FEDERAL PUBLIC SERVICE
MINISTRY OF ECONOMY
BRAZILIAN NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY
DIRECTORATE FOR PATENTS, COMPUTER PROGRAMS AND TOPOGRAPHIES OF INTEGRATED CIRCUITS

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Note C. 9072
Standing Committee on the Law of Patents[1]
Brazil

Updated Information on Certain Aspects of the Applicable National and Regional Patent Law

I. Law No. 14,195, of August 26, 2021

On August 26, 2021, the President of Brazil, Mr. Jair Bolsonaro, sanctioned Law No. 14,195, which revoked (according to Item XXVI of art. 57 of the said Law) the sole paragraph of article 40 and article 229-C of Law No. 9,279, of May 14, 1996 (Brazilian Industrial Property Law - IPL).

It is noteworthy that the unconstitutionality of the sole paragraph of article 40 of the IPL had already been declared in the decision of the Direct Action of Unconstitutionality (ADI) No. 5529, issued on May 13, 2021, by the Minister of the Superior Federal Court (STF), Dias Toffoli, which culminated in the revocation of the provision in the Industrial Property Law – IPL. This means that all patents granted from this date will be valid for 20 years and all utility model patents granted from this date will be valid for 15 years, counting from the filing date.

In addition, considering the modulation of the decision published on May 14, 2021, which establishes the *ex tunc* (retroactive) effect to patents related to pharmaceutical products and processes and to equipment and/or materials for use in health, the patents of these technological areas underwent adjustments in their terms of validity.

For the purposes of adjustment of the validity term and eventual extinction, all patents granted with an extended term were considered (under the terms of the extinct sole paragraph of article 40 of the IPL), which were still in force on May 14, 2021.

[1] The answers to this Note have been provided on behalf of Brazil by Brazilian National Institute of Industrial Property (INPI).

The methodology used to select the patents that have undergone adjustments in the term of validity can be found in the statement published in the *Revista da Propriedade Industrial* (RPI) No. 2628, of May 18, 2021.

Information can be found at:

https://www.gov.br/inpi/pt-br/central-de-conteudo/noticias/comunicado-sobre-extincao-do-paragrafo-unico-do-art-40-da-lpi

Law No. 14,195, of 2021, also established the end of the prior consent of the National Health Surveillance Agency (ANVISA) for patent applications for pharmaceutical products and processes. Article 57, item XXVI, of the new Law revoked article 229-C of Law No. 9,279, of 1996 (IPL).

As a result:

- The flow of patent applications between INPI and ANVISA has been extinct since August 27, 2021;

- INPI notified the return of the patent applications by ANVISA through order 7.7, with text adapted to the revocation of article 299-C;

- INPI also notified the patent applications analysis that have been concluded by ANVISA and sent to INPI (Official Letters 335 to 346/2021 COOPI/GGMED/ANVISA, of August 23) before the revocation of the article 229-C of IPL (RPI No. 2763); Prior consent decisions were notified under order 7.5 (allowance) and 7.7 (non-compliance with art. 229-C);

- Patent applications that were pending analysis at ANVISA were returned to INPI through Official Letters 347 to 358/2021 on August 30, 2021. INPI received a total of 1,316 unanalyzed patent applications;

- Applications filed until 12/31/2016, which are included in the Backlog Combat Plan, will proceed for examination.

Below, we present a comparative table highlighting the main differences introduced by Law No. 14,195, of 2021, in the IPL.

Original text	In force
Art. 40. An invention patent shall remain in force for a period of 20 (twenty) years, and a utility model patent for a period of 15 (fifteen) years from the date of filing. Sole Paragraph. The term shall not be less than 10 (ten) years for an invention patent and 7 (seven) years for a utility model patent, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of force majeure.	Art. 40. An invention patent shall remain in force for a period of 20 (twenty) years, and a utility model patent for a period of 15 (fifteen) years from the date of filing.
Art. 229-C. The granting of patents on pharmaceutical products or processes shall depend on the prior consent of the National Sanitary Supervision Agency (ANVISA).	(Revoked)

II. Law No. 14,200, of September 2, 2021

In view of the recognition of public calamity nationwide, in the scenario of combating the new coronavirus, the President of the Republic sanctioned Law No. 14,200, of September 2, 2021, which provides for the compulsory license of patents or patent applications. Such legal mechanism amends article 71 of IPL and includes article 71-A, enabling adaptation to the world scenario at this time of pandemic. Below, we present a comparative table highlighting the main differences introduced by Law No. 14,200, of 2021, in the IPL.

Original Text	In force
Article 71. In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patent holder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio, without prejudice to the rights of the respective holder.	Article 71. In cases of national or international emergency or of public interest declared by law or in an act of the Federal Executive Power, or recognition of a state of public calamity nationwide by the National Congress, a compulsory, *ex-officio*, temporary and non-exclusive license may be granted, for the exploitation of the patent or patent application, without prejudice to the rights of the respective holder, provided that its holder or its licensee does not meet this need.
Sole Paragraph. The act of granting the license shall establish its term and the possibility of extension.	Paragraph 1. The act of granting the license shall establish its term and the possibility of extension.
	Paragraph 2. In the cases provided for in the caput of this article, the Federal Executive Power shall publish a list of patents or patent applications, not applicable the period of secrecy provided for in art. 30 of this Law, potentially useful in dealing with the situations provided for in the caput of this article, within 30 (thirty) days after the date of publication of the declaration of emergency or public interest, or recognition of a state of public calamity, excluding patents and patent applications that are the subject of technology transfer agreements production or voluntary licensing capable of ensuring that internal demand is met, under the terms provided for in the regulation.
	Paragraph 3. Public entities, educational and research institutions and other entities representing society and the productive sector must be consulted in the process of drawing up the list of patents or patent applications that may be subject to compulsory licensing, under the terms provided for in the regulation.
	Paragraph 4. Any public or private institution may submit a request for inclusion of a patent or patent application in the list referred to in

	Paragraph 2 of this article.
	Paragraph 5. The list referred to in Paragraph 2 of this article will contain sufficient information and data to allow for an individual analysis of the usefulness of each patent and patent application and will include, at least: I – the individual number of patents or patent applications that may be subject to compulsory licensing; II – the identification of the respective holders; III – the specification of the objectives for which each compulsory licensing will be authorized.
	Paragraph 6. From the list published pursuant to Paragraph 2 of this article, the Executive Power shall carry out, within a period of thirty (30) days, extendable for an equal period, the individual evaluation of the listed inventions and utility models and will only grant the compulsory license , in a non-exclusive way, for producers who have proven technical and economic capacity to produce the object of the patent or patent application, provided that it concludes for its usefulness in facing the situation that underlies it.
	Paragraph 7. Patents or patent applications that have not yet been subject to a compulsory license may be excluded from the list referred to in Paragraph 2 of this article in cases where the competent authority defined by the Executive Power considers that their holders have assumed objective commitments capable of ensuring compliance of domestic demand in conditions of volume, price and term compatible with the needs of national or international emergency, public interest or state of public calamity nationwide through one or more of the following alternatives: I – direct exploitation of the patent or patent application in the country;

	II – voluntary licensing of the patent or patent application; or III – transparent product sales contracts associated with the patent or patent application.
	Paragraph 8. (VETOED)
	Paragraph 9. (VETOED)
	Paragraph 10. (VETOED)
	Paragraph 11. Public institutions that have information, data and documents related to the object of the patent or patent application are obliged to share all the elements useful for the reproduction of the licensed object, in which case the rules relating to the protection of data nor the provisions of item XIV of the main section of art. 195 of this Law.
	Paragraph 12. In arbitrating the remuneration of the patent holder or patent application, the circumstances of each case shall be considered, obligatorily observing the economic value of the license granted, the duration of the license and the estimates of investments necessary for its exploitation, as well as the production costs and the selling price of the product associated with it in the national market.
	Paragraph 13. The remuneration of the patent holder or patent application subject to compulsory license shall be fixed at 1.5% (one whole and five tenths percent) of the net selling price of the product associated with it until its value comes to be effectively established.
	Paragraph 14. The remuneration of the holder of the patent application subject to a compulsory license will only be due if the patent is granted, and the payment, corresponding to the entire period of the license, shall be made only after the grant of the patent.
	Paragraph 15. The competent authority shall give priority to the analysis of patent

	applications that are subject to a compulsory license.
	Paragraph 16. Products that are subject to the sanitary surveillance regime must comply with all the requirements provided for in sanitary legislation and may only be marketed after authorization has been granted, definitively or for use on an emergency basis, by the federal sanitary authority, under the terms provided for in regulation.
	Paragraph 17. (VETOED)
	Paragraph 18. Regardless of the granting of a compulsory license, the public authority will give priority to the execution of technical cooperation agreements and contracts with the patent holder for the acquisition of productive technology and its transfer process.
	Article 71-A. For humanitarian reasons and under the terms of an international treaty to which the Federative Republic of Brazil is a party, a compulsory license for patents on products intended for export to countries with insufficient or no manufacturing capacity in the pharmaceutical sector to serve their population may be granted.

Updated Information on International Worksharing and Collaborative Activities for Search and Examination of Patent Applications

On January 1, 2021, INPI launched Phase II of the PPH Program, governed by Ordinance No. 404, of December 21, 2020, published in the Industrial Property Magazine (RPI) No. 2608. The main differences from Phase I are as follows:

Phase I	Phase II
Up to 400 total requests per year	Up to 600 total requests per year
Up to 100 requests per IPC Section per year	Up to 150 requests per IPC Section per year
1 request per applicant per month	1 request per applicant per week
OFF = OEE (Patent Family has started at the Office of Earlier Examination)	OFF = Any Partner Office (Patent Family has started at any Partner Office)
Fee refund in standard cases only	Fee refund in standard cases and for requirements that exceed the stipulated limits
Appeal (based on specific grounds)	No appeal is admitted in the event of refusing entry

Note: OFF designs “Office of First File”; OEE means “Office of Earlier Examination”

To date, 510 requests have been submitted in the Phase II PPH Program (Figure 1). Most of PPH requests (almost 68%) are related to patent applications of the following technological fields: Digital Communications (54), Computer Technology (33), Civil Engineering (32), Audiovisual Technology (30), Special Machines (28), Medical Technology (28), Organic Chemistry (25), Biotechnology (24), Machines and Electrical Equipment (22), Transport (21), Information Technology (17), Pharmaceutical Products (17) and Chemical Engineering (15).

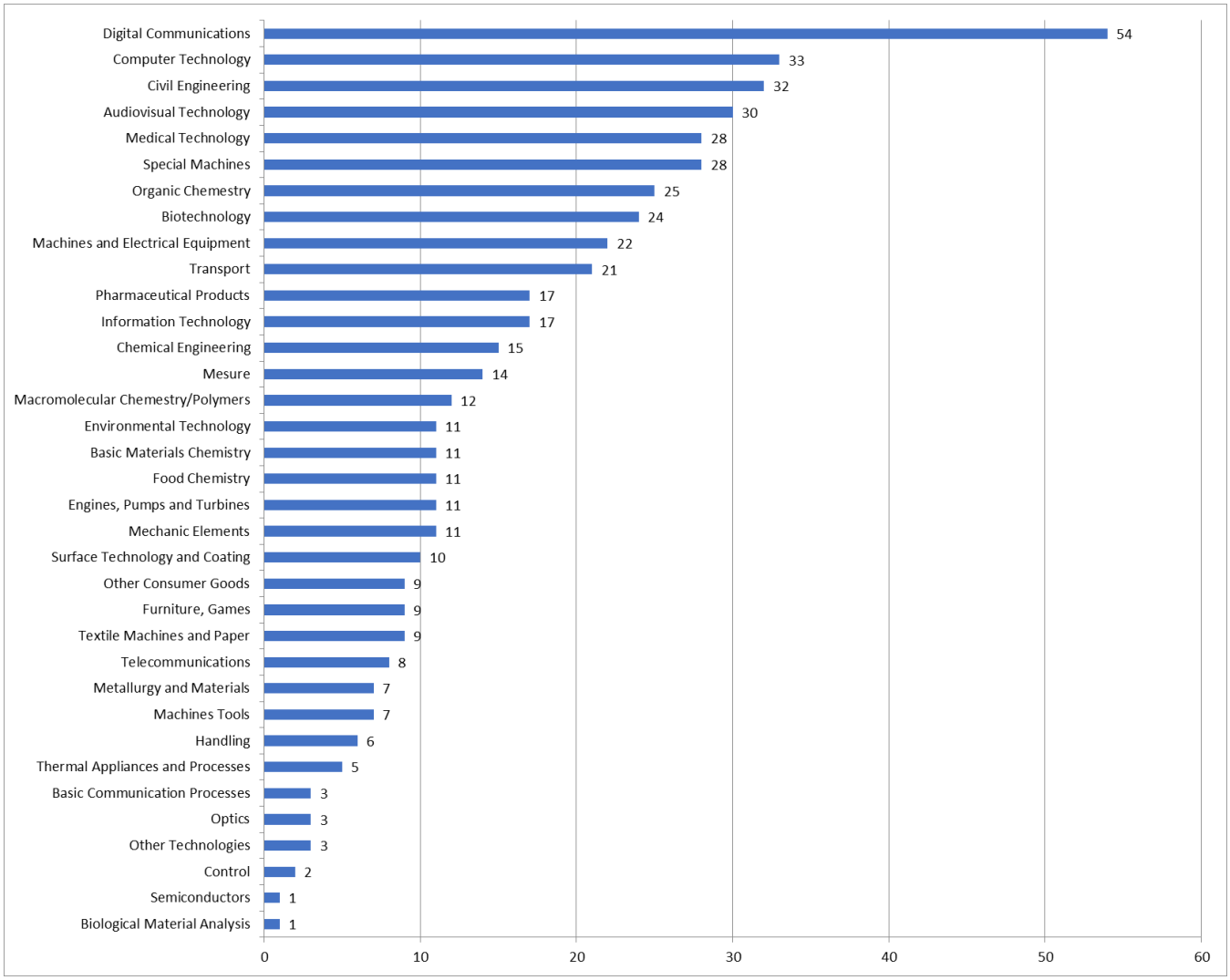

Figure 1 – Number of Phase II PPH requests per technological area.

Currently, INPI PPH Partner Offices are:

APO (Austria), CNIPA (China), KIPO (Republic of South Korea), DKPTO (Denmark), EPO (Europe - Regional), IPOS (Singapore), JPO (Japan), PRV (Sweden), USPTO (USA), and UKIPO (United Kingdom).

More details on the Phase II PPH Program can be found at:

https://www.gov.br/inpi/pt-br/servicos/patentes/pph