

HOT TOPICS ON PATENT PROSECUTION IN BRAZIL 2024



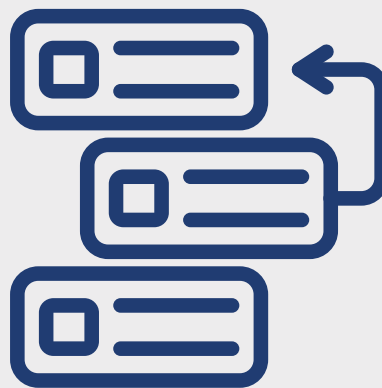
Recent months have brought notable legal and procedural shifts, shaping the innovation landscape in Brazil. Join us as we uncover the key developments and insights within the patent arena, keeping you informed on the dynamic evolution of this vital sector.

In this pamphlet, we will update you on the current status of the patent backlog combat program (launched by the BPTO in 2019) and provide highlights on the new guidelines for examination of industrial design applications and fast track programs available for patent applications.

We will also discuss how the Brazilian National Strategy of Intellectual Property has driven the elaboration of the BPTO's strategic plan for the period of 2023-2026, and comment on the ANVISA's Resolution approving skinny labeling in Brazil, as well as the PDL aiming to approve the Budapest Treaty in our country. We hope you enjoy the read!

By Murta Goyanes's Patent team

CURRENT STATUS OF BACKLOG OF PATENT APPLICATIONS IN BRAZIL

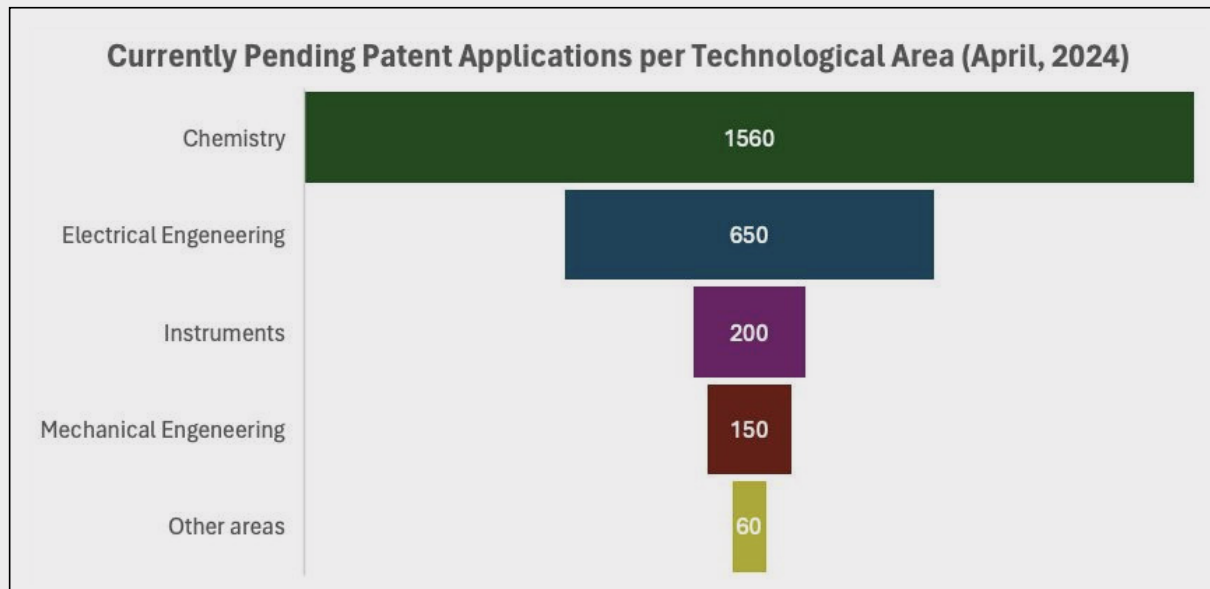


In the past few years, the Brazilian Patent and Trademark Office (BPTO) has launched a fruitful program to substantially reduce the backlog of patent applications with pending examinations, consequently diminishing the average time for technical examinations.

For this purpose, the BPTO has published Resolutions permitting the Examiners to issue “preliminary” Office Actions availing of results of examinations already conducted by foreign Patent Offices to aid them in uncovering prior arts cited in counterpart applications. Applicants are then allowed to adjust the claims to such documents, to submit arguments to overcome them, and/or to adapt the application to the local rules. Upon filing responses to such Office Actions, the applications were often placed in proper conditions of being allowed, which overall streamlined the whole examination process.

According to the official data provided by the BPTO, on the occasion the program was launched in 2019, more than 147,000 patent applications were pending at the Patent Office, and it used to take, on average, as long as 11 years to have a patent granted in Brazil. Fortunately, after 4 years of “combat”, we have now less than 3,000¹ applications “in stock” to be examined, which led to a substantial reduction of the pendency time. This is a clear indication of the BPTO’s compromise in streamlining its examination procedures, fostering innovation and attracting new investments in Research & Development for the country.

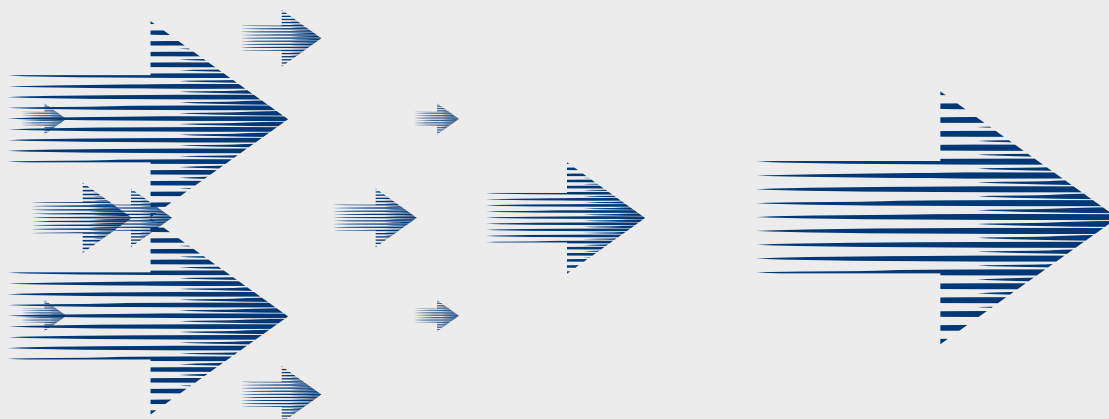
¹Data obtained from the BPTO’s website, with information uploaded on April 4, 2024.



Source: BPTO website (<https://www.gov.br/inpi/pt-br/servicos/patentes/plano-de-combate-ao-backlog>)

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FAST TRACK EXAMINATIONS AVAILABLE FOR PATENT APPLICATIONS AT THE BPTO



The BPTO makes available programs for fast-tracking the examination of patent applications under some circumstances. Applicants may avail of the legal provisions in force to substantially reduce the overall prosecution time of their applications. These are the main pathways that can be followed to have an expedited technical examination in Brazil.

A. Patent Prosecution Highway (PPH)

A PPH program is a bilateral agreement stipulating that each of the two signing Patent Offices can make use of the results of searches and examinations conducted by each other.

The BPTO currently establishes PPH programs for patent applications which families started in a foreign PTO with which the BPTO has collaboration agreements. The list of countries with valid collaborative agreements is dynamic and may change from time to time depending on the renewal of the agreements and the signature of new ones. The list is extensive and encompasses several countries (please consult).

According to the rules in force, the obtainment of a positive technical report by one of the counterpart applications belonging to the family of the relevant BR application is sufficient for requesting the entry into the program. Furthermore, more recently, the BPTO also included the positive results obtained in the International Preliminary Report on Patentability (IPRP) as another manner of expediting examination through the PPH.

It should be highlighted that the program is currently available for all technological fields. The odds are that there is a limited number of applications that can enroll in the program per year, this number being of 800 requests per yearly cycle starting on January 1st and ending on December 31st, respecting the following limits:

- Up to 1 PPH request per Applicant per week;
- Up to 100 requests using the results from the IPRP; and
- Up to 250 requests per International Patent Classification (IPC) Section per year.

**Statistics of PPH requirements filed from January 1 until March 27, 2024
(as made available at the BPTO's website, consulted on April 01, 2024):**

- Filed requests: **468**
- Evaluated requests: **145**
- Applications with substantive decision: **9**
- Average time between the request to enter into the PPH and first technical action: **48 days**
- Average time between the request to enter into the PPH and decision: **52 days**
- Shortest time until decision: **39 days**

For the year 2024, the maximum number of 100 requests using results of the IPRP has already been reached, showing a clear interest of the Applicants in using the system.

It is important to highlight that according to the BPTO's 2024 Action Plan, one of its goals for this year is the entry into the plurilateral PPH pilot program called Global-PPH. Under such program, a request for accelerated processing can be made at any participating office based on work products, including PCT work products, from any one of the other participating offices under unified criteria.

B. Fast-track examination based on BPTO's Ordinance No. 79/2022

Besides the option indicated above, BPTO's Ordinance No. 79/2022 establishes that fast-track examination can be requested by the Applicant in the following situations:

- ▶ when the Applicant is a natural person: *(i)* older than 60 years old; *(ii)* having mental or physical disabilities; or *(iii)* having a serious illness;
- ▶ when the application is filed by Brazilian micro and small entities;
- ▶ when the Applicant is a legal person and belongs to a Brazilian Scientific, Technological and Innovation Institute ("ICT");
- ▶ when the Applicant belongs to a Brazilian Startup;

- ▶ when the application is directed to a pre-selected green technology, referring to (i) alternative energy; (ii) transportation; (iii) energy conservation; (iv) waste management; or (v) sustainable agriculture;
- ▶ when the application relates to health technologies for the diagnosis, prophylaxis and treatment of (i) Acquired Immunodeficiency Syndrome (AIDS), (ii) cancer, (iii) rare diseases (i.e., diseases affecting 65 for each 100,000 individuals); (iv) (pre-defined) neglected diseases or (v) public health emergencies of National importance, as defined by internal regulation; or of International relevance, when declared by the World Health Organization (WHO);
- ▶ when the Applicant is in need of a granted patent to obtain financial resources from official national credit institutions, as an economic subsidy, financing or partnership;
- ▶ when there is evidence that the unauthorized reproduction of the subject matter object of a patent application is taking place in Brazil;
- ▶ when the technology object of the patent application results from public financing, deriving from direct financial support from public revenues, with express objective for its development;
- ▶ when the application claims an object which was licensed, sold, imported or exported, taking as reference the Brazilian market; or
- ▶ when the patent application refers to an object which patent protection has been firstly filed in Brazil, i.e., the application belongs to a family which prosecution has been initiated in Brazil or had Brazil as a Receiving Office within the scope of the PCT.

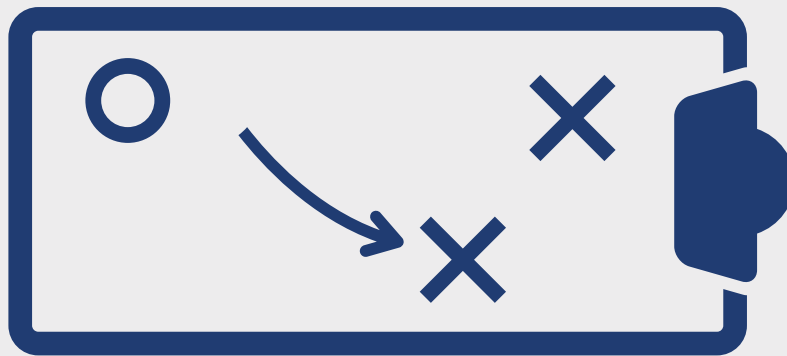
It should be highlighted that for some of the circumstances indicated above, specific documentation is required for proving that the application is eligible for entering the fast-track program.

Statistics of priority examination request filed from January 1 until March 27, 2024 (as made available at the BPTO's website, consulted on April 1, 2024):

- Filed requests: **229**
- Evaluated requests: **25**
- Applications with substantive decision: **3**
- Average time between the request to enter into the fast-track program and first technical action: **31 days**
- Average time between the request to enter into the fast-track program and decision: **N/A²**
- Shortest time until decision: **N/A²**

²Data not available for the year of 2024. For the year of 2023, the average time between the request to enter into the fast-track program and decision was of 147 days; and the shortest time until decision was of 14 days.

BRAZILIAN NATIONAL STRATEGY OF INTELLECTUAL PROPERTY DRIVES THE ELABORATION OF THE BPTO'S STRATEGIC PLAN FOR THE PERIOD OF 2023-2026



On December 7, 2021, the Brazilian Government enacted the National Intellectual Property Strategy (ENPI), through Decree No. 10,886. The purpose of the ENPI is to establish governance and coordination for initiatives, projects, and programs related to intellectual property in the country, aiming at boosting Brazil's competitiveness and socio-economic development.

The Brazilian ENPI is set to have a duration of 10 years (i.e., from 2021 to 2030), and encompasses 210 actions, systematically organized in 7 structural axes: (i) Intellectual Property for Competitiveness and Development; (ii) Dissemination, Education, and Training in Intellectual Property; (iii) Governance and Institutional Strengthening; (iv) Modernization of Non-Statutory Law and Legal Landmarks; (v) Compliance and Legal Certainty; (vi) Intelligence and Future Perspective; and (vii) Inclusion of Brazil into the Global IP System. The execution of these actions will be facilitated through biennial Action Plans.

ENPI is at the center of the work agenda of the Interministerial Group on Intellectual Property (GIPI), which established, in September 2019, a Technical Group of government representatives for its preparation and implementation.

According to the WIPO, a national IP strategy enhances a country's ability to create, protect and disseminate economically valuable IP assets. It fosters an enabling environment to harness a country's innovative and creative potential³. Thus, the ENPI emerged from the perspective that it is strategic that creativity and inventiveness transform into wealth generation for the country, favoring economic and sociocultural development⁴.

In response to the ENPI, the BPTO published its "2023-2026 Strategic Plan", which ushers in a new four-year institutional strategic planning cycle. While on the one hand it strives to uphold and consolidate the advances achieved in recent years by the PTO, it also indicates the new paths and challenges that are intended to be addressed from now on, based on a firm commitment to the ongoing improvement of the services provided to the society.

The BPTO Strategic Plan established nine main goals, which define the core themes and transformational axes which will guide its actions, namely:

1. Optimize quality and agility for granting and registering industrial property rights, achieving performance standards that are international benchmarks;
2. Promote the culture and strategic use of industrial property for enhancing competitiveness and innovation, for the development of Brazil;
3. Consolidate the inclusion of Brazil as a protagonist in the international industrial property system;
4. Highlight knowledge and acknowledgment of the value of the BPTO to society;
5. Deepen digital transformations while striving to upgrade its performance and the services it renders to users;
6. Ensure sustainable financing for the modernization and expansion of service delivery capacity;
7. Provide logistics support and thrifty, efficient and sustainable infrastructure; and
8. Upgrade governance and management practices, while strengthening institutional relationships.

³See <https://www.wipo.int/ipstrategies/en/>

⁴Brasil. Grupo Interministerial de Propriedade Intelectual (GIPI). Secretaria Executiva do GIPI: Ministério da Economia. Estratégia Nacional de Propriedade Intelectual (ENPI), Brasília, 2020.

With these goals in mind, the BPTO Directors shall establish guidelines and priorities focused on institutional actions for pursuing the strategic goals above.

Specifically, within the context of patents, it should be highlighted the goal of the BPTO to reduce the average examination time from the current 6.9 years to 2.0 years, counted as from the filing date of the application. For this purpose, a Public Hearing has been initiated by the BPTO to receive comments and suggestions about the potential revision of rules and of the terms for requesting examination of patent applications.

Overall, we view positively the initiatives from the BPTO to streamline even more its processes and improve its performance and the quality of the services provided to the society, consolidating its status as a world class Industrial Property Office and as a disseminator of the Intellectual Property in the country.

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THE PDL APPROVING THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF MICROORGANISM DEPOSITS FOR PATENT PURPOSES ADVANCES IN CONGRESS



The Project of Legislative Decree (PDL) 466/2022 from the Commission of Foreign Affairs and National Defense, approving the text of the Budapest Treaty, which is being processed under an urgency regimen, has been receiving recommendations for its approval from several Commissions designated to evaluate it. After such assessments, the PDL will be voted by the Chamber of Deputies and the Senate.

According to the Industrial Property Law, IPL No. 9279/96, as well as Normative Instruction No. 118/2020 (which establishes examination guidelines for Patent Applications in the Biotechnology field), when a patent application involves biological material essential to the realization of an invention, which cannot be sufficiently described under the terms of the law and is not accessible to the public, there is a need to supplement the description of the object of the invention by means of the deposit of said material in an appropriate depository institution.

In this context, the Budapest Treaty, adopted on April 28, 1977, and amended on September 26, 1980, administered by the World Intellectual Property Organization (WIPO), establishes that a contracting State that allows or requires the deposit of microorganisms for patent purposes, like Brazil, must recognize, for such purposes, the deposit of a microorganism with any “International Depositary Authority”, regardless of whether such authority is located within or outside the country. This avoids that Applicants need to deposit the biological material in each country where they wish to obtain patent protection for their inventions.

According to current regulations, the BPTO already considers the deposit of biological material made with International Depositary Authorities recognized by the Budapest Treaty for the purpose of supplementing the description of patent applications. However, with the approval of the Treaty, it will be possible for Brazilian institutions to be accredited as International Depositary Authorities. According to the CCTI's opinion, the Treaty under analysis will be welcome as it streamlines and facilitates the recognition of Brazilian patents in other countries worldwide and also promotes cost reduction for domestic Applicants of patent applications involving biological material. Still, the approval of the Budapest Treaty aligns with the efforts made by the country to integrate into a new scenario in the field of biotechnology and the protection of intellectual property assets developed in this sector. In this regard, in his vote, Congressman Marangoni stated that *“Brazilian biotechnology has much to gain with the country's effective entry into the International System for Deposit of Microorganisms, in a world undergoing increasing technological dynamism in this field”*.

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BPTO PUBLISHES THE 2ND EDITION OF THE INDUSTRIAL DESIGNS MANUAL



In order to promote a reduction in barriers that hinder the international registration of industrial designs in Brazil, offering uniform and homogeneous treatment before other international Patent Offices, in addition to improving the services provided to Applicants, the BPTO issued the 2nd edition of the Industrial Designs Manual, established by Ordinance INPI/PR No. 36/2023, published on September 12, 2023 in the BPTO's Official Gazette and in the Official Gazette of the Union (DOU).

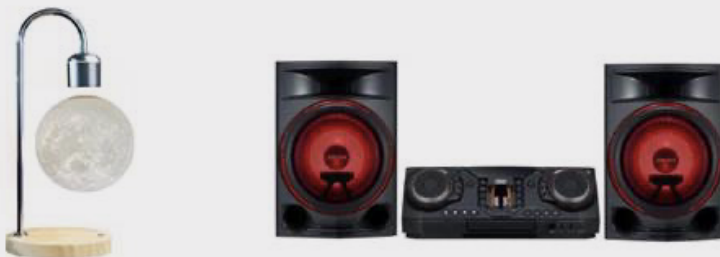
The aforementioned Manual derives from the analysis of public contributions, received in the consultation period between November 7 and December 16, 2022, carried out by the Permanent Committee for the Improvement of Procedures and Guidelines for the Examination of Trademarks, Industrial Designs and Geographical Indications (CPAPD).

Among the most relevant topics, the following stand out:

- ▶ Possibility of protecting the industrial design of ornamental two-dimensional or three-dimensional configurations applied on electronic devices (e.g., watertight or dynamic graphic interfaces, icons, typographic families etc.);



- ▶ Possibility of protecting the industrial design of three-dimensional configurations made up of parts with no mechanical connection between them (e.g., sound equipment made up of a receiver and two speakers);



- ▶ Possibility of protection of the industrial design that includes a trademark or protection of the industrial design of the logo;



- ▶ Possibility of protecting industrial designs that include textual elements of any nature, in any language;



- ▶ Expansion of the possibilities for representing the object of the registration, especially regarding the representation of unclaimed illustrative elements (e.g., use of dashed lines to represent the renunciation of illustrative elements that are not part of the claim);



- ▶ Publication of the conditions for maintaining priority based on the analysis of the correspondence between this claim and the claim in the registration application in Brazil;
- ▶ Possibility of presenting and examining priority documentation through the WIPO-DAS electronic access service;
- ▶ Publication of parameters for novelty and originality assessments (e.g., merit examination); and
- ▶ Incorporation of guidelines for processing assignments arising from the Hague Agreement, as established by Ordinance INPI/PR n° 25/2023.

The Manual came into force on October 2, 2023.

THE BRAZILIAN NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA) APPROVES "SKINNY LABELING" IN BRAZIL



On December 6, 2023, the Board Resolution (RDC) No. 831 was published, amending RDC No. 47 of September 8, 2009, which establishes rules for the elaboration, harmonization, updating, publication, and availability of medicament labels for patients and healthcare professionals.

RDC No. 831 modifies the prior resolution with regard to the requirement that labels for generic and similar (branded generic) medicaments must contain the same therapeutic indications as those in the labels of reference medicaments. This modification will allow the labels for these medicines to differ from the Standard Labels, by suppressing the therapeutic indications protected by patents or claimed in published patent applications.

The Resolution provides that labels different from the Standard ones must include the sentence: "Information referring to indications of the medicament protected by patent has been omitted," in bold, in the section "1. FOR WHAT THIS MEDICAMENT IS INDICATED?" in the patient's label and "1. INDICATIONS" in the healthcare professional's label. Upon expiration of the patent or rejection of the patent application, the labels of generic and similar medicaments should then incorporate the suppressed indications, and the above-mentioned sentence must be removed.

RDC No. 831 entered into force on February 6, 2024, and will allow generic and similar medicaments containing active ingredients and formulas already in the public domain (but still protected by patents for second medical uses) to be marketed in Brazil without infringing, through their labels, existing patents or pending patent applications covering these novel therapeutic uses. The purpose of the regulation is to increase the availability of generic and similar medicaments in the country and reduce their costs. The practice of skinny labeling is not exclusive to Brazil and is already being adopted by the regulatory agencies from the USA (Food and Drug Administration) and Europe (European Medicines Agency), for example.

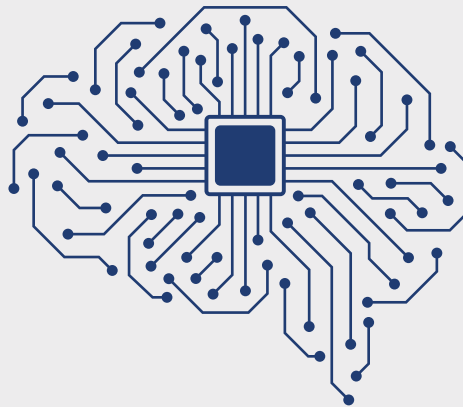
This new rule may be seen with concern by patent holders in Brazil, as it could impose challenges in the enforcement of their patents in the country, raising questions within the judiciary related to a potential patent infringement.

Furthermore, the legality of this Resolution may be questioned as Law No. 6.360/76 sets forth that similar and generic medications must contain the same active principles, concentration, pharmaceutical form, route of administration, dosage, as well as therapeutic indications as of the reference medicaments.

RDC No. 831/2023 (in Portuguese language) can be read in this [link](#).

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THE BPTO ESTABLISHES A NEW ORDER FOR CARRYING OUT THE TECHNICAL EXAMINATION OF PATENT APPLICATIONS



On December 12, 2023, BPTO published in its Official Gazette No. 2762, a communication informing about the new procedures for distributing patent applications for the conduction of technical examinations. In its communication, the BPTO asserts that this procedure aims to reduce the processing and decision timeframe for patent applications, in addition to align the PTO's current practices with the practices already adopted by other International Patent Offices.

According to the Patents, Computer Programs and Topographies of Integrated Circuits' Board (DIRPA), said distribution, as well as the conduction of the technical examination of patent applications, will now be ordered by the date of the request for examination, instead of being ordered by the application filing date - in accordance with current practice.

This new procedure is a result of the statements obtained through the Public Consultation No. 1, of 2023, which invited "interested bodies, entities or individuals" to contribute with subsidies, considering the effect of the provisions set out in the Articles 32 and 33 of Law n° 9279/96.

Article 33 of Law n° 9279/96 rules that the applicant or any interested party must request the examination of the patent application within 36 (thirty-six) months from the filing date.

Article 32 of Law n° 9279/96 establishes the possibility that the applicant effects voluntary amendments to the application, up to the date of the examination request, provided that they are limited to the matter initially disclosed in the application. It is worth mentioning that due to the provisions of the BPTO's Resolution No. 93/2013, currently in force, which establishes the guidelines on the applicability of the provisions of art. 32 for patent applications, after the examination request, only amendments that better define and/or restrict the scope of protection are accepted. Those amendments that broaden the scope of the subject matter for which examination has been requested, even if they are duly grounded on the specification, will not be accepted.

The ordering of the technical examination of the applications based on the date of the examination request was implemented as from January 1st, 2024.

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THE BPTO PUBLISHES NEW RULES REGARDING THE SUBMISSION OF APPEALS AGAINST NON-FINAL REJECTION DECISIONS



The BPTO recently published new guidelines on the limits and scope of administrative appeals that affect patent, industrial design and trademark prosecution. Such guidelines became effective as of April 2, 2024.

Pursuant to the previous appeal practice, the substantive technical examination of a patent application was carried out by a First Level Examiner, who may issue office actions or unfavorable opinions, allowing Applicants to amend the application to overcome the objections raised (provided that such amendments are grounded on the specification as originally filed and are of limitative nature). If unconvinced, the Examiner issues a non-final rejection decision, triggering a 60-day term for appeals. In addition to challenging the Examiner's decision, the BPTO's prior long-standing practice allowed Appellants to amend the set of claims provided that there was no enlargement of claimed scope and/or addition of new matter, as well as submit new evidence and arguments to the Appeal Board to demonstrate that the application meets the patentability requirements.

Under the new rules, innovations within appellate proceedings will not be accepted, as it will now be considered to be barred by the effects of preclusion (the inability to act due to an omission).

The most recent Ordinance No. 10/2024 issued by the BPTO, contains guidelines in what concerns the amendments that will be admitted at Appellate stage, namely:

- ⊙ Restrictive amendments submitted at the appeal stage will be analyzed to assess whether they "imply a new request". On the contrary, these restrictive amendments may be accepted to overcome objections raised during the first-instance examination, provided that:
 - ▶ The applicant establishes a causal connection between the changes in the set of claims and the objection raised at the first instance;
 - ▶ The amendments are restrictive logical derivations of the rejected set of claims, that is, the amended set of claims must consist of a restriction of the set of claims object of rejection, and it is prohibited to bring subject matter that was abandoned during the First Examination Level or constitute an addition of new matter under the terms of the current rules;
 - ▶ The proposed restrictions must have been expressly provided in dependent claims or arising from the combination of independent/interconnected claims. Restrictions originating from the specification, and therefore not expressly contained in the rejected set of claims, will not be accepted; and
 - ▶ No change in nature (e.g., from patent of invention to utility model) will be allowed on appeal level, unless such a change was requested by the Applicant in the first level examination and unduly denied.

For patent applications whose appeals were pending at the date issuance of the new guidelines, the BPTO established the deadline of April 02, 2024 for the Applicants to submit supplemental petitions aiming to conform the appeals to the current rules. For those appeals not meeting the criteria outlined in the guidelines, the BPTO will issue an office action for the Applicants to adapt them to the current rules.

The new guidelines came as a surprise to IP practitioners and were not preceded by public consultations, as usually adopted by the BPTO. They are also highly controversial as they, inter alia, (i) conflict with article 212, first paragraph, of the Industrial Property Law, that establishes that appeals will be received with full devolutive effects and that all pertinent provisions governing the first level examination are applicable to the appellate stage; (ii) offend the legal certainty principle as they are an abrupt change from the BPTO's long-standing practice; and (iii) exceed what the BPTO is allowed to regulate, especially when the new guidelines are issued by the BPTO's president as a result of an internal legal consultation.

Still, we understand that the terminology employed in the most recent Ordinance is vague and insufficient to preserve the legal safety of Applicants who may have lodged appeals before the new guidelines enter into force, thereby permitting the adjudication of such guidelines.

murta
goyanes
advogados

 @murtagoyanes

 murta-goyanes

 patents@murtagoyanes.com.br

 murtagoyanes.com.br/en