DOI: 10.1111/jwip.12143

ORIGINAL ARTICLE

THE JOURNAL OF WORLD INTELLECTUAL PROPERTY WILEY

The status of patenting plants in the Global South

Carlos M. Correa[1] | Juan I. Correa[2] | Bram De Jonge[3]

[1]South Centre, Geneva, Switzerland

[2]Centre for Interdisciplinary Studies on Industrial Property and Economics, University of Buenos Aires, Buenos Aires, Argentina

[3]Law Group, Wageningen UR, Wageningen, The Netherlands

Correspondence
Bram De Jonge, Law Group, Wageningen University, Hollandseweg 1, Wageningen 6706 KN, The Netherlands.
Email: bram.dejonge@wur.nl

Funding information
Dutch Ministry of Foreign Affairs, Strategic Partnership Program

Abstract

Over the last few decades, the number of patents on plants and plant parts has greatly increased in various parts of the world. Most research, however, has focused exclusively on developed countries—the United States and European Union states in particular—while little is known about the extent to which plants are being patented in other parts of the world. This article aims to fill this information gap by providing an overview of the status of patenting plants in the developing countries and emerging economies of the Global South. The research is based on the analysis of legal provisions, patentability guidelines, court decisions (where they exist) and a sample of patents granted in the countries selected for this study. The findings indicate that despite the flexibilities of the World Trade Organization Trade-Related Aspects of Intellectual Property Rights Agreement regarding the nonpatentability of plants, 60% of the 126 countries in the Global South for which data were available to allow for the patenting of plants or parts thereof, and many such patents have been identified. This situation warrants further reflection and, potentially, review of existing patent laws as developing countries search for ways of responding optimally to the needs of feeding a growing population while adapting to the challenges of climate change.

KEYWORDS
developing countries, Global South, patents, plants, seed

1 | INTRODUCTION

Over the last half-century, patent law has gradually been extended to cover plants and their parts and components. Currently, patents are granted in many jurisdictions on the basis of claims relating to phenotypic and/or genotypic characteristics.[1] A wide range of claims are often admitted in relation to genetically engineered plants, including genetic constructs and/or their components as well as modified cells and plants. In some countries, plant varieties as such may also be patented. Plant-related patents may cover DNA sequences (complete or partial genes), promoters, enhancers, individual exons, plasmids, cloning vectors, expression vectors, nucleic acid probes, amino acid sequences (proteins), transit peptides, isolated host cells transformed with expression vectors, plant cells, parent lines and hybrids, seeds, and processes to genetically modify plants and to obtain hybrids (Balachandra & Ramachandranna, 2010; Blakeney, 2012; Janis, 2014; Jefferson, Köllhofer, Ehrich, & Jefferson, 2015; Oldham, Hall, & Forero, 2013; Thomas, 2004).

As discussed below, an extensive literature addresses the patentability of plants and plant materials, particularly in the context of developed countries' legislation. Much of it addresses issues around the patentability of biotechnology in general, including but not limited to plants (Barton, 1991; Ducor, 1998; United States Congress, Office of Technology Assessment, 1989). A growing number of scientific publications and books have specifically addressed issues relating to plants including what could be claimed under utility patents, such as plants derived by cell culture, plants generated by selective breeding and transgenic plants (Agris, 1999; Parvin, 2009).

Academic interest in the subject was boosted in the United States by three important decisions. In *Diamond v. Chakrabarty* (1980), the U.S. Supreme Court ruled that living matter was patentable. Significantly, it did not limit its decision to genetically engineered bacteria and enunciated a very broad interpretation of "manufacture" and "composition of matter," thereby opening up the possibility of obtaining patents on plants. In Ex parte Hibberd (1985), the Appeal Board of the U.S. Patent and Trademark Office (USPTO) held that plants could be the proper subject of a patent even though they could be protected under the Plant Patent Act or the Plant Variety Protection Act. In *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* (2001), the U.S. Supreme Court confirmed for the first time that utility patents could be issued for crops and other flowering (sexually reproducing) plants.[2] Several studies found that plant-related patents had a wide-ranging scope as they could cover all aspects of transgenic technology, from selectable markers and novel promoters to methods of gene introduction (Dunwell, 2005).

The situation of plant-related patents has also been thoroughly examined in the context of the European Patent Convention (EPC) and jurisprudence developed by the European Patent Office. Particular attention has been paid to the legal treatment of methods that are akin to traditional breeding, hybrid seeds and products obtained by essentially biological processes, and the viability and effects of introducing a breeders' exemption in the patent system (Bostyn, 2004, 2013). Discussions on these topics have been ongoing in the European Union (EU) for years (Llewelyn, 2000) and seem equally alive today (Prifti, 2017; Then, Tippe, & Dolan, 2018).

The possible effects of patents on the further use of plants and plant materials are controversial. A number of studies have examined the impact of intellectual property rights (IPRs) protection of plants, particularly on seed supply (Binenbaum, Nottenburg, Pardey, Wright, & Zambrano, 2003; Santaniello, Evenson, Zilberman & Carlson, 2000), and the ongoing consolidation in the global breeding sector (Jefferson et al., 2015; Louwars et al., 2009). Some analyses advanced the view that patents on plants and licensing would not inhibit but promote research and development, both in developed and developing countries (Adams & Adams, 1992; Price, 1992). However, a study of this issue found that stronger plant-related IPR protection had apparently not increased the diversity of plant material available to farmers or enhanced the rate of innovation in plant breeding (Wijk, 1996).

Much of the literature has addressed the implications for countries in the Global South of the biotechnology industry's expansive interpretation of patent law as applied to genetic resources and genetically engineered living organisms (McNally & Wheale, 1996). Various studies have found diverging views both in developed and in developing countries on the patent protection of plants and how it affects the behaviour of and interaction between the public and private sectors (Harfouche, Meilan, Grant, & Shier, 2012). A recent analysis has found that IPRs provide scant encouragement for biodiversity and a questionable distribution of support for research

programmes in the development of crops, including through genetic modification, conventional commercial and traditional breeding, and seed exchange practices (Jarvie, 2016).

Overall, the patenting of plants and plant materials raises several concerns: The granting of patents on plants and plant materials may have significant implications for access to and use of seeds and other propagating materials because the presence of a single patented component in a plant may create a barrier for research and breeding. Likewise, if patents on processes to produce a plant are accepted, the product obtained by using such a process may be protected as well, on the basis of an extension—mandated by Article 28.1(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)—of the protection accorded to the process to the product directly obtained with it.[3] The scope of protection granted by plant-related patents becomes particularly problematic when they cover not only plants or plant materials but the products that may be obtained from them, such as food and feed. In addition, patent laws do not usually allow for the use and exchange of farm-saved seeds of a protected variety.[4] This may have far-reaching implications for farmers, as exemplified by the Schmeiser case in Canada (*Monsanto Canada, Inc. v. Schmeiser*, 2004), in which it was found that patent infringement through use was possible "even where the patented invention is part of, or composes, a broader unpatented structure or process."

Whereas these concerns are equally relevant for developing countries, the patenting of plants has predominantly received attention in the United States and the EU. Some studies have examined the granting of plant patents at the national level, often in the context of broader analyses of the patentability of biotechnological inventions (Gomes da Silva d'Ornellas & Tonello, 2013; Singh, 2016). Also, the emergence of plant variety protection (PVP) and its (potential) impact in developing countries has received attention (Braunschweig, Meienburg, Pionetti, & Shashikant, 2014; De Jonge & Munyi, 2016; Prifti, 2016). Very few studies, however, specifically address the patent protection of plants and plant materials in developing countries and emerging economies.

This article addresses this lack of attention. It aims to provide an up-to-date overview of the legislation on, and status of, plant patents in the Global South. It reviews the legal provisions in force in the developing world in general, and specifically covers the legal status and policies in a group of selected countries: Argentina, Brazil, China, India, Peru, South Africa, Uganda and Vietnam. This selection of emerging economies and developing countries—spread over Africa, Asia and Latin America—allows for country-specific analyses of case law and a sample of patents granted.[5]

A review of the extent to which patents apply to plants cannot be circumscribed to an analysis of whether or not there are provisions specifically addressing the patentability of plants or plant varieties. Many national laws permit the patenting of genetic materials and other parts of plants, such as cells, or processes to produce plants, thereby practically or potentially allowing the patent owner to exercise control indirectly over the further use of a whole plant or any plant variety that contains the patented component or was obtained by use of the patented process.

First, the article discusses international and national legal provisions dealing with patents relating to plants and plant materials, including provisions in free trade agreements (FTAs) entered into with the United States that oblige partners to provide for patent protection for plants (The research also looked into FTAs signed with the EU, but these do not include an obligation to grant or endeavour to grant patents on plants.) Second, it explores in some detail how the relevant legal provisions have been interpreted by patent offices and the courts, including in relation to discoveries, genetic materials, plants and their parts and components, plant varieties, and methods to obtain plants and plant varieties. Third, it considers, on the basis of the available information and expert opinions,[6] how the patentability requirements have been applied in relation to plants and plant materials.

2 | THE INTERNATIONAL FRAMEWORK

At the outset of the international regime on IPRs, the Paris Convention for the Protection of Industrial Property (1883, Article 1(3)) clarified that such rights may be applied "not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour."[7] This convention, however, did

not oblige the granting of patents in all fields of technology; there was no obligation, in particular, to grant protection to plants or plant varieties.

The TRIPS Agreement, adopted in 1994 as one of the multilateral agreements of the World Trade Organization (WTO, 2017), introduced such an obligation, but it explicitly allowed WTO members to exclude "plants" from patent protection (Article 27.3(b)). It also required members to provide protection for "plant varieties," but left open the option to do so under patents or in the form of a sui generis regime (such as PVP, whether consistent or not with the International Convention for the Protection of New Varieties of Plants (UPOV), or a combination (Article 27.3(b)).

The wording of the facultative exclusion for "plants" under the TRIPS Agreement gives WTO members the possibility of denying patent protection to any plant, whether wild or obtained through conventional breeding methods of crossing and selection, hybridisation, mutagenesis, genetic modification or any other method. As will be discussed below, many national laws enacted by developing countries that are WTO members have provided for a plant-related exclusion from patentability. In some cases such an exclusion has been broadly crafted, but many developing countries have limited the exclusion—as under European law—to "plant varieties." This means that, for instance, a genetically modified plant may be deemed patentable as such.

While the TRIPS Agreement allows WTO members to exclude plants from patentability, a number of FTAs entered into by developing countries with the United States have included, among other "TRIPS-plus" provisions, an obligation to provide for the grant of patents on plants or to make efforts to ensure that such patents are granted. These FTAs have followed three different approaches (Correa, 2014):

(1) Some contain a straightforward obligation to provide for the grant of patents on plants, if requests to that end are submitted.
(2) Some include "best effort" or "reasonable endeavour" obligations, which may be interpreted as obliging the parties to make all necessary efforts to implement patent protection for plants.
(3) Some do not specifically refer to the patentability of plants, but nor do they mention plants as subject matter for which an exclusion from patent protection is allowed.

The first approach can be found, for instance, in Article 14.8(2) of the U.S. FTA with Bahrain, which stipulates that "[E]ach Party shall make patents available for plant inventions." The U.S. FTA with Morocco also makes plant patents mandatory: Article 15.9(2) states "Each Party shall make patents available for the following inventions: (a) plants, and (b) animals … ." In these cases, the obligation is likely to be interpreted as extending to parts and components of plants, such as seeds and plant cells.

The second approach is found, for instance, in Article 17.9.2 of the U.S. FTA with Chile, which provides that:

> *Each Party will undertake reasonable efforts, through a transparent and participatory process, to develop and propose legislation within 4 years from the entry into force of this Agreement that makes available patent protection for plants that are new, involve an inventive step, and are capable of industrial application.*

While this provision imposes an obligation to make "reasonable efforts" to "develop and propose legislation," and provides for a deadline to that end, the only actual obligation on the government is to put a legislative process in motion. In this regard, Roffe (2004) has interpreted this obligation as follows: "[A]ccording to this obligation, that in practice applies only to Chile, the latter is not obliged to consider plants as a patentable subject matter, but to engage in a process to legislate to that effect." Arguably, the obligation would not be violated if a government found opposition to the introduction of patent protection for plants, or if other conditions were not met (such as lack of capacity to examine their patentability). Although reciprocal in appearance, the provision is irrelevant for the United States, where patent protection for plants was already available at the time the FTA was signed. Chile does not yet seem to have introduced patent protection for plants.

A similar obligation—although less detailed than in the U.S. FTA with Chile—can be found in the US-CAFTA-DR (Dominican Republic-Central America FTA),[8] but in this case the fact that plant patents were already granted in the United States is reflected in the text. Article 15.9(2) reads:

> *Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection.*

The third approach is found, for instance, in the U.S. FTAs with Jordan, Singapore and Australia, which allow only the exceptions provided for in Articles 27.2 and 27.3(a) of the TRIPS Agreement, without any reference to plants (or animals). The U.S. FTA with Oman (Article 15.8: Patents) allows for the exclusion of patents in respect of animals, but does not mention plants:

> *1. Subject to paragraph 2, each Party: (a) shall make patents available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step, and is capable of industrial application; and (b) confirms that it shall make patents available for any new uses for, or new methods of using, a known product, including new uses and new methods for the treatment of particular medical conditions.*
>
> *2. Each Party may exclude from patentability: (a) inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; (b) animals other than microorganisms, and essentially biological processes for the production of animals other than non-biological and microbial processes; and (c) diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals.*

A question arises as to whether the obligation to issue patents for "plants" implies the need to extend such protection to "plant varieties." Countries bound by FTAs' obligations in this respect may consider that these are two different categories of subject matter. Article 27.3(b) of the TRIPS Agreement, for instance, as noted above, distinctly refers to them as different subject matter.

FTAs signed with the EU or the European Free Trade Association do not include an obligation to grant or endeavour to grant patents on plants, but to ensure PVP under the standards of UPOV (generally the 1991 Act). The Trans-Pacific Partnership Agreement, now renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, introduced a new type of obligation in relation to patents on plants, the implications of which still need to be clarified. Article 18.37.4 stipulates that:

> *A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.*

The concept of "inventions that are derived from plants" was new in FTAs and national patent laws. It is unclear what this phrase was intended to mean. In any case, the second sentence of Article 18.37.4 was suspended in the ongoing negotiations that took place after the withdrawal of the United States (Geist, 2017).

In summary, we can conclude that the international patent regime, as contained in the TRIPS Agreement, allows WTO members to broadly exclude plants from patentability. This policy space, however, is totally or partially limited in many FTAs that contain TRIPS-plus obligations, particularly those with the United States.

3 | LEGAL PROVISIONS IN NATIONAL LAWS

Establishing the precise status of the patentability of plants, plant materials and related processes in developing countries and emerging economies in the Global South requires, as a first step, the determination of the applicable national legal provisions, including, where appropriate, the provisions of international treaties.

The legal provisions contained in patent laws that may affect the patentability of plants and plant materials may refer to the following matters and relate to associated definitions:

- Discoveries, natural materials and traits
- Plants
- Plant varieties
- Essentially biological processes and other methods to produce or modify plant varieties or plants
- Genes and other plant parts, including promoter DNA sequences, transit peptides, cells and so forth.

As summarised in Table 1 and Figure 1,[9] plants are excluded from patentability in 40% of the 126 countries for which legal information was available in 2018 (Oxfam Novib, 2018).[10] In other words, the majority of these countries have not used the TRIPS flexibility regarding the nonpatentability of plants. Of these countries, 43% exclude the patentability of plant varieties and essentially biological processes to obtain them, as is the case under European law, and would hence allow the granting of patents on plants and their parts and components, including plant cells. To the extent that patented elements are incorporated into plant varieties, the production and commercialisation of the latter (and eventually of the products derived from them) may be controlled by the patent owners, despite the fact that the plant varieties as such might not be patentable. In the other 17% of the countries studied, plant varieties might also eventually be patentable, generally due to the lack of an explicit exclusion.

Table 2 summarises the relevant provisions of patent laws in force in the selected countries, that may affect the patentability of plants and plant materials.

As shown in Table 2, patent laws contain different types of exclusions from patentability relevant to plants and plant materials. Some specifically refer to plants, while others contain more general provisions that may prevent plants or plant materials from being patented (e.g., the exclusion under the Brazilian law of "all or part of living beings"). However, a key issue is how the scope of these exclusions is interpreted. Whether the exclusions are, in administrative or judicial practice, broadly or narrowly interpreted will determine the extent to which access to and use of propagating material may be subjected to patent rights. For instance, a narrow interpretation of an exclusion of "plants" may lead to the possibility of indirectly controlling access to and use (notably for saving and reusing seeds) of

TABLE 1 Patentability of plants in countries in the Global South

Plants are not patentable	Exclusion of plants	51
Plants are patentable	No reference to plants or plant varieties	17
	Plant varieties are patentable	4
	Plant varieties and essentially biological processes are excluded	54
No information		28
Total countries		154

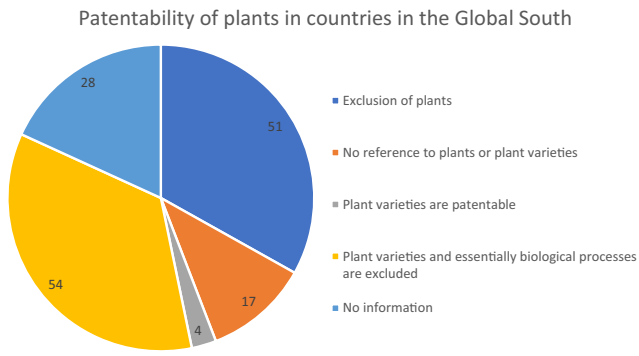

FIGURE 1 Patentability of plants in countries in the Global South [Color figure can be viewed at wileyonlinelibrary.com]

plant propagating material through the patenting of the parts and components of plants, such as gene constructs designed to modify a plant genetically.

In some cases, the relevant legal provisions are clarified by guidelines issued by patent offices for the examination of patent applications. Argentina, Brazil and India have adopted specific guidelines for the examination of biotechnological inventions that shed light on the patentability of plants and plant-related materials and processes. However, since the ultimate interpretation of legal provisions is made by courts, it is crucial to analyse jurisprudence regarding the patentability of plant materials to understand the patenting policies that are actually applied in a country. For instance, Monsanto filed lawsuits in the courts of Brazil and Argentina contesting patent offices' decisions to deny patents over transgenic modifications. Case law regarding the patentability of plants, plant materials and breeding processes is scarce in developing countries and emerging economies, as patent litigation has mostly focused on pharmaceuticals. Review of a sample of patents granted in those countries is needed to develop a further understanding of how the legal framework is applied.[11]

The patent laws in the countries shown in Table 2 limit the scope of allowable protection through a *negative* approach, detailing the matters that can *not* be considered an invention or patentable. Such lists may include discoveries, naturally occurring genetic materials, plants and/or plant varieties and essentially biological processes for the production of plants. These different categories of exclusions are examined in more detail below.

3.1 | Patentability of plants and plant materials: Administrative and court interpretation

3.1.1 | Invention versus discovery

According to the ordinary meaning of the term, a "discovery" is the act, process or circumstance of acquiring knowledge or verifying the existence of something previously unknown or not recognised, or the outcome of such acts or processes, while "invention" is the result of the action of humans on the forces of nature, which necessarily implies a human contribution.

Patent laws generally do not define invention. One notable exception exists in Argentina, where invention is defined as "any human creation that allows the transformation of matter or energy that exists in nature, for its use by man and to meet their specific needs" (Article 4(a) of Law No. 24.481). The meaning is thus linked to the result of intellectual activity, in the form of new knowledge of a technical nature. This suggests a distinction between creations and mere discoveries and, more generally, between inventions and other objects that are not the result of

TABLE 2 Patenting of plants and plant materials in selected countries

Countries	Legislation	Relevant provisions
Argentina	24.481 Article 7 Decree 260/96	The following shall not be patentable: (b) All biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature
	Decree 260/96, Article 6	Plants and animals and essentially biological processes for their production shall not be patentable
Brazil	9.279 Articles 10/18	Article 10. The following are not considered to be inventions or utility models: I. Discoveries, scientific theories, and mathematical methods IX. All or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and the natural biological processes Article 18. The following are not patentable: II. All or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability—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 are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions
China	Patent Law Article 25	Patent rights shall not be granted for any of the following: (1) Scientific discoveries (4) Animal or plant varieties
India	Patents Act 1970 Section 3	3. What are not inventions? The following are not inventions within the meaning of this Act: (c) The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substance occurring in nature (h) A method of agriculture or horticulture (j) Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals
South Africa	Patents Act Section 25	A patent shall not be granted: (b) For any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process
Peru	Decision 486 (CAN) Article 15	The following shall not be considered inventions: (a) Discoveries, scientific theories and mathematical methods (b) The entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germplasm of any natural living being.

(Continues)

TABLE 2 (Continued)

Countries	Legislation	Relevant provisions
Uganda	The Industrial Property Act 2014 Article 33	(2) The following shall not be regarded as inventions within the meaning of subsection (1): (a) Discoveries and scientific and mathematical theories (b) Plant or animal varieties or essentially biological processes for the production of plants or animals, other than biological processes and the products of those processes
Vietnam	Law No. 50/2005/QH1 Article 59	Subject matters not protected as inventions. The following subject matters shall not be protected as inventions: 1. Scientific discoveries or theories, mathematical methods 5. Plant varieties, animal breeds 6. Processes of plant or animal production which are principally of biological nature other than microbiological ones

Source: WIPOLex (https://wipolex.wipo.int/en/main/legislation), national laws (translated, as appropriate by authors).

an inventive process. A rigorous application of the concept of discovery is likely to lead to the rejection of patent applications relating to natural traits[12] and plants as found in nature.

In most selected countries there is no such explicit definition, and the meaning of invention must be deduced from the provisions of the law. In some cases (such as in Brazil), the law specifies what is *not* deemed to be an invention as well as the subject matter that, even for inventions, is not patentable. Other countries make a more general reference to what is not patentable. This reflects the flexibility allowed by the TRIPS Agreement, which mandates in Article 27.1 that patents be granted for inventions without defining them, thereby leaving national laws significant leeway to determine what may or may not be deemed patentable, including in the area of plants.

Most laws indicated in Table 2 consider that discoveries are excluded from patent protection. This means, for example, that a wild plant as found in nature may not be considered an invention. Depending on the criteria applied by the patent offices and courts (discussed later in this article), a natural gene found in a plant, even if isolated, may also be deemed nonpatentable, in spite of the identification of its utility for a specific product or process. Similarly, a known plant does not become patentable just because a new property is found (such as use for medicinal purposes). The exclusion of patents on discoveries may be based on the lack of novelty (since they already exist) and/or inventive activity (in a discovery the intellectual activity is not to create but to find).

However, the boundaries between invention and discovery have become blurred in the case of biotechnology, as it uses biological systems and living organisms or their derivatives (such as biochemical compounds) as found in nature for the creation or modification of products or processes for specific uses. Thus, notwithstanding that Article 52(2)(a) of the EPC excludes the patentability of "discoveries," a patent may be granted under European law when a substance found in nature can be characterised by its structure, by its process of obtention or by other criteria, if it is new in the sense that it was not previously available to the public.[13]

3.1.2 | Genetic materials

Genes themselves are pre-existing in nature and therefore may be considered as discovered rather than invented. The same applies—if unmodified—to genetic sequences used in biotechnology, such as those involved in the expression of genes and their regulation, including: promoters (DNA sequences that are operatively linked to a gene or a coding sequence and allow the expression of these, which in turn may lead to the synthesis of a protein); enhancers (DNA sequences that increase the level of expression of a gene in general or under specific conditions);

transcription terminator sequences (sequence-based elements that define the end of a transcriptional unit, such as a gene) and localisation signals (amino acid sequences that target proteins for import into the nucleus).

Nonetheless, these sequences have often been the subject of patent applications.[14] Many countries have allowed the patenting of genes and nucleotide sequences, based on the argument that by isolating them there would be no appropriation of a natural product.

For instance, in accordance with the EU Directive 98/44/EC on the legal protection of biotechnological inventions and the practice and jurisprudence of the European Patent Office, patents on isolated genes are admissible and may be granted. The USPTO has also granted thousands of patents based on the artificial differentiation between "natural" and "isolated" genes, although in *Association for Molecular Pathology v. Myriad Genetics* (2013) the U.S. Supreme Court ruled that naturally occurring DNA, even if claimed as isolated, is not a valid patentable subject matter. However, as noted below, the court considered that complementary DNA (cDNA; a form of DNA artificially synthesised used in genetic engineering to produce gene clones) was patentable.

The patentability of genetic material is specifically addressed by Brazil's patent law, which is very precise in stipulating that "all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being" are not patentable. This means, inter alia, that a natural trait would not be patentable in Brazil, even if a gene is claimed as "isolated."

Although similar provisions do not exist in other selected countries, expert opinion obtained for the study reported in this article holds that the same solution would apply in Argentina, Peru, Uganda and Vietnam. In Vietnam, for instance, a natural plant genetic trait can be considered as a discovery and cannot be patented in accordance with Article 59 of the industrial property law. In Peru, an isolated gene, even if not characterised before, is not considered to be an invention (Decision 486, Article 15(b)).

However, in China, a gene or a DNA fragment per se and the process to obtain it might be patented if the gene or DNA fragment is unknown as prior art and can be accurately characterised and exploited industrially (Li & Cai, 2014). In India, although the patentability of isolated genes would be excluded if the law were strictly interpreted, according to available studies, such as Ravi (2013), and expert opinion, patents on isolated genes have been granted.[15]

This situation may change or be clarified on the basis of a recent case, *Nuziveedu Seeds Ltd and Ors v. Monsanto Technology LLC and Ors*, in April 2018, relating to Bt cotton developed by Monsanto and protected under patent IN214436, which was licensed to several Indian seed companies. Nuziveedu Seed Ltd., Prabhat Agri Biotech Ltd. and Pravardhan Seeds Pvt. Ltd. requested that Monsanto reduce the trait fee, and suspended payments when Monsanto refused; Monsanto initiated a lawsuit seeking an injunction for patent and trademark infringement (*Monsanto Technology LLC and Ors v. Nuziveedu Seeds Ltd and Ors*, 2018). In response, the defendants filed a counter-claim for the revocation of the plaintiff's patent (Shiva, 2019; Trivedi & Beniwal, 2019). The High Court of New Delhi observed that:

> *The conclusion that the court draws therefore, is that transgenic plants with the integrated Bt. Trait, produced by hybridization (that qualifies as an "essentially biological process" as concluded above) are excluded from patentability within the purview of section 3(j), and Monsanto cannot assert patent rights over the gene that has thus been integrated into the generations of transgenic plants (Monsanto Technology LLC and Ors v. Nuziveedu Seeds Ltd and Ors, 2018).*

On January 8, 2019, however, the Supreme Court overturned the Delhi High Court decision arguing that the division bench should have confined itself to the question of whether the injunction granted by the single judge was justified or unjustified in the facts and circumstances of the case. The Supreme Court has directed that the issue of patentability will be determined by the Single Judge Bench of the High Court after hearing expert evidence.

In South Africa, patent 2010/01012 filed by Shanghai Institutes for Biological Sciences, Chinese Academy of Sciences (2010), covers a crop height regulatory gene from *Arabidopsis thaliana*, "expression and regulatory sequences thereof and uses thereof," which can be used to regulate the "plant height, volume, tiller, yield, flower organ size, or seed size of crops." It is important to note that in South Africa patents are granted without prior

substantive examination, under a depository system. Hence, there is no ex ante analysis of patentability and the validity of deposited patents is determined by courts after a legal challenge has been made.

The nonpatentability of genetic material is generally limited to natural, unmodified material.[16] DNA constructs, gene promoters, transit peptides[17] and other components designed to genetically modify a plant may be patentable in most countries as long as the modified sequences meet the requirements of novelty, inventive step and industrial application. Significantly, the protection granted on some of these elements may extend to any cell or plant incorporating them.

In India, for instance, patent 257711 (2013) covers "a nucleic acid sequence having promoter activity when introduced into plant cells" (claim 1), which is described as "strong, constitutive plant promoters … which remain strong and constitutive under biotic and/or abiotic stress conditions." This patent also claims "transgenic cells and organisms, especially plant cell and plants comprising the claimed promoters and methods for expressing nucleic acid sequences in cells and organisms using them." In Uganda, several patents have been identified that also protect a genetic "event" and the modified cells, seeds and plants. For instance, patent AP 2872 (2014) covers "a transgenic soybean event MON 87708 and plants, plant cells, seeds and plant parts containing the event."

The examined sample of patents includes many examples of patents granted on gene constructs developed to modify plants. For instance, CN 1564866 B, granted in China to Syngenta in 2010, covers "Self-processing Plants And Plant Parts." Similarly, a patent granted in Vietnam to Bayer CropScience N.V. covers "novel DNA sequences encoding insecticidal Cry1 C proteins derived from *Bacillus thuringiensis*, and their use in plants to control insect pests."

In Brazil, however, the guidelines on the examination of biotechnological patents (Instituto Nacional da Propriedade Industrial, 2015) provide that transgenic tissues or organisms are not patentable, but the methods for producing a transgenic plant are patentable if they meet the patentability requirements (para 7.2). This means that despite the exclusions from patentability contained in Brazilian law (see Table 2), agrobiotechnology companies may effectively control the market of transgenic varieties on the basis of process patents. Fourteen patents were granted in Brazil in relation to Monsanto's RR1 technology, the last of which expired in 2010 (De Avila, 2016a). In Bayer CropScience S/A v. Instituto Nacional da Propriedade Industrial (2010), the Brazilian Supreme Court considered the patentability of a plant DNA sequence (transit zone), a chimeric gene and a vector for the transformation of plants. It discussed whether the claimed matters could be deemed a "chemical substance" and admitted, as a matter of principle, the patentability of products obtained through biotechnological processes.

As mentioned above, a particularly problematic situation may arise when patent claims cover not only plant materials but the products derived from processing plants or their parts. Several examples were found in the sampled patents where the claimed protection extends to food or feed. For example, Monsanto's patent CN 101321873 B (granted in China in 2013) covers "corn meal prepared from" protected corn seed (claim 40) and "a processed product of the seed … wherein said product is a feed, flour, meal or partially purified protein composition" (claim 42). Brazilian patent PI 0610654-4 (2017) covers Monsanto's event M0N89788 for genetically modified soybean and any product derived from it, including food, meal and oil. In Argentina, AR049130 A1, filed by Agrinomics LLC (2005), claims genetically modified plants with increased oil content, including seeds, meal and food. Similarly, the Uganda patent AP 2872 (2014), already mentioned, covers a commodity product derived from a plant, plant cell or seed of soybean modified by event MON87708.

3.1.3 | Plants, cells, seeds and other components

As indicated in Table 2, some of the selected countries (Argentina, India and Uganda) specifically exclude "plants" from patent protection. This is in line with Article 27.3(b) of the TRIPS Agreement.

A general reference to "plants" can be interpreted as excluding the patentability of plant varieties and species, and may also be deemed to exclude parts and components of plants such as cells that can lead to a complete plant with stems, leaves and flowers (Wageningen University & Research, 2014). Somatic plant cells have cellular totipotentiality, the ability to develop a complete plant when placed in a suitable medium: by in vitro plant culture techniques, plants can be multiplied and regenerated from one or a few isolated cells. Claims on such cells are not uncommon. Often patent

applications also claim seeds[18] alone or with other subject matter. If allowed, such claims would lead to a de facto protection of the resulting plants, and also make the prohibition of granting patents on plants irrelevant.

For instance, in the patent application AR011036 A1, the main invention relates to a purified nucleic acid sequence encoding a fungicidal polypeptide of the alfalfa plant (AlsAFP1 or AlfAFP2) which, when expressed in a plant, confers resistance to fungal pathogens. A recombinant plant cell, including a polynucleotide (a DNA sequence) encoding an alfalfa antifungal polypeptide, is also claimed as part of the invention. This cell can be selected from apple, alfalfa, barley, broccoli, cabbage, canola, carrot, citrus, corn, cotton, garlic, oats, onion, pea, peanut, pepper, potato, rice, rye, sorghum, soybean, strawberry, sugar beet, sugar cane, tomato, turf and wheat. The claimed plant cell can lead to a complete individual and, if a patent were to be granted, would indirectly permit control over the use and commercialisation of any plant of these crops incorporating the modified cell.

In *Monsanto Technology LLC v. Instituto Nacional de la Propiedad Industrial s/denegatoria de patente* (2015), an Argentine appeal court (Cámara Federal Civil y Comercial) confirmed the patent office's rejection of a patent application, on the basis of the argument, inter alia, that the genetically modified cells were apt to generate a full plant and hence would violate the ban on granting patents on plants. In 2015 the Argentine patent office (INPI) issued revised guidelines for the examination of biotechnological patents (Resolution P283, 2015) that specifically addressed the patentability of plant parts and components, particularly including organelles (cellular structures that perform specific functions within a cell). In accordance with these guidelines, biological parts and components, whether modified or not, from which a complete plant may be regenerated are not patentable. This excludes the patenting of elements (plant parts and components) that may indirectly allow for the control of a full plant or plant variety. Reportedly, the guidelines on biotechnological patents adopted in 2015 in Argentina (Resolución INPI P283, 25-9-2015) have led to the rejection of most examined patent applications relating to plants.

In Peru, the patenting authority INDECOPI refused (in Resolución No. 000765-2012/DIN-INDECOPI, 22-06-2012) claims in a patent filed by Monsanto Technology LLC on the argument, inter alia, that it related to a hybrid seed. It is worth noting that GMO crops and food were banned in Peru with the passing of a law on the subject in 2011 (Michaelis, 2012). A similar decision was taken (Resolución No. 001241-2013/DIN-INDECOPI, 23-9-2013) in relation to another patent application by the same company on soya plants and seeds modified by the transgenic event MON87701 and methods to detect it. INDECOPI also rejected (in Resolución No. 000983-2015/DIN-INDECOPI, 31-07-2015) a claim in a patent application filed by BASF SE from Germany covering plant-propagating material (including seeds, roots and rhizomes), using the argument that it violated Article 20(c) of Decision 486, which bans the patentability of plants. Similarly, a patent application by SG Biofuels Ltd. relating to hybrid seeds was rejected because it involved material that is the "germ of a plant" (Resolución No. 002176-2016/DIN-INDECOPI, 28-12-2016).

3.1.4 | Plant varieties

Patent laws in some of the selected countries (China, South Africa and Vietnam) and many other countries in the Global South have followed the approach of the EPC and provide that plant varieties (rather than plants) are not patentable. This exclusion is clearly narrower than that applicable to "plants" as it would allow for the patentability of transgenic plants, including their parts and components such as genetic constructs, cells and seeds.

In Argentina and Brazil, the cumulative protection of plant varieties by patents and PVP is banned. These countries are parties to the UPOV Convention, as amended in 1978,[19] which prohibits such cumulative protection. Brazil's PVP law (Article 2) clarifies that:

> *The protection of the intellectual property rights in plant varieties is effected through the granting of a Plant Variety Protection Certificate, which shall be considered a commodity for all legal purposes and the sole form of protection in the Country for plant varieties.*

Argentina's exclusion of cumulative protection was confirmed by the court of appeal in *Consejo Superior de Investigaciones Cientificas v. INPI* (2016):

> *Article 2.1 [of UPOV 78] provides that the breeder's right may be recognised by granting a particular title or a patent, and a single form of protection should be chosen when the legislation admits both ways and therefore a double protection is forbidden …*

3.1.5 | Methods of obtaining a plant or plant variety

Most patent laws in the selected countries exclude from protection essentially biological processes for the production of plants.[20] This exclusion—also found in the EPC and in the TRIPS Agreement—has generally been interpreted as excluding conventional breeding methods.[21] These methods may include the utilisation of methodologies to study and breed with the plant's genome, such as marker-assisted selection.

While the patent laws of Argentina, India, Uganda and Vietnam use the concept of "essentially" (or "principally") biological, in Brazil and Peru (Decision 486) the exclusion refers to "natural" biological processes. These exclusions do not extend to other methods, such as those using genetic material to modify a plant if it is not an essentially biological process for production or propagation of plants.

In Brazil, Resolution 144/2015, establishing guidelines for the examination of patent applications in the area of biotechnology, considers that conventional breeding processes are not patentable; biological processes are deemed not "natural," and hence patentable, when the human intervention is permanent and has a direct influence on the genetic composition of a plant (para 7.3). In India, the *Guidelines for Examination of Biotechnology Applications for Patent* (Office of the Controller General of Patents, Designs and Trade Marks, 2013) clarify that producing pure hybrid seeds, plants and crops by producing a male parent which is fertile, breeding the male parent with a female parent which is substantially male-sterile, and harvesting seeds from the female parent which contains pure hybrid seeds, is an essentially biological process not patentable under Section 3(j) of the Patents Act.

Hybridisation methods are routinely carried out in breeding new varieties; they would not normally meet the "inventive step" requirement. However, the sample examined for this study shows examples of patents covering methods to produce hybrids, such as Chinese patent CN 101213943 B (2011) relating to maize hybrids.[22] In India, also, patents on methods for the introgression of alleles have been identified.[23]

In the decisions taken by the patent office INDECOPI in Peru, in relation to patents filed by Monsanto covering a method to produce hybrid seeds of maize (Resolución No. 000765-2012/DIN-INDECOPI, 22-06-2012) and SG Biofuels to produce hybrid seeds of *Jatropha curcas*, a plant native to Central America used as a source of biofuel (Resolución No. 002176-2016/DIN-INDECOPI, 28-12-2016), the claims were refused on the argument that the methods were essentially biological and hence not patentable under Article 20(c) of Decision 486.

In Argentina, the patentability of a method based on chemical mutagenesis to obtain sunflower seeds with a higher content of stearic acid was rejected in *Consejo Superior de Investigaciones Cientificas v. INPI* (2016). The appeal court argued that there was no single legal definition of the concept of "essentially biological" and that the possibility of obtaining patent protection depended on the interpretations of the patent offices according to the different national legislations regarding the degree of intervention of human activity required for a plant breeding process to be patentable.

In Brazil, in a legal action by a group of farmers (*Sindicato Rural de Passo Fundo RS e outros v. Monsanto*, 2012) the court admitted the possibility of "dual protection" over plant varieties as a result of the cumulative effect of PVP and patent protection over transgenic processes to modify a plant. The court rejected Monsanto's claim to charge a 2% royalty on all sales of harvested material containing the so-called "Round-up-Ready" gene construct; it found that the relevant patent (PI 1100008-2) had already expired and that payment to Monsanto would be due only in case of licensing for the development by third parties of varieties incorporating such gene construct.

Methods of producing plants are often presented as "use claims," but these may also be subject to objections regarding patentability. A use claim describes what an invention *does* rather than what it (structurally) is.[24] In Peru, for instance, INDECOPI refused Monsanto's aforementioned application to patent a method to produce hybrid seeds of maize on the basis, inter alia, that uses, as distinct from products or processes, are not patentable under the Andean Community law (Tribunal de Justicia de la Comunidad Andina, 2001). A decision on the same argument was taken in relation to claims in another application by the same company regarding polynucleotide molecules for regulating endogenous genes in plants (Resolución N° 001230-2017/DIN-INDECOPI, 21-06-2017). In other jurisdictions, however, use claims are considered equivalent to and admitted as process claims (European Patent Office, n.d., a).

As mentioned above, if patents on processes to produce a plant are accepted, the product obtained with such processes may be protected as well, on the basis of an extension—mandated by Article 28.1(b) of the TRIPS Agreement—of the protection accorded to the process to the product directly obtained with it.[25] The experts' opinion and analysis of legislation show that in many of the selected countries there is uncertainty regarding whether such extension should be allowed in the case of methods of obtaining plants or plant varieties. In India, for instance, it has been noted that the statute is not very clear whether the replication of a plant arising from a patented process would result in an infringement of the patent. In Vietnam, the protection conferred on a process would extend to a product directly obtained with that process (Article 124.1.c of the IP law). In Uganda and Peru, it is considered that the extension may not occur if the product is a plant or plant variety.

3.2 | Patentability requirements

Patents are generally granted after a substantive examination[26] to determine whether the patentability standards (novelty, inventive step or nonobviousness, and industrial applicability or utility) have been met. Patent offices also check the sufficiency of disclosure and whether the claims in the patent application are sufficiently clear and concise. Importantly, WTO members have policy space to define not only what an invention is but also how the patentability standards are interpreted and applied.

In the case of biotechnological products and processes, for instance, key issues are whether a substance that exists in nature may be considered "novel," and whether prior knowledge of gene coding sequences or protein amino acid sequences is destructive of the novelty of the other.

Similarly, the standard of inventive activity or nonobviousness can be applied more or less rigorously depending on the policy adopted by patent offices and courts. A large number of techniques in biotechnology, molecular biology or biochemistry are widely known and used in practice, and are the basis of many technological innovations. Many biotechnological developments that use elements of the art should therefore not be patentable if examined under a rigorous standard of inventive activity or nonobviousness.

For example, the technology of recombinant DNA has allowed the construction of new DNA molecules by rearranging or combining different genetic elements—defined DNA sequences that have a biological function, such as promoter or polyadenylation site. The function of each element is determined solely by its sequence, and not by the elements with which it is combined in a DNA construct. Therefore, once a genetic element is within the state of the art, its function within a recombinant DNA construct will be evident. The combination of different known genetic elements can result in a new DNA molecule, designed to fulfil a particular function when found in the appropriate cellular environment. However, if the purpose or function of the DNA construction results from the simple addition of the individual functions of each genetic element previously described, the developed construct—even if novel—will not generate an advance over the state of the art and, being evident to a person normally skilled in the art, will lack inventive activity.

A situation of particular interest, from the perspective of patent laws and access and benefit-sharing regimes, arises when a claimed plant-related invention has been obtained on the basis of digitised genetic information

(Bagley, 2016; Halewood et al., 2018). This is made possible by what is termed the "dematerialisation of genetic resources" (Bhatti, 2013). For instance, patent 284831 granted in India in 2017 to SweTree Technologies AB covers a method of producing a transgenic woody plant that "pertains to a novel and extensive analytical platform for selecting genes with a possible commercial phenotype from a large group of candidate genes identified using tools in bioinformatics, data from EST sequencing and DNA array."[27]

In principle, whether a claimed plant-related invention has been obtained by using physical materials or digitised information—for instance through gene editing using the CRISPR-Cas9 technique[28]—would not affect its eligibility for patent protection, provided that the patentability requirements were met. However, patents based on the use of that technique may become harder to obtain due to objections regarding inventive step, as knowledge of the gene-editing technique has been widely disseminated. It is to be noted that a key patent on CRISPR-Cas9 was revoked (due to flaws in the application's procedure) by the European Patent Office in January 2018 (Houldsworth, 2018; Tottie, Skoglösa, & Hoffmann, 2018).

Patent applications on transgenic events are generally accompanied by claims that protect methods to detect the presence of the event in a sample.[29] The most widely used methods for the detection of specific DNA molecules are based on molecular biological techniques widely described in the state of the art, such as the hybridisation of complementary sequences of DNA (under stringent hybridisation conditions) or polymerase chain reaction (PCR). These techniques are based on interaction between two molecules of single-stranded DNA of complementary sequence: for the detection of a specific DNA fragment, small single-stranded DNA molecules are used (probes in the case of hybridisation, primers in the case of PCR) that bind to a specific DNA sequence in a biological sample. The design of these testing methods does not represent an advance beyond the knowledge of a person skilled in the art. Various computer applications can design specific probes or primers to use these techniques.

However, in the sample of patents examined for the study reported in this article, there are many examples of claims covering detection methods of this type and patents granted on them, such as patent CN 101528934 B obtained by Monsanto in China in 2013[30]; patent 278035 granted in India in 2016 to the Scientific Institute of Public Health, covering methods, reagents, kits and reference materials for detecting the presence or absence in a sample of genetic material derived from and attributable to select transgenic plant events; and Monsanto's patent 284409 granted in India covering "corn plant event MON87460 and compositions and methods for detection thereof."[31]

Several judicial decisions in the selected countries have addressed issues relating to the application of the inventive step standard to claims relating to plant materials.

In Argentina, in *Monsanto Technology LLC v. Instituto Nacional de la Propiedad Industrial s/denegatoria de patente* (2015) the appeal court (Cámara Federal Civil y Comercial, sala III) deemed not patentable DNA molecules, a method to produce a transgenic plant and modified cell plants, on the ground of lack of inventive step. It found, inter alia, that the claimed sequences had only minimal differences with sequences known before the date of the application.

In Brazil, the Regional Federal Tribunal confirmed in *Mycogen Corporation e Outros v. INPI-Instituto Nacional de Propriedade Industrial* (2016) the patent office's decision, based on the lack of inventive activity, to refuse a patent application (PI 97061352) regarding polynucleotide sequences optimised for the expression of pesticide toxins in plants. The reason given was that the claimed gene sequences, the improved expression of the claimed chimeric gene, and the methodology for optimisation were known at the time of filing the application.

In an important resolution (a final decision is still pending), in response to a challenge by farmers from the Mato Grosso the Patent Division of Brazil's INPI considered that Monsanto's patent PI 0016460-7, regarding its INTACTA technology (De Avila, 2016b), was invalid, inter alia due to the lack of inventive step (SOJA, 2018). It was estimated that 53% of planted soya in Brazil incorporates INTACTA technology (Mano, 2017). The revocation of this patent, which would otherwise be valid until 2022, would have a significant impact on the cost of soya production as Monsanto would lose the right to charge royalties for the use of the technology.

Objections relating to lack of inventive step (in addition to lack of clarity of several claims and violation of the ban on obtaining patents on plants) were also made by INDECOPI in Resolución N° 001241-2013/DIN-INDECOPI

relating to a patent application by Monsanto Technology LLC on soya plants and seeds modified by the transgenic event MON87701, and methods to detect it.

The patent office of Colombia rejected a patent filed by Monsanto Technology LLC on cotton event MON15985 and a method to detect it, on the argument of lack of inventive activity. The Tribunal Andino de Justicia was requested to make a prejudicial interpretation of the applicable provisions of Decision 486. In its ruling, Proceso 187-IP-2016, on April 24, 2017, the Tribunal provided the Colombian patent office with guidance on how to assess inventive activity, based on the problem–solution approach (European Patent Office, n.d., b) and other aspects of the application, including the nonpatentability of plants.

In addition to considerations of inventive activity, under most laws in the selected countries patentability requires industrial applicability (or a technical effect). Patent applications involving transgenic events or transgenic plants often claim DNA (binding) sequences that make up the site where the heterologous DNA has been inserted into the plant genome.[32] Generally, the insertion of the DNA construct in the plant genome occurs randomly, generating novel DNA sequences at the junctures between the heterologous DNA and the genome of the plant. Although binding sequences may be considered in some cases as novel, they lack industrial application. The transgenic events are characterised by a DNA construct, which allows the expression of an RNA or protein molecule in the transformed cell, which in turn causes an effect in the transgenic plant. The binding sequences between the DNA construct and the plant genome are a result of the process of insertion of the event, are of secondary importance and generally do not possess a biological function in the effect generated by the event on the transgenic plant (e.g., herbicide resistance). Moreover, if a plant were transformed only with the binding sequences, without including the entire functional DNA construct, the effect generated by the transgene would not be observed in the new transgenic plant. Accordingly, these binding sequences between the heterologous DNA and the flanking genomic sequences will have no industrial applicability.[33]

Insufficiency of disclosure, or claims not being clear and concise enough, are often reasons for the rejection of individual claims or a full patent application in biotechnology. In several of the decisions by INDECOPI (Peru) mentioned above, objections based on lack of clarity of claims have been raised. For instance, some claims do not refer to a particular genetic sequence, but to a type of sequence or functional element such as "a DNA molecule encoding a transit peptide to chloroplasts," "a DNA molecule terminator of transcription" or "a DNA molecule encoding a glyphosate-tolerant EPSPS."[34] If a protein or DNA sequence is defined on the basis of a "class, type or function," it is possible that new elements or variants of it will fall within the scope of the claims made, even if these are not yet known or included in the description of the invention. The patent may thus cover technical developments the patentee has not conceived, and block further research and development. The biological elements claimed in this way may then be challenged for lack of clear and concise description.

A very common problem in patent applications related to biotechnological inventions is the definition of genetic elements on the basis of a percentage of identity or sequence similarity.[35] Generally, the identity or similarity between two biological sequences allows for the inference of a certain level of homology between them, and in practice is used to find new elements that may have the same biological function. However, it cannot be guaranteed that the two sequences will have the same biological function. For example, the change of a single amino acid can cause the loss of the biological function of a protein (although at the same time that protein maintains a high degree of similarity with another enzyme of known biological function).

The sample examined for the study reported in this article shows several examples of patents granted on the basis of the identity or similarity of biological sequences. For instance, patent CN 102037125 B on "Use of rice polypeptides/nucleic acids for plant improvement" claims:

> *… a method of producing a transgenic plant, comprising transforming a host plant with a recombinant DNA construct containing a promoter sequence operably linked to a polynucleotide encoding a polypeptide having an amino acid sequence at least 80% identical to the sequence of SEQ ID NO:103, the promoter sequence being functional in a cell of the host plant.*

The Brazilian and Argentine guidelines for the examination of biotechnological patents mentioned above specifically address the issue of claims covering sequences characterised as having a similarity with other sequences. They consider such claims as not acceptable due to insufficient disclosure, and require a precise definition of all claimed sequences and information showing that they have the same disclosed function (Resolución INPI (Argentina) P283, 25-9-2015INPI, para 1); Resolution INPI (Brazil) No. 44, 2015, para 6.2). In *Consejo Superior de Investigaciones Científicas v. INPI* (2003) the court of appeal considered that the invention, as claimed, was not reproducible and that the applicant had not satisfied the disclosure requirement despite the observation made by the patent office during the examination process. In the case mentioned above regarding Monsanto's INTACTA technology, an additional argument for the invalidity of the patent was the insufficient disclosure of the invention (SOJA, 2018).

Functional claims, that is, claims that disclose what an invention *does* rather than what an invention (structurally) *is*, are another problem often found in plant-related patents. Examples include Monsanto's patent CN 101321873 B (2013) which claims, inter alia, "a transgenic corn seed comprising more than 4000 ppm lysine" (claim 38); and Monsanto's patent 279135 granted in India in 2017 covering a method "of producing a soybean plant comprising a linolenic acid content of less than about 6% of total seed fatty acids by weight and an oleic acid content of about 55% to about 80% of total seed fatty acids by weight" (claim 1). When functional claims are accepted, *any* plants that perform as described will be covered, granting the patent owner broad control over varieties that are unknown to them or are later developed by third parties.

4 | CONCLUSIONS

At least 51 countries exclude the patentability of plants, thereby fully using one of the important flexibilities permitted by the TRIPS Agreement in Article 27.3(b). A larger number of countries in the Global South, however, do not specifically exclude the patentability of plants. Most have followed the European approach and exclude plant varieties and essentially biological processes for obtaining them, rather than plants as such.

In these countries, patents on parts and components of plants may be used to control the production and commercialisation of plant varieties under conditions that are more stringent than those generally applicable under PVP regimes. In particular, patents that cover methods of genetic modification and/or the products obtained through them, such as modified cells and seeds, indirectly subject plants to the control of the patent owner even if they do not specifically claim plants. In some cases, food and feed obtained with the use of patented materials may also fall under the control of the patent owner. Functional claims (that is, claims based on what an invention does and not on what it structurally is) may extend the protection conferred beyond what was actually developed by the patent owner.

Even in some developing countries which limit obtaining patents on plants, patents have been granted covering gene constructs, promoters, peptides and so forth, used to modify plants genetically. In other instances, however, patent offices or the courts have rejected or invalidated patents on the argument that protecting a plant cell would be equivalent to obtaining protection on the whole plant. This would indicate that when patents on plants are not permissible, parts and components of plants may be equally excluded from patentability.

A number of countries in the Global South have committed to the patentability of plants through FTAs signed with the United States. The extent to which such commitments, if complied with, will affect the patentability of plants depends on the manner in which patent offices and courts interpreted and applied the provisions and exclusions on patentability at the time the FTA entered into force. If, for instance, modified plant parts and components (such as cells) were deemed patentable, as was the case in many countries, the implementation of the FTA's obligations would strengthen the level of protection but, in practical terms, only marginally change the pre-existing situation with regard to genetically engineered plants.

Essentially biological processes to obtain plants are excluded from patentability in most countries in the Global South, in line with the European approach and pursuant to the exception allowed under 27.3(b) of the TRIPS

Agreement. While clear definitions of that concept do not seem to exist in the selected countries, in some cases a very elastic interpretation has allowed for the grant of patents on methods that are ordinarily used in conventional breeding, such as hybridisation.

Only a few of the selected countries have adopted guidelines for the examination of biotechnological inventions, including plants. These guidelines address some important issues relating to patentability, in particular, the admissibility of claims based on the similarity of sequences, as it is not sufficient to prove that all claimed sequences have the same disclosed function. Noncompliance with the sufficiency of disclosure requirement has been one argument often articulated by patent offices or courts to deny the patentability of materials for the genetic modification of plants.

The situation in the selected countries can be summarised as follows:

Argentina does not allow patents on plants and plant varieties as such, nor on essentially biological processes to produce plants. Patents on genetic constructs and their components have been granted, however. The patentability guidelines in force and some jurisprudence point to a rather rigorous application of the patentability requirements regarding inventive step and sufficiency of disclosure, and to the exclusion of patents over plant varieties.

Brazil has adopted legislation with some unique provisions limiting the patentability of biological materials. The cumulative protection of plant varieties by patents and breeders' rights is excluded. Despite this, several patents have been granted in relation to methods for the genetic transformation of plants that, in practice, may allow the right owners to control the commercialisation of plant varieties and derived products. The judiciary has found that such patents do not violate the prohibition regarding the cumulative protection of plant varieties.

China is one of many developing countries that exclude patents only on plant varieties, not on plants. However, patents may protect not only genetic constructs to modify plants, but also the modified cells and plants, and the products obtained from them, such as food and feed. Despite the exclusion of plant varieties, in practice this broad coverage gives the patent owner legal tools to control the production and commercialisation of plant varieties that incorporate patented components.

India has incorporated a broad exclusion from patentability in its law, which bans the protection of plants, seeds, plant varieties and essentially biological processes for their production. Patent office guidelines point toward rigorous implementation, but a number of patents have been identified that would suggest some flexibility in the way these requirements are applied. The High Court decision in *Monsanto Technology LLC and Ors vs. Nuziveedu Seeds Ltd. and Ors* (2018) clarified some aspects of the legislation, notably the nonpatentability of essential biological processes and the products exclusively obtained with them, and that a claim over a nucleic sequence which is introgressed and hybridised into a transgenic plant falls under the exclusions of Section 3(j) of the Patents Act. This decision has, however, been recently overturned by the Supreme Court.

South Africa is a very peculiar case as patents are registered without substantive examination. The patent law follows the European approach, thereby allowing in principle for patents on plants and their parts and components. South Africa is one of the few African countries where planting of GMOs is admitted. No case law seems to exist on the scope or conditions of patentability in this field.

Peru is bound to apply the industrial property regime of the Andean Community, which prescribes exclusions from patentability regarding biological materials including the “entirety or part of living beings.” Several decisions by the Peruvian patent office suggest a rigorous enforcement of these limitations.

Uganda follows the European approach, in which only plant varieties and essentially biological processes for their production are not patentable. Patents have been granted with broad coverage, including cells, seeds and the products obtained with planted material. Although Uganda has only recently adopted the Genetic Engineering Regulatory Bill 2018 to allow the introduction of GMOs in the country, several patents covering genetic constructs have been identified.

Vietnam has also aligned itself with the European approach. The sampled patents show several cases of patents covering DNA, modified cells and plants, methods to detect genetic events, and even a “cropping system for managing weed growth” (Monsanto's patent 1-0014994-000). Although the available sample is

insufficient to make an assessment, the patent office seems to apply flexible standards regarding patentability in this field.

In summary, analysis shows considerable diversity in legal status regarding the patentability of plants in the countries of the Global South in general, and in the selected countries in particular. While 40% of the developing countries and emerging economies for which information is available have used the flexibility accorded by the TRIPS Agreement not to patent plants, most have admitted plant patents by deliberate choice (notably those following the European approach which excludes only plant varieties) or by allowing the patentability of plant parts and components, such as nucleic sequences, that indirectly but effectively confer on patent owners exclusive rights to control the production and commercialisation of plant varieties that incorporate such parts, and eventually the products obtained from them, such as food and feed.

This legal situation, together with the substantial number of patents that have been identified in the selected countries, warrants further research and debate on its implications for access to and use of seeds and breeding materials for both farmers and breeders in the Global South. Public debate on plant patents is, for example, a constant practice in Europe, where the patent laws of some countries now include more and broader exemptions for farmers and breeders than in the majority of developing countries. These countries should be encouraged to review their legislation and learn from the examples of others that, consistent with the TRIPS Agreement, have narrowed down the scope of patentability or of the exclusive rights conferred in this field. To feed a growing world population and optimally adapt to the challenges of climate change, developing countries may opt for a patent system that facilitates rather than restricts access to the building blocks of life.

ACKNOWLEDGEMENTS

We would like to thank the following experts for their valuable inputs and contributions to previous versions of this article: Aurora Ortega (Peru), Pedro Barbosa (Brazil), Zhenyan Zhu (China), K. M. Gopkumar (India), Gilbert Agaba (Uganda), Franco Puccio (Argentina), Do Thi Hanh (Vietnam), Viola Prifti (Italy) and Christoph Then (Germany), the anonymous reviewers, plus all participants of the *Global Trends in Patenting of Seeds Workshop*, which took place in The Hague in October 2018. All errors remain the responsibility of the authors. Funding for this study was provided by the Dutch government through the Strategic Partnership programme. The research was coordinated by Oxfam Novib and is part of Oxfam's Sowing Diversity = Harvesting Security programme (https://www.sdhsprogram.org/).

ENDNOTES

[1] See, for example, patentability guidelines that include examples of claims: EPO (2018): Guidelines for Examination in the European Patent Office November 2018 (München: Europäisches Patentamt) and Instituto Nacional da Propriedade Industrial (INPI): "Diretrizes de exame, diretrizes de exame de pedidos de patente na área de biotecnología," Resolution 144/2015, Guidelines for patent examination INPI. Resolutions 243/2003 y 263/2003 Joint resolution MI N° 118/MS N° 546/INPI N° 107 2012, Resolution INPI N° P-318/2012 Disposition ANP N° 73/2013 and Resolution INPI; RGNIIPM Guidelines for Examination of Biotechnology Applications for Patent, available at: http://www.ipindia.nic.in/guidelines-patents.htm.

[2] The academic literature on U.S. developments has extensively examined what was patentable subject matter under U.S. law and many questions about the reach of biotechnology patents that the courts needed to settle (Janis, 2001).

[3] While the European Commission has taken the view that the EU legislators' intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) obtained by means of essentially biological processes, it is unclear whether the same approach is being or may be taken in developing countries. See Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52016XC1108(01)&from=EN.

[4] PVP regulations usually include, with different scope, what is known as the "farmers' privilege" (i.e., to save and reuse seeds) but this kind of exception is usually not included in patent laws. An exception is the EU Biotech Directive Article

11 which allows farmers to use their harvest for propagation or multiplication to the extent and conditions provided for under Article 14 of Regulation (EC) No 2100/94.

[5] Samples were obtained from public databases from Argentina, Brazil, China, India and South Africa. Online information was not obtainable from Peru, Uganda and Vietnam. See Annexes 3 and 4 in Oxfam Novib (2018), available at: https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth/.

[6] A questionnaire was circulated among experts in the selected countries to clarify some technical issues relating to patentability and the scope of the protection conferred. It was responded to by the following experts: Aurora Ortega (Peru), Pedro Barbosa (Brazil), Zhenyan Zhu (China), K. M. Gopkumar (India), Gilbert Agaba (Uganda), Franco Puccio (Argentina) and Do Thi Hanh (Vietnam).

[7] The Convention currently has 177 contracting parties (World Intellectual Property Organization, n.d.).

[8] See also Article 16.9(2) of the U.S. FTA with Peru.

[9] The table and figure are based on whether in the text of the statute a reference of the exclusion and its scope is made.

[10] The full inventory of the provisions specifically dealing with the patentability of plants contained in patent laws of countries in the Global South can be found in Annex 2 in Oxfam Novib (2018), available at: https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth/.

[11] Information on granted patents (based on the International Patent Classification) is not always readily accessible in developing countries. The study described in this paper is based on patent grants reported in publicly available online databases that can be searched through IPC classes and for which at least the first claim was published. Although it is not possible to make, within the remit of this study, a full analysis of the extent to which the application of the patentability standards may limit the protection of plants and plant materials, some judicial decisions illustrate the way in which such standards have been applied to prevent the patenting of plants or plants materials in particular cases.

[12] "The term "native traits" refers to traits already existing in germplasm, including wild relatives of crop species, or that can be produced by recombination of existing traits" (Wiel, Lotz, Bakker, & Smulders, 2016; see also Matthews & Zech, 2017).

[13] The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) stipulates that "biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature" (Article 3.2).

[14] For instance, PCT application WO 2006/031780 A2 Claim 1: A promoter comprising a polynucleotide sequence selected from:

(a) A polynucleotide sequence comprising the nucleic acid sequence of SEQ ID NO: 4.
(b) A polynucleotide sequence comprising a fragment of at least 750 contiguous nucleotides of the nucleotide sequence of (a) capable of directing the transcription of an operably transcribable polynucleotide molecule ligated into developing seeds 3–40 days after pollination.
(c) A polynucleotide sequence comprising at least 95% sequence identity with the nucleotide sequence of (a) capable of directing the transcription of an operably transcribable polynucleotide molecule bound in developing seeds 3–40 days after pollination.

In this example, the promoter of the Arabidopsisthal diacylglycerolacyl transferase 2 gene (P-Dgat2) is claimed, which is described in the sequence SEQ ID NO: 4. This promoter, like any fragment of its nucleotide sequence, is a genetic material pre-existing in nature, and therefore may be excluded from being patented.

[15] Some examples include: "Gene for improving salt tolerance and drought tolerance of plant," 787/MUMNP/2010; "An isolated polypeptide comprising MCP1 fusions," 743/CHENP/2008; "An isolated promoter capable of driving and/or regulating expression in plants," 564/DELNP/2008 and "An isolated and purified peptide," 9996/DELNP/2007.

[16] A possible modification of the genetic material is the so-called cDNA, an artificially created molecule that contains all the genetic information of a gene, but not the same sequence. The genes of eukaryotic organisms (fungi, plants and animals) are composed of regions called exons that encode genetic information, and other regions called introns that are discarded in the process of protein synthesis. Through molecular biology techniques, cDNA which contains only the exons of a gene can be obtained. In the Myriad Genetics case mentioned above, the U.S. Supreme Court held that while isolated DNA is not patentable, cDNA is not excluded from patentability, but this solution has been questioned as cDNA is essentially the same DNA; see, for example, Liptak (2013).

[17] For instance, patent AP3098 (2005) granted to Monsanto Technology Ltd. in Uganda covers chloroplast transit peptides for efficient targeting of dicamba monooxygenase and uses thereof.

[18] For instance, claim 1 of the PCT application WO 2005/077117 A2 reads: "Seeds for producing transgenic maize with an improved amino acid content, having integrated in its genome a recombinant DNA construct that transcribes an RNA oriented in the opposite direction of the reading frame that suppresses the production of a protein in a catabolic pathway of amino acids, wherein the recombinant DNA comprises a seed-specific promoter operably linked to a DNA that is transcribed into said RNA, and wherein said seeds have a high amino acid content as compared with the seeds of the progeny of control corn plants, where the production of said protein has not been suppressed." This example deals with genetically modified corn plants with a recombinant DNA construct that suppresses the expression of the enzyme lysine-ketoglutarate reductase, which consequently allows a greater accumulation of the amino acid lysine in the transgenic maize plant.

[19] Article 2(1) of UPOV 1978: "Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species."

[20] An example of a patent application (filed in Argentina) covering such a process is AR063688 A1. Claim 1 reads: "A method of plant breeding consisting in: delineating at least one haplotype window comprising at least two haplotypes within the genome of a plant; associating each of said at least two haplotypes with at least one numerical value related to one or more phenotypic traits; and make a decision about plant breeding based on at least one numerical value." In this case, a classic plant breeding method is claimed, which consists of the selection of parental plants with two or more haplotypes each associated with a phenotypic character of interest, to then cross the parental plants and achieve a progeny with a desired phenotypic improvement.

[21] For instance, in Decision G2/07 concerning the "Method for the selective increase of anti-carcinogenic glycosinolates in Brassica species" (application 99915886.8), the Board of Appeals of the European Patent Office stated that:"1. A non-microbiological process for the production of plants that contains or consists of the steps of sexually crossing all the genomes of plants and then the selection of such plants is, in principle, excluded from patentability as being 'essentially biological'2. This type of process does not escape the exclusion that Article 53 (b) EPC makes by the fact of containing, as a step or as part of any of the crossing and selection steps, a step of a technical nature that serves to allow or help the realisation of the stages of sexual crossing of all the genome of the plants or later wing selection of plants."

[22] Claims 23 and 24 of the patent on "Hybrid Corn Plant And Seed" read: "23. Method for producing a PP59302-derived maize plant, comprising: a) crossing a hybrid maize PP59302 plant with a second maize plant and harvesting the resultant maize seed, wherein representative seed of PP59302 has been deposited under ATCC Accession Number PTA-7428; and, b) growing said resultant maize seed to produce a PP59302-derived maize plant. 24. A method for developing a maize plant in a plant breeding programme using plant breeding techniques comprising employing a maize plant, or its part, as a source of plant breeding material comprising using the maize plant, or its part, of claim 2 as a source of breeding material."

[23] Patent 284578 (granted in 2017) covering a "method of introgressing at least one brilliant white curd allele into a cauliflower plant" (claim 1); patent 291357 (2018) protecting a "method of introgressing an allele into a soybean plant."

[24] In accordance to the EPO Guidelines for Examination, a "use" claim in a form such as "the use of substance X as an insecticide" is regarded as equivalent to a "process" claim of the form "a process of killing insects using substance X," see para 4.16, available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_4_16.htm.

[25] The European Commission has taken the view that EU legislators' intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) obtained by means of essentially biological processes, thereby dismissing the possibility of extending the protection conferred on processes to the products themselves (see European Commission, 2016).

[26] In the case of South Africa patents are registered without substantive examination. For this reason, analysis of the patents registered there does not permit an assessment of the impact of the patentability standards regarding the protection of plants. No case law relating to the matter has been identified.

[27] Patent grant number 28483. Application 3752/DELNP/2009, PCT PCT/SE2007/050939. From abstract: "The present invention pertains to a novel and extensive analytical platform for selecting genes with a possible commercial phenotype from a large group of candidate genes identified using tools in bioinformatics, data from EST sequencing and DNA array. The analytical platform is concentrated on analyses of growth behaviour based on a combination of multiple criteria. The invention provides a method for producing a transgenic plant by changing the expression of one or more genes selected from a group of genes which fulfil said criteria."

[28] This technique is often referred to as "molecular scissors" as it allows DNA to be easily cut and pasted to alter genomes. It is increasingly seen as a complement to traditional plant breeding strategies (see, e.g., Webb, 2018).

[29] For instance the PCT application WO 2004/070020 A2 included the following claim 11: "A method for detecting the presence of a DNA corresponding to DNA of the alfalfa plant J-101 in a sample, characterised in that it comprises: a) placing the sample comprising DNA in contact with a set of primers which, when it is used in a nucleic acid amplification reaction with genomic DNA from the alfalfa event J-101, produces a DNA amplicon comprising SEQ ID No. 1 or SEQ ID No. 2 *; and b) performing a nucleic acid amplification reaction, thereby producing the amplicon; and c) detect the amplicon."

[30] This patent covers "a method for identifying transgenic corn plants, comprising:(a) obtaining corn plant cells transformed with a DNA segment comprising a nucleic acid sequence of interest;(b) regenerating a plurality of corn plants or differentiated corn plant parts from the cells without first selecting for the presence of said DNA segment;(c) identifying at least a first transgenic corn plant or transgenic differentiated plant part from the plurality of corn plants or differentiated corn plant parts."

[31] See also Brazilian patent PI 0418683-4 (Dow Agrosciences LLC (US), 2016), which covers a method of detecting insect-resistant genetically modified cotton.

[32] For example, claim 1 of the PCT application WO 2013/012775 A1 reads: "A nucleic acid molecule, preferably isolated, comprising a nucleotide sequence that is unique to the MZDT09Y event, wherein the sequence is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEC ID NO: 4 *, and its complements." The sequences SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 described in the invention correspond to the binding sequences between the insert and the genome of the plant.

[33] However, another point of view is that DNA sequences that bind to a genetic sequence introduced into a plant cell may be used to check if gene insertion has occurred, whether the introduced sequence is retained by the progeny, and whether it is present in the cells of plants produced by a suspected infringer.

[34] For example, claim 1 of BR 0100752A reads: "A DNA construct characterised in that it comprises: a first and a second expression cassette, wherein said first expression cassette, operatively linked, comprises: (i) a rice actin 1 promoter; (ii) an intron of rice actin 1; (iii) a DNA molecule encoding a transit peptide to chloroplasts; (iv) a DNA molecule encoding a glyphosate-tolerant EPSPS; and (v) a DNA molecule terminator of transcription; and said second expression cassette, operatively linked, comprises: (a) a 35S CaMV promoter; (b) an Hsp70 intron; (c) a DNA molecule encoding a chloroplast transit peptide; (d) a DNA molecule encoding a glyphosate-tolerant EPSPS; and (e) a DNA molecule terminator of transcription." Claim 2: "The DNA construct of claim 1, wherein the DNA molecule encoding a glyphosate-tolerant EPSPS consists of the sequence AGRTU.aroA: CP4."

[35] For example, claim 1 of WO 2006/006956 A2 reads: "An isolated polynucleotide characterised in that it comprises: (a) a nucleotide sequence encoding a polypeptide necessary for proper root formation, wherein the polypeptide has an amino acid sequence with at least 70% sequence identity, on the base of the Clustal V alignment method, when compared to a SEQ ID No. 6, 8, 30 or 38; or (b) a complement to the nucleotide sequence, where the complement and the nucleotide sequence consist of the same number of nucleotides and are 100% complementary." In this example, the sequence of the DNA molecule is not specified, nor is the polypeptide sequence. Furthermore, it is stated that the polynucleotide encodes a polypeptide that "has an amino acid sequence with at least 70% sequence identity," which implies that any DNA sequence that codes for any polypeptide with at least 70% identity with the sequences SEQ ID No. 6, 8, 30 or 38, would be achieved by this claim. This includes numerous DNA sequences that have no support in the description of the invention. On the other hand, sequence identity does not necessarily imply that the polypeptides possess the same biological function. Therefore, the polynucleotide thus claimed can include DNA sequences encoding polypeptides that are not involved in root formation or that are not functional, which can lead to the lack of reproducibility of the invention.

ORCID

Bram De Jonge http://orcid.org/0000-0003-0456-9491

REFERENCES

Adams, R. P., & Adams, J. E. (Eds.). (1992). *Conservation of plant genes: DNA banking and in vitro biotechnology*. San Diego, CA: Academic Press.

Agris, C. H. (1999). Patenting plants: What to claim? *Nature Biotechnology*, *17*(7), 717–718.

Association for Molecular Pathology v. Myriad Genetics. (2013). 569 US 12-398.

Bagley, M. A. (2016). *Digital DNA: The Nagoya protocol, intellectual property treaties, and synthetic biology* (Virginia Public Law and Legal Theory Research Paper No. 11). Emory Legal Studies Research Paper. Available from SSRN https://ssrn.com/abstract=2725986 or https://doi.org/10.2139/ssrn.2725986

Balachandra, N. R., & Ramachandranna, P. J. (2010). Patenting of microorganisms: Systems and concerns. *Commer Biotechnol*, *16*, 337–347. https://doi.org/10.1057/jcb.2010.20

Barton, J. H. (1991). Patenting life. *Scientific American*, *264*(3), 40–46.

Bayer CropScience S/A v. Instituto Nacional da Propriedade Industrial. (2010). Recurso Especial No. 1.201.981-RJ 2010/0120977-6.

Bhatti, S. (2013). *Report of the secretary of the international treaty on plant genetic resources for food and agriculture* (Fifth session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture, IT/GB-5/13/4). Paragraph 7. Muscat: Food and Agricultural Organization of the United Nations.

Binenbaum, E., Nottenburg, C., Pardey, P. G., Wright, B. D., & Zambrano, P. (2003). South–North trade, intellectual property jurisdictions, and freedom to operate in agricultural research on staple crops. *Economic Development and Cultural Change*, *51*(2), 309–335. https://doi.org/10.1086/346177

Blakeney, M. (2012). Patenting of plant varieties and plant breeding methods. *Journal of Experimental Botany*, *63*(3), 1069–1074. https://doi.org/10.1093/jxb/err368

Bostyn, S. J. R. (2004). *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: An evaluation*. Luxembourg: Office for Official Publications of the European Communities.

Bostyn, S. J. R. (2013). Patentability of plants: At the crossroads between monopolizing nature and protecting technological innovation? *Journal of World Intellectual Property*, *16*(3–4), 105–149. https://doi.org/10.1002/jwip.12012

Braunschweig, T., Meienburg, F., Pionetti, C., & Shashikant, S. (2014). *Owning seeds, accessing food: A human rights impact assessment of UPOV 1991 based on case studies in Kenya, Peru and the Philippines*. Zurich: The Berne Declaration. Retrieved from https://www.publiceye.ch/en/publications/detail/owning-seeds-accessing-food

Consejo Superior de Investigaciones Cientificas v. INPI. (2003). Cámara Federal Civil y Comercial, sala I, 15-05-2003.

Consejo Superior de Investigaciones Cientificas v. INPI. (2016). Cámara Federal Civil y Comercial, sala III, 16-3-2016.

Correa, C. M. (2014). *Patent protection for plants: Legal options for developing countries* (Research Paper 55). Geneva: South Centre.

De Avila, C. (2016a). Da expectativa de direitos da Monsanto no Brasil sobre os pedidos de patente da "tecnologia" Intacta RR2 PRO: onde está de fato a inovaçao? In D. Borges Barbosa & M. Wachowicz (Eds.), *Propiedade intelectual. Desenvovimiento na agricultura* (p. 231). Curitiba: GEDAI.

De Avila, C. (2016b). A antinomia jurídica da intercessao entre patentes e cultivares. In D. Borges Barbosa & M. Wachowicz (Eds.), *Propiedade intelectual. Desenvovimiento na agricultura* (p. 177). Curitiba: GEDAI.

De Jonge, B., & Munyi, P. (2016). A differentiated approach to plant variety protection in Africa. *Journal of World Intellectual Property*, *19*(1–2), 28–52.

Diamond v. Chakrabarty. (1980). 447 U.S. 303.

Ducor, P. (1998). *Patenting the recombinant products of biotechnology and other molecules*. London/The Hague/Boston, MA: Kluwer Law International.

Dunwell, J. M. (2005). Review: Intellectual property aspects of plant transformation. *Plant Biotechnology Journal*, *3*(4), 371–384. https://doi.org/10.1111/j.1467-7652.2005.00142.x

European Commission. (2016). Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03). *Official Journal of the European Union*. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1108(01)&from=SK

European Patent Office. (n.d., a). 4.16 Use claims. *Guidelines for Examination*, Part F. Retrieved from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_4_16.htm

European Patent Office. (n.d., b). 5. Problem-solution approach. *Guidelines for Examination*, Part G. Retrieved from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm

Ex parte Hibberd. (1985). 227 USPQ 443 (Bd. Pat. App. & Int).

Geist, M. (2017, November 11). Rethinking IP in the TPP: Canadian Government plays key role in suspending unbalanced patent and copyright rules [Web log post]. Retrieved from http://www.michaelgeist.ca/2017/11/rethinking-ip-in-the-tpp/

Gomes da Silva d'Ornellas, M. C., & Tonello, J. (2013). Intensificaçao de proteçao da propriedade intellectual na area da biotecnologia agricola e impactos no desenvolvimento da agricultura nacional. In *Direito, Inovaçao e desenvolvimento: tópicos de propriedade intellectual e concorrência*, Vol. 2, Reúne Artigos do XX Congresso Nacional do CONPEDI (Vitória). Belo Horizonte: Conpedi/Arraes Editores.

Halewood, M., Chiurugwi, T., Sackville Hamilton, R., Kurtz, B., Marden, E., Welch, E., … Powell, W. (2018). Plant genetic resources for food and agriculture: Opportunities and challenges emerging from the science and information technology revolution. *New Phytologist*, *217*(4), 1407–1419. https://doi.org/10.1111/nph.14993

Harfouche, A., Meilan, R., Grant, K., & Shier, V. K. (2012). Intellectual property rights of biotechnologically improved plants. In A. Altman & P. M. Hasegawa (Eds.), *Plant biotechnology and agriculture: Prospects for the 21st century*. San Diego, CA: Academic Press. https://doi.org/10.1016/B978-0-12-381466-1.00033-X

Houldsworth, A. (2018, March 9). Patents on CRISPR-related technology are going to become a lot harder to obtain, expert predicts. *IAM*. Retrieved from http://www.iam-media.com/Blog/Detail.aspx?g=0ac5038f-9fdd-472a-ab87-1c91f9149ff6

Instituto Nacional da Propriedade Industrial (INPI). (2015). Resolution no. 144/2015. Retrieved from http://www.inpi.gov.br/menu-servicos/patente/consultas-publicas/arquivos/resolucao_144-2015_-_diretrizes_biotecnologia.pdf/view

J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc. (2001). 534 U.S. 124.

Janis, M. D. (2014). Patenting plants. In R. L. Okediji & M. A. Bagley (Eds.), *Patent law in global perspective* (pp. 213–242). New York, NY: Oxford University Press. https://doi.org/10.1093/acprof:oso/9780199334278.003.0008

Janis, M. D. (2001). Sustainable agriculture, patent rights, and plant innovation. *Indiana Journal of Global Legal Studies*, *9*(1), 91–117. http://www.repository.law.indiana.edu/ijgls/vol9/iss1/6/

Jarvie, A. M. (2016). Productivity and diversity in research and agriculture: Improving the IPR landscape for food security. *William and Mary Environmental Law and Policy Review*, *40*(3), 849–892.

Jefferson, O., Köllhofer, D., Ehrich, T. H., & Jefferson, R. A. (2015). The ownership question of plant gene and genome intellectual properties. *Nature Biotechnology*, *33*(11), 1138–1143. https://doi.org/10.1038/nbt.3393

Li, W., & Cai, L. (2014). The scope of patent protection for gene technology in China. *Nature Biotechnology*, *32*, 1001–1003. https://www.nature.com/articles/nbt.3031

Liptak, A. (2013). Justices, 9–0, bar patenting human genes. *The New York Times*. Retrieved from http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html

Llewelyn, M. (2000). The patentability of biological material: Continuing contradiction and confusion. *European Intellectual Property Review*, *22*(5), 191–197.

Louwars, N., Louwaars, N. P., Dons, H., van Overwalle, G., Raven, H., Arundel, A., … Nelis, A. (2009). *Breeding business: The future of plant breeding in the light of developments in patent rights and plant breeders' rights*. Wageningen: Centre for Genetic Resources. Retrieved from. http://library.wur.nl/WebQuery/wurpubs/393066

Mano, A. (2017, November 9). Produtores de MT pedem na Justiça nulidade da patente da soja Intacta da Monsanto. *Reuters*, Brazil. Retrived from https://br.reuters.com/article/topNews/idBRKBN1D91AJ-OBRTP

Matthews, D., & Zech, H. (2017). *Research handbook on intellectual property and the life sciences*. Cheltenham, UK: Edward Elgar Publishing.

McNally, R., & Wheale, P. (1996). Biopatenting and biodiversity: Comparative advantages in the new global order. *The Ecologist*, *26*(5), 222–228.

Michaelis, K. (2012, December). Peru bans monsanto and GMOs. *Food Renegade*. Retrieved from https://www.foodrenegade.com/peru-bans-monsanto-gmos/

Monsanto Canada Inc. v. Schmeiser. (2004). 1 S.C.R. 902, 2004 SCC 34. Retrieved from https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2147/index.do

Monsanto Technology LLC and Ors v. Nuziveedu Seeds Ltd and Ors. (2018). FAO (OS) (COMM) 76/2017, CAV. 328/2017, C.M. APPL.13348-13352/2017. Retrieved from https://indiankanoon.org/doc/96804771/

Monsanto Technology LLC v. Instituto Nacional de la Propiedad Industrial s/denegatoria de patente. (2015). Causa n° 8.044/07/CA1, 26-11-2015.

Mycogen Corporation e Outros v. INPI-Instituto Nacional de Propriedade Industrial. (2016). CNJ: 0001996-10.2013.4.02.5101, 2013.51.01.001996-4, 25-08-2016.

Nuziveedu Seeds Ltd and Ors v. Monsanto Technology LLC and Ors. (2018). FAO (OS) 86/2017 and FAO (OS) (COMM) 76/2017.

Office of the Controller General of Patents, Designs and Trade Marks. (2013). *Guidelines for examination of biotechnology applications for patent*. Retrieved from http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf

Oldham, P., Hall, S., & Forero, O. (2013). Biological Diversity in the Patent System. *PLOS One*, *8*(11):e78737. https://doi.org/10.1371/journal.pone.0078737

Oxfam Novib. (2018). *The status of patenting plants in the Global South. Position statement and research report*. The Hague: Author. https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth/

Parvin, M. (2009). Patentability of plants: Technical and legal aspects. *Journal of Intellectual Property Rights*, *14*, 203–213.

Price, S. C. (1992). The economic impact of novel genes in plant biotechnology: Not without strong intellectual property rights. In R. P. Adams & J. E. Adams (Eds.), *Conservation of plant genes: DNA banking and in vitro biotechnology*. San Diego, CA: Academic Press.

Prifti, V. (2016). An answer to the plant variety controversy in Chile. *Journal of World Intellectual Property*, *19*(5–6), 178–202.

Prifti, V. (2017). The breeder's exception to patent rights as a new type of research exception. *Rights and Science*, *2017*, 109–116. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3134547

Ravi, B. (2013). Gene patents in India: gauging policy by an analysis of the grants made by the Indian Patent Office. *Journal of Intellectual Property Rights*, *18*, 323–329.

Roffe, P. (2004). *Bilateral agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement* (TRIPS Issues Papers, 4). Ottawa: Quaker International Affairs Programme. Retrived from http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_other_Topics/Chile-USAFTAP.Roffe.pdf

Santaniello, V., Evenson, R., Zilberman, D. & Carlson, G. (Eds.). (2000). *Agriculture and intellectual property rights: Economic, institutional, and implementation issues in biotechnology*. Wallingford: CABI.

Shiva, V. (2019, January 9). The Supreme Court ruling upheld India's law, not Monsanto's false claims on patents on seeds. Seed Freedom. Retrieved from https://seedfreedom.info/monsantos-false-claims-on-patents-on-seeds/

Sindicato Rural de Passo Fundo RS e outros v. Monsanto do Brasil e Monsanto Technology LLC., 04-04-2012, Comarca de Porto Alegre 15ª Vara CIVEL 1° Juizado.

Singh, K. (2016). Intellectual property rights in agricultural biotechnology and access to technology: A critical appraisal. *Asian Biotechnology and Development Review*, *18*(3), 3–23.

SOJA. (2018, January 23). *INPI quer nulidade da patente da Intacta, diz Aprosoja*. Retrieved from https://revistagloborural.globo.com/Noticias/Agricultura/Soja/noticia/2018/01/inpi-quer-nulidade-de-patente-da-intacta-diz-aprosoja.html

Sowing Diversity=Harvesting Security. (n.d.). *Resources*. Retrieved from https://www.sdhsprogram.org/resources/

Then, C., Tippe, R., & Dolan, K. (2018). *No patents on broccoli, barley and beer! European patent law must be changed to safeguard the wider public interest*. Munich: No Patents on Seeds! Retrieved from https://www.no-patents-on-seeds.org/sites/default/files/2018-10/Report_No_Patents_on_Seeds_2018.pdf

Thomas, S. (2004). Plant patents and agriculture. *Science*, *305*(5680), 40b. https://doi.org/10.1126/science.305.5680.40b

Tottie, V., Skoglösa, V., & Hoffmann, B. (2018). Revocation of a European patent relating to CRISP [sic] technology. *Valea Technology and Law*. 29 January. http://www.valea.eu/en/news/2018/revocation-european-patent-relating-crisp-technology

Tribunal de Justicia de la Comunidad Andina. (2001). Proceso 89-AI-2000, *Gaceta Oficial*, 722. Retrieved from http://intranet.comunidadandina.org/documentos/Gacetas/gace722.pdf

Trivedi, U., & Beniwal, V. (2019, January 8). Bayer gets rare Monsanto reprieve with cotton seed ruling. *Bloomberg*. Retrived from https://www.bloomberg.com/news/articles/2019-01-08/india-court-rules-monsanto-s-patent-claim-on-cotton-seeds-valid

United States Congress, Office of Technology Assessment. (1989). *New developments in biotechnology: Patenting life* (Special report, OTA-BA-370). Washington, DC: U.S. Government Printing Office. Retrieved from https://www.princeton.edu/~ota/disk1/1989/8924/8924.PDF

Wageningen University & Research. (2014, August 7). How plants grow and develop. Retrieved from https://www.wur.nl/en/newsarticle/How-plants-grow-and-develop.htm

Webb, S. (2018). Plants in the CRISPR. *Future Science: BioTechniques*, *63*(3), 96–101. https://www.future-science.com/doi/10.2144/000114583

van de Wiel, C. C. M., Lotz, L. A. P., de Bakker, H. C. M., & Smulders, M. J. M. (2016). *Intellectual property rights and native traits in plant breeding: a quick scan of patents involving products of conventional plant breeding*. Wageningen: Wageningen UR Plant Breeding. https://doi.org/10.18174/382232

Wijk, J. (1996, November, 13). How does stronger protection of intellectual property rights affect seed supply? Early evidence of impact (Number 13). *Natural Resource Perspectives*. Retrieved from.http://www.odi.org.uk/nrp/index.html

World Intellectual Property Organization. (n.d.). *WIPO-administered treaties: Contracting parties*. Retrieved from https://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=2

World Trade Organization. (2017). TRIPS Agreement (as amended on January 23, 2017), Part II Section 5 Patents. Retrieved from https://www.wto.org/english/docs_e/legal_e/31bis_trips_04c_e.htm#5

AUTHOR BIOGRAPHIES

Carlos M. Correa is Executive director of the South Centre, has been professor in postgraduate courses of several universities and consultant to UNCTAD, UNIDO, UNDP, WHO, FAO, IDB, INTAL, World Bank, SELA, ECLA, and other regional and international organisations.

Juan I. Correa, LL.M in Intellectual Property WIPO-TURIN, is research fellow at the Center for Interdisciplinary Studies of Industrial and Economic Law at the Faculty of Law of the University of Buenos Aires (CEIDIE-UBA) and research fellow at the SmartIP Initiative for Latin-America for the Max Planck Institute for Innovation and Competition.

Bram De Jonge is Researcher at the Law Group of Wageningen University. Seed Policy Advisor at Oxfam, the Netherlands, as part of the Sowing Diversity = Harvesting Security (SD=HS) program (https://www.sdhsprogram.org/). Member of the CGIAR System Council IP Group.

How to cite this article: Correa CM, Correa JI, De Jonge B. The status of patenting plants in the Global South. *J World Intellect Prop.* 2020;23:121–146. https://doi.org/10.1111/jwip.12143