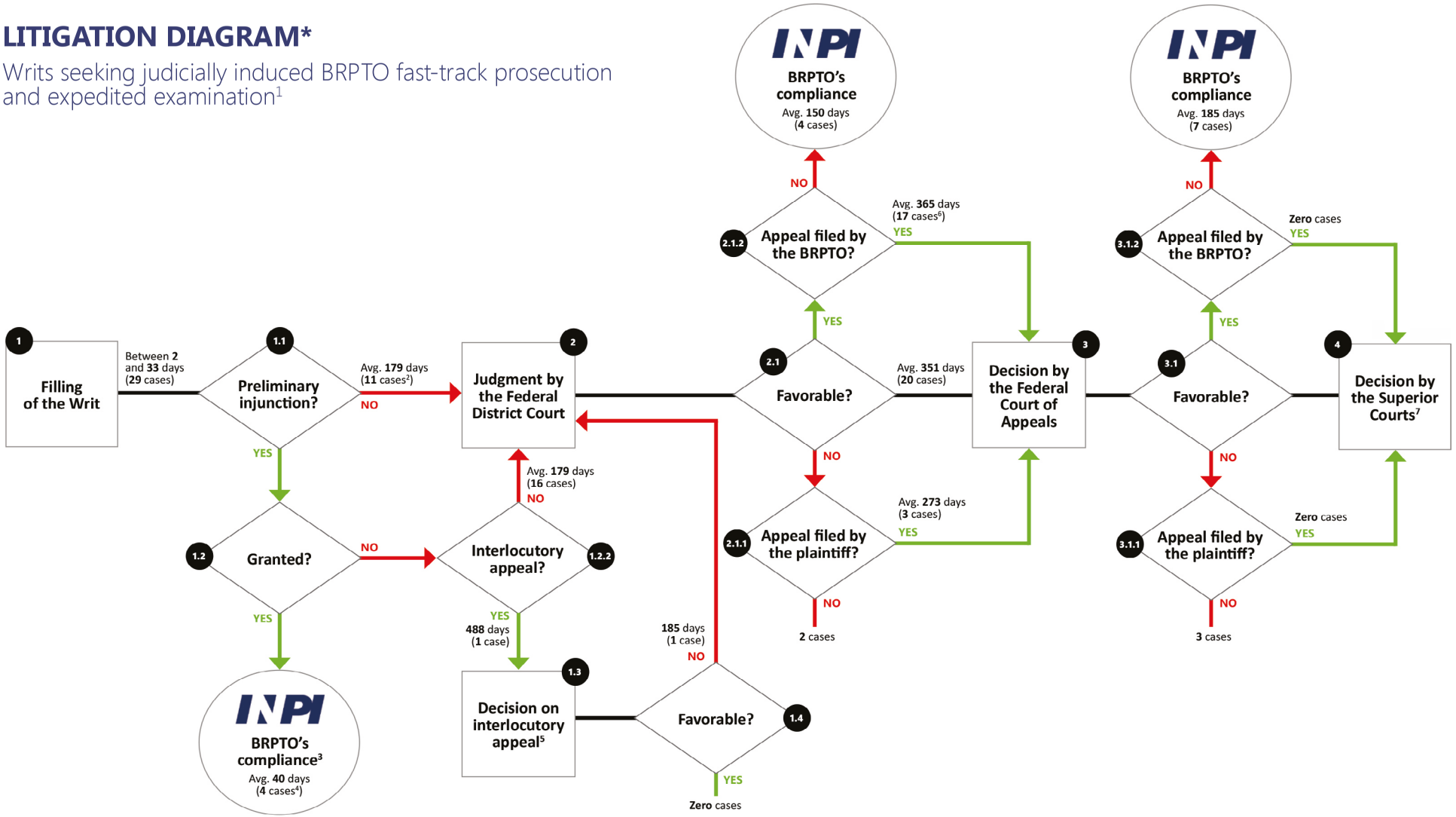
The best strategy in those cases is to file a writ of mandamus, instead of a regular lawsuit. In addition to being less expensive and faster, the appeal on the writ does not stay the trial court judgment. Thus, the BRPTO should comply with the judgment immediately, despite appealing from the judgement. In the case of a regular lawsuit, the immediate compliance would only happen if the trial judge granted an injunction with the judgment, as the appeals for regular lawsuit have staying effects. We also included a litigation diagram (see graph 9) to best represent the steps and timing of the proceedings before the Federal Courts.

On pages 15 and 16, the visual aids show an overview of the success of this type of litigation against the BRPTO to seek expedite examination.

The procedure ends up being faster than the fast-track obtained administratively, under the BRPTO resolutions.

LITIGATION DIAGRAM*

Writs seeking judicially induced BRPTO fast-track prosecution and expedited examination[1]



*The diagram shows an abbreviated version of the judicial proceedings to obtain BRPTO fast-track prosecution and expedited examination of a pending application.
[1]This litigation diagram comprises information that is publicly available on courts' search engines and electronic databases. Information on the 45 cases available in September, 2016 was analyzed.
[2]Cases where preliminary injunctions were not requested or not addressed by the court.
[3]The BRPTO has never appealed a decision granting a preliminary injunction to the plaintiff.
[4]Preliminary injunctions were recently granted on 3 other cases but BRPTO's compliance is still pending.
[5]In only 1 of the 45 cases an interlocutory appeal was filed (#0019269-13.2012.4.02.0000). It took 488 days for the Federal Court of Appeals to issue a decision and 185 days later the Federal District Court rendered the judgement.
[6]In 8 of the 17 cases the BRPTO complied with the judgment before appealing. In these cases the BRPTO took on average 53 days to comply.
[7]No decision from the Federal Courts of Appeals was appealed to the Supreme Court or to the Superior Court of Justice.

Graph 9

JUDGMENTS

Judicially induced BRPTO fast-track prosecution and expedited examination of pending applications

The BRPTO's pendency is on average 11 years for patent applications and 3 years for trademarks. The backlog continues to build up. There is an increasing number of lawsuits and writs being filed by applicants seeking expedited examination of pending applications before the BRPTO. The Judiciary is aware of the ever-worsening situation and has sided with the applicants, issuing favorable judgments on 84% of the cases. Judgments have ordered the BRPTO to begin examination of pending applications and opposition proceedings and to issue final decisions on pending applications.

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**

9th Federal District Court of Rio de Janeiro

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

PATENTS: 1 | 1

TRADEMARKS: 4 | 3 | 1

TOTAL CASES BEFORE THE COURT: **10**

13th Federal District Court of Rio de Janeiro

JUDGE: **Hon. Marcia Maria Nunes de Barros [8 | 5]**

PATENTS: 2 | 1 | 2

TRADEMARKS: 5 | 1 | 4 | 1

TOTAL CASES BEFORE THE COURT: **16**

25th Federal District Court of Rio de Janeiro

JUDGES: **Hon. Eduardo André Brandão [7 | 0]** and **Hon. Guilherme Bollorini [1 | 0].** Assisted by Hon. Luciana Cunha Villar [1 | 0]

PATENTS: 2

TRADEMARKS: 7 | 1

TOTAL CASES BEFORE THE COURT: **10**

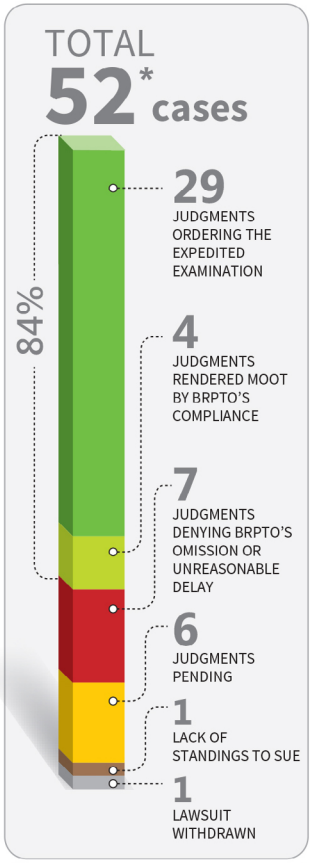
31st Federal District Court of Rio de Janeiro

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

PATENTS: 1

TRADEMARKS: 9 | 1 | 1

TOTAL CASES BEFORE THE COURT: **13****

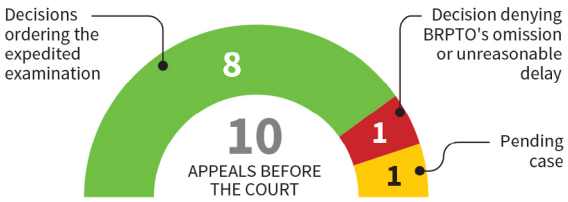


*Includes one case that is pending judgment before the 9th Federal District Court of Sao Paulo. Includes two cases that are pending judgments before the 13th and 22nd Federal District Courts of Brasilia.

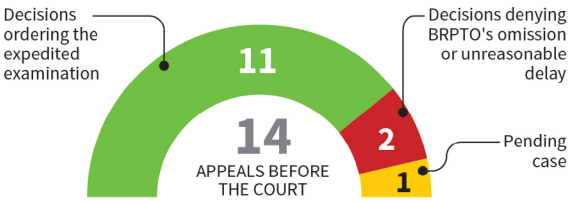
**Includes the case filed by Floatec against the BRPTO seeking the copies of a post-grant review proceeding.

Federal Court of Appels

1ST SPECIALIZED PANEL



2ND SPECIALIZED PANEL



Graph 10

PRELIMINARY INJUNCTIONS

Judicially induced BRPTO fast-track prosecution and expedited examination of pending applications

The BRPTO's pendency is on average 11 years for patent applications and 3 years for trademarks. The backlog continues to build up. There is an increasing number of lawsuits and writs being filed by applicants seeking expedited examination of pending applications before the BRPTO. The Judiciary is aware of the ever-worsening situation and has sided with the applicants, granting preliminary injunctions on several occasions.

9th Federal District Court of Rio de Janeiro

JUDGES:
Hon. Ana Amelia Silveira Moreira Antoun Neto [0 | 1]. Assisted by Hon. Caroline Somesom Tauk [0 | 2] and Hon. Karina de Oliveira e Silva [0 | 1]

PATENTS: 2

TRADEMARKS: 2 | 2 | 1 | 3

TOTAL CASES BEFORE THE COURT: **10**

13th Federal District Court of Rio de Janeiro

JUDGES:
Hon. Marcia Maria Nunes de Barros [2 | 11]. Assisted by Hon. Sergio de Oliveira Dias [1 | 0]

PATENTS: 2 | 3

TRADEMARKS: 1 | 8 | 1 | 1

TOTAL CASES BEFORE THE COURT: **16**

25th Federal District Court of Rio de Janeiro

JUDGES:
Hon. Eduardo André Brandão [0 | 4] and **Hon. Guilherme Bollorini [0 | 1].** Assisted by Hon. Caroline Somesom Tauk [0 | 1]

PATENTS: 2

TRADEMARKS: 2 | 4 | 2

TOTAL CASES BEFORE THE COURT: **10**

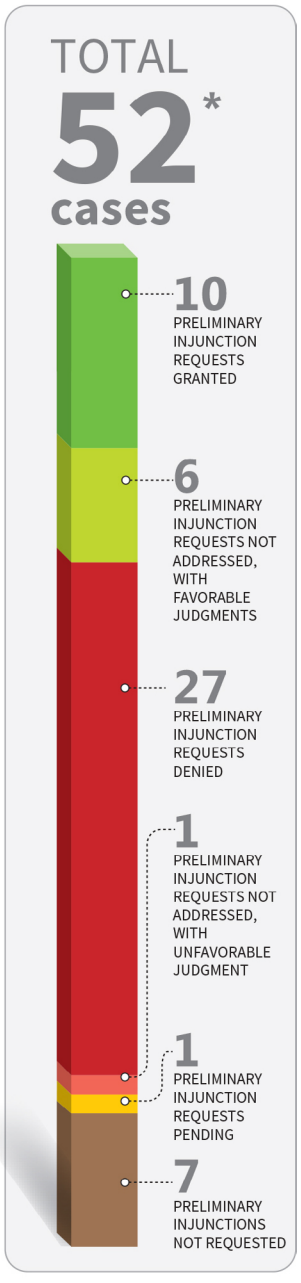
31st Federal District Court of Rio de Janeiro

JUDGES:
Hon. Marcelo Leonardo Tavares [1 | 4]. Assisted by Hon. Caroline Somesom Tauk [3 | 1] and Hon. Marcio Solter [0 | 1]

PATENTS: 1

TRADEMARKS: 3 | 2 | 6 | 1

TOTAL CASES BEFORE THE COURT: **13****



*Includes a preliminary injunction granted by the 9th Federal District Court of Sao Paulo.
Includes two preliminary injunctions granted by the 13th and the 22nd Federal District Court of Brasilia.

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

Graph 11

LAWSUITS CHALLENGING MAILBOX PATENTS

Under the former Brazilian Patent Statute (Law 5.772/71), agrochemical compounds as well as pharmaceutical products and their respective processes were not considered patentable subject matters. Such technologies have become patentable subject matter in Brazil under current Brazilian Patent Statute (Law # 9.276/96) enacted on May 15, 1997.

The TRIPS Agreement came into effect on January 1, 1995. Article 70.8 of the TRIPS Agreement mandated that when a TRIPS Member Country held pharmaceutical or agrochemical products as an unpatentable subject matter, such Member Country should develop means to accept patent applications directed to these matters for subsequent prosecution under its new Patent Statute adapted to the TRIPS provisions.

As a developing country, Brazil was granted transitional period to enact new laws that were TRIPS compliant. Thus, those applications filed in Brazil based on Article 70.8 of TRIPS were designated as "mailbox" applications, because they were to be stored in "mailboxes", while awaiting the 1997 Patent Statute to be enacted.

In 1999, the Brazilian Patent Statute was amended by a Provisional Measure, which later matured into Brazilian Law # 10.196/2001, to include, among others, provisions regarding "mailbox" patent application, with the purpose of regulating the prosecution of such applications filed based on Article 70.8 of TRIPS.

Under these new provisions, the pending patent applications covering pharmaceutical products or agrochemical compounds filed between January 1, 1995, and May 15, 1997 should be: (a) examined and granted under the provisions of the Patent statute (which allows patentability of these matters) before December 31, 2004; and (b) granted with a 20-year term of protection counted from their respective filing dates. Accordingly, those "mailbox" patents granted before December 31, 2004 would receive a 20-year term from their respective filing date. On the other hand, the "mailbox" patents granted after December 31, 2004, in view of the huge backlog of work at the PTO, would receive a 10-year from their granting date (minimum term guaranteed by the general rule).

In 2013, the BRPTO issued a legal opinion stating that the term of "mailbox" patents would be limited to 20 years from the filing date, irrespectively of their granting date (either before or after December 31, 2004). After the issuance of the legal opinion, the BRPTO filed several court actions challenging the validity of almost all "mailbox" patents granted since 2004. On Federal District Courts, the BRPTO managed to reduce the patent term in 48% of the cases which had a final decision on the merits. However, on the Court of Appeals for the Second Circuit, the BRPTO managed to revert all decisions denying the patent term reduction and to confirm the decisions that have reduced the challenged patent terms.

In 2013, the BRPTO issued a legal opinion stating that the term of "mailbox" patents would be limited to 20 years from the filing date, irrespectively of their granting date (either before or after December 31, 2004). After the issuance of this legal opinion, the BRPTO filed several court actions challenging the validity of almost all "mailbox" patents granted since 2004.

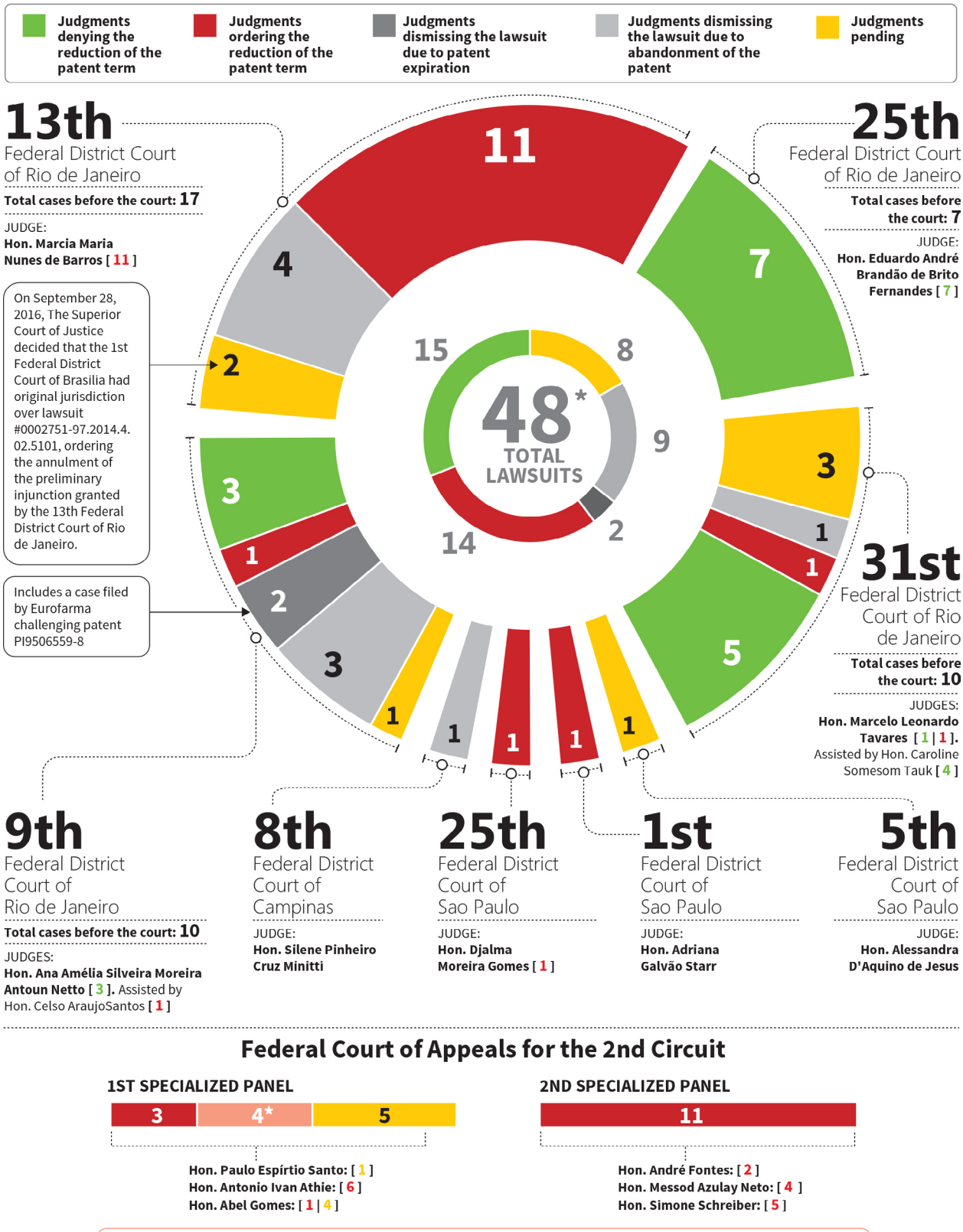
Most these lawsuits have been filed at the Federal Court of Rio de Janeiro, where these are four specialized IP Courts. Although there is some success on behalf of pharmaceutical companies at the Trial Courts, the Court of Appeals for the 2nd Circuit ruled in favor of the BRPTO on all judgments up to now.

On the following page, a visual aid presents an overview of the success of this type of litigation where the BRPTO sues pharmaceutical and agrochemical companies, seeking to reduce their patents term.

JUDGMENTS

Lawsuits challenging mailbox patents in Brazil

Mailbox patents are patents for pharmaceutical inventions filed after the enactment of the WTO TRIPS Agreement but before the enactment of the Brazilian patent law allowing pharmaceuticals as patentable subject matter. The only difference between normal patents and mailbox patents is the maximum term of validity, limited to 20 years from filing. In 2013 the BRPTO realized it had granted several mailbox patents with the benefit of a 10-year term from grant and filed lawsuits seeking the invalidation or reduction of the term of 240 patents.



Federal Court of Appeals for the 2nd Circuit

1ST SPECIALIZED PANEL

3 | 4* | 5

Hon. Paulo Espírtio Santo: [1]
Hon. Antonio Ivan Athie: [6]
Hon. Abel Gomes: [1 | 4]

2ND SPECIALIZED PANEL

11

Hon. André Fontes: [2]
Hon. Messod Azulay Neto: [4]
Hon. Simone Schreiber: [5]

*Appeals with two votes for the reduction of the patent term, Hon. Paulo Espírito Santo requested more time to study the case files.

Graph 12

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