

## Invention versus discovery: case study on the examination of patents in biotechnology 2015 - 2020<sup>1</sup>

### *Invenção versus descoberta: estudo de casos sobre o exame de patentes em biotecnologia 2015 – 2020*

Daniela Lippstein\*

Salete Oro Boff\*\*

#### Abstract:

The present study is concerned with analyzing the granting of invention patents, in the area of biotechnology, from 2015 to 2020, through the study of multiple cases. The objective is to highlight the difficulties present in the application of patentability criteria in the face of the conceptual clash of invention and discovery. The problem lies in the question about the (im)possibility of meeting the patentability criteria by applications for patents in the area of biotechnology. The present research is characterized by a qualitative approach, of a basic nature, with an explanatory objective, developed from the inductive method. As for the procedures, document analysis and multiple case studies were adopted. The results and discussions showed a peculiar and differentiated treatment, regarding the application of patentability criteria, to patent applications involving biotechnology, especially in the identification of materials considered "discovery" present in the applications.

**Keywords:** Intellectual Property; Industrial property; Patents; Biotechnology; Patentability Criteria.

#### Resumo:

*O presente estudo ocupa-se de analisar a concessão de patentes de invenção, na área da biotecnologia, no período de 2015 a 2020, por meio do estudo de casos múltiplos. Busca-se, como objetivo, evidenciar as dificuldades presentes na aplicação dos critérios de patenteabilidade frente ao embate conceitual de invenção e de descoberta. A problemática reside na indagação a respeito da (im) possibilidade de atendimento dos critérios de patenteabilidade por parte dos pedidos de patente de invenção na área da biotecnologia. A presente pesquisa caracteriza-se pela abordagem qualitativa, de natureza básica, com objetivo explicativo, desenvolvida a partir do método indutivo. Quanto aos procedimentos, foram adotados a análise documental e*

<sup>1</sup> Texto traduzido a partir de Inteligência Artificial.

\* Doutora em Direito pela Universidade Federal de Santa Catarina - UFSC. Mestre em Direito pela Universidade de Santa Cruz do Sul - UNISC, na linha de pesquisa de Políticas Públicas de Inclusão Social com bolsa PROSUP, Tipo II, fornecida pela CAPES. Mestre em Direitos Humanos pela Universidade do Minho (Portugal) (Convênio Dupla Titulação UNISC-UMinho). Especialista em Direito Internacional - UNIASSELVI (Especialização Lato Sensu). Graduada em Direito pela Faculdade IMED. Integrante do Grupo de Estudos em Desenvolvimento, Inovação e Propriedade Intelectual (GEDUPI). Em estágio pós-doutoral, com pesquisa na área da Propriedade Intelectual e Biotecnologia, no âmbito do Programa de Pós-Graduação Stricto Sensu em Direito da Faculdade IMED - Mestrado Acadêmico em Direito (PPGD/IMED). Orcid: <https://orcid.org/0000-0001-7368-0260>.

\*\* Pós-Doutora pela Universidade Federal de Santa Catarina (2008). Doutora em Direito pela Universidade do Vale dos Sinos (2005). Mestre em Direito pela Universidade do Vale dos Sinos (2000). Especialista em Direito Público pela Universidade Regional do Noroeste do Estado do Rio Grande do Sul (1998). Especialista em Literatura Brasileira pela Universidade Regional do Noroeste do Estado do Rio Grande do Sul (1997). Graduada em Direito pela Universidade Regional do Noroeste do Estado do Rio Grande do Sul (1992). Graduada em Letras pela Universidade Regional do Noroeste do Estado do Rio Grande do Sul (1987). Tem experiência como docente da Graduação e da Pós-Graduação (lato e stricto sensu); como Coordenadora do Curso de Graduação, Pós-Graduação e Mestrado em Direito. É coordenadora e docente do Programa de Pós-Graduação - Mestrado - em Direito da Faculdade Meridional (IMED). É professora da UFFS - Universidade Federal da Fronteira Sul, sem dedicação exclusiva. É bolsista produtividade em pesquisa do CNPq. Líder do Grupo de Pesquisa-CNPq "Direito, Novas Tecnologias e Desenvolvimento. Atua na área de Direito, principalmente nos seguintes temas: propriedade intelectual, bioética/biodireito, constitucional, tributário, administrativo e desenvolvimento. É membro de Conselho Editorial de revistas na área jurídica e Consultora do Boletim Mexicano de Direito Comparado (UNAM). Avaliadora do MEC. Orcid: <https://orcid.org/0000-0002-7159-1878>.

*o estudo de casos múltiplos. Os resultados e discussões evidenciaram um tratamento peculiar e diferenciado, quanto a aplicação dos critérios de patenteabilidade, aos pedidos de patente envolvendo biotecnologia, especialmente na identificação de matérias consideradas "descoberta" presente nos pedidos.*

**Palavras-Chave:** *Propriedade Intelectual; Propriedade Industrial; Patentes; Biotecnologia; Critérios de Patenteabilidade.*

## 1 Introduction

Human intellectual effort, materialized in the result of creations, is subject to protection by the field of Intellectual Property. Even if it is for a certain time, it is possible to recognize the inventive step through intellectual property instruments, especially with regard to the protection of patents of invention, relevant to Industrial Property.

The creations, in turn, have an indeterminate extension of materials and contents, being driven by the advance of the state of the art, in the search for new solutions. In particular, this study is concerned with analyzing the granting of patents in the area of biotechnology, in the period between 2015 and 2020, with the aim of verifying the application of patentability criteria, specifically with regard to the understanding of the conceptual clash between "invention" and "discovery".

The methodology used will be addressed in more detail in the next section. Next, the scope of legal protection that encompasses intellectual property is contextualized, followed by the focus on biotechnology and the guidelines for examining this matter, to finally list the cases selected for study. Once the details of each case study are presented, the results and discussions are weighed.

## 2 Methodology

The present research is characterized by a qualitative approach, with an explanatory objective, developed from the inductive method. In terms of procedures, documentary analysis and multiple case studies were adopted. The research techniques used, in turn, were the review of specialized literature, legislation, resolutions, documents of official bodies and compilation of the database of the National Institute of Industrial Property (INPI - BR).

As a procedure for selecting cases, the choice was random, in the period from 2015 to 2020. The search was carried out in the Industrial Property Magazines, Section VI Patents, published in the first half of January of each year, locating by general index the grants of patents

published under code 16.1. The journal's reading aimed to identify granted patents involving biotechnological material in their title. After consulting the filing number in the BPTO database, and verifying the presence of a list of biological sequences, as well as the requirements formulated that implied, in the examiner's analysis, some discussion of "invention" and "discovery", the case was selected for analysis. Cases in which the application was rejected were not analyzed

In total, 6 (six) cases were selected for analysis (one per year), consisting of the following documents: Information from the BPTO Database, Letters Patent, Technical Examination Report (Publication of Technical Requirement) and the Technical Examination Report (Publication of Approval).

### **3 Intellectual property and the protection of inventions**

As a way of attributing protection to the effort coming from the human intellect, Intellectual Property is concerned with recognizing creations as one of the forms of property, of an immaterial nature, that has value and is subject to legal protection. In its breadth, three types are traditionally recognized, such as Copyright and Related Rights, Industrial Property and Human Rights. *Sui generis*. This study will deal in particular with Industrial Property, specifically the Institute of Invention Patents (Barbosa, 2014; Boff, Pimentel, 2009; Silveira, 2014).

In Brazil, the main legislation regulating Industrial Property is Law No. 9,279, of May 14, 1996, Industrial Property Law (LPI), which stipulates the criteria and conditions for the granting of patents in the national territory, in addition to other matters pertinent to Industrial Property (Brazil, 2021).

In this sense, the legislation clarifies the patentability criteria by establishing in Article 8 that "An invention that meets the requirements of *novelty, inventive step and industrial application is patentable*" (Brasil, 2021, emphasis added). In this order, the criterion of novelty refers to the overcoming of the state of the art, while the inventive step has the right to the use of intellectual effort to obtain the result of the invention and the industrial application, in turn, materializes in the possibility of repeatability of the invention on an industrial scale (Barbosa, 2014).

However, the possibilities of patenting are not unlimited, the legislation indicates what is considered an invention and what, even if it is considered an invention, cannot be the subject

of patents. In particular, Articles 10 and 18 of the Intellectual Property Law will serve as the basis for the analysis of the case studies that will be seen below. In this regard, the wording of Article 10 of the Intellectual Property Law states that:

Article 10. The following are not considered inventions or utility models:

- I - discoveries, scientific theories and mathematical methods;*
- II - purely abstract conceptions;
- III – schemes, plans, principles or commercial, accounting, financial, educational, advertising, lottery and inspection methods;
- IV – literary, architectural, artistic and scientific works or any aesthetic creation;
- V - the software itself;
- VI - presentation of information;
- VII – rules of the game;
- VIII – surgical or surgical techniques and methods, as well as therapeutic or diagnostic methods, for application in the human or animal body; and*
- IX - all or part of the natural living things and biological materials found in, or even isolated from, nature, including the genome or germplasm of any natural living thing and natural biological processes. (Brazil, 2021, art. 10, emphasis added)*

It should be noted in particular that the legislation does not consider inventions as discoveries, therapeutic methods, all or part of living beings and biological matter, as found in nature, among other matters (Brazil, 2021). In this sense, the legislation shows a different treatment for invention and discovery, considering that the former will have the presence of the inventive step of the human being, since "The object must result from the intellectual activity of the author [...]. There has to be a new and unexpected effect" (Boff, 2009, p. 43). While discovery will be understood as everything that is found in nature, being a creation of the natural environment itself, without human intervention, "Invention, in general, consists of the creation of something that did not exist until then; discovery is the revelation of something existing in nature" (Cerqueira, 2010, p. 153).

In this context, as mentioned above, in addition to being understood as an invention, the subject matter of the patent application must also be patented, since Article 18 of the Intellectual Property Law lists the subject matter that cannot be patented, providing that:

Article 18. The following are not patentable:

I - that which is contrary to morals, good customs and public safety, order and health;

II – substances, materials, mixtures, elements or products of any kind, *as well as the modification of their physicochemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of the atomic nucleus; and*

III - *all or part of living beings, with the exception of transgenic microorganisms which meet the three patentability requirements - novelty, inventive step and industrial application - provided for in Article 8 and which are not mere discoveries.*

*Sole paragraph. For the purposes of this Law, transgenic microorganisms shall be understood as organisms, with the exception of all or part of plants or animals, which express, through direct human intervention in their genetic composition, a*

*characteristic that the species cannot normally achieve under natural conditions.*  
(Brazil, 2021, emphasis added)

Therefore, living beings and biological matter, as a creation of nature, are not patentable, corroborating Article 18 with the provisions of Article 10 of the Intellectual Property Law. In this regard, Brazilian legislation recognizes that creations that meet the criteria of novelty, inventive step and industrial application are subject to protection, with the exception of the provisions listed in Article 18 of the LPI. In this sense, Barbosa (2014, p. 1355) teaches that "[...] solving a specific technical problem, any human creation, which thus goes beyond the mere action of knowledge to arrive at the pragmatics of a technical solution, will be inventions."

In Brazil, the federal body competent to process and grant invention patents is the National Institute of Industrial Property - INPI, created in 1970 (INPI, 2022). The applicant must file the application for a patent for an invention with the BPTO, in accordance with Article 19 of the Intellectual Property Law, accompanied by the application, specification, claims, drawings (where necessary), abstract and proof of payment of fees. In a continuous act, the BPTO will process the stages of examination of the application, publications, searches, and the applicant must follow up and proceed with the required manifestations. All publications related to the patent application process are published in the Revista de Propiedad Industrial – RPI. The technical examination, in turn, will be the occasion in which the examiner will rule on patentability, adaptations to the application and/or technical requirements, with the applicant being given the due time limits for the response. The examination shall be concluded with the grant or rejection of the patent (Brazil, 2021). The following section will address guidelines for the examination of patents, especially in the field of biotechnology.

Once the patent application has been granted and the respective payments have been verified, the patent will be granted through the issuance of the Letters Patent. The validity of this concession will have a term of twenty (20) years, counted from the date of deposit, non-extendable. It is worth noting the recent repeal of the sole paragraph of Article 40 of the Intellectual Property Law, by Law No. 14,195, of 2021 and also the discussion aired in ADIN 5529, corroborating the total term of 20 (twenty) years in the granting of patents (Brazil, 2021).

Once the legal aspects of the protection of inventions by the invention patent institute have been exposed, the guidelines for the examination of patents in the area of Biotechnology are analyzed.

## **4 Biotechnology and the peculiarities of biotechnological creations**

This section will briefly address the contextualization of biotechnology and the guidelines for the examination of patents in the area of biotechnology, applicable by the BPTO in the period 2015-2020.

Because it relates life and technology, biotechnology, considered as such, has gained special prominence in recent decades due to the remarkable scientific progress and the development of previously unimaginable creations. These creations pertain to genetics, plant and animal alteration, food, health, methods of reproduction, among many other topics that can be mentioned. This development simultaneously raises concerns about regulation and the ethical limits that should weigh on biological interventions, as they alter the natural order of life and have an impact on the ecosystem as a whole. This is the thinking of Rifkin (1999) when he considers the twenty-first century as the century of biotechnology and states that "the biotechnological revolution raises fundamental questions about the nature of science, the types of new technologies we introduce into the market, and the role of trade in the issues inherent in biology" (Rifkin, 1999, p. 247).

It is worth mentioning that invention patents are considered an important indicator of development and sources of information and innovation, especially for the area of biotechnology, including sectors such as food production, medicines, development related to biochemistry and the environment, among others. In this scenario, they also highlight the United States as a leader in these technologies, since its policy of protection and promotion of these inventions is much more permissive than prohibitive, as a whole, it still has a strategic policy and priority investments (Freitas; Zucoloto, 2013).

However, as Marques (2007) points out, considering that patents for inventions on biological matter differ greatly from what is understood as industrial property in the form of their traditional conception. This is because there is a certain difficulty, either conceptually or in fact, in meeting the requirements of "industriality", either by industrial application or by descriptive sufficiency. Thus, there is a certain flexibility in the contemplation of biologically derived inventions in patent protection and this concession also ends up being given in a restricted manner, since it will be limited by its description and application (Marques, 2007, p. 20).

Such particularities are highlighted by the specialized literature in the area of biotechnological development. As Zorzal (2017) states, there are difficulties and restrictions that require better reflection when it comes to biotechnology patents. The author points out that when it comes to the description of biological sequences, commonly present in patent

applications related to biotechnology, the description presented in the specification of these applications must allow a technician in the field to reproduce them, in order to verify the presence of the industrial application. However, the description of these topics (entirely literal) confronts the coding particularities of the field of biology. This particularity may give rise to generic or equivalence descriptions that may, perhaps, exceed the limits of protection of the invention itself, calling into question whether or not it is possible for an extension of patent protection to occur in these situations. Likewise, the biologist reflects, technical errors can still occur when an attempt is made to present the description of these sequences in different or generic ways, such as a claim strategy, which generates legal uncertainty, protection, and also technological information (Zorzal, 2017).

Attentive to the applications and specificity required by patent applications in biotechnology, the BPTO published, in 2019, within the "Technology Radar" series, the topic on Biotechnology and the Budapest Treaty. One of the most salient aspects of the report is the difficulty of descriptively representing the biological contents of inventions, which motivated the provision in Article 24 of the LPI on the supplementary deposit of such material. To this end, the Budapest Treaty regulates, at the international level, the International Depository Authorities (IDAs) as competent for the deposit of material of biological origin. The report considers that this provision creates an additional difficulty, as this procedure places a burden on the claim for obtaining the patent. In addition, Brazil does not provide an institution that has IDA recognition. In this scenario, alternatively, the depositor can submit a list of the claimed biological sequences or deposit the respective material with an International Depository Authority, in the country that makes this resource available (Von Der Weid; Verde, 2018).

In the report, the BPTO concluded that the low demand for the repository of biological material and the more frequent option of using biological sequence listings do not justify the investment in the creation of an institution for this purpose alone. On the other hand, it considers that there are already consolidated institutions in Brazil with the potential to absorb this demand, and it only remains for them to be recognized and accredited as such (Von Der Weid; Verde, 2018).

The BPTO, as the competent authority for the processing of patent applications, among others, also regulates the guidelines for the examination of these applications, with the aim of interpreting and applying the legislation in force. Thus, in a comprehensive manner, the guidelines for the examination of patents of invention are governed by the resolutions: "Resolution PR No. 64 of 03/18/2013 – Instituting Guidelines for the Examination of Patents"; "Resolution No. 124 of 04/12/2013 - Establish the guidelines for the examination of patent

applications - Content of the Patent Application"; "Resolution No. 169, of 07/15/2016 – Establishes the Guidelines for the Examination of Patent Applications – Block II – Patentability". Due to the particularities demanded by the area and the peculiar content of biological material, patent examinations in the area of biotechnology have a complementary resolution, specific for this purpose. Until December 2020, "Resolution No. 144, of 12/03/2015 – Establishing the guidelines for the examination of patent applications in the area of biotechnology" was in force. This Resolution was revoked by the "INPI PR Normative Instruction No. 118, of November 12, 2020 – Establishes the new version of the guidelines for the examination of patent applications in the area of biotechnology" (INPI, 2022).

In the following section, the cases under analysis, in the period from 2015 to 2020, that obtained the patent granted by the BPTO, will be listed.

## **5 Case studies on patent examination in biotechnology 2015 – 2020**

The analysis of the 6 (six) cases of granting of patents by the BPTO, in the period 2015-2020, in the area of biotechnology is carried out. The search for cases was carried out in the Industrial Property Journals, Section VI Patents, published in the first half of January of each year, locating by general index the patent grants published under code 16.1, which involve biotechnological matter in their title.

### **5.1 Case I: patent filing PI 0214653-3 (Grant 2015)**

The patent application under PI No. 0214653-3, filed on December 5, 2002, obtained the grant of the invention patent issued by the BPTO on January 6, 2015. Under the title "Construction of nucleic acid, recombinant expression vector, cell of recombinant host microorganism, method to produce a polypeptide, use of at least one protease, method to improve the nutritional value of an animal feed, additive for animal feed, composition of animal feed and, method for the treatment of aegetic proteins", the invention belongs to the international classification C12N 9/58; C12N 9/62 with Unionist Priority 07/12/2001 DK PA 2001 01821; 03/01/2002 DK PA 2002 00005. The holders are non-residents, of Danish origin (Hatzack; Wu; Tang, 2015, p.1).

This invention proposes to solve the improvement of animal feed, in relation to the composition, nutritional value and conditions for the metabolism of ingredients by them (Hatzack; Wu; Tang, 2015, p. 1; 4-5).

In the first analysis, the technical opinion issued under code 7.1, in the technical examination report published by RPI 2216 of 25 June 2013, was based on the analysis of the application originally made under the title "Polypeptide, isolated nucleic acid sequence, nucleic acid construction, recombinant expression vector, recombinant host cell, method to produce a polypeptide, strain, use of at least one protease, method to improve the nutritional value of an animal feed, additive for animal feed, composition of animal feed and method for the treatment of vegetable proteins" (INPI, 2013, p.1). On the occasion, the examiner proceeded to analyze, in a digital environment, the necessary documents, as well as the sequence list (INPI, 2013, p.1).

In the order presented in the technical examination report, it considered that the presentation of the negative declaration of access to the national genetic heritage was present (INPI, 2013, p.1). The technical examination was limited to the analysis of 18 claims, which indicated that there was no unity of invention in the application as they were two inventions formulated in a single presentation, in violation of Article 22 of the LPI. As for the novelty criterion, it was found that some claims were originally new in relation to prior art, while others were already available in the field of knowledge. Regarding the knowledge available in this field, the examiner considered that the results offered by the invention were an obvious result of the combinations of the claimed components, not complying with the inventive step requirement (INPI, 2013, p.4).

It then ponders the presence of additional irregularities, especially with regard to Article 10 of the Intellectual Property Law, when it mentions that "Brazilian legislation does not recognize as inventions, all or part of nucleic acids and proteins that have been isolated from nature or that have natural correspondents" (INPI, 2013, p. 4), thus establishing a distinction with what is considered discovered. In the same vein, the applicant must clarify that the claimed components "are made up of technically well-defined sequences in such a way that the resulting set of sequences included in each of them is not found as such in nature" (INPI, 2013, p.5).

However, it considers that claim 9 which refers to the "host cell" is in conflict with item III, of article 18, of the LPI, since the legislation considers as patentable only transgenic microorganisms, which are different from what is understood by cells, animal or vegetable, transgenic or not, that are not susceptible to protection (INPI, 2013, p.5). In addition, the examiner considered that the descriptive sufficiency and clarity of the claims were impaired,

precisely because they related to matters that were not subject to protection and also because they included components that were not within the domain of the petitioners. Once the technical opinion was issued, under code 7.1, a period of time was granted for the declaration of the holder (INPI, 2013, p. 5-6).

In compliance with the opinion, the owner submitted a new table of complaints for consideration, consisting of 11 complaints with adequate explanations for the modifications. The title was also reworked as stated in the grant of the patent. Once the requirements were adequate and met, the examiner understood that the patentability criteria were met, which are novelty, inventive step and industrial application, in view of the exclusion of matters faced by the legislation and the adequacy of the wording of the claims clarifying the respective content (INPI, 2014a, p. 2). Upon approval of the invention patent application and the charges due, the National Institute of Industrial Property issued the document on January 6, 2015.

## **5.2 Case II: patent filing PI 0116305-1 (Grant 2016)**

Filed on December 19, 2001, under number PI 0116305-1, the patent application under the title "DNA molecules associated with the proliferation and development of plant cells and methods of production of plants with larger organ size" was granted on January 12, 2016. The international classification of the application includes category C12N 15/82, with unionist priority 21/12/2000 US 60/257.896. The holder is of non-resident origin, located in the United States (He; Dotson, 2016, p.1). According to the descriptive report of the invention, it belongs to the field of molecular biology and genetic engineering, of plant quality (He; Dotson, 2016, p. 2).

The opinion elaborated in the first analysis by the technical examination report, considered that the application, as originally formulated, could not be considered an invention and was also not subject to patent protection, in addition to not having unity of invention, complying, however, with article 32 LPI. When analyzing the 34 claims, the examiner considered that "claims 1 to 6 include nucleic acid molecules isolated from nature in the scope of protection, and are therefore natural sequences" (INPI, 2014, p. 1), thus facing Article 10 of the Intellectual Property Law. In relation to Article 18 III. In addition, for the examiner "claims 10 to 12 referring to plant cells, claims 13 to 15, 21, 23 and 25 to 28 referring to plants and claims 16 to 18 referring to propagules are not patentable because they involve subject matter excluded from protection" (INPI, 2016, p. 2). In relation to inventive unity, the examiner

understood that a single inventive concept was absent in the application, in divergence from Article 22 of the LPI. In addition, the technical aspects that relate the claims are not new in the face of the state of the art, which reinforces the absence of inventive unity (INPI, 2014b, p. 2).

Subsequently, the technical opinion also considered that the request did not comply with articles 24 and 25 of the LPI, in terms of the descriptive report and the table of complaints. The examiner also understood that the application was described exhaustively, not allowing a technician in the field to reproduce the experiment objectively, requiring several combinations that are not described in the application. Therefore, the descriptive sufficiency required for patent applications was not contemplated (INPI, 2014b, p. 3).

As for the analysis of the patentability criteria, the examiner excluded from the examination the claims included in Articles 10 and 18 of the LPI, explained above. Of the complaints analyzed, all met the industrial application criterion; As for the novelty criterion, claims 29 to 34 were positively met and claims 7 to 9, 16 to 20, 22 and 24 were not considered new; Finally, as regards inventive step, none of the claims satisfied this criterion. Once the opinion was concluded, a period of time was granted for the applicant to present his argument (INPI, 2014b, p. 4).

In a second analysis, after the reformulations and compliance with the first opinion, the examiner understood that the new table of claims, composed of 10 claims, contemplated the criteria for patentability. However, as a condition for final approval, a technical requirement was prepared in order to better meet the criteria of clarity and precision in relation to some elements of the invention, in addition to the exclusion of claims 2, 3 and 5 from the table on the understanding that they do not correspond to the object of the application for protection (INPI, 2015a, p. 3).

In a final opinion, the technical examination report indicated that the application was not sent to ANVISA, but that it complied with the requirements relating to the Genetic Heritage Management Council - CGen and presented a list of biological sequences. 5 claims were reformulated and submitted, all patentability criteria and compliance with legislation were deemed to be met (INPI, 2015b, p. 1-3). Once the respective remunerations had been paid, letters patent were issued.

### **5.3 Case III: filing of patent BR 122015025435-3 (Grant 2017)**

Titled "Vaccine to Immunize Cats Against Feline Calicivirus," Invention Patent Application No. BR 122015025435-3, filed on July 17, 2006, received the patent on January 3, 2017. The application was internationally classified in the categories A61K 38/16; A61K 39/12; A61K 48/00; C07K 14/08; C07K 16/10; C12N 15/40. The origin of the depositor is non-resident, from the United States, with unionist priority US 60/703,109 of 28/07/2005, being an invention that confers the immunization of cats against the calicivirus virus (Lowery *et. al.*, 2017, p. 1).

In the first analysis, the technical examination report understood that it was not a matter that required the prior consent of ANVISA, which is why the application was not referred to the application. Regarding access to the national genetic heritage, the applicant submitted a negative declaration of access. Finally, in relation to the aforementioned table, it also presented, in electronic format, the List of Biological Sequences (INPI, 2016a, p. 1).

Regarding the legislation, the examiner understood that the application complies with the legal requirements and is not within Articles 10 and 18 of the LPI, as well as presents unity of invention and Article 32 of the LPI (INPI, 2016a, p. 2). With respect to Articles 24 and 25 of the LPI, the examiner understood that the descriptive report was partially adequate and that the framework of the demand was inadequate (INPI, 2016a, p. 2).

In this regard, the examiner pointed out that the claim framework did not meet the criteria of clarity and precision, as required by the Patent Examination Guidelines for the area of Biotechnology, as provided for in Resolution INPI/PR No. 144/2015, with only the simple reference of nomenclature, without unequivocal identification or deposit in a recognized institution. In addition, the application uses expressions that generalize and do not delimit the alleged matter, thus considering that the descriptive insufficiency could be argued for the purposes of non-compliance with Article 24 of the Intellectual Property Law (INPI, 2016a, p. 3).

In this regard, regarding the patentability criteria, 3 (three) claims were analyzed and claims 1 to 3 met the criteria of industrial application and novelty, while claims 2 and 3 partially met the inventive step criterion, while claim 1 did not meet this criterion (INPI, 2016a, p. 4). The inventive step criterion was undermined, as the examiner was unable to identify the subject matter of the request without experimenting. Therefore, the requirements were prepared in the sense of the adequacy of the complaints framework (INPI, 2016a, p. 5).

In compliance with the requirements, the applicant submitted a statement with the adequacy of the claims framework, reformulated to 2 claims. In which the examiner understood,

in the description of the technical report, that the requirements were met and concluded that the patent application had been granted (INPI, 2016b, p. 3).

#### **5.4 Case IV: patent filing PI 0614338-5 (Grant 2018)**

Filed on August 1, 2006, the patent was granted on January 2, 2018 to the invention patent application entitled "Processes for the identification of an elite event in biological samples, for the confirmation of seed purity, for the selection of seeds in relation to the presence of such an elite event [...]", in Brazil. The application relates to the CIP classification of categories C12N 15/82; C12Q 1/68; A01H 5/00. The applicant's origin is non-resident, United States. The deposit comes from the unionist priority EP 05 076826.6 of 08/08/2005; EP 60/707.067 of 10/08/2005, of the EUROPEAN PATENT ORGANIZATION, as described in the Letters Patent (Trolinder; Habex, 2018, p.1). The invention, according to the descriptive report present in the aforementioned Letters Patent, refers to "cotton plants, plant materials and transgenic seeds" (Trolinder; Habex, 2018, p.2).

For the first technical examination report, the application was originally submitted as "Herbicide-tolerant cotton plants and processes for their identification" (INPI, 2017a, p.1). In the analysis of the objective requirements, with regard to the participation of other agencies, the request was not sent to ANVISA, due to the matter; submitted a negative declaration of access to the national genetic heritage and a list of biological sequences, in electronic format (INPI, 2017a, p.1).

As for the second examination table, the examiner considered that the subject matter falls within articles 10 and 18 of the LPI, and cannot be considered an invention and patent. The examiner justifies, based on the LPI and the 2015 BPTO Review Guidelines, that all or part of the biological material relevant to the natural state, i.e. without distinction as to how it is found in nature, are not considered inventions, even if they are isolated or synthetically formulated. Articles 22 and 32 of the LPI were positively complied with (INPI, 2017a, p. 2).

And with respect to the third table, the examiner understood that the patent application did not comply with Articles 24 and 25 of the LPI, in relation to the descriptive report and the table of claims. To the point, the examiner understood that the criteria of precision and clarity in the wording of the claims were absent, in addition to the lack of reasoning. It also contradicts the BPTO examination guidelines, since the claims, as presented, must allow their reproduction by a technician in the area, without the need for additional experimentation (INPI, 2017a, p. 4).

Regarding the analysis of the patentability criteria, the examination of Table 5, of the 40 claims, "claims 11 to 14, 19, 22 and 31 to 37" were excluded from this stage of the analysis, in accordance with the examiner's interpretation of the classification in Articles 10 and 18 of the LPI. The other claims met the criterion of industrial application. And the criteria of novelty and inventive step, only claim 15 was negative (INPI, 2017a, p. 6). The technical examination report then concluded with the elaboration of requirements briefly requesting the suitability of the technical terms, the suitability of the sequence listing, the exclusion of claims and the adequacy of the clarity, precision and reasoning of the applications, with the granting of the legal deadline for the applicant's statement (INPI, 2017a, p. 7 - 8).

In a statement, the applicant submitted the reformulated table of claims with 26 claims. As regards the examination tables relevant to the legislation, the examiner understood the requirements to be present. Regarding the framework of examination of Articles 24 and 25 of the Intellectual Property Law, the completion remained negative, however, without the presence of justification, which, in view of the granting of the patent application, seems to be an error in the updating of the previous form (INPI, 2017b, p. 4). Subsequently, the examiner concluded, therefore, that the new claims met the legislation and patentability criteria, granting the application (INPI, 2017b, p. 3)

### **5.5 Case V: patent filing PI 0417992-7 (Grant 2019)**

Under the title "Methods for purifying recombinant human FSH or a variant of FSH", the invention patent application, under file number PI 0417992-7, obtained the issuance of the patent on January 02, 2019. The origin of the holder is a non-resident, of Swiss nationality. The application has unionist priority EP 03 104925.7 of 22/12/2003, classified in the IPC category C07K 14/59 (ROSSI, 2019, p. 1). According to the description of the invention, in the patent document, it is "a new method for purifying recombinant FSH or a variant of FSH" (ROSSI, 2019, p. 5).

The first technical analysis verified that the requirements related to ANVISA and CGen were met, as well as a list of biological sequences (INPI, 2017c, p. 1). As for the second framework of examination, the application falls within the scope of Article 10, which provides for issues that are not considered inventions, in relation to claims 23 and 24. The examiner justified, in relation to this examination, that it was not possible to differentiate the result obtained by the invention from what is found in nature (INPI, 2017c, p. 2).

The review then found that the narrative report was in accordance with the law, while the application framework was at odds. The absence of the expression "characterized by" and the use of the expression "on", configure, in the examiner's analysis, a lack of clarity and precision with respect to the claims, resulting in a lack of harmony with Article 25 of the LPI (INPI, 2017c, p. 2)

Regarding the analysis of the patentability criteria, the 24 claims submitted met the industrial application criterion; Claims 23 and 24, on the other hand, did not meet the novelty criterion, being excluded from the examination of the subsequent criterion, which is inventive step; in the latter, in turn, the examiner understood that claims 1 to 14 did not meet the criterion (INPI, 2017c, p. 3). Thus, the examiner formulated technical requirements, in the sense of presenting a new framework of claim, as well as the appropriateness of the use of expressions in the application (INPI, 2017c, p. 4).

After the submission of the declaration by the applicant, the examiner understood that all the requirements had been fully met, so he granted the patent application, in accordance with the legislation and patentability criteria (INPI, 2018, p. 3).

## **5.6 Case VI: patent filing PI 0713503-3 (Grant 2020)**

Granted on January 7, 2020, the patent application under the title "Pathogen-inducible synthetic promoter, recombinant gene and process for the preparation of a pathogen-resistant plant" was filed on June 16, 2007 by a non-resident holder of Germany. According to the Letters Patent, the application has an IPC rating of C12N 15/82; C07K 14/415; A01H 5/00; A01H 5/10 and unionist priority DE 10 2006 029 129.8 of 22/06/2006 (SCHMIDT, 2020, p.1).

In the first analysis, in the technical examination report, the examiner understood that the requirements related to ANVISA, CGen and Biological Sequence Listing were met. Regarding the examination of the second table, it understood that the application complies with the legislation, except with regard to Article 18 of the Intellectual Property Law, considering that "claims 6 to 8 are in disagreement with Article 18(III) because they are all or part of living beings, even if they are transgenic, and therefore they are not patentable" (INPI, 2019a, p. 2). Subsequently, it considers that the framework of the claim does not conform to the legislation, specifically in relation to claims 1 and 2, by pointing out that these are not clearly and precisely described as to the object claimed (INPI, 2019a, p. 2). Regarding the analysis of patentability requirements, the examiner understood that claims 1 to 4 and 9 met the criteria of industrial

application, novelty and inventive step. Claims 5 to 8 were not examined and their exclusion was suggested by the examiner. In addition, an injunction was also prepared in order to adapt the clarity and precision of the main demand, concluding with the granting of a period of time for the applicant to respond to the requirements (INPI, 2019a, p. 3 - 4).

In view of the applicant's statement, the examiner understood that the insufficiencies had been remedied, and a new table of claims reduced to 6 claims was then presented, which in the opinion of the examination complied with the legislation and the criteria for patentability, concluding that the application for a patent for invention had been granted (INPI, 2019b, p. 3).

## 6 Results and discussions

The first case under study, concerning the filing PI 0214653-3, lasted 12 years between the filing of the application and the grant of the patent. The origin of the deposit is non-resident, of Danish nationality. Unionist priority (DK) and submission through the PCT are present. The applicant submitted a list of biological sequences, and the deposit of biological material with the depository authority was not evidenced in the material analysed.

Prior to approval, the formulation of requirements that identified the subject matter not considered an invention (discovery) and that was also not patentable. The examiner considered, in relation to Article 10 of the LPI, that "Brazilian legislation does not recognize as invention all or part of nucleic acids and proteins that have been isolated from nature or that have natural correspondents" (INPI, 2013, p. 4). It then reflects, in relation to Article 18 of the Intellectual Property Law, that "[...] both plant-derived cells and those derived from animals or even those of human origin, transgenic or not, are not subject to privilege by virtue of the legal provision in question" (INPI, 2013, p. 5). Thus, it is clear, according to the description of the technical examination, that the subject matter initially submitted to obtain the patent included elements of nature that are considered discovery, and it is not possible to protect them by patents, unlike what is understood by invention.

The applicant reformulated the table of claims, reducing the claims from 18 to 11 claims, a reduction of approximately 38.8% of the table of claims, adapting the issues pointed out by the examiner and obtaining the patent granted in 2015.

Subsequently, the second case, under file number PI 0116305-1, took 14 years until the issuance of the Letters Patent, of non-resident origin of the United States. The submission took

into account the trade union priority (USA) and the PCT submission. The examination report showed the presence of a list of biological sequences, in electronic format, and there was no evidence of the existence of a repository of biological material with a competent authority.

In the first analysis, the examiner considered that the material submitted comprised elements in the form found in nature, which contravenes the provisions of Articles 10 and 18 of the Intellectual Property Law. To the point, the examiner indicated that "synthetically obtained sequences that have a correspondence of natural occurrence, without there being any way to distinguish them from these, are not considered inventions either" (INPI, 2014b, p. 1), in violation of Article 10 of the Intellectual Property Law and also in disagreement with the Examination Guidelines, specific to the area of biotechnology, in addition, it considered that "the mere characterization of the sequence as 'recombinant', 'synthetic', 'isolated' or 'artificial' is not sufficient to adapt a claim to the aforementioned article" (INPI, 2014b, p. 1).

Throughout the examination, other points were also pointed out, highlighting the inadequacies of the application with the legislation and also with the patentability criteria, highlighting the importance of the wording of the claims, as well as compliance with the clarity and precision of the terms.

In compliance with the demands made, the applicant submitted a new table of claims, which was reduced from 34 claims originally filed to 5 claims, a reduction of approximately 85.29 per cent of the table of claims. The patent was granted in 2016 after the claims were adjusted.

The third case study, in turn, filed under No. BR 122015025435-3, reached the time of 10 years between the filing of the application and the issuance of the letters patent. The origin of the applicant is a non-resident of the United States, as well as the unionist priority and the application is filed via PCT. The indication of deposit of genetic material was not evidenced in the documentation analyzed, while the biological sequences were presented in the format of electronic lists.

Before the application was granted, the examiner developed requirements to adapt the claim framework, the examiner used the following terms: "does not meet the criteria of clarity and precision" (INPI, 2016a, p. 3); "mere indication of the nomenclature of the strain" (INPI, 2016a, p. 3); "Moreover, the expression 'about' confers imprecision on the matter alleged." (INPI, 2016a, p. 3); "it is not possible to identify without experimentation which variants are effectively capable of conferring protection on vaccinated animals" (INPI, 2016a, p. 4), indicating divergences or inconsistencies in relation to the wording of the applications that undermine the descriptive sufficiency related to them.

Thus, 3 complaints were originally analyzed, and in response to the demands made, 2 complaints were filed, an approximate reduction of 33.3%. After meeting the requirements, the invention patent was granted to the application in 2017.

The case study on the grant of a patent issued in 2018, it took 11 years for the filing of PI No. 0614338-5 to obtain the grant of the patent. Of Belgian origin, non-resident, the application has unionist priority by the European Patent Organization and filing via PCT. In the documents available in the INPI database, there was no evidence of the deposit of biological material in the depository authority, the biological sequences were presented through electronic lists.

The examiner considered that the application included non-patentable subject matter and was not considered an invention, compared to Articles 10 and 18 of the LPI, respectively. On occasion, some of the expressions present in the report evidenced the presence of content understood as discovery, stating that "Claims 31 to 37 referring to transgenic cotton plants and seeds that make up the elite EE-GH3 event are not patentable because they involve subject matter excluded from protection according to Article 18 (III) of LPI No. 9.279/96" (INPI, 2017a, p. 2). However, following the Examination Guidelines, which guide the area of biotechnology, the examiner assures that "animal and plant cells are not subject to protection since all or part of plants and animals, even if they are transgenic, are not patentable" (INPI, 2017a, p. 2). It also considers, in accordance with the same guidelines, that biological elements as they are found in nature, even though "[...] isolated or synthetically produced that have a corresponding natural fact, and there is no way to distinguish them from natural ones: they are considered natural biological products, and will not be considered inventions [...]" (INPI, 2017a, p. 2).

In this way, the examiner prepared a technical requirement to adapt the application to the legislation and the patentability criteria. Of the 40 claims originally filed, the new claims framework proposed 26 claims, a 35 per cent reduction in relation to the filing of the claim. Once the requirements were met, the examiner decided to grant the application for a patent for the invention.

Subsequently, the fifth case study, referring to the filing of invention patent No. PI 0417992-7, granted in 2019, elapsed 14 years until the issuance of the Letters Patent. The originator is a non-resident, of Swiss nationality. The application has unionist priority by the European Patent Organization and the filing via PCT. The repository had a list of biological sequences, and it was not evidenced in the database of the repository of biological material in a competent authority.

In the first examination, 24 claims were analyzed, where the examiner evidenced the presence of matter considered as a discovery, stating that "Since it is not possible to differentiate the FSH obtained in recombinant form from the natural FSH, this molecule constitutes biological material found in nature" (INPI, 2017c, p. 2). Other issues were also argued, in the sense of the use of some expressions to adapt the wording of the claims, in order to satisfy the precision and clarity of the applications, as considered by the examiner when he considered that "... There is the absence of the expression "characterized by" before the characterizing part that contains the particularities of the invention [...]. The term "about" contained in claims 5, 12, 20, 22 (points 1, 2, 2(a), 3 and 4) causes imprecision in the claims [...]" (INPI, 2017c, p. 2).

Once the technical requirements have been formulated and the applicant's declaration has been submitted, the examiner understands that the legislative requirements and patentability criteria are met. Claims were reduced to 18, representing a 25 per cent reduction in the originally submitted list of demands.

Finally, the case study presented under No. PI 0713503-3 obtained the issuance of the Letters Patent in 2020, with a period of 12 years elapsing between the filing and issuance of said title. The applicant is a non-resident originator of Germany. The petition has unionist priority and is filed via PCT. An electronic list of biological sequences was submitted for reference, without mentioning the deposit of biological material with a depository authority.

The technical examination report considered in its first analysis this natural content, included in the concept of discovery, non-patentable, stating that "claims 6 to 8 are at variance with Article 18(III) because they are the whole or part of living beings, even if they are transgenic, and are therefore not patentable" (INPI, 2019a, p. 2). Weaknesses in the wording were also noted in terms of compliance with the criteria of clarity and precision.

Once the requirements were prepared, the applicant submitted a declaration that, in the opinion of the examiner, met the requirements and concluded that the patent application should be granted. The table of complaints was modified from 9 to 6 complaints, which represents a reduction of 33.3%.

The results are in line with the specialized doctrine and with the BPTO indicators, previously discussed, by demonstrating that the area of biotechnology has peculiarities not contemplated, with specificity, by legislation. As a result, the agency, faced with the need to respond to the technologies that are presented, in a growing and continuous technological development, apparently adapts the examination of patents in the area of biotechnology by establishing specific guidelines that change according to the period, updating and

contemplating the specificities of the area. In this context, the patentability criteria seem to be adapted to the reality surrounding patent applications in biotechnology.

Just in case, what can be seen is that the applicants present a wide range of claims, so it is up to the examiner to decide what can be considered an invention and what will be dismissed as matter understood in nature, "mere discovery", not subject to protection. This process may involve both the elements themselves and the way they are described or the use of certain terms, and it is possible to tailor the request before the final opinion.

In addition, it is also observed that the average time between the filing and granting of the patent is 12 years, a high period influenced by factors such as the availability of expert examiners in the area of the application, the consent of ANVISA, the authorization of the CGen, the proper presentation of the list of genetic sequences, compliance with formal and technical requirements, among other issues. which are added to the duration of the exam until the final opinion is obtained.

## **7 Final considerations**

Intellectual Property is the area that grants legal protection to the creations of the human intellect, subdivided into Copyright and Related Rights, Industrial Property and Related Rights *sui generis*. Industrial Property is the branch that includes the protection of invention patents, which, in turn, managed by the BPTO, precede registration and require compliance with the criteria of novelty, inventive step and industrial application, in accordance with the specific legislation for Industrial Property. Invention patents are granted for a non-extendable period of 20 years from the date of filing, which confers temporary privileges of exclusivity and exploitation to their holders.

Through the studies analyzed, it was possible to identify that, throughout the processing of the invention patent application, the applicant is given the opportunity to adapt and make changes to grant the patent, without this implying a summary rejection. This means that, in addition to the possibilities of appeal, throughout the examination, examiners indicate to applicants the necessary measures and adjustments before the final opinion, bringing economy and speed to the patent examination processes, correcting non-conformities within the same application.

Next, it is pointed out that the legislation on patent protection, which dates back more than 25 years, has a generic scope, not having the peculiarities that biotechnological inventions

comprise. For this reason, since the competence for the analysis and granting of patents is the responsibility of the BPTO, these processes are defined administratively by the agency, which establishes guidelines to guide the examination of patents when legislation is insufficient.

In this context, there seems to be, to a certain extent, an adaptation, extension or relaxation of the requirements for the granting of patents to the peculiarities of biotechnology, since it must be recognized that the technological scenario of 25 years ago does not correspond to the current context. The peculiarities and speed of biotechnological development require better legislation that corresponds to this reality.

For example, in all the cases studied, in the original application, some subject matter considered as "discovery" is mentioned, which requires the formulation of requirements by the examiners to the effect that the applicant adapt the use of certain expressions, the exclusion or inclusion of others, in order to adapt the application to the patentability criteria. In such a way that, in all cases, there was a change in the original claim framework, due to the requirements formulated, reaching an average reduction of 41.78% in the initial claim framework in relation to the final claims, in which the patent was granted.

In addition, the origin of the deposit was predominantly nonresident, with the highest occurrence in the United States. Applications are also filed with unionist priority and filed via PCT. The average time for the granting of patents in biotechnology, achieved by the cases subject to this study, was 12 years. There was no evidence of information indicating the deposit of biological material with the International Deposit Authority, all cases presented lists of biological sequences, which does not require the deposit of such material.

Without claiming to be exhaustive, the present study shows that there are sensitive issues in the patenting of biotechnological inventions, especially in the definition and distinction between what can be considered an "invention" and what can be considered a "discovery". It shows that the BPTO, in turn, as the competent authority for the analysis of these applications, ends up filling the gaps in legislation that has not kept pace with biotechnological advances in the last three decades.

On the other hand, it is in the face of the need to respond to contemporary problems that the patentability criteria, generically stipulated in the 90s, seem to end up undergoing some adaptation, extension or flexibility in the granting of patents in the field of biotechnology, seeking to adapt the examination of these applications to the reality of the time.

Thus, it is observed, in this context, that the experience already lived by the institute and the demand of the biotechnology sector provide sufficient subsidies for the legal improvement of the legislation, in the regulation of the granting of patents in biotechnology.

## References

BARBOSA, Denis Borges. **Intellectual Property Treaty: Patents**. Rio de Janeiro: Lumen Juris, 2014. t. II.

BOFF, Salete Oro. **Intellectual property and development: innovation, management and technology transfer**. Passo Fundo: IMED, 2009.

BOFF, Salete Oro; PIMENTEL, Luiz Otávio (ed.). **Intellectual property, management and development of innovation: patents, trademarks, software, cultivars, geographical indications, technological innovation centers**. Passo Fundo: IMED, 2009.

BRAZIL. **Law No. 9.279 of 14 May 1996**. It regulates the rights and obligations related to industrial property. Presidency of the Republic, [2021]. Available at: [http://www.planalto.gov.br/ccivil\\_03/leis/19279.htm](http://www.planalto.gov.br/ccivil_03/leis/19279.htm). Access date: 15 Nov. 2021.

CERQUEIRA, João da Gama. **Industrial Property Treaty: Industrial Property and the Object of Rights**. Rio de Janeiro: Editora Lumen Juris, 2010. v. I, p. I.

FREITAS, Rogério Edivaldo; ZUCOLOTO, Graziela Ferrero. Intellectual Property and Regulatory Aspects in Biotechnology: United States. *In*: ZUCOLOTO, Graziela Ferrero; FREITAS, Rogério Edivaldo (ed.). **Intellectual property and regulatory aspects in biotechnology**. Rio de Janeiro: Ipea, 2013. pp. 33-58. Available at: [https://www.ipea.gov.br/portal/images/stories/PDFs/livros/livro\\_propriedade\\_intelectual.pdf](https://www.ipea.gov.br/portal/images/stories/PDFs/livros/livro_propriedade_intelectual.pdf). Access date: Dec 10 2021.

HATZACK, Frank; WU, Wenping; TANG, Lan. **Nucleic acid construction, recombinant expression vector, recombinant host microorganism cell, method for producing a polypeptide, use of at least one protease, method for improving the nutritional value of an animal feed, additive for animal feed, composition of animal feed, and method for treatment of plant proteins**. Depositor: NOVOZYMES A/S (DK). Lawyer: Momsen, Leonardos & Cia. PI 0214653-3. Deposited: 05 Dec. 2002, Awarded: 6 Jan. 2015. Available at: <https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=653515&SearchParameter=PI%20214653-3%20%20%20%20%20%20&Resumo=&Titulo=>. Access date: 05 Dec. 2021.

HE, Steve S.; DOTSON, Stanton B. **DNA molecules associated with plant cell proliferation and development and plant production methods with increased organ size**. Depositor: Monsanto Technology LLC (USA). Lawyer: Dannemann, Siemsen & Ipanema Moreira. PI 0116305-1. Deposited: 19 Dec. 2001. Award: 12 Jan. 2016. Available: <https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=44e011e1251c96bbe1778670bab04e1f821aba1106b3ff304bab0c8c198ded9a&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=628836>. Access date: 05 Dec. 2021.

LOWERY, David Earl, *et. al.* **Vaccine to immunize cats against feline calicivirus**. Applicant: ZOETIS P LLC. Lawyer: DANNEMANN, SIEMSEN, BIGLER & IPANEMA

MOREIRA. BR 122015025435-3. Deposited: 17 Jul. 2006. Award: 03 Jan. 2017. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=3d7b02598c9a71446ccb4fa9e120470a9005c6d0efedfe122fbb8adfb369a1f1&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=1352388>. Access date: 05 Dec. 2021.

MARQUES, João Paulo Fernandes Remédio. **Biotechnology(s) and intellectual property:** plant varieties, traditional knowledge, distinctive signs, bioinformatics and databases, competition law. Coimbra: Almedina, 2007. v. II.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 7.1 Knowledge of the technical opinion. Patent. Deposit PI 0214653-3. Researcher Karla Kovary. **RPI**, Rio de Janeiro, n. 2216, p. 1-6, 25 June 2013. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=ea8ace6a7c4abde048f46577c3bea33c7fa35594f47ccab00aa940b418683da0&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=653515>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit PI 0214653-3. Researcher Karla Kovary. **RPI**, Rio de Janeiro, n. 2272, p. 1-3, 22 July 2014a. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=2f493d6dc9519fbc3e79ac1335faef09647fce504948f9a58f769a9792594468&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=653515>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 7.1 Knowledge of the technical opinion. Patent. Deposit PI 0116305-1. Researcher Erika Tarré Borges Antonelli. **RPI**, Rio de Janeiro, n. 2292, p. 1-5, 09 dez. 2014b. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=83e939f1bd48359783e021ccd150b2b050f6f5ffeeab511a12034dbe84a51692&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=628836>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 6.1 Requirement - Art.36 of the LPI. Patent. Deposit: PI 0116305-1. Researcher: Erika Tarré Borges Antonelli. **RPI**, Rio de Janeiro, n. 2312, p. 1-3, 28 Apr. 2015. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=fdc5ba480a547d7c6ea36e1a0c9c242441e8b74a404d58617fd21b97da67e2b7&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=628836>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit PI 0116305-1. Researcher Erika Tarré Borges Antonelli. **RPI**, Rio de Janeiro, n. 2338, p. 1-3, 28 Apr. 2015b. Available at:  
<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=4e0407d20dbfd602a5fe065346bbf506c8e82c54bccfd76dd58eb459fd99134d&certif>

icado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=628836. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 6.1 Requirement: Art.36 of the Intellectual Property Law. Patent. Deposit: BR 122015025435-3. Researcher Víctor Genu Faria. **RPI**, Rio de Janeiro, n. 2371, p. 1-5, 14 Jun. 2016a. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=66f862f3673ded3d86692aab1545119a7300024469cccbde3edbe7e900b925a2&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=1352388>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit: BR 122015025435-3. Researcher Víctor Genu Faria. **RPI**, Rio de Janeiro, n. 2391, p. 1-4, 01 Nov. 2016b. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=663b9fd4b089de04b7e02e7e10e3bc3934045ba56affd3775d576b9c4b763ffb&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=1352388>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 6.1 Requirement: Art.36 of the Intellectual Property Law. Patent. Deposit: PI 0614338-5. Researcher Erika Tarré Borges Antonelli. 2017a. **RPI**, Rio de Janeiro, n. 2413, p. 1-8, 04 Apr. 2017a. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=a52b050cfaf36af66ec9b5809a824e88a4f7433be1dfb9a6755ce2441effd5d9&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=759343>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit: PI 0614338-5. Researcher Erika Tarré Borges Antonelli. **RPI**, Rio de Janeiro, n. 2433, p. 1-3, 22 years ago. 2017b. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=32c878f031003572dd619a6cdc9a948ad8b3724359f34e8ac8cd64607c85df45&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=759343>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 6.1 Requirement: Art.36 of the Intellectual Property Law. Patent. Deposit: PI 0417992-7. Researcher Cláudio Picanço Magalhães. **RPI**, Rio de Janeiro, n. 2485, p. 1-5, 21 years ago. 2018. 2017c. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=91ee00537d8a520c9dda609c7b077d6a8678f21056807c44db4c89e6d1cdacd6&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=709884>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit: PI 0417992-7. Researcher Cláudio Picanço Magalhães. **RPI**, Rio de Janeiro, n. 2496, p. 1-3, 06 Nov. 2018. Available at:

<https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=a7f90ee991f6357c8e79ab7e641013d951febfa4b04a3145bde7ed6f65640d89&certif>

icado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=709884. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 6.1 Requirement: Art.36 of the Intellectual Property Law. Patent. Deposit: PI 0713503-3. Researcher: Elielton Rezende Coelho. **RPI**, Rio de Janeiro, n. 2520, p. 1-4, April 24, 2019a. Available at: <https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=789214&SearchParameter=PI%200713503-3%20%20%20%20%20%20%20&Resumo=&Titulo=>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Technical Examination Report. 9.1 Approval. Patent. Deposit: PI 0713503-3. Researcher: Elielton Rezende Coelho. **RPI**, Rio de Janeiro, n. 2548, p. 1-3, 05 Nov. 2019b. Available at: <https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=789214&SearchParameter=PI%200713503-3%20%20%20%20%20%20%20&Resumo=&Titulo=>. Access date: 05 Dec. 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Legislation. **INPI**, Brasilia, Jul 28. 2022. Available at: <https://www.gov.br/inpi/pt-br/servicos/patentes/legislacao>. Access date: 15 Dec 2021.

NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (Brazil). Visual identity. **INPI**, Brasilia, [202?] **element**. Available in: <https://www.gov.br/inpi/pt-br/central-de-conteudo/identidade-institucional>. Access date: 10 Dec 2021.

RIFKIN, Jeremy. **The century of biotechnology: the valorization of genes and the reconstruction of the world**. Translation: Arão Sapiro. São Paulo: Makron Books, 1999.

ROSSI, Mara. **Methods for purifying recombinant human FSH or a variant of FSH**. Depositor: Ares Trading S.A. (CH). Lawyer: Dannemann, Siemsen, Bigler & Ipanema Moreira. PI 0417992-7. Deposited: 16 Dec. 2004. Scholarship: 02 Jan. 2019. Available in: <https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=9471a223c6cdf017c2614059e0b5fe9422e5212321d5197a14c35940642747d7&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=709884>. Access date: 05 Dec. 2021.

SCHMIDT, Klaus. **Pathogen-inducible synthetic promoter, recommender gene, and process for preparing a pathogen-resistant plant**. Depositor: KWS SAAT SE (DE). Lawyer: Dannemann, Siemsen, Bigler & Ipanema Moreira. PI 0713503-3 Deposited: June 16, 2007. Award: 07 Jan. 2020. Available at: <https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=789214&SearchParameter=PI%200713503-3%20%20%20%20%20%20%20&Resumo=&Titulo=>. Access date: 05 Dec. 2021.

SILVEIRA, Newton. **Intellectual property: industrial property, copyrights, software, cultivars, trade name, patent abuse**. 5. ed. Barueri: Manole, 2014.

TROLINDER, Linda; HABEX, Veerle. **Processes for the identification of an elite event in biological samples, for the confirmation of seed purity, for the selection of seeds in relation to the presence of such an elite event, for the determination of the zygosity**

**status of a plant, plant material or seed comprising such elite event, for the detection of the presence of such elite event, and for the production of a plant or cottonseed comprising the said elite event, as well as kits for the identification of such elite event, a pair of primers suitable for use in the specific detection of such elite event, and a specific probe for the identification of such elite event.** Depositor: Bayer Cropscience NV. Lawyer: Dannemann, Siemsen, Bigler & Ipanema Moreira. PI 0614338-5. Deposited: 01 Aug. 2006. Awarded: 02 Jan. 2018. Available in: <https://busca.inpi.gov.br/pePI/servlet/ImagemDocumentoPdfController?CodDiretoria=200&NumeroID=dea21a756c9806493d60f0c221589719b886529d9051150ae02a527d27905692&certificado=undefined&numeroProcesso=&ipasDoc=undefined&codPedido=759343>. Access date: 05 Dec. 2021.

VON DER WEID, Irene; VERDE, Flávia Romano Villa. **Biotechnology and Filing of Biological Material for Patent Purposes/Budapest Treaty**. Rio de Janeiro: National Institute of Industrial Property – INPI, Directorate of Patents – DIRPA DIRPA, General Coordination of Studies, Projects and Dissemination of Technological Information – CEPIT, Coordination of Research in Innovation and Intellectual Property – COPIP, Division of Studies and Projects – DIESP, 2018. Available in: [https://www.gov.br/inpi/pt-br/aceso-a-informacao/radar-tecnologico/arquivos/documentos/radarbiotecnologiagetradodebudapeste\\_abril2019final.pdf](https://www.gov.br/inpi/pt-br/aceso-a-informacao/radar-tecnologico/arquivos/documentos/radarbiotecnologiagetradodebudapeste_abril2019final.pdf). Access date: 15 Dec. 2021.

ZORZAL, Poliana Belisário. **Biotechnological inventions in Brazil: protection of biological sequences through gender claims in patents**. 2017. Thesis (PhD in Biotechnology) - Graduate Program in Biotechnology (PPGBIO), Federal University of Espírito Santo, Espírito Santo, 2017. Available at: <http://repositorio.ufes.br/handle/10/7142>. Access date: 15 Nov. Year 2021.