



SERVIÇO PÚBLICO FEDERAL  
MINISTÉRIO DA INDÚSTRIA, COMÉRCIO EXTERIOR E SERVIÇOS  
INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL  
DIRETORIA DE PATENTES, PROGRAMAS DE COMPUTADOR E TOPOGRAFIAS DE CIRCUITOS INTEGRADOS

October 19<sup>th</sup>, 2018

## NOTE C. 8787

The answers to this Note have been provided on behalf of:

Country: Brazil

Office: Brazilian National Institute of Industrial Property (INPI)

(i) **Certain aspects of the applicable national or regional patent law, available at:**

[http://www.wipo.int/scp/en/annex\\_ji.html](http://www.wipo.int/scp/en/annex_ji.html)

- **WIPO LEX UPDATE**

Although there was no modification in the Brazilian legislation on Industrial Property (Law No. 9,279 of May 14<sup>th</sup>, 1996), INPI would like to take this opportunity to update the WIPO Lex database with the following regulations:

### **Guidelines for Examination of Patent Applications in the Chemistry Field**

On January 2<sup>nd</sup>, 2018, INPI published Rule No. 208, of December 27, 2017, which established the Guidelines for Examination of Patent Applications in the Chemistry Field. The Guidelines address particular aspects of the examination of patent applications in the field of Chemistry, com-



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plementing general aspects of patentability and formalities found in the Guidelines for Examination of Patent Applications (Blocks I and II). The following topics are covered: chemical compound (salts, N-oxides, prodrugs, intermediates, selection of compounds), stereoisomers, polymorphs, solvates, clathrates, co-crystals, pharmaceutical compositions, combinations of chemical compounds, processes, and new medical uses.

In view of this new rule, the normative effects conferred to the “Guidelines for the Examination of Patent Applications in the areas of Biotechnology and Pharmaceutical Filed after December 31, 1994” were revoked.

### **Guidelines for Examination of Patent Applications in the Biotechnology Field**

The Guidelines for Examination of Patent Application in the Biotechnology Field were established on March 12<sup>th</sup>, 2015, through Rule No. 144. The text addresses the particularities of the substantive examination of patent applications in the area of biotechnology, such as natural products and biological processes, transgenic microorganisms, biological sequences, animals, plants, among others. Rules related to patent applications involving components of the National Genetic Resources are also presented.

At the present time, the Guidelines are being updated, aiming to provide clarification and improvement of some topics, for example, use of stem cells, monoclonal antibodies, and proper characterization of biological sequences. The new version will continue to contribute to the harmonization and greater efficiency of substantive examination, and will soon be available for public consultation (second half of 2018).



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### **Joint Ordinance INPI-ANVISA**

The Brazilian INPI and the National Sanitary Surveillance Agency (ANVISA) have signed the Joint Ordinance No. 1 of April 12<sup>th</sup>, 2017, which regulates procedures for the application of Article 229-C of Law No. 9,279 of May 14<sup>th</sup>, 1996 (introduced by Law No. 10,196 of February 14<sup>th</sup>, 2001).

According to the new Rule, ANVISA's analysis for prior consent to pharmaceutical patent applications will be carried out in the light of public health, by means of a decision based on a substantive opinion issued by the competent organizational unit within the Agency. The health risk will be characterized when the pharmaceutical product comprises, or the pharmaceutical process results in, a substance whose use has been prohibited in Brazil. In the absence of such risk, consent shall be granted by the Agency.

In patent applications containing a pharmaceutical product or process considered of interest for the Brazilian Public Health Care System (so called SUS), ANVISA may issue an opinion with a focus on patentability requirements, which will correspond to subsidies by the INPI during the examination, pursuant to article 31 of Law No. 9,279 of 1996.

The Ordinance also establishes the Inter-Institutional Working Group, including representatives of INPI and ANVISA, with the purpose of providing a wide exchange of technical information and harmonization of understandings. More information about the Working Group can be found at: <http://www.inpi.gov.br/menu-servicos/patente/grupo-de-articulacao-inpi-anvisa>.



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- **AVAILABILITY OF THE NATIONAL SYSTEM FOR MANAGEMENT OF THE GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE (SisGen)**

Law No. 13,123, of May 20<sup>th</sup>, 2015, created the register of activities related to access to the national genetic heritage and/or associated traditional knowledge, replacing the authorization system that was in force under the ruling of MP 2,186-16 of August 23<sup>rd</sup>, 2001.

According to article 2<sup>nd</sup> (XII) of Law No. 13,123, of 2015, registration is a mandatory instrument for the declaration of the access or consignment activities related to the national genetic heritage or associated traditional knowledge, whose operation was disciplined in Decree No. 8,772, of May 11<sup>th</sup>, 2016 (Articles 22 to 26). The registration must be done prior to the request of intellectual property rights (Article 12, § 2 of Law 13,123, 2015), and constitutes a condition for granting these rights (Article 47 of Law 13,123, of 2015).

INPI would like to inform that the new registration system created by the CGen - called SisGen - was made available to the public on November 6, 2017, in accordance with CGEN Ordinance No. 1, dated October 3, 2017. This date is relevant for establishing registration or regularization deadlines for the of activities in accordance with Law No. 13,123, of 2015, and Decree No. 8,772, of 2016.

Thus, for patent applications filed between the date of entry in force of Law No. 13,123, of 2015, and the date that SisGen was made available to the public, applicants must register within one year from the date of the availability of SisGen. In addition, patent applications filed during the period of MP 2,186-16, of 2001, should also be regularized within one year of the availability of SisGen to the public, by means of presentation of the registration or authorization document, if applicable.



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**(ii) National and regional laws on opposition systems and other administrative revocation and invalidation mechanisms, available at:**

[http://wipo.int/scp/en/revocation\\_mecanismos/](http://wipo.int/scp/en/revocation_mecanismos/)

The Brazilian legislation on Industrial Property provides 3 (three) ways in which third parties may oppose the grant of patents:

- presentation of third party observations during substantive examination;
- filing of an administrative request for nullity at INPI;
- filing of a legal procedure before the Brazilian Federal Courts.

Below is a brief discussion of each one.

### **THIRD PARTY OBSERVATIONS**

In Brazil, from the publication of the patent application until the end of the examination, third parties may present documents and information to subsidize the substantive examination (Article 31 of Law No. 9,279 of May 14<sup>th</sup>, 1996).

Frequently, interested third parties present documents found in the state of the art and report based on a substantive analysis on patentability. The subsidies are not published, but are incorporated into the administrative process for eventual public consultation. The filing of subsidies is free of charge.



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The documents and arguments presented by interested third parties are considered by INPI patent examiners during the application substantive examination. Examiners usually comment in their opinions on the relevance of third party observations, taking advantage of the content of the subsidies as appropriate.

The filing of third party observations should not be confused with the administrative opposition proceedings prior to the grant of the patent (so called pre-grant opposition), available in some foreign legislation. It should be clarified that the participation of third parties in the substantive examination proceeding is limited to the presentation of information. No opportunity is given to the third party to file a letter in response to the examiner report or to participate in the review procedure in second administrative instance, as is usually done in the patent pre-grant opposition procedures of other jurisdictions.

The great advantage of this system is that it is faster than the pre-grant opposition procedures, which should allow for the opening of deadlines for the manifestation of all the parties involved in the process. In addition, through this mechanism, it is possible for third parties to participate in patent applications examination, in a simple and free of charge manner.

### **ADMINISTRATIVE NULLITY PROCEEDINGS**

Law No. 9,279, of May 14<sup>th</sup>, 1996 (IPL), provides for the nullity of the patent granted contrary to the legal provisions, with effect from the date of filing of the application. Nullity proceedings may be instituted either administratively or in the judicial sphere (Articles 50 to 57 of the IPL).



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Administrative nullity proceedings may be instituted either by INPI or by the request of any person having a legitimate interest, within a period of 6 (six) months of patent granting, for the following reasons:

I – any of the legal requirements were not satisfied;

II – the specification did not comply with the condition of sufficiency of disclosure, that is, it does not clearly and sufficiently describe the object in order to enable its realization by a technician in the subject;

III – claims are not based on the specification, characterizing the particularities of the application, and clearly and precisely defining the subject matter that is the object of the protection;  
or

IV – any of the essential formalities that are indispensable to granting has been omitted during the processing thereof.

The request for administrative nullity of a patent must be accompanied by reasons and evidence, and the burden of proof must be borne by the applicant. The patent holder is notified of the nullity proceedings beginning and is invited to speak in defense of the patent maintenance. The case analysis is carried out by a collegiate of experienced examiners of the Coordination of Appeals and Nullities of the INPI. Nullity may not apply to all claims, a condition for partial nullity being that the remaining claims are patents in themselves. It should be noted that the nullity proceedings will continue even if the patent expires.

The administrative nullity process is decided by the INPI's President, closing the administrative jurisdiction.



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## **JUDICIAL NULLITY PROCEEDINGS**

The validity of a Brazilian patent can also be questioned in the federal justice system (Articles 56 and 57 of Law No. 9,279 of May 14<sup>th</sup>, 1996).

Judicial nullity proceedings may be proposed, at any time during the patent term, either by the INPI or by any person having a legitimate interest. Exception is made for cases of defense, in which the patent nullity may be questioned at any time. INPI, when not the plaintiff, shall participate in the proceedings.

The judge may, as a preventive or incidental measure, determine the patent effects suspension, provided that the proper procedural requirements have been satisfied.

Legal proceedings for patent nullity are conducted by INPI's legal sector with the assistance of the technical staff. The instruction of the judicial case is carried out by a collegiate, made up of experienced examiners.

Frequently, since the case involves technical matters, the judge responsible for the analysis of the nullity suit summons a specialist in the patent technical field, who will be appointed Legal Expert, to assist the judicial nullity proceedings. The Legal Expert will study the case, taking into account the questions presented by the Parties, and will elaborate the Expert Report. The Parties involved (including INPI) are invited to submit comments to the Expert Report, expressing agreement or disagreement with the Expert's understanding. The Expert Report shall be used, together with the manifestations of the Parties, as a subsidy for the Judge's decision.

Once the decision on the judicial nullity proceedings has become final, the INPI shall publish the entry thereof, so that third parties are informed.





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**(iii) International worksharing and collaborative activities for search and examination of patent applications, available at:**

<http://www.wipo.int/patents/en/topics/worksharing/>

At present time, INPI participates in the following sharing activities of research results and substantive examination:

**- PPH (Patent Prosecution Highway)**

INPI participates in 7 (seven) pilot projects using the Patent Prosecution Highway (PPH) format for sharing information regarding search and substantive examination. The INPI partner offices to date are:

1. USPTO: United States Patent and Trademark Office;
2. JPO: Japanese Patent Office;
3. PROSUL: Offices of PROSUR (Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Paraguay, Peru and Uruguay);
4. EPO: European Patent Office;
5. SIPO: State Intellectual Property Office of China;
6. UKIPO: United Kingdom Intellectual Property Office;
7. DKPTO: Danish Patent and Trademark Office.

The cooperation agreements differ mainly in relation to the patent applications technical fields, as shown in Table 1.



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Table 1 – PPH Agreements in Brazil.

Partner Office	Duration	Technical Field	Quantity
USPTO	From 05/01/2018 to 04/30/2020	Oil and Gas; Information Technology	up to 50 applications based on PCT results, with 200 applications in total
JPO	From 04/01/2017 to 03/31/2019	Information Technology	Up to 200 applications
PROSUR	From 07/01/2017 to 06/31/2018	Any	Not defined
EPO	From 12/01/2017 to 11/30/2019	Chemistry and Medical Technology (except drugs)	Up to 600 applications
SIPO	From 02/01/2018 to 01/31/2020	Information Technology; Packaging; Measurement Technology; or Chemistry (except Drugs)	Up to 200 applications
UKIPO	From 08/01/2018 to 07/31/2020	Biotechnology; Information Technology	Up to 200 applications
DKPTO	From 09/01/2018 to 08/31/2020	Mechanics	Up to 200 applications

If a partner patent office considers patentable the subject matter of an application, it becomes possible to prioritize the patent application of the same invention and proprietary in the INPI. More details on the project can be found at <http://www.inpi.gov.br/menu-servicos/patente/projeto-piloto-pph>.



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**- Electronic Platform for Collaborative Examination (e-PEC)**

E-PEC is an online platform created for collaborative examination between patent offices in order to increase the quality of the examination results. The tool has multiple functionalities: (a) allows examiners to access preliminary (not yet published) search and examination reports produced by their peers for applications from the same patent family; (b) allows the interaction between examiners in charge of the examination of patent applications of the same patent family through electronic messages; (c) allows to record relevant information on patent applications.

In the first half of 2018, the INPI launched the "Pilot Project for Cooperation between the Patent Offices of Brazil and Uruguay" with the use of the Electronic Platform for Collaborative Examination of Patent Applications (e-PEC). Currently, the results of this project are being evaluated by the Institute.