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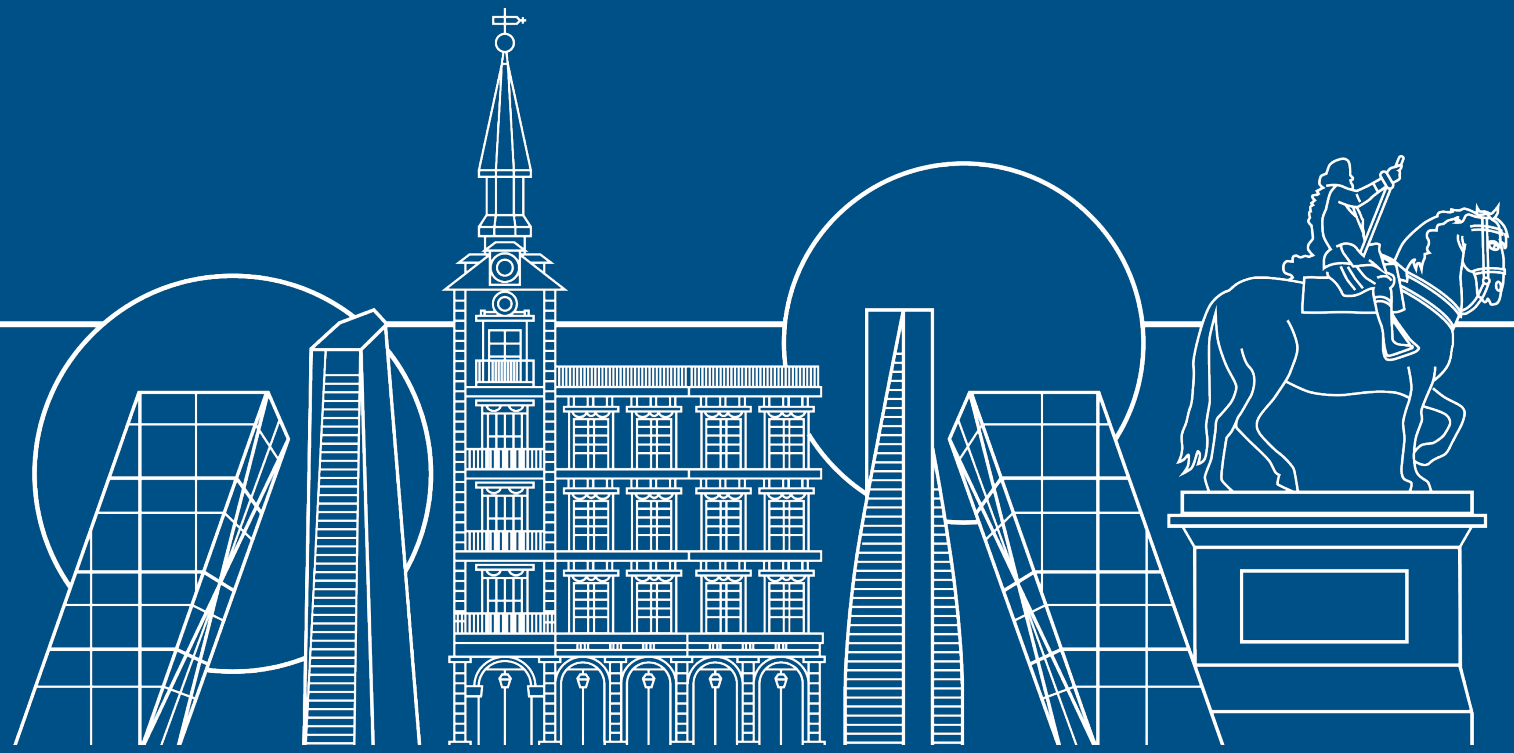

DRAFTING WITHOUT BORDERS

LIFE SCIENCES

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Introduction

Clarissa Regler
Patent Attorney, Winter Brandl, Germany
Co-Founder, TRUVENTO GmbH

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Clarissa Regler
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Rana Gosain
Brazil

Serge Shahinian
Canada

Archana Shanker
India

CHEMICAL AND BIOTECHNOLOGICAL INVENTIONS UNDER THE EPC

Clarissa Regler
Patent Attorney, Winter Brandl, Germany
Co-Founder, TRUVENTO GmbH

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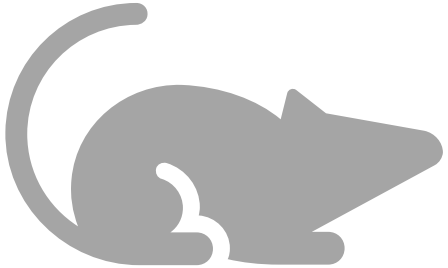
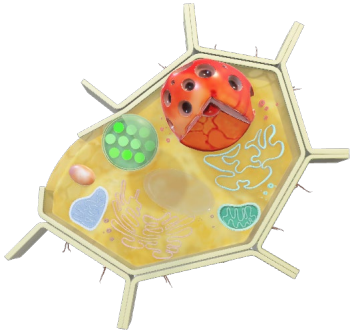
Life Sciences





Introduction

„*Biotechnological inventions*“ are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Rule 26(2) EPC).

„*Biological material*“ means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Rule 26(3) EPC).

- EU Biotech Directive (Directive 98/44/EC)

Patent subject-matter eligibility

- European patents shall be granted for any invention, in all fields of technology, provided that they are **new**, involve an **inventive step** and are susceptible of **industrial application** (Art. 52(1) EPC).

- An invention is not

  a) a discovery, scientific theory or mathematical method;

  b) an aesthetic creation;

  c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a computer program; or

  d) a presentation of information (Art. 52(2) EPC).

- Invention ☑

  Does its subject-matter fall under the exceptions to patentability? (Art. 53 EPC)

Exceptions to patentability (Art. 53 EPC)

Ordre public, morality
Art. 53(a) EPC

Plant / animal varieties
Art. 53(b), R. 26(4) EPC

Essentially biological processes for the production of plants or animals
Art. 53(b), R. 26(5) EPC

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body
Art. 53(c) EPC, Art. 54(5) EPC

Excluded biotechnological inventions:

- Processes for cloning human beings;
- Processes for modifying the germ line genetic identity of human beings;
- Uses of human embryos for industrial or commercial purposes;
- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal

R. 28(1) EPC

Human body, discovery gene
R. 29(1) EPC

Exclusions for biotechnological inventions

- **G 3/19** (reversing G 2/12 and G2/13)
- No patent for plant or animal exclusively obtained by an **essentially biological process**.
- This negative effect does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that day and are still pending.

A plant produced by introgression of gene, i.e. by introducting it into the genome by crossing and selection (not allowable any more).

A plant part obtained exclusively by means of an essentially biological process which is propagation material, e.g. a seed or plant embryo (not allowable any more).

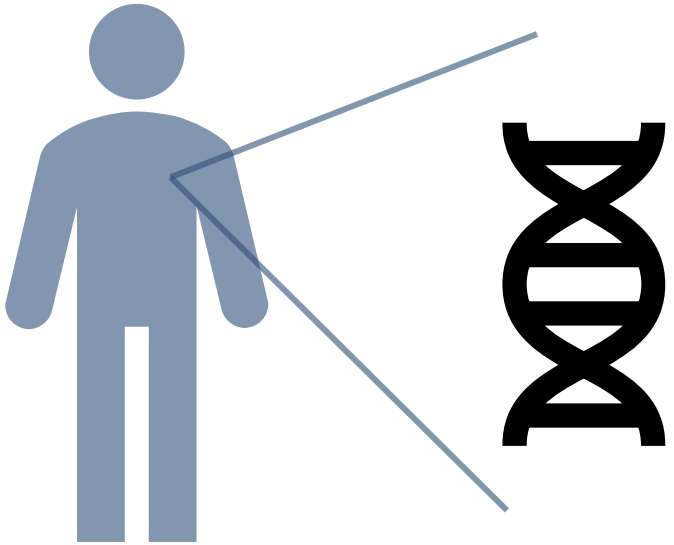
Patentable biotechnological inventions

Biotechnological inventions concerning plant / animal not confined to variety
R. 27(b) EPC

Biotechnological inventions:

- Biological material isolated or technically produced
- Plants / animals not confined to variety
- Microbiological process or other technical process of product thereof (not variety)

R. 26(1), (2) EPC,
Art. 53(b), R. 26(6), R. 27 EPC



Element isolated from the human body, e.g. sequence or partial sequence of a gene
+ Disclosure of the industrial application
R. 29(2), (3) EPC

Patentable biotechnological inventions

A transgenic plant carrying transgene X.

Method of producing a (transgenic) plant having trait X comprising introducing by transformation a vector comprising the sequence of SEQ ID NO: 1.

Use of the nucleic acid of SEQ ID NO:1 to select a plant having trait X.

Patentabilty

European patents shall be granted for any invention, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application (Art. 52(1) EPC).

Invention

New

Inventive step

Industrial application

Unity

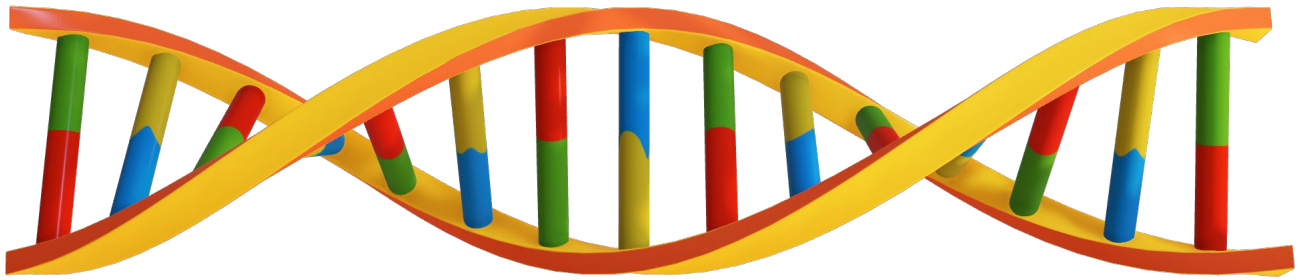
Sufficiency of Disclosure

Clarity

Industrial application (Art. 57 EPC)

- Biotechnological inventions are quite often concerned with substances found in nature (e.g. a protein, a DNA sequence, etc.)

- Indication of a profitable use of the invention in industry.



General novelty related issues (Art. 54 EPC) in the context of Life Sciences

- Generic – specific: a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure

- Novelty of chemical inventions:
  - Art. 64(2) EPC: Protection of process patent extends to directly obtained products
  - **T 150/82**: Product-by-process claim admissible if product patentable and no other definition possible
  - **T 296/87**: Chemical substance is new if it differs from a known substance in a reliable parameter

General novelty related issues (Art. 54 EPC) in the context of Life Sciences

- "Reach-through" claims
  - Are defined as claims attempting to obtain protection for a chemical product (and also uses thereof, compositions thereof, etc.) by defining that product functionally in terms of its action on a biological target such as an enzyme or receptor.
  - In many such cases, the applicant functionally defines chemical compounds in this way by reference to a newly identified biological target.
  - However, compounds which bind to and exercise this action on that biological target are not necessarily novel compounds simply because the biological target which they act on is new.
- Selection inventions: lists, numerical ranges

Selection Inventions (lists)

- A selection from a single list of specifically disclosed elements does not confer novelty.

- However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then the resulting combination of features, not specifically disclosed in the prior art, confers novelty (the "**two-lists principle**").

- Examples of such selections from two or more lists are the selection of:
  - (a) individual chemical compounds from a known generic formula whereby the compound selected results from the selection of specific substituents from two or more "lists" of substituents given in the known generic formula. The same applies to specific mixtures resulting from the selection of individual components from lists of components making up the prior art mixture;
  - (b) starting materials for the manufacture of a final product;
  - (c) sub-ranges of several parameters from corresponding known ranges.

Claiming purity of a compound

- A claim defining a **compound** as having a **certain purity lacks novelty** over a prior-art disclosure describing the same compound only if the prior art discloses the claimed purity at least implicitly, for example by way of a method for preparing said compound, the method inevitably resulting in the purity as claimed.

- Such a claim, however, **does not lack novelty if the disclosure of the prior art needs to be supplemented, for example by suitable (further) purification methods** allowing the skilled person to arrive at the claimed purity.

Drafting medical use claims

Allowed claims:

- Substance / composition X (novel substance/composition)
- Substance / composition X for use as a medicament (First medical indication, Art. 54(4) EPC)
- Substance / composition X for use in the treatment of cancer (Second medical use claim, Art. 54(5) EPC)
- Dosage regime: Substance / composition X for use in the treatment of cancer by "dosage regime" (e.g. by oral administration once per day, i.e. different dosage, administration regime, group of subjects or route of administration)
- Allowed medicine claims for a combined preparation (kits of parts):
- Combined preparation of X and Y for simultaneous, separate or sequential use in therapy (first medical indication)

NOT allowed: *Use of substance / composition X for treatment of disease Y*

- Such a claim will be regarded as relating to a method for treatment explicitly excluded from patentability by Art. 53(c) EPC and therefore will not be accepted.

Product-by-process claims

- Product-by-process claims are only exceptionally allowed, when there is no other way to describe the product with structural features.

- This typically occurs for substances such as polymers or glasses for which no definable structure is available.

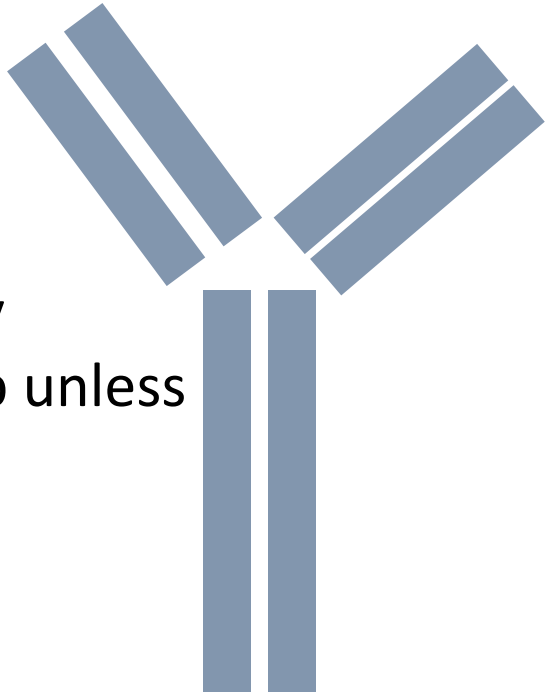
- The claimed product must itself be new and have distinct properties due to its modified method of manufacture.

„Product X obtainable by process Y“.

Inventive step in the field of biotechnology (Art. 56 EPC)

- Definition of the person skilled in the art in the field of biotechnology

- Expectation of success, especially in the field of genetic engineering and biotechnology



- Inventive step of antibodies:
  - The subject-matter of a claim defining a novel, further antibody binding to a known antigen does not involve an inventive step unless
    - i) a surprising technical effect is shown by the application or
    - ii) unless there was no reasonable expectation of success of obtaining antibodies having the required properties.

Antibodies under the EPC

- An antibody can be claimed by:
  - **structural** definitions, e.g. amino acid sequences

    AND / OR by
  - **functional** definitions, e.g. by reference to the (target) antigen, by identification of the bound epitope (or target), by the production process

- The Board provided guidance when functional features are acceptable (**T 68/85**):
  - the features provide instructions for the skilled person to reduce the invention to practice without undue burden; and
  - such features could not otherwise be defined more precisely without restricting the scope of the invention.

„Antibody specifically binding to target X“.

Claim drafting - Antibodies

- *Antibody specifically binding to target X.*

- **Product claims charcterizing an antibody by its structure:**
  - *An antibody X having the amino acid sequence of SEQ ID NO. 1.*
  - *An antibody having a VH of SEQ ID NO. 1 and a VL of SEQ ID NO. 2.*
  - *An antibody having 6 CDR regions with SEQ ID NOs. 1-6.*
- **Product-by-process claims characterizing an antibody by a process for its preparation:**
  - *An antibody X obtainable by a process comprising steps ….*
- **Product claims comprising antibodies as essential elements:**
  - *A kit for detecting compound X comprising antibody Y.*
  - *A pharmaceutical composition comprising antibody X.*
- **Process claims for antibodies:**
  - *A process for isolating antibodies X from source Y comprising the steps of …*
  - *A process for preparing antibody X, comprising the steps of expressing SEQ ID NO.Y in host cell Z and obtaining the antibody from the cultivated cells.*

Plausibility at the EPO

- If the technical effect is **not in the claim**, but contributes to the **solution of the technical problem**, the evidence will need to be considered under the heading of **inventive step** (Art. 56 EPC).

- If the technical effect is **in the claim** the evidence for this will need to be considered under the heading of **sufficiency of disclosure** (Art. 83 EPC).

The requirements of sufficiency of disclosure (Art. 83 EPC)

- One way of implementing invention over whole scope of claim
- Repeatability
- Requirements relating to nucleotide and amino acid sequences
  - Attention is drawn to the new WIPO Standard ST.26 for sequence listings that apply to applications filed on and after 1 July 2022.
- Deposit of living material

BEST PRACTICES IN FILING AND PROSECUTING PHARMA & BIOTECH INVENTIONS

Rana Gosain
Partner, Daniel Law, Brazil

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DANIEL

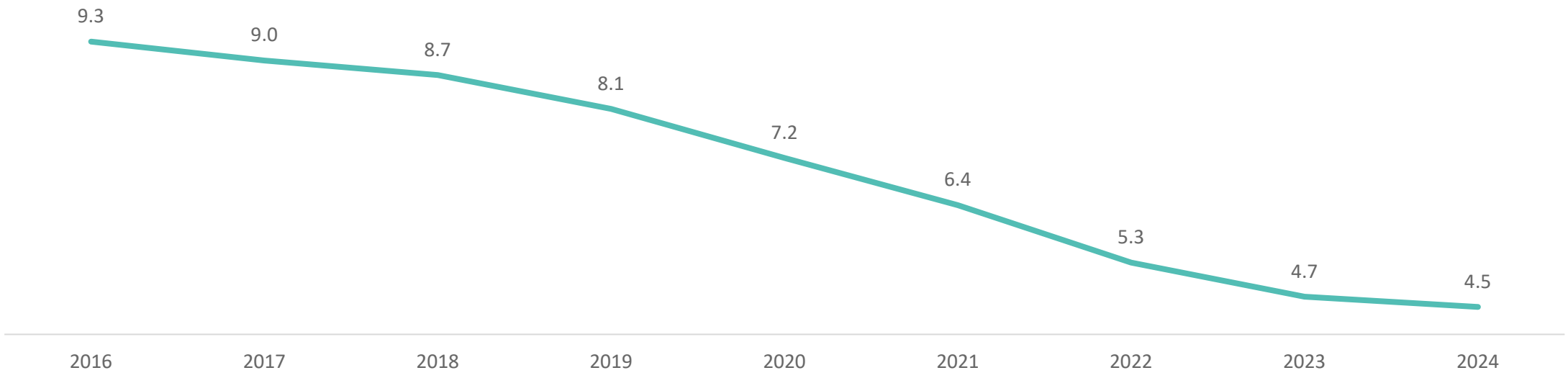
PATENTS IN BRAZIL: RECENT DEVELOPMENTS

Brazil has finally **tackled the backlog problem**

Beating the backlog in Brazil

4.7 years is the average time to obtain a notice of allowance in **2023.**

Average time to obtain patent protection (order 9.1; in years)



\ The BPTO implemented specific programs to tackle the backlog problem and to allow expedited examination that already have had great outcomes, but reducing the backlog is still a work in progress.

Source: BPTO

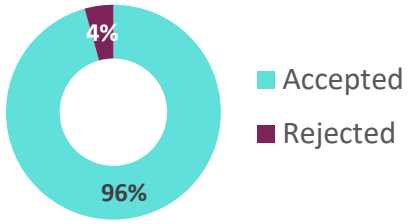
Fast-track programs
as tools to expedite examination

PPH – PATENT PROSECUTION HIGHWAY IN BRAZIL

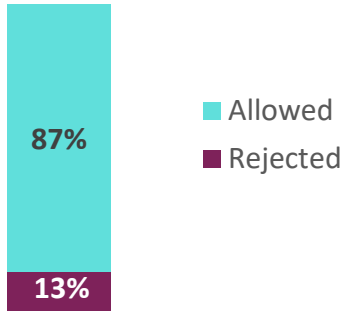
The PPH is a program resulting from international agreements between several patent offices. It accelerates the prosecution of Brazilian patent applications containing a member of its patent family that has already been examined in other countries with which the BPTO has an PPH agreement. Since the program began at the BPTO in 2016, there were 3287 PPH requests made by applicants in Brazil.

In 2023, the annual limit for PPH requests (800) was reached in July. In 2024, the 800 cap was also hit in July.

Most applications are accepted into the PPH Program[1]

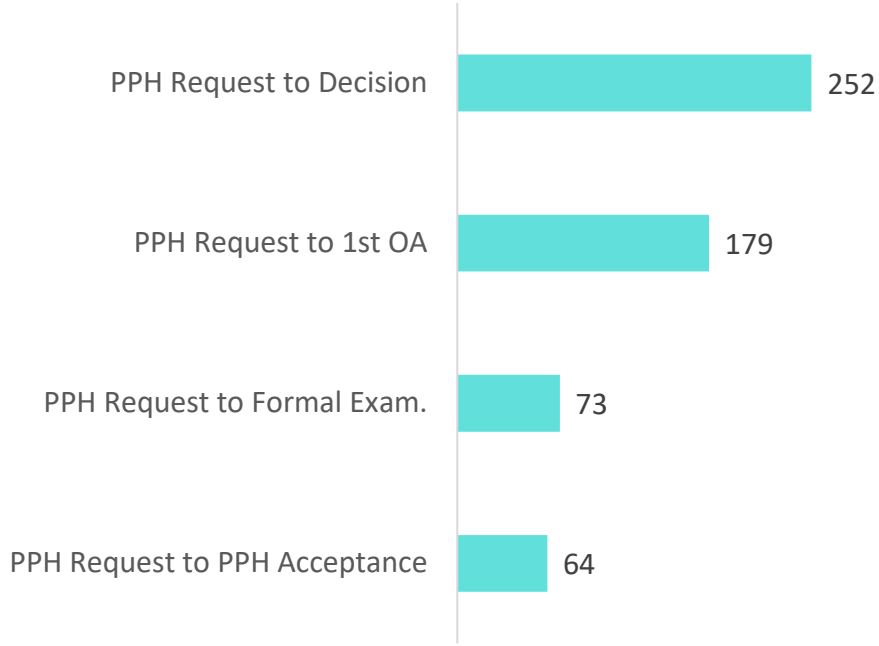


BPTO Decision[1]



49% of these cases were **granted without further office actions.**

Average timeframes[1] (days)

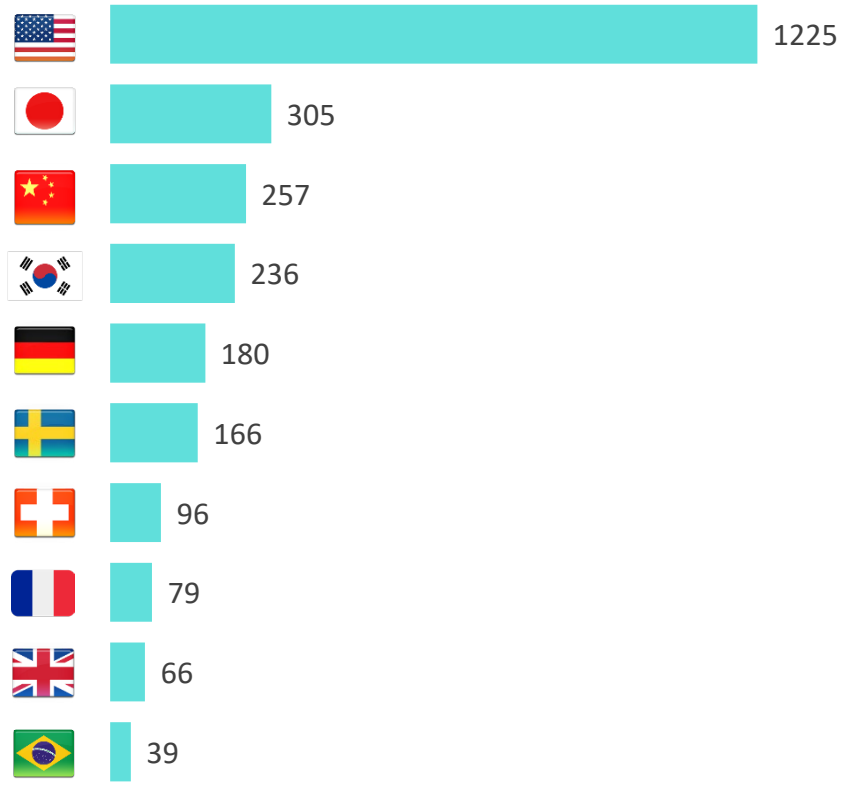


Source: BPTO
[1] Requests filed between 2020 and September 2024

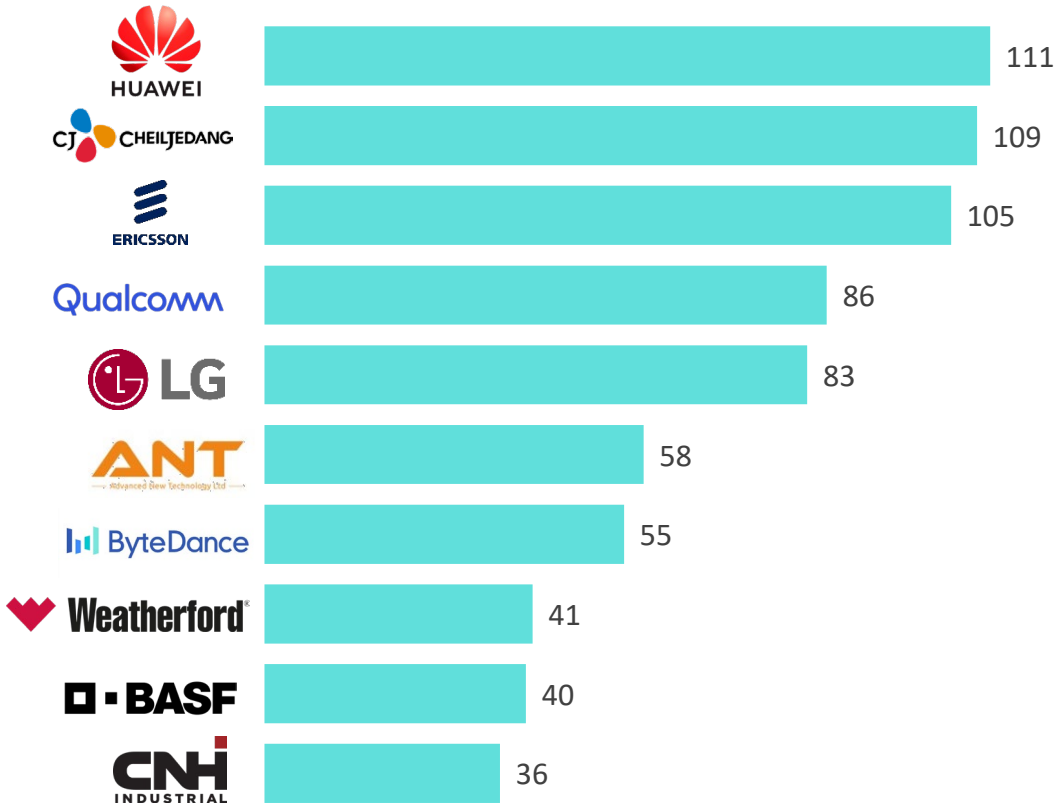
PPH – PATENT PROSECUTION HIGHWAY IN BRAZIL

DANIEL

Top 10 PPH Requests by applicants' country of origin[1]



Top 10 PPH applicants[1]



Source: BPTO
[1] Requests filed between 2020 and September 2023

GREEN PATENTS

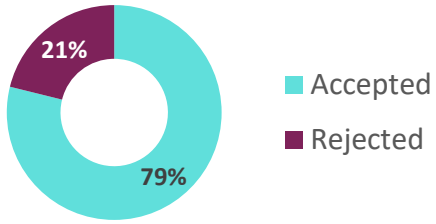
This program accelerates the prosecution of patent applications related to “green” technologies in the following areas:

- Alternative energy (e.g. biofuels, wind energy, solar energy etc);
- Transport (e.g. electric vehicles, hybrid vehicles etc);
- Energy conservation/saving (e.g. electric or thermal power storage, saving power consumption etc);
- Waste management (e.g. waste treatment, waste disposal etc); and
- Sustainable agriculture (e.g. reforestation techniques, irrigation techniques, alternative pesticides etc).

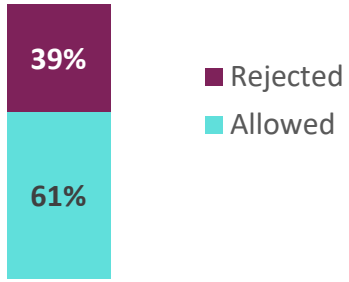
Requests for participation into this program[1]

663

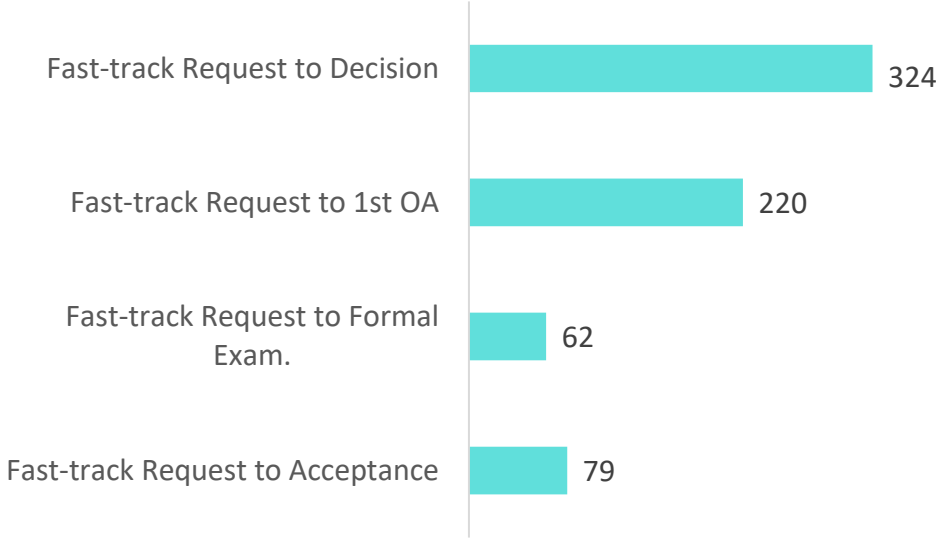
Status of such requests[1]



BPTO Decision[1]



Average timeframes[1] (days)



Source: BPTO
[1] Requests filed between 2020 and September 2023

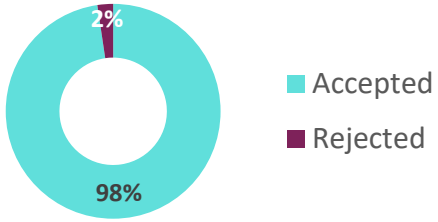
TECHNOLOGY AVAILABLE IN BRAZILIAN MARKET

The prosecution of the patent application can be accelerated through this program if the patent application covers (totally or partially) a technology already made available in the Brazilian market, through commercialization, licensing, import or export.

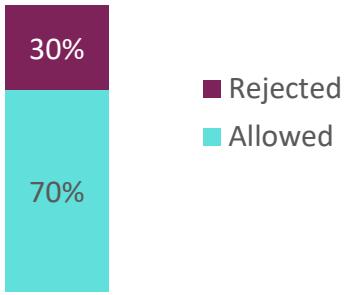
Requests for participation into this program[1]

262

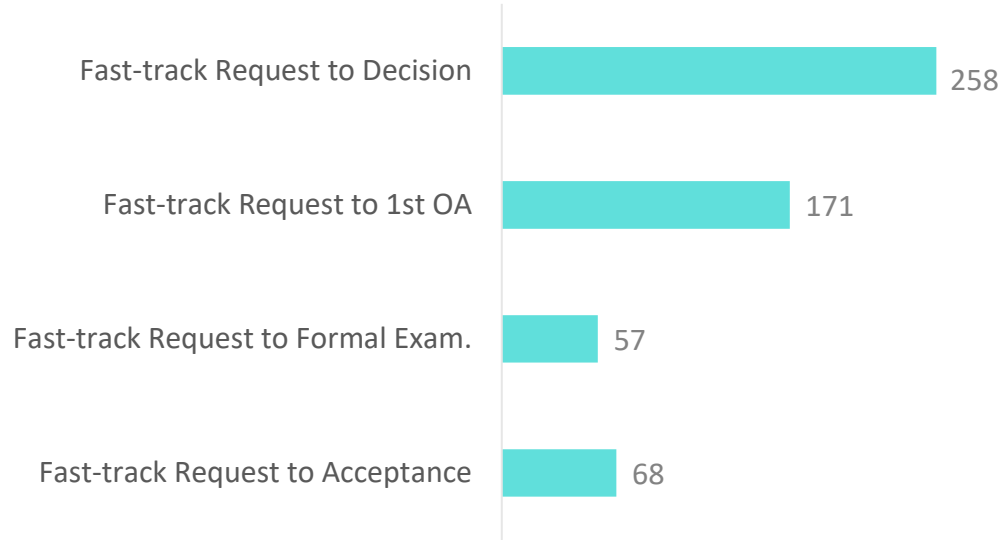
Status of such requests[1]



BPTO Decision[1]



Average timeframes[1] (days)



Source: BPTO
[1] Requests filed between 2020 and September 2023

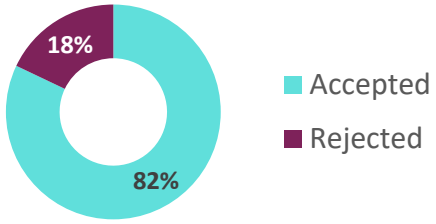
FAST-TRACK FOR CASES OF POSSIBLE INFRINGEMENT

If unauthorized third parties are reproducing the object of a patent application, expedited prosecution of application may be requested under this program.

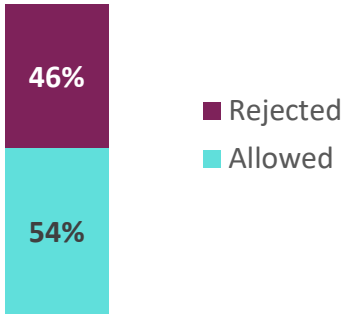
Requests for inclusion into this program[1]

341

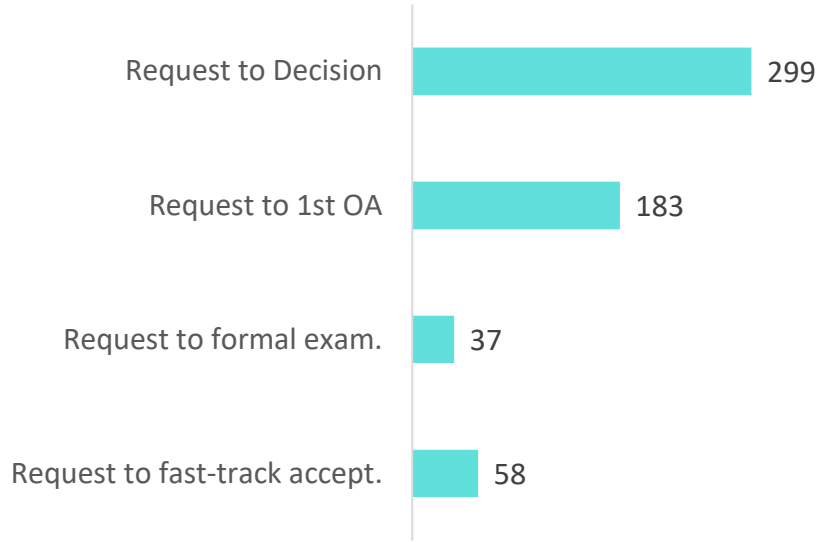
Status of such requests[1]



BPTO Decision[1]



Average timeframes[1] (days)



Source: BPTO
[1] Requests filed between 2020 and September 2023

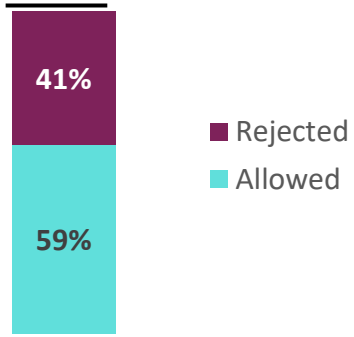
HEALTHCARE PRODUCTS

This program accelerates the prosecution of patent applications related to pharmaceutical products, processes and materials used in healthcare for the diagnosis, prophylaxis and treatment of AIDS, cancer, and rare or neglected diseases.

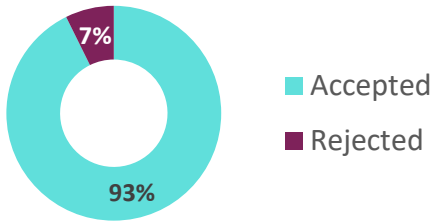
Requests for participation into this program

341

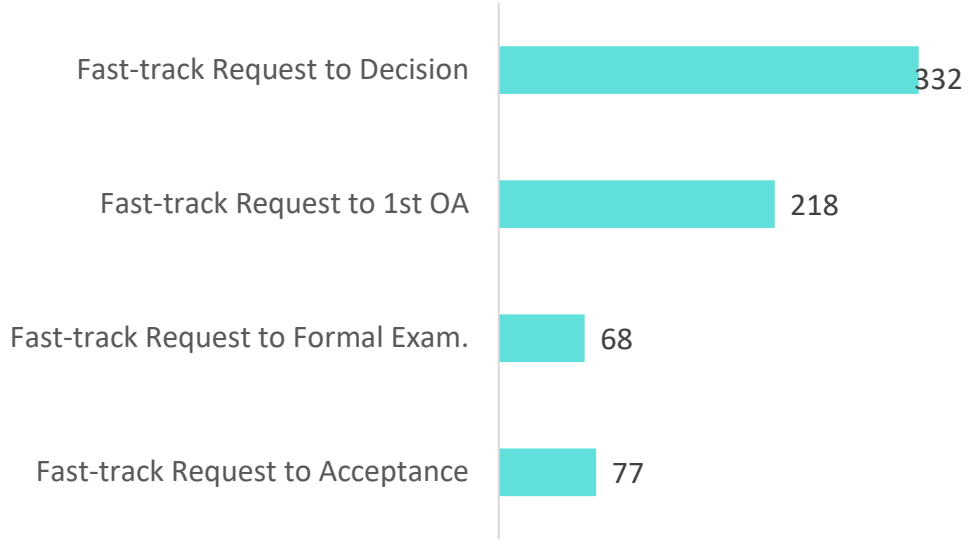
BPTO Decision[1]



Status of such requests[1]



Average timeframes[1] (days)



Source: BPTO
[1] Requests filed between 2020 and September 2023

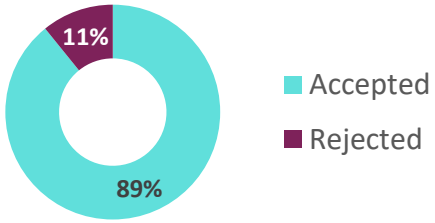
APPLICANT OVER 60 YEARS OLD, SERIOUS ILLNESS, MENTAL/PHYSICAL DISABILITY

This program expedites the prosecution of patent applications filed by an individual who is 60 years or older; or has a serious illness; or physical/mental disability

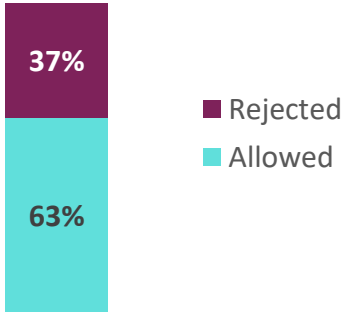
Requests for participation into this program

1,525

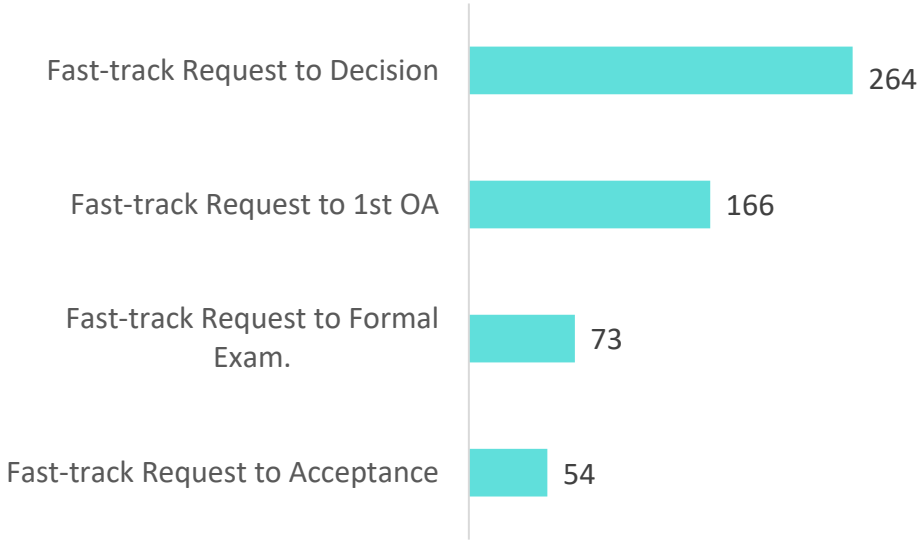
Status of such requests[1]



BPTO Decision[1]



Average timeframes[1] (days)



Source: BPTO
[1] Requests filed between 2020 and September 2023

BPTO **Patent Backlog Combat Program** initiated in 2019

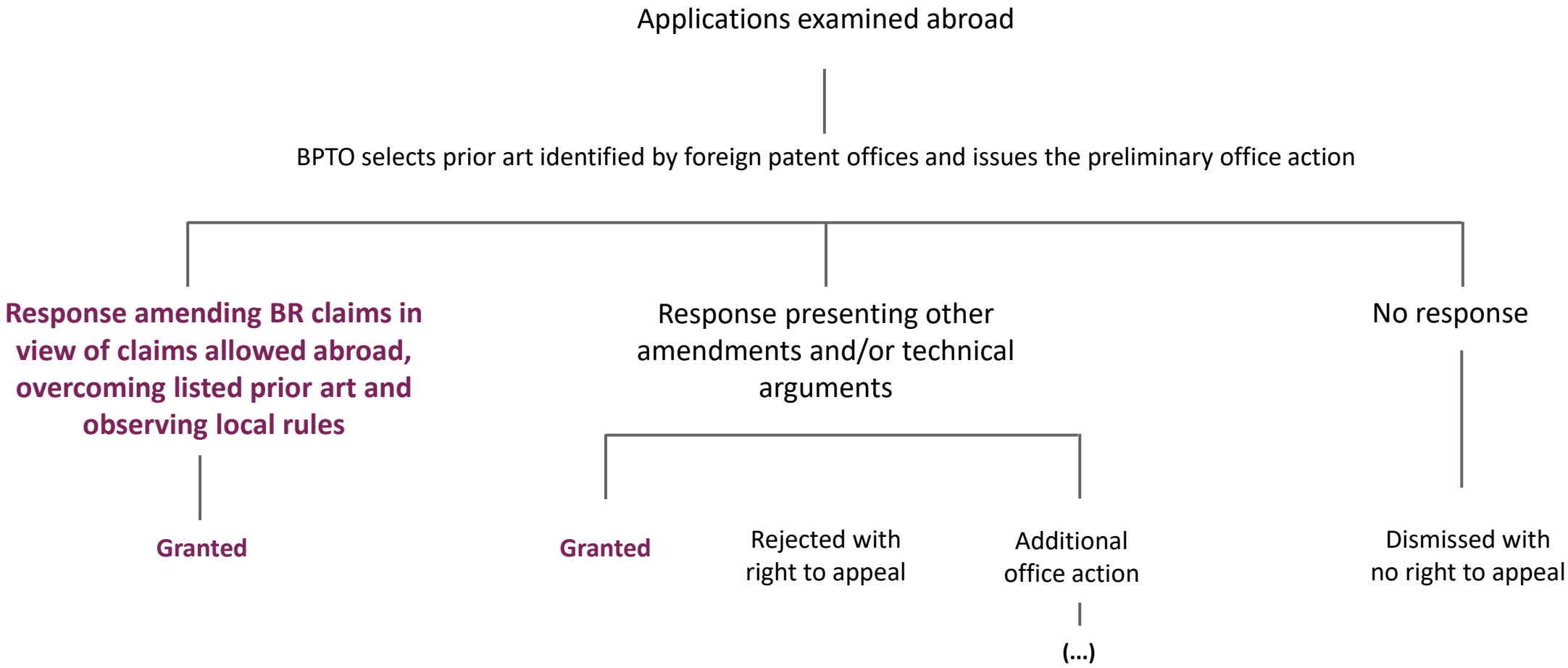
PATENT BACKLOG COMBAT PROGRAM

Cases eligible to receive a Preliminary Office Action (6.23 order)

- ✓ Applications that have been already examined abroad
- ✓ Filing date from January 1st , 2017
- ✓ No office actions on patentability issued by the Brazilian PTO
- ✓ No requests for fast-track examination
- ✓ No third-party observations (similar to a pre-grant opposition)

PATENT BACKLOG COMBAT PROGRAM

Cases eligible to receive a Preliminary Office Action (6.23 order)

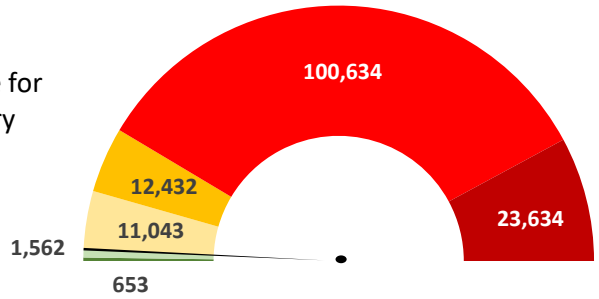


RESULTS SO FAR...

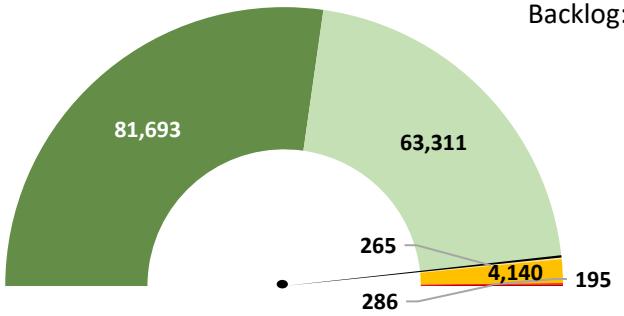
Changes from **2019** to **2023**

- Under formal examination
- Applications eligible for receiving preliminary office actions
- Under technical examination
- Lapsed
- Definitely lapsed
- Decided

September 2019
Backlog: 147,743



October 11th 2023
Backlog: 4,886



98% of the eligible cases to the program were decided.

17 months in average for the BPTO to decide a case after a preliminary office action has been issued.

89% is the allowance rate of the cases decided after a preliminar office action.

64% of the cases were allowed without further office actions.

- The BPTO created the program to beat the brazilian patent backlog. In Sep. 2019, the BPTO had about 148 thousand cases waiting for a decision. Out of these cases, there are only 4.9 thousand remaining.

Source: BPTO

Changes regarding the sequence of the **patent examination queue**

Patent examination queue changed

- The examination queue for patent applications will now be determined by the date of the request for examination, a step that must be completed within 36 months of the filing date.
- Previously, applications entered the queue based on their filing date once examination was requested.
- This strategic shift aims to streamline patent prosecution in Brazil, aligning it with global practices.
- The change also empowers applicants by granting them more control over the examination timeline for their patent applications.

New rules **restricting claim amendments at appellate stage**

Key changes and Concepts

DANIEL

Administrative Preclusion:

- All objections must be thoroughly addressed during the regular stage.
- Failure to address objections precludes addressing them later.

Filing Amendments:

- First Instance of examination:
  - Before Examination Request: Broadening scope and adding new claims permitted.
  - After Examination Request: Only restrictive amendments allowed.
  - Translation corrections allowed anytime.

- Appellate Stage:
  - Only restrictive amendments permitted.
  - Amendments must address specific objections from the first instance of examination.

Key changes and Concepts

Reassessment at First Instance of Examination:

- Possibility to revert to first instance of examination if specific arguments were overlooked.

- Allows addressing unresolved issues and making further amendments.

No Defined Deadline for Rejection Decisions:

- No specific deadline for issuing rejection decisions.

- Every office action response should be treated as potentially final.

Retroactive Application of New Rules

- New rules do apply retroactively.
- Applications that received the first substantive office action from April 1st are subjected to the new rules
- Applications that received the first substantive office action before April 1st will be examined according to the previous rules
- Brazilian PTO will issue a special type of office actions in the appeal procedures of applications that received the first substantive office action until April 1st 2024.
- The objective is to “educate” the applicants and explain how the case would be examined if the new rules were applied

Best practice and recommendations

DANIEL

Responding to Office Actions

- Add dependent claims to overcome objections related to patentability.
- Ensure compliance with formal objections even if contested.
- Provide well-founded reasons for not complying with objections.

Preparing an Appeal

- Appeals should not be seen as a continuation of examination.
- Primary claim set examined is the rejected claim set.
- Present arguments defending the rejected claim set.
- Assist appellate examiners by pointing out examination errors.

Best practice and recommendations

Conclusion

- Thorough and strategic responses are crucial under the new guidelines.

- Emphasis on addressing all objections and preparing comprehensive appeals.

Patent litigation and the enforcement of **standard-essential patents** in Brazil

FAVORABLE LEGAL FRAMEWORK

- Independent judiciary system
- Bifurcated system
- No bias against foreign companies
- Civil law system (no binding precedents)
- No juries, no trials (only written bench decisions)
- **Pro-plaintiff, pro-patentee jurisdiction**

INJUNCTIONS ARE WIDELY AVAILABLE

No need to give notice to the defendant

No need to post a bond or give security

No discussions regarding balance of hardships or public interest

Plaintiffs are allowed to have *ex parte* in-chambers meetings

Forum shopping strategy is key

Chances of obtaining PI >60% in certain venues

ENFORCEMENT OF SEPS IN BRAZIL

Two leading cases: **Vringo v. ZTE** and **Ericsson v. TCL**

More recent disputes: **DivX v. Netflix** and **Nokia v. Lenovo**

Preliminary injunctions available for SEPs even when encumbered with FRAND commitments

Injunctions also available for NPEs

Injunctions can be broad in scope

WHAT WE LEARNT SO FAR

Injunctions more likely if:

- There is evidence that defendant is an unwilling licensee, refuses to negotiate in good faith, refuses arbitration re royalties
- Defendant's competitors acknowledge patent and pay royalties
- Defendant denies infringement and only talk about FRAND later
- Other arguments: defendant has no assets in Brazil, potential for obsolecence of the technology, defendant's bad reputation, no harm to consumers
- Antitrust authority (CADE) normally does not interfere

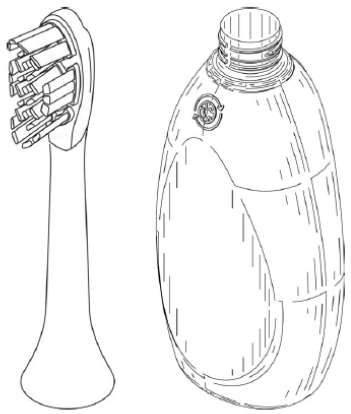
Brazil officially joined
the HAGUE SYSTEM

HAGUE SYSTEM IN BRAZIL

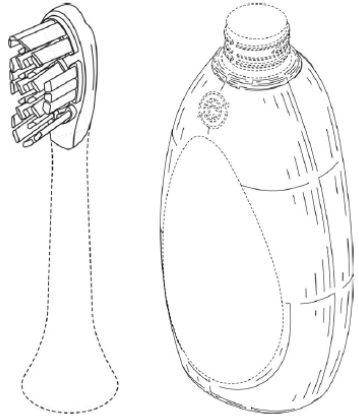
The Hague System for International registration of designs came into effect for Brazil on 1 August 2023 and introduced several changes on Brazilian Industrial Designs Rules

INCLUSION OF DASHED/BROKEN LINES OR SHADED SURFACES TO DISCLAIM ELEMENTS OR PORTIONS.

BEFORE HAGUE
(no dashed lines)



TODAY



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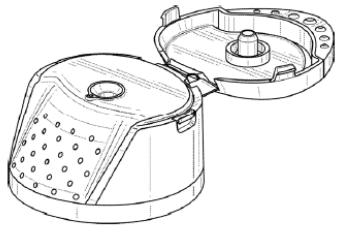

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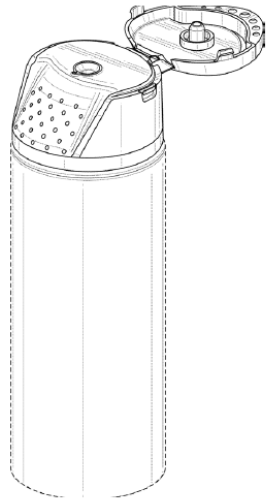

BEFORE HAGUE

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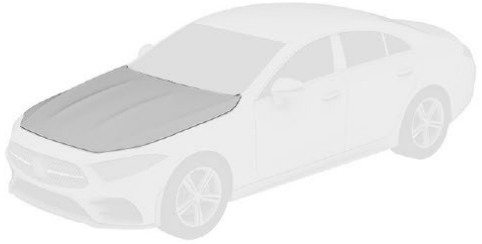

HAGUE SYSTEM IN BRAZIL

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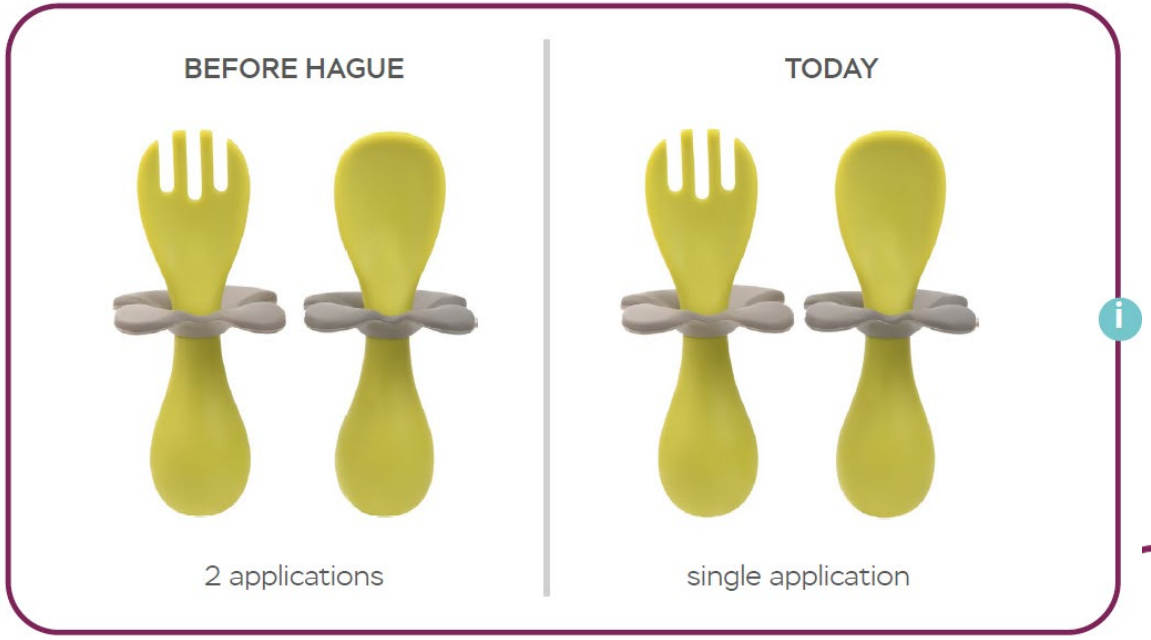
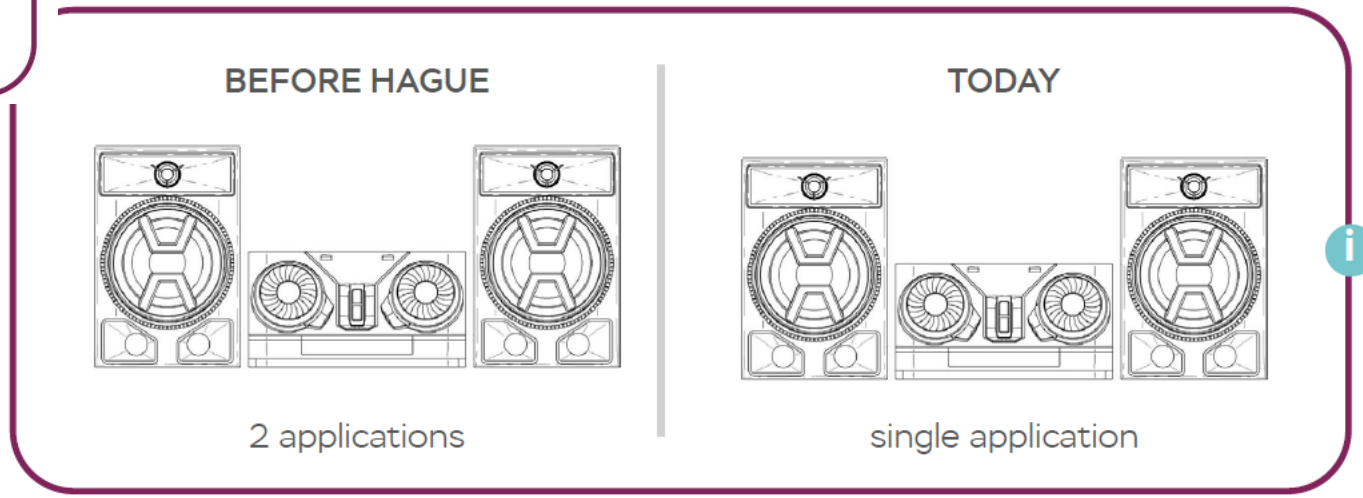
DESIGNS INCLUDING AN ASSOCIATION OF ELEMENTS





HAGUE SYSTEM IN BRAZIL

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DESIGNS INCLUDING TRADEMARKS. HOWEVER, THE PROTECTION WILL NOT COVER THE TRADEMARK.

BEFORE HAGUE

TODAY

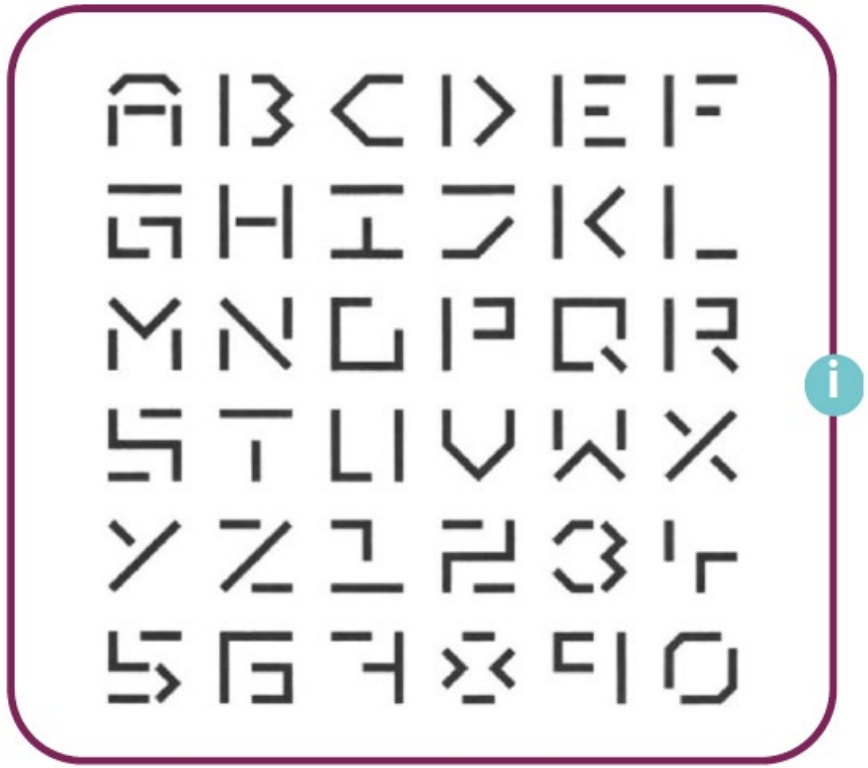
BEFORE HAGUE

TODAY

HAGUE SYSTEM IN BRAZIL

The Hague System for International registration of designs came into effect for Brazil on 1 August 2023 and introduced several changes on Brazilian Industrial Designs Rules

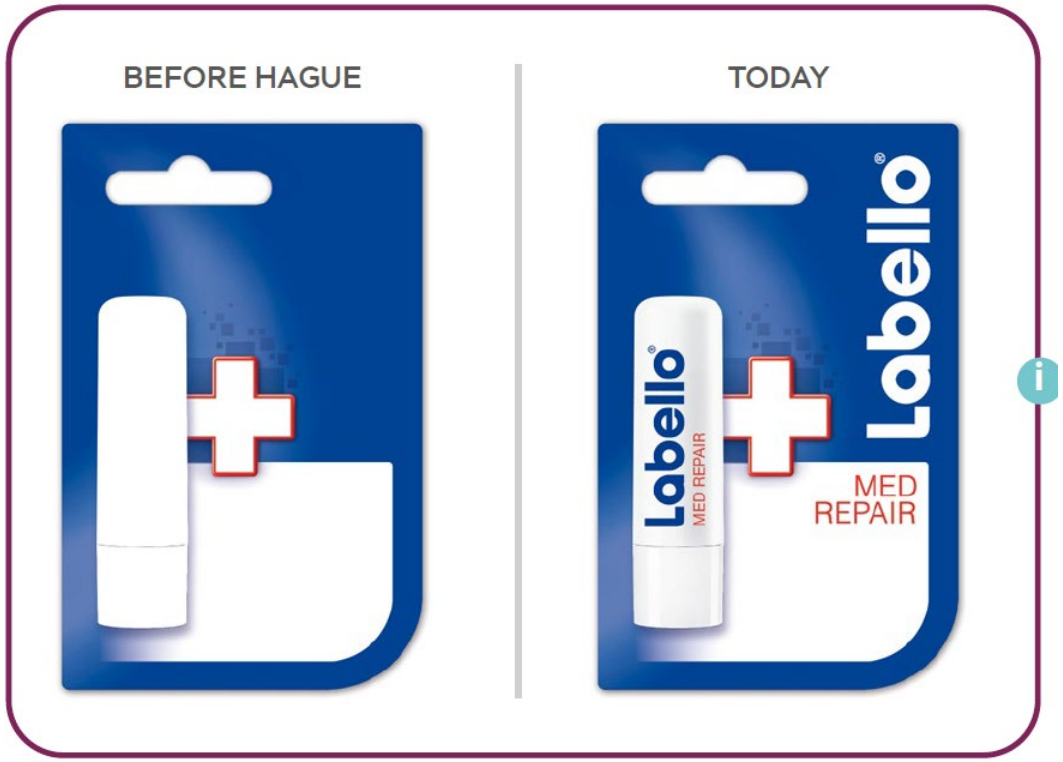
PROTECTION FOR TYPOGRAPHY FONTS.

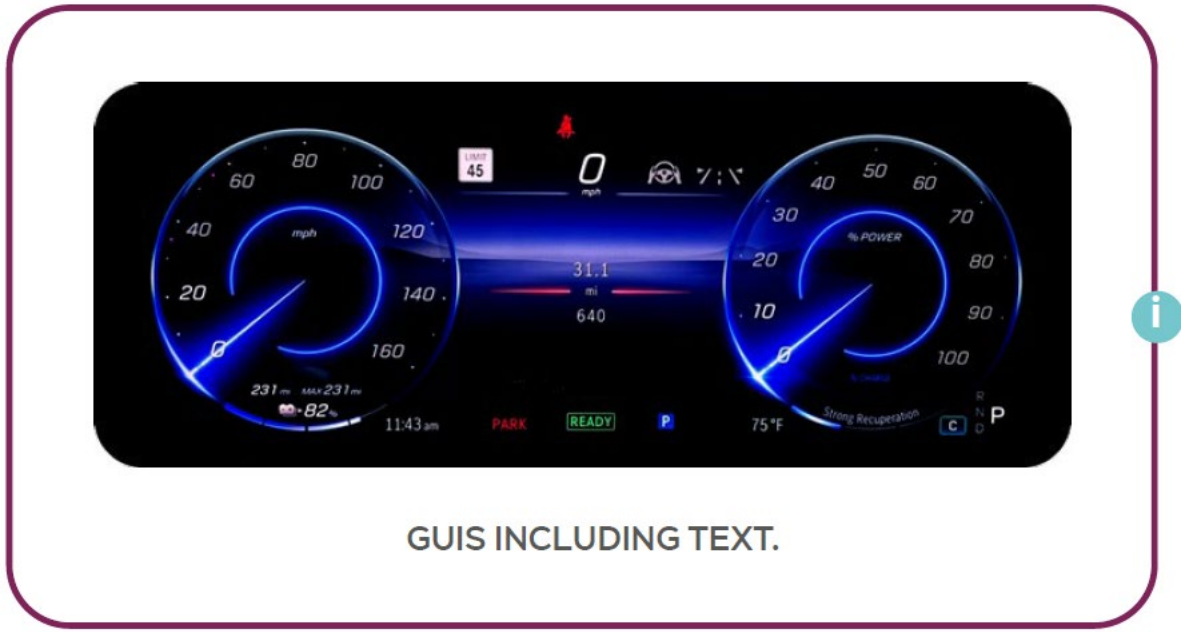


HAGUE SYSTEM IN BRAZIL

The Hague System for International registration of designs came into effect for Brazil on 1 August 2023 and introduced several changes on Brazilian Industrial Designs Rules

DESIGNS INCLUDING TEXT.





GUIS INCLUDING TEXT.

HAGUE SYSTEM IN BRAZIL

The Hague System for International registration of designs came into effect for Brazil on 1 August 2023 and introduced several changes on Brazilian Industrial Designs Rules

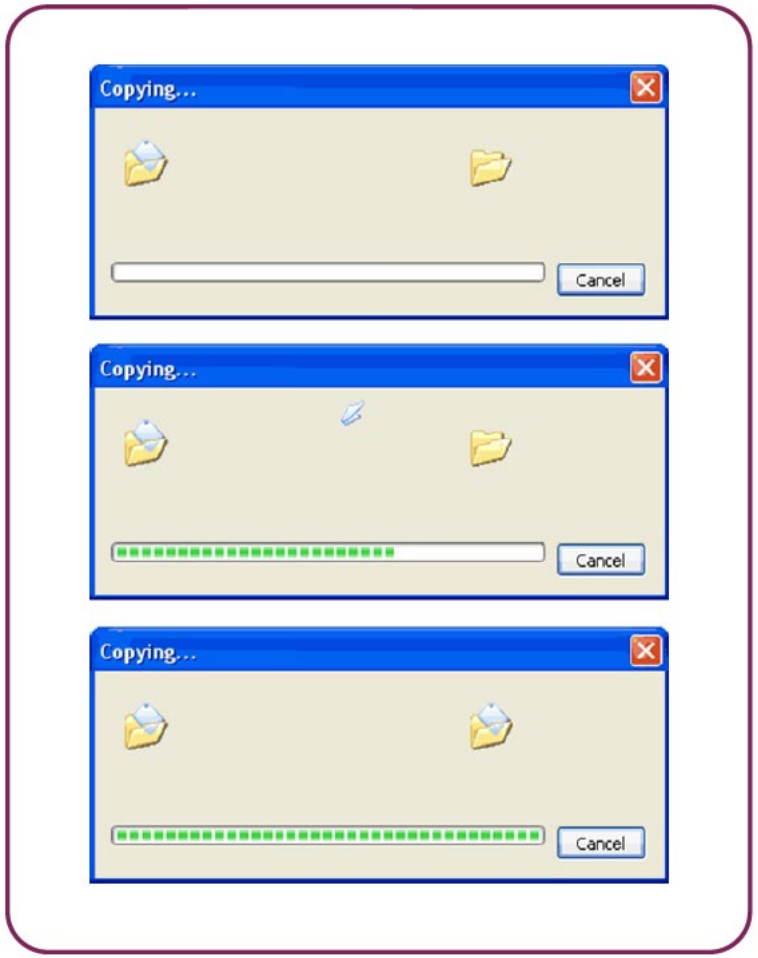
IMPROVEMENTS ON GUIs PROTECTION

	Before Hague	Today
Static icons	☑	☑
Dynamic icons		☑
Static interfaces	☑	☑
Dynamic interfaces		☑
Wallpapers	☑	☑
Static screensavers	☑	☑
Dynamic screensavers		☑
Transitional images		☑
Animated characters		☑

HAGUE SYSTEM IN BRAZIL

The Hague System for International registration of designs came into effect for Brazil on 1 August 2023 and introduced several changes on Brazilian Industrial Designs Rules

Transition images will be accepted. Previously they were understood as individual designs, which sometimes required divisional applications for each reproduction.



RANA GOSAIN

SENIOR PARTNER

Rana Gosain is a Senior Partner at Daniel Law. He has worked with Intellectual Property for more than 30 years. He is an Intellectual Property Agent accredited by the Brazilian PTO and has a postgraduate degree in Intellectual Property from the Pontifical Catholic University in collaboration with the Brazilian PTO.

Rana specializes in patents and industrial design and has great experience of handling patents, litigation strategies, validity and infringement studies and providing legal advice. Much of his work focuses on the pharmaceuticals and biotechnology area.

Rana's current role is to develop the best strategies for protecting and managing IP Portfolios. He also advises clients on a broad range of issues related to Intellectual Property.

RANKINGS

PRATICE AREAS

- Biotechnology
- Industrial Design
- Litigation
- Patents

EDUCATION

- Degree from the Veiga Almeida University Law School (UVA) in 2005;
- Postgraduate degree in Intellectual Property from the Pontifical Catholic University of Rio de Janeiro.

AFFILIATIONS, COMMISSIONS AND COLLEGIATE

- Member of the Brazilian Bar Association, registered in the States of Rio de Janeiro and São Paulo;
- Member of the Brazilian Intellectual Property Association – ABPI;
- Member of the Association Internationale pour la Protection de la Propriété Intellectuelle – AIPPI;
- Member of the Fédération Internationale des Conseils en Propriété Industrielle – FICPI;
- Member of the Licensing Executives Society – LES;
- Member of the American Intellectual Property Law Association – AIPLA;
- Member of the Director Council from ABPI;
- Member of the Brazilian Association of Industrial Property Agents – ABAPI.

GUSTAVO **SARTORI**

PARTNER | Co-HEAD OF PATENT PROSECUTION

Gustavo is an accomplished patent attorney with over 19 years of experience in patents and industrial designs. He holds a BSc in Electronic Engineering, an MSc in Mechanical Engineering, and a law degree, combining technical expertise with legal acumen. Recognized for his outstanding skills, Gustavo has been cited in prestigious legal rankings such as The Legal 500, IP Stars, IAM, and Leaders League.

Throughout his career, Gustavo has worked in renowned intellectual property firms in Brazil and gained industry experience as a patent engineer in a large mining company. In addition, he worked at a large technology company, in the department responsible for deploying the 3G access network and overseeing the quality of installation for base stations, antennas, links, and other components, equipment, and nodes of the access network. At an Intellectual Property firm, he worked on one of the first major patent litigation cases involving telecom standard essential patents in Brazil.

His diverse background has equipped him to handle inventions from various technical fields. With a deep understanding of both technology and the law, Gustavo also represents clients in patent-related lawsuits.

With a solid reputation, extensive experience, and a comprehensive understanding of patent law, Gustavo is a valuable asset for clients seeking effective patent protection and strategic legal guidance.

RANKINGS

PRATICE AREAS

- Competitive Intelligence
- Industrial Design
- Patents
- Mechanical, Electrical, Automotive, Industrial Equipment, Medical Devices, Agricultural Machinery and Telecommunications.

EDUCATION

- Electrical Engineering Degree with emphasis on electronics from “Instituto de Tecnologia Mauá” (2008);
- Bachelor in Law at the “Universidade Presbiteriana Mackenzie” (2016);
- Master’s Degree in Mechanical Engineering (2019).

AFFILIATIONS, COMMISSIONS AND COLLEGIATE

- Member of the Regional Council of Engineering, Architecture and Agronomy (CREA-SP);
- Member of the Brazilian Association of Industrial Property Agents – ABAPI.

ARTICLES

- Successful Patent Prosecution Highway program reaches annual limit in Brazil
- Patent Prosecution Highway Acceleration Program between Brazil and South Korea is renewed
- Brazilian Patent Prosecution Highway shows strong results in the first half of 2022
- Speeding up the patent process in Brazil
- Can you patent a software in Brazil?

DANIEL

www.daniel-ip.com

Drafting without borders – life sciences
The Canadian perspective – eh?

Serge Shahinian
Partner, Patent Agent
Lavery, Canada

alive

Most subject matter in the life sciences is patent-eligible in Canada

- **Chemical or biological molecules/products**
- **Living matter**
- **Therapeutics**
- **Diagnostics**
- **Personalized medicine**
- **Research tools, reagents**
- **Methods/processes**
- **New uses of known compounds**

***invention** means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter* (*Patent Act*, S. 2)

… As always – the devil is in the details!

Chemical or biological molecules/products

- Chemical compounds
- Salts; crystal forms/polymorphs
- Nucleic acids; proteins/peptides (sequence listing); can have combined structural (% identity) + functional definition
- Vectors
- Antibodies, antigen-binding molecules
- No exclusion *per se* based on occurrence in nature
- Compositions (including vaccines) comprising the above (at least 2 components – additionally recite generic carrier/excipient)
- Packages or kits comprising the above (for kits, need at least 2 components – additionally recite a further, generic component)

Antibodies

No strict "rule" as to what is required; fact-specific

- Functional definitions possible based on:
  - antigen
  - specific epitope of antigen
  - binding properties
- Structural definition
  - Sequences of 6 CDRs

Generally, not as strict as other jurisdictions, however, there has been considerable development in this area = growth of "prior art" regarding antibodies, especially for certain therapeutic targets – this raises the bar for disclosure and claim details for new antibodies against such targets

Living matter: “Lower” vs. “higher” life forms

Lower life forms – patent-eligible

- Cells (eukaryotic or prokaryotic), cultures, cell lines (can make biological deposits under Budapest treaty), host cells
- OK as long as the cell cannot become a higher life form:
  - Pluripotent and multipotent stem cell: patent-eligible
  - Fertilized embryo, totipotent stem cell: not patent-eligible

Higher-life forms – not patent-eligible

- Animals, plants, fertilized eggs, totipotent stem cells
- Certain plant parts (cutting, seed, tuber, fruit)
- Note: CA also offers Plant Breeders' Rights protection for new, distinct, uniform and stable plant varieties

In most cases, can obtain coverage for a higher-life form by claiming the corresponding cell.

Therapeutics – acceptable formats

Typically, simply a matter of recasting claims into "product for use" and "use" formats

- **X for use in treating Y (similar to EPO)**
- **Use of X for treating Y**
- **Use of X for the preparation of a medicament for treating Y (Swiss-type)**

Note: Avoid "active" language:

Bad: **Use of X for treating Y, comprising administering X subcutaneously.**

Good: **Use of X for treating Y, wherein X is for subcutaneous administration.**

Therapeutics – general principles

Prohibition of "method" claims only applies to medical treatment

- e.g., can claim a method of contraception in "method" format (because pregnancy is not a disease)
- e.g., can claim a method of administering an agent to a subject for imaging/diagnostics (as long as the agent does not also have a therapeutic benefit)

Regardless of claim format, claim cannot require professional skill

- Ranges of values may provoke an objection:
  - Dosage ranges
  - Ranges in frequency/timing of administration

Such issues, if raised can often be overcome by argument/amendment, and various precedents have been set by the CA authorities

Diagnostics

- Diagnostic methods are generally patentable as long as there is some kind of physical step
  - e.g., physical step of measuring analyte/marker (vs. “receiving data”)
- *In vivo* OK, as long as no therapy involved – e.g., can claim a method of administering a non-therapeutic agent for imaging/diagnostics
- Can also claim in “use” or “product for use” formats if necessary
- **Personalized medicine (treat a “responsive” patient subpopulation)**
  - Patent eligible; can also use “use” or “product for use” formats
  - Possible prior art inherency issues

Unity of invention; divisionals

CA divisionals cannot be used as "continuation" applications:

- "Voluntary" divisionals prone to "double patenting" objections
- No "terminal disclaimer" practice
- Reserved for pursuing claims removed due to a unity objection
- In view of new CA claim fee regime, take into account potential unity issues when preparing reduced claim set (to ensure representation of all potential invention groups)
- Don't need to put "favorite" invention first (but will probably be first anyway due to PCT practice)

Chemical & Biotech inventions

Archana Shanker
Senior Partner, Anand and Anand, India

alive

Chemical & Biotech inventions

1. Inventions u/s 2(1)(j)
2. Naturally corollary-what is not “product” or “process” is not allowed [claim format] e.g. USE claims and Swiss-type claims
3. Five pillars
    i. Novelty
    ii. Inventive step
    iii. Industrial applicability
    iv. Sufficiency
    v. Patent eligible subject matter

4. Patent eligible: under sections 3(b), 3(c), 3(d), 3(e), 3(i), 3(j)
5. Claim formats
    a) Pharma products
        - New chemical entities
        - Formulations/concepts
        - Combinations
        - New forms of known substances (polymorphs , salts)
        - Kits
        - Product by process

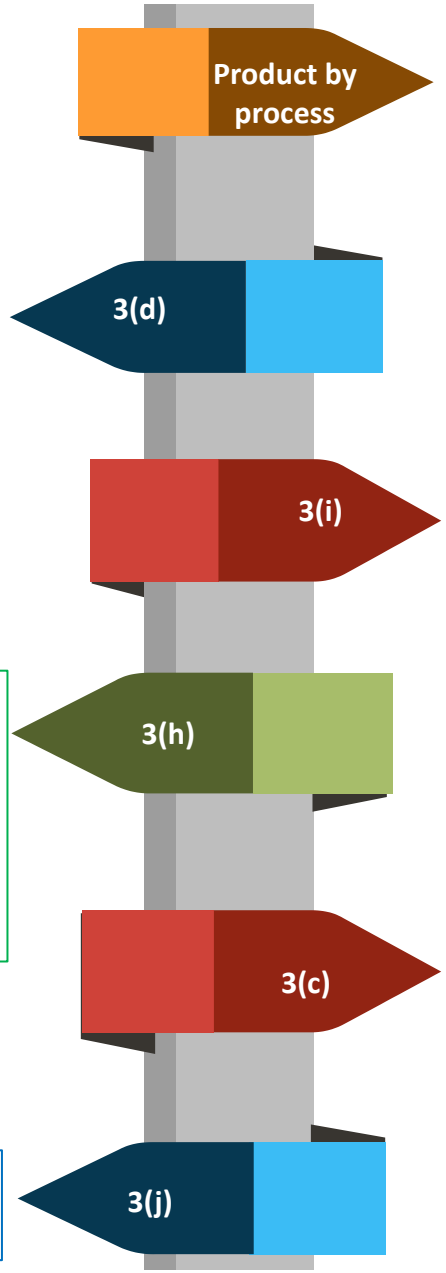
Chemical & Biotech inventions

- Method of manufacturing
- Intermediates and method
- Selection invention

b) Biotech Inventions

- Polynucleotides/gene sequences
- Protein sequences
- Vectors
- Host cells, microorganisms, stem cells
- Vaccines
- Antibodies /antigen bending fragment
- Diagnostic kits
- Assays

Some Important Cases



- ***Novartis V. Natco- DHC***
- ***Novozymes V. Controller***
- ***Novartis V. UoI- SC***
- ***BMS V. Controller***
  - MHC clarified that Section 3(d) only restricts incremental inventions and does not prohibit it.
  - Increased bioavailability may not always lead to enhanced *therapeutic efficacy*
- ***D.S Biopharma PMS***

VIFOR V. MSN

- DHC mentioned that 8. Claim protection over process does not act as a limitation on a product, in a product-by-process claim.
- Product-by-process claims are tested on the touchstone of novelty of the product

- ***Chinese University V. Asst. Controller***
- ***Anthrogen GmbH V. Controller***
  - Scope of method of diagnostic methods have to be discerned from the specification to determine whether the claims in substance relate to a method of diagnosis or not.

- ***Decco Worldwide V. Controller of Patents***
  - Calcutta HC opined that Controller failed to explain why a way of treating plants to combat fungal diseases would not fall inside section 3(h), which includes traditional practices of agriculture.

- ***Monoclonal Ab - MHC***
- ***Genmab A/s V. Assistant Controller***
- ***Imclone LLC V. Assistant Controller of Patents and Designs***
  - MHC observed that the qualifier “mere” in section 3(c) is limited to “discovery of a scientific principle” and does not extend to “the discovery of any living thing or non-living substance occurring in nature.”
  - The qualifier “occurring in nature” apply only to “non-living substances”.

- Plants and animals or parts thereof, host cells

Chemical & Biotech inventions

Novelty

- Chemical
  - Genus vs species
  - Selection invention: therefore, include data to demonstrate selections even if not "a selection"
- Biotech
  - Define the sequences
  - Claims with properties not allowed
  - Identify differences with wild type sequences

Inventive Step

- Chemical + Biotech
  - Comparative data with closest prior art
  - Do include technical advantage of invention to be able to later provide post-filing date (*AstraZeneca - before DHC*).
  - Unexpected & surprising technical effect
  - Experimental studies with examples

Industrial Application

- Low threshold
- Distinction between commercial utility + patentable utility (*Roche vs Cipla Delhi HC-DB order*)

Sufficiency

- Enabled
- Working example (*Titan, Nestle, Bayer*)
- Scope of Markush: every substituent should be supported by one example
  e.g. Halogen -> e.g. for chlorine is Ok
  C1-C3 alkyl -> e.g. ethyl is Ok

Chemical & Biotech inventions

In Biotech cases

-> Include if possible, at least one example of full polynucleotide
-> If claim has expressions like "at least 95% identity" include one example of 98, 99 , 96 % similarity
-> eukaryotic cells not patentable
-> host cells generally not allowed

GENERAL TIPS

- AMENDMENT- if the claims relate to non eligible subject matter, do amend the claims as soon as possible

- DIVISIONAL APPLICATIONS;
  - File divisional applications for unclaimed subject matter provided they relate to " distinct inventive concept" or else move an amendment to the claims of the parent application;
  - Don't abandon the parent application in the hope that the claims of the divisional will be allowed. Ensure that the claims of parent and divisional are distinct even before you decide to give up the parent case.

FICPI 22nd Open Forum
Madrid
25-28 September 2024

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