

THE STATUS OF PATENTING PLANTS IN THE GLOBAL SOUTH



OXFAM



POSITION STATEMENT
AND RESEARCH REPORT

THE STATUS OF PATENTING PLANTS IN THE GLOBAL SOUTH

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COVER PICTURE: Lino Mamani, papa arariwa (potato guardian), working on native Andean potato varieties in the seed multiplication centre in Potato Park, Peru. By Ilvy Njikiktjen/Oxfam Novib

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FOREWORD

Over the last few decades, the number of patents on plants and plant parts has greatly increased in various parts of the world. This has triggered social debate about possible negative consequences for the breeding sector, farmers and society. Despite the urgency of these questions, most research and literature has focused exclusively on developed countries – the USA and European Union, in particular – while little is known about the extent to which plants are being patented in other parts of the world. This research report 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.

In different countries, patents can be applied to plants; plant parts, such as cells or genetic sequences; processes, such as breeding methods; and products obtained with these methods, including plant varieties. Patents are granted if the invention is considered novel (i.e. new in comparison to everything previously available to the public), inventive (i.e. it should not be obvious to an average person skilled in the relevant field) and to have industrial applicability (i.e. it can be made or used in some kind of industry). Once granted, a patent provides the inventor with the exclusive right to reproduce, use, sell and distribute the patented invention within the territory where the patent is granted and for a specific period, which is usually 20 years. In this period, anyone wanting to use the patented invention must first get formal permission from the patent holder, which may be provided in exchange for a fee.

This research report 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets minimum standards with respect to intellectual property rights for all 164 member countries of the World Trade Organization (WTO). It allows countries to exclude from patentability ‘plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.’ However, it requires member countries to ‘provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof’ (Article 27.3b). Plant breeders’ rights are one example of a *sui generis* system which can be tailored to the specific needs of a country’s agricultural sector and which typically include the so-called breeders’ exemption: allowing anyone to use a protected variety for the purpose of breeding a new variety. Least developed countries (LDCs) have at least until 2021 to comply with the TRIPS agreement, or until the moment they cease to be a LDC.

Despite these flexibilities being available, the research described in this report shows that 60% of the 126 countries in the Global South for which data was available allow for the patenting of plants or parts thereof, and many such patents were identified. With this research report, Oxfam aims to contribute to awareness and understanding of the current status of patenting of plants in developing countries and emerging economies, to inform societal discussion and decision-making. The findings of this research – plus inputs from stakeholders during a workshop on global trends in patenting of seeds that took place in The Hague in October 2018 – informed the Oxfam Position Statement on the Patenting of Plants, presented in the coming pages.

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Oxfam Novib

OXFAM POSITION STATEMENT ON THE PATENTING OF PLANTS

To feed a growing world population and optimally adapt to the challenges of climate change, all farmers and breeders need unrestricted access to the building blocks of life. Oxfam is concerned that the growing number and scope of patents on plants, plant parts and DNA sequences will threaten food and nutrition security by blocking the free availability of these materials for further breeding and re-planting. Oxfam promotes the implementation of Farmers' Rights to save, use, exchange, and sell farm-saved seed in order to support indigenous peoples' and smallholder farmers' continuing contributions to feeding the world, and the considerate use of plant breeders' rights as an alternative to patents.

Food and nutrition security will remain a major global challenge in the coming decades. Crop diversity is vital for food and nutrition security, and countries and regions depend on each other as none has sufficient crop diversity on its own.¹ Food production systems require a wide range of plant varieties that are nutritious and resistant to pests and diseases – and also, given climate change, that are capable of adapting to shifting conditions of increased salinity, drought and flooding, and more irregular weather patterns. Oxfam helps to empower indigenous peoples and smallholder farmers to reclaim their role in contributing to food and nutrition security and to strengthen their adaptive food production capacities through improved access to and use of crop diversity. By creating a coalition of farmers, local communities, scientists, and national and global policymakers, Oxfam strives for more crop diversity to secure sustainable and gender-just food production systems that serve all.

Various laws and policies have an impact on the extent to which indigenous peoples and smallholder farmers are able to manage their agro-biodiversity and participate in decision-making processes that govern the food and seed systems in which they operate. These include

land rights, rules that govern seed production and trade, conservation policies and intellectual property laws. This Oxfam position statement relates to the application of patent law to plants and plant parts. Since the 1980s, countries have granted patents on newly developed plants or plant parts, such as cells or genetic sequences. Breeding methods and products obtained with these methods, including plant varieties, are patentable in some jurisdictions. Thousands of patents on plants have already been granted across the globe, in particular in North America, Europe and Japan, and the research described here shows that this trend is spreading to the Global South: 60% of developing countries and emerging economies now allow for the patenting of plants or parts thereof.

Since patent laws do not normally allow the use of a patented plant, plant part or DNA sequence for the development of a new variety without permission of the patent holder, Oxfam is concerned that the growing number of patents on plants across the world will decrease the gene pool from which farmers and breeders can source freely the seeds and breeding materials they want. This threat is amplified by the broad scope of many patents. A patented trait, for example, can provide monopoly rights over all

the varieties and crops that contain the trait, and may even cover food products derived from them.

This situation is unacceptable as the world faces both the challenge of feeding a growing population and weather patterns that have become increasingly extreme and unpredictable. The position of indigenous peoples and smallholder farmers in developing countries needs particular attention. They are among the first whose lives are affected by climate change and among the last to benefit from new technological developments.^{II} Patents steer research into fields where the most money can be made, leaving millions of poor farmers dependent on the few remaining investments in plant breeding and their own efforts. There is no evidence that patenting plants stimulates innovation in developing countries, despite assertions to the contrary.^{III}

As substantive legal expertise and financial resources are needed to navigate and exploit crop patent portfolios, patents contribute to further consolidation in the global breeding sector.^{IV} With the approval of mega-mergers between Dow and DuPont Pioneer, ChemChina and Syngenta, and Bayer and Monsanto, just three multinationals control 60% of the global seed market^V and 71% of the agrochemical market. This leaves the world with only a few seed and agrochemical corporations deciding what crops will be bred and cultivated for which environments and farming systems.

Patents do not allow for smallholders' traditional farming practices of using, exchanging and selling farm-saved seed of a protected variety. Multiple studies have shown that smallholder farmers in developing countries depend for their seed security on the exchange and local trade of farm-saved seed of all sources.^{VI} Indeed, this phenomenon motivated the enshrining of Farmers' Rights as a central component of

the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. In some countries, multinational seed companies that hold the major share of plant patents have sued commercial farmers for patent infringement.^{VII} From these court decisions, it appears not to matter whether or not a farmer deliberately plants and grows a patented variety on his or her land: any use, even unintentional, may constitute a patent infringement. This would make any farmer vulnerable to patent litigation if the wind brings pollen from a patented plant into his or her field.

There have also been several examples of patents that claim crop varieties, or their properties, which have been grown for many years or are based on the knowledge of traditional communities obtained without their prior informed consent or any form of recognition or benefit-sharing.^{VIII} Most patent laws do not even require information about the source of the patented plant material. Monsanto's (now Bayer's) patent on screening and selecting soybean plants adapted to various climate zones, for example, claims the identification of genetic variation for climate adaptation that can be found amongst 250 plants from around 20 species of wild and cultivated soybean species originating from the Asia-Pacific region.^{IX} Yet, it remains unclear when and from where Monsanto has accessed these species and whether any ABS obligations should have been complied with. The patent, which has been granted in Europe, the USA, Canada, Argentina, Brazil, South Africa and China, provides Bayer with the monopoly rights over the use of hundreds of gene sequences that reflect the natural genetic diversity of the plants that were examined and that are needed for the selection of plants for further breeding to adapt to conditions of climate change. Such patents can have major consequences for future breeding efforts to adapt crops to climate change.

Given these negative effects, Oxfam believes that no patents on plants or plant parts should be allowed, and all farmers and breeders should have unrestricted access to the building blocks of life. This is necessary also to meet the Sustainable Development Goals of zero hunger in 2030 (SDG 2), combating climate change (SDG 13) and halting biodiversity loss (SDG 15) while leaving no one behind.^x

The TRIPS Agreement provides countries with the flexibility to exclude from patentability ‘plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes’ (Article 27.3b). The main alternative requirement, from which least developed countries are excluded, is to provide ‘an effective sui generis system’ for the protection of plant varieties. Plant breeders’ rights are an example of such a sui generis system, which can be tailored to the needs of a country’s agricultural sector and which typically includes the so-called breeders’ exemption: allowing anyone to use a protected variety for the purpose of breeding a new variety.^{xi} Oxfam stresses the

need to include certain exemptions and provisions in legislation on plant breeders’ rights to recognize Farmers’ Rights as incorporated in Article 9 of the FAO International Treaty.^{xii}

If countries decide to allow patents on plants, Oxfam recommends the implementation of specific provisions that maintain the accessibility of plant genetic resources for further breeding and minimize the adverse effects of patent legislation on society in general and indigenous peoples and smallholder farmers in particular. One viable approach is the inclusion of a breeders’ exemption in the patent law.^{xiii} Other provisions can support recognition for Farmers’ Rights as set out in the FAO International Treaty, or be directed at limiting the scope of patents on plants and plant parts.^{xiv} As part of its efforts to promote an enabling policy and institutional environment for farmers’ seed systems and the implementation of Farmers’ Rights, Oxfam will continue to monitor patent trends in the Global South and assist stakeholders to raise awareness about the impacts, organize advocacy and take remedial actions where needed.

ⁱ C. Fowler and T. Hodgkin. (2004). Plant Genetic Resources for Food and Agriculture: Assessing Global Availability. Annual Review of Environment and Resources 29(1), 143-179. Retrieved from <https://www.annualreviews.org/doi/abs/10.1146/annurev.energy.29.062403.102203>

ⁱⁱ Oxfam, ANDES, CDT and SEARICE. (2017). The power to exercise choice: Implementing Farmers’ Rights to eradicate poverty and adapt to climate change. SD=HS Briefing Note no. 3. The Hague: Oxfam Novib. Retrieved from <https://www.sdhsprogram.org/publications/the-power-to-exercise-choice-implementing-farmersrights-to-eradicate-poverty-and-adapt-to-climate-change-briefing-note/>

ⁱⁱⁱ B.D. Wright and P.G. Pardey. (2006). The evolving rights to intellectual property protection in the agricultural biosciences. Int. J. Technology and Globalisation 2(1-2), 12-29. Retrieved from <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.532.5297&rep=rep1&type=pdf>

^{iv} O. Jefferson et al. (2015). The ownership question of plant gene and genome intellectual properties. Nature Biotechnology 33, 1138-43. Retrieved from <https://www.nature.com/articles/nbt.3393>. N. Louwaars et al. (2009). Breeding business: the future of plant breeding in the light of developments in patent rights and plant breeder’s rights. Wageningen: Centre for genetic resources (CGN). Retrieved from <http://library.wur.nl/WebQuery/wurpubs/393066>

^v IPES-Food. (2017). Too big to feed: Exploring the impacts of mega-mergers, concentration, concentration of power in the agri-food sector.

Retrieved from http://www.ipes-food.org/_img/upload/files/Concentration_FullReport.pdf

^{vi} A recent study, drawing conclusions from 9660 observations across six countries and covering 40 crops, shows that smallholder farmers access 91% of their seed from informal systems with the majority (51%) being bought from local markets. S.J. McGuire and L. Sperling. (2016). Seed systems smallholder farmers use. Food Security, 8(1), 179-195. Retrieved from <http://link.springer.com/article/10.1007/s12571-015-0528-8>

^{vii} See e.g. Federal Court of Canada, Monsanto Canada Inc. v. Schmeiser Date: 20010329 Docket: T-1593-98, retrieved from <http://decisions.fct-cf.gc.ca/en/2001/2001fct256/2001fct256.html>; Bowman v. Monsanto Co., 569 U.S. 278 (2013), retrieved from https://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf; Organic Seed Growers & Trade Ass’n v. Monsanto Co., No. 11-CV-2163, 851 F.Supp.2d 544 (S.D.N.Y.2012), retrieved from <http://www.nysd.uscourts.gov/cases/show.php?db=special&id=156>

^{viii} C. Then et al. (2018). No patents on broccoli, barley and beer! European patent law must be changed to safeguard the wider public interest. Retrieved from https://www.no-patents-on-seeds.org/sites/default/files/2018-10/Report_No_Patents_on_Seeds_2018.pdf; R. Andersen and T. Winge. (2012). The Access and Benefit-Sharing Agreement on Teff Genetic Resources: Facts and Lessons. Retrieved from http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Publications/FNI/FNI-R0612.pdf

^{ix} EP2134870 - Utility of snp markers associated

with major soybean plant maturity and growth habit genomic regions. Retrieved from <https://register.epo.org/espace/registrier?AP=08742297&CY=EP&LG=en&SDB=REG>

^x Transforming our world: the 2030 Agenda for Sustainable Development. Retrieved from <https://sustainabledevelopment.un.org/post2015/transformingourworld>

^{xi} C.M. Correa et al. (2015). Plant Variety Protection in Developing Countries: A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991. Retrieved from <http://www.apbrebes.org/news/new-publication-plant-variety-protection-developing-countries-tool-designing-sui-generis-plant>

^{xii} Oxfam. (2016). Reconciling Farmers’ and Plant Breeders’ Rights. Retrieved from <https://www.sdhsprogram.org/assets/wbb-publications/568/Oxfam%20Publicatie%20Reconciling%20Farmers%20&%20Plant%20Breeders%202016.pdf>

^{xiii} This has been done in some European countries and the proposed EU Unitary Patent System, see e.g. V. Pifti. (2017). The Breeder’s Exception to Patent Rights as a New Type of Research Exception. Rights & Science. Retrieved from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3134547

^{xiv} C.M. Correa. (2014). Patent protection for plants: Legal options for developing countries. Retrieved from https://www.southcentre.int/wp-content/uploads/2014/11/RP55_Patent-Protection-for-Plants_EN.pdf

THE STATUS OF PATENTING PLANTS IN THE GLOBAL SOUTH

RESEARCH REPORT
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EXECUTIVE SUMMARY

Over the last half century patent law has gradually been extended to cover plants and their parts and components, despite the existence of plant variety protection (PVP), a special regime for new plant varieties. Currently, patents are granted in many jurisdictions on the basis of claims relating to phenotypic and/or genotypic characteristics. 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.

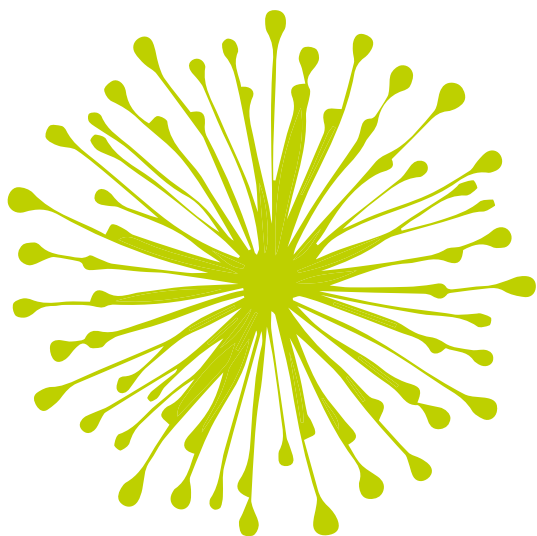
The granting of patents on plants and plant materials may have significant implications for access to and use of seeds and other propagating materials. The presence of a single patented component in a plant may create a barrier for further research and breeding, as well as prevent farmers from saving and re-using seeds that incorporate that component.

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, hybridization, mutagenesis, genetic

modification or any other method. However, a number of free trade agreements (FTAs) entered into by some developing countries with the USA 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.

This study shows that plants are excluded from patentability in only 40% of the 126 developing countries and emerging economies for which legal information was available. In other words, the majority of these countries have not used the TRIPS flexibility regarding the non-patentability of plants and would hence allow the granting of patents on plants and their parts and components, including plant cells: 43% exclude the patentability of plant varieties and essentially biological processes to obtain them, as is the case under European law; but in 17% plant varieties might also eventually be patentable, generally due to the lack of an explicit exclusion thereof.

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 indicate that legal provisions prescribing the non-



Most countries have admitted plant patents by deliberate choice or by allowing the patentability of plant parts and components.

patentability of discoveries may prevent the protection of unmodified plant materials. Merely isolated genes are not patentable in many of the selected countries. However, genetic constructs used to genetically modify plants are generally deemed patentable. Provisions excluding the patentability of 'plants' have been interpreted in some countries as also excluding the patentability of plants' parts and components, such as seeds and cells. Despite the lack of a commonly accepted definition of essentially biological processes to obtain a plant, this concept has been effectively applied in some of the selected countries to deny method claims regarding plants. The application of patentability requirements, notably 'inventive step' and the requirement of sufficient disclosure, has often led to the rejection of patent applications relating to plants.

Overall, there is considerable diversity in legal status regarding the patentability of plants in the countries of the Global South. Most have admitted plant patents by deliberate choice (notably those following the European approach, which excludes only plant varieties from patentability) 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 commercialization of plant varieties that incorporate such parts and components and eventually the products obtained from them, such as food or feed.

In developing countries where a broad coverage of patents is allowed (including plants and/or their parts and components, or plant varieties), patent laws may be used to prevent farmers from saving and re-using seeds that incorporate patented materials, thereby curtailing an essential right of farmers and putting food security at risk. Those countries should be encouraged to review their legislation and learn from the examples of countries that, consistently with the TRIPS Agreement, have appropriately narrowed down the scope of patentability in this field.

INTRODUCTION

Over the last half century patent law has gradually been extended to cover plants and their parts and components, despite the existence of plant variety protection (PVP), a special regime for new plant varieties. Currently, patents are granted in many jurisdictions on the basis of claims relating to phenotypic and/or genotypic characteristics. 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.¹² In some countries, plant varieties as such may also be patented.

The granting of patents on plants and plant materials may have significant implications for access to and use of seeds and other propagating materials, since the rights conferred by patents are broader than under a PVP regime and the presence of a single patented component in a plant may create a barrier for research and breeding. Notably, patent laws would normally prevent third parties from using a plant variety which is patented as such, or which incorporates patented parts or components, to develop and commercialize a new variety. Moreover, patent laws may not permit the saving and re-use of seeds that incorporate such patented parts and components, curtailing a basic right of particular importance for farmers and food security.

Plants and plant materials are patentable to differing extents in developed countries. In the USA, for instance, plants, plant materials and plant varieties are patentable, while European law excludes the patentability of plant varieties. The impact of the different legal models applied in these jurisdictions has not yet been sufficiently studied, and there is also limited knowledge about the patent policies applied in relation to plants in developing countries.

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, thereby practically

or potentially allowing the patent owner to indirectly exercise control over the further use of a whole plant or any plant variety that contains the patented component. Such a protection may have far-reaching implications, as exemplified by the *Schmeiser* case in Canada,¹³ in which patent infringement was found in a situation of non-intentional use of patented material present in canola plants.

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.¹⁴ 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 therefrom, such as food and feed.

Although the main provisions affecting the patentability of plants will be found in patent laws themselves, other legislation (such as plant variety protection) may also have an impact on the availability or scope of plant-related patents.

An extensive literature discusses 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. In 1989, for instance, a report by the Office of Technology Assessment reviewed US patent law as it related to the patentability of microorganisms, cells, plants and animals. The report included a range of options for congressional action related to intellectual property protection for plants.¹⁵ 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.¹⁶

Academic interest in the subject was boosted in the USA by three important decisions. In *Diamond v. Chakrabarty* (1980),¹⁷ the US 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),¹⁸ the Appeal Board of the US 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),¹⁹ the US Supreme Court confirmed for the first time that utility patents could be issued for crops and other flowering (sexually reproducing) plants.²⁰ 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.²¹

The situation of plant-related patents has been thoroughly examined in the context of the European Patent Convention 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.²² Several studies have critically discussed the protection of plants through patents vis-à-vis PVP, with one noting that the failure to reach agreement on the issue of the provision of patent protection for genetic material within Europe should have served as evidence that it was time to ban patent protection for all plant material and to rely on PVP as the sole means of protection.²³

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 (IPR) protection of plants, particularly on seed supply.²⁴ Some analyses advanced the view that patents on plants and licensing will not inhibit but promote research and development, both in developed and developing countries.²⁵ However, a study into 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.²⁶ Much of the literature has addressed the implications for Southern countries of the biotechnology industry’s expansive interpretation of patent law as applied to genetic resources and genetically engineered living organisms.²⁷ Various studies have found diverging views in developed and developing countries on the patent protection of plants and how it affects the behaviour of and interaction between the public and private sectors. A recent analysis 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.²⁹

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.³⁰ However, very few studies specifically address the patent protection of plants and plant materials in developing countries and emerging economies.

This study addresses this lack of attention. It is intended to provide an up-to-date overview of the legislation on and status of plant patents in the Global South. It considers 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.³¹ The selection of emerging economies and developing countries – spread over Africa, Asia and Latin America, along with some regional organizations – allows for country-specific analyses of case law and a sample of patents granted.³²

Firstly, the paper 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 USA that oblige partners to provide for patent protection for plants.³³ Secondly, 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. Thirdly, it considers, on the basis of the available information and expert opinions,³⁴ how the patentability requirements have been applied in relation to plants and plant materials.



THE INTERNATIONAL FRAMEWORK

At the outset of the international regime on intellectual property rights, the Paris Convention for the Protection of Industrial Property (1883) 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’ (article 1(3)).³⁵ 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 WTO) 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 UPOV Convention) 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, hybridization, mutagenesis, genetic modification or any other method. As 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 – like 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 USA have included, among other TRIPS-plus provisions,³⁶ 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:

- a) Some contain a straightforward obligation to provide for the grant of patents on plants, if requests to that end are submitted.
- b) 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.

- c) 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 US FTA with Bahrain, which stipulates that '[E]ach Party shall make patents available for plant inventions'. The US FTA with Morocco also makes plant patents mandatory.³⁷ In these cases, the obligation is likely to be interpreted as extending to plants' parts and components, such as seeds and plant cells.

The second approach is found, for instance, in article 17.9.2 of the US 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.³⁸ Arguably, this obligation would not be violated if a government finds opposition to the introduction of patent protection for plants, or other conditions are not met (e.g. lack of capacity to examine their patentability). Although reciprocal in appearance, the provision is irrelevant for the USA 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.³⁹

A similar obligation – although less detailed than in the US FTA with Chile – can be found in the US-CAFTA-DR,⁴⁰ but in this case the fact that plant patents were already granted in the USA is reflected in the text.⁴¹

The third approach is found, for instance, in the US FTAs with Jordan, Singapore and Australia, which allow only the exceptions provided for in

Article 27.2 and 27.3(a) of the TRIPS Agreement, without any reference to plants (or animals). The US FTA with Oman allows for the exclusion of patents in respect of animals, but does not mention plants.

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 European Union or EFTA 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 (TPP) Agreement⁴⁴ 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 USA.⁴⁵

Summary: 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 USA.

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, determining 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, etc.

An inventory of the provisions specifically dealing with the patentability of plants contained in patent laws of countries in the Global South is included in Annex 2.⁴⁶ As summarized in Table 1 and Figure 1, plants are excluded from patentability in 40% of the 126 countries for which legal information was available.⁴⁷ In other words, the majority of these countries have not used the TRIPS flexibility regarding the non-patentability 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 commercialization of the latter (and eventually of the products derived therefrom) 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 studied countries, plant varieties might also eventually be patentable, generally due to the lack of an explicit exclusion thereof.

60%

of the 126 countries in the Global South for which data was available allow for the patenting of plants or parts thereof.

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 plant or plant varieties	17
	Plant varieties are patentable	4
	Plant varieties and essentially biological processes are excluded	54
	No information	28
TOTAL COUNTRIES		154

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

FIGURE 1. PATENTABILITY OF PLANTS IN COUNTRIES IN THE GLOBAL SOUTH

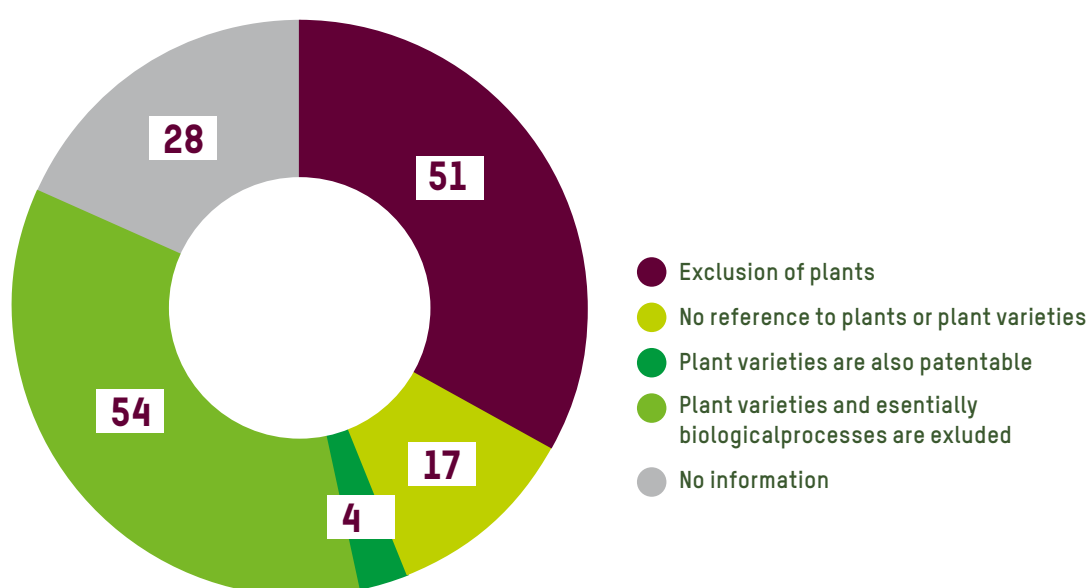


TABLE 2. PATENTING OF PLANTS AND PLANT MATERIALS IN SELECTED COUNTRIES

COUNTRY	LEGISLATION	RELEVANT PROVISIONS
Argentina	24.481, Article 7	The following shall not be patentable: b) The totality of the biological and genetic material existing in nature or its replication, in the biological processes implicit in animal, plant and human reproduction, including the genetic processes related to the material capable of conducting its own duplication under normal and free conditions, as it happens in nature; c) Plants and animals, except microorganisms and essentially biological processes for their production, without prejudice to the special protection conferred by Law 20.247 and that which eventually results in accordance with international conventions of which the country is a party.
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 non-living substance occurring in nature; ...(h) a method of agriculture or horticulture; (j) plants and animals in whole or any part thereof other than micro organisms 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 micro-biological process or the product of such a process.

COUNTRY	LEGISLATION	RELEVANT PROVISIONS
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;
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;
OAPI	Bangui Agreement, Article 6	Non-Patentable Subject Matter: (c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes.
ARIPO	Harare Protocol, section 3(10)	(j) Patents shall not be granted in respect of: (ii) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.
	Rule 7bis	vi) a single plant and its reproductive material (such as seed, etc.) which maintains its life by synthesizing carbohydrates and protein from the inorganic substances such as water, carbon dioxide and mineral salts and so on through photosynthesis belong to the category of plant variety,

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 re-using seeds) of plant propagating material through the patenting of plants’ parts and components, such as gene constructs designed to genetically modify a plant.

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, analysis of jurisprudence⁴⁸ regarding the patentability of plant materials is crucial to understand the patenting policies that are actually applied in a country.⁴⁹ Review of a sample of patents granted in those countries⁵⁰ is needed for further understanding of how the legal framework is applied.

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.

SUMMARY

Diverse provisions in national laws may affect the patentability of plants. Most developing countries and emerging economies have not fully utilized the TRIPS flexibilities and exclude only plant varieties and essentially biological processes to obtain them. The scope of these exclusions ultimately depend on interpretations by patent offices and courts.

PATENTABILITY OF PLANTS AND PLANT MATERIALS: ADMINISTRATIVE AND COURT INTERPRETATION

a) Invention v. discovery

Patent laws generally do not define ‘invention’. One notable exception is Argentina, which defines it 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)). 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 an inventive process. A rigorous application of the concept of ‘discovery’ is likely to lead to the rejection of patent applications on or replicating natural traits 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 (e.g. Brazil), the law specifies what is *not* deemed to be an invention as well as the subject matter that, even for inventions, are 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 (see below), a natural gene found in a plant, even if isolated, may also be deemed non patentable, in spite of the identification of its utility for a specific product or process. Similarly, the discovery of a new property of a plant (such as for medicinal purposes) may be deemed non patentable. The exclusion of patents on discoveries may be grounded on the lack of novelty (since they pre-exist) and/or inventive activity (in a discovery the intellectual activity is not to create but to find).⁵¹

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 (e.g. biochemical compounds) as found in nature for the creation or modification of products or processes for specific uses. Thus, notwithstanding that the European Patent Convention excludes the patentability of ‘discoveries’,⁵² a patent may be granted under European law when a substance found in nature can be characterized 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.⁵³

SUMMARY

Legal provisions prescribing the non-patentability of discoveries may prevent the protection of unmodified plant materials.

b) 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 (a sequence-based element that defines the end of a transcriptional unit, such as a gene); and localization signals (amino acid sequences that target proteins for import into the nucleus).

Nonetheless, these sequences have often been the subject of patent applications.⁵⁴ Many countries have allowed the patenting of genes and nucleotide sequences, on the argument that by isolating them there would be no appropriation of a natural product.

For instance, in the practice and jurisprudence of the European Patent Office, patents on isolated genes are admissible and may be granted with a broad scope, including functions that the applicant was unaware of when filing for or obtaining a patent. The USPTO has also granted thousands of patents based on the artificial differentiation between ‘natural’ and ‘isolated’ genes, though in *Association for Molecular Pathology v. Myriad Genetics* (2013)⁵⁵ the US Supreme Court ruled that naturally occurring DNA, even if claimed as isolated, is not a valid patentable subject matter.⁵⁶

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 this study 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 characterized 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.⁵⁷ In India, although the patentability of isolated genes would be excluded if the law were strictly interpreted, according to available studies⁵⁸ and expert opinion, patents on isolated genes have been granted.⁵⁹ This situation may change if the Supreme Court confirms the decision of the High Court of India in *Monsanto Technology LLC And Ors Vs. Nuziveedu Seeds Ltd. And Ors* (April 2018).⁶⁰

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 non-patentability of genetic material is generally limited to natural, unmodified material.⁶¹ DNA constructs, gene promoters, transit peptides⁶² 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 patents⁶³ 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 above), agrobiotechnology companies may effectively control the market of transgenic varieties on the basis of process patents.⁶⁴ In *Bayer CropScience S/A v Instituto Nacional da Propriedade Industrial* (2010),⁶⁵ 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 MON89788 for genetically modified soybean and any product derived therefrom, 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 already mentioned Uganda patent AP 2872 (2014) covers ‘commodity products derived from event MON 87708’.

SUMMARY

Summary: merely isolated genes are not patentable in many of the selected countries. However, genetic constructs used to genetically modify plants are generally deemed patentable. The coverage of patents on such materials, if extended to modified cells and plants, may limit the effect of any legal exclusion of plants or plant varieties from patentability.

c) Plants, cells seeds and other components

As indicated by Table 2, some of the selected countries (Argentina, India and Uganda, plus OAPI) 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 plants' parts and components such as cells that can lead to a complete plant with stems, leaves and flowers.⁶⁶ 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 seeds⁶⁷ alone or with other subject matter. If allowed, such claims would lead to a de facto protection of the resulting plants, and also make a prohibition to grant 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 (AlfAFP1 or AlfAFP2) which, when expressed in a plant, confers resistance to fungal pathogens. A recombinant plant cell, including a polynucleotide (i.e. 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, soybeans, 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 commercialization of any plant of these crops incorporating the modified cell.

In Monsanto Technology LLC c/ Instituto Nacional de la Propiedad Industrial s/

denegatoria de patente (2015),⁶⁸ an Argentine appeal court (Cámara Federal Civil y Comercial) confirmed the patent office's rejection of a patent application on 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 (Instituto Nacional de Propiedad Industrial, 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.⁶⁹

In Peru, the patenting authority INDECOPI refused⁷⁰ claims in a patent filed by Monsanto Technology LLC on the argument, *inter alia*, that it related to a hybrid seed.⁷¹ A similar decision was taken 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.⁷² INDECOPI also rejected a claim in a patent application filed by BASF SE from Germany covering plant propagating material (including seeds, roots, rhizomes) on the argument that it violated article 20 (c) of Decision 486 that bans the patentability of plants.⁷³ 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'.⁷⁴

In India, as noted above, the High Court decision in *Monsanto Technology LLC And Ors vs. Nuziveedu Seeds Ltd. And Ors* has clarified that under section 3(j) of the Patents Act a claim over a nucleic sequence which is introgressed and hybridized into a transgenic plant is not admissible, thereby dismissing the defendant's argument that 'a nucleic acid sequence or part of a genome, is not a 'part' of a plant'.⁷⁵

SUMMARY

Case law in some countries shows that provisions excluding the patentability of 'plants' can be interpreted as also excluding the patentability of plants' parts and components, such as seeds and cells.

Many countries in the Global South have followed the approach of the European Patent Convention and provide that plant varieties (rather than plants) are not patentable.

d) Plant varieties

Patent laws in some of the selected countries (China, South Africa and Vietnam) and many other countries in the Global South (see Annex 2⁷⁶) have followed the approach of the European Patent Convention and provide that plant varieties (rather than plants) are not patentable.⁷⁷ 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 1978,⁷⁸ which prohibits such cumulative protection. Brazil’s PVP law 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’ (Article 2). Argentina’s exclusion of cumulative protection was confirmed by the appeals court in *Consejo Superior de Investigaciones Cientificas v. INPI* (2016):⁷⁹ ‘Article 2.1 [of UPOV 78] provides that the breeder’s right may be recognized 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...’.

SUMMARY

A large number of countries in the Global South exclude the patentability of plant varieties, rather than plants, in line with the European approach. This leaves open the possibility of patenting plants and their parts and components.

e) Methods to obtain a plant or plant variety

Most patent laws in the selected countries exclude from protection essentially biological processes for the production of plants.⁸⁰ This exclusion – also found in the European Patent Convention (EPC) and in the TRIPS Agreement – has generally been interpreted as excluding conventional breeding methods.⁸¹ These methods may include the utilization 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.⁸² These exclusions do not extend to other methods, such as methods that use genetic material to modify a plant if it is not a essentially biological process for production or propagation of plants.

In Brazil, the guidelines on the examination of biotechnological patents consider 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 (paragraph 7.3). In India, the guidelines on biotechnological inventions 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 contain pure hybrid seeds, is an essentially biological process not patentable under Section 3 (j) of the Patents Act.⁸³

Hybridization 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.⁸⁴ In India, also, patents on methods for the introgression of alleles have been identified.⁸⁵

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 maize⁸⁶ and SG Biofuels to produce hybrid seeds of *Jatropha curcas*,⁸⁷ 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 Científicas v. INPI*. The appeal court⁸⁸ 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 different national legislations regarding the degree of intervention of human activity required for a plant breeding process to be patentable.⁸⁹

In Brazil, in a legal action by a group of farmers⁹⁰ 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.⁹¹

Methods to produce plants are often presented as 'use claims',⁹² but these may also be subject to objections regarding patentability. In Peru, for instance, INDECOPI refused Monsanto's aforementioned application to patent a method to produce hybrid seeds of maize on the argument, inter alia, that uses, as distinct from products or processes, are not patentable under the Andean Community law.⁹³ A decision on the same argument was taken in relation to claims in another application by the same company⁹⁴ regarding polynucleotide molecules for regulating endogenous genes in plants.

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.⁹⁵ 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 for the

obtention of 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 coming out of 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.

SUMMARY

Despite the lack of a commonly accepted definition of essentially biological processes to obtain a plant, this concept has been effectively applied in some of the selected countries to deny method claims regarding plants.

PATENTABILITY REQUIREMENTS

Patents are generally granted after a substantive examination⁹⁶ to determine whether the patentability standards (novelty, inventive step or non-obviousness, 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 on gene coding sequences or protein amino acid sequences is destructive of the novelty of each other. For instance, under US law the 'structural dissimilarity between gene sequences and the protein sequences they code for can deem one or the other of them novel and inventive even though we now know that a PSA [person skilled in the art] can decode one from the other'.⁹⁷

Similarly, the standard of inventive activity or non-obviousness 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 non-obviousness.

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

In principle, whether a claimed plant-related invention has been obtained by using physical materials or digitized information – for instance through gene editing using the CRISPR-Cas9 technique – would not affect its eligibility for patent protection, provided that the patentability requirements are met.

on the basis of digitized genetic information. This is made possible by what is termed the ‘dematerialization of genetic resources’.⁹⁸ 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’.

In principle, whether a claimed plant-related invention has been obtained by using physical materials or digitized information – for instance through gene editing using the CRISPR-Cas9 technique⁹⁹ – would not affect its eligibility for patent protection, provided that the patentability requirements are 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 and a key patent was revoked (due to defects in the application procedure) by the European Patent Office in January 2018.¹⁰⁰

Patent applications on transgenic events are generally accompanied by claims that protect methods to detect the presence of the event in a sample.¹⁰¹ 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 hybridization of complementary sequences of DNA (under stringent hybridization 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 hybridization, 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 this study 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;¹⁰² 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’.¹⁰³

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 c/ Instituto Nacional de la Propiedad Industrial s/ denegatoria de patente* (2015)¹⁰⁴ 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)¹⁰⁵ the patent office's decision, based on the lack of inventive activity, to refuse a patent application (PI 97061352) regarding polynucleotide sequences optimized 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 optimization 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,¹⁰⁶ was invalid, *inter alia*, due to the lack of inventive step.¹⁰⁷ It was estimated that 53% of planted soya in Brazil incorporates INTACTA technology.¹⁰⁸ 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 technology's use.

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,¹⁰⁹ the Tribunal provided the Colombian patent office with guidance on how to assess inventive activity (based on the problem-solution approach¹¹⁰) and other aspects of the application, including the non-patentability 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.¹¹¹ 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 characterized 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 have no industrial applicability.

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.¹¹² 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’.¹¹³ 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 thereof 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.¹¹⁴ 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, that the two sequences will have the same biological function can not be guaranteed. 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 said protein maintains a high degree of similarity with another enzyme of known biological function).

The sample examined for this study 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

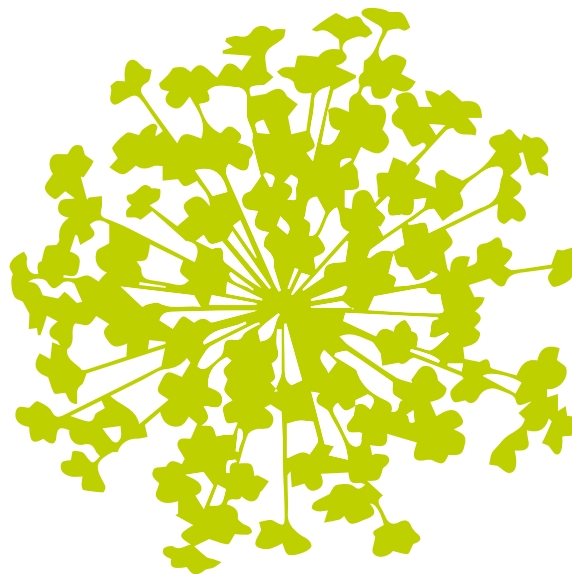
polypeptide having an amino acid sequence at least 80% identical to the sequence of SEQ ID NO:103, the promoter sequence being functional in a cell of the host plant’.

The Brazilian and Argentine guidelines for the examination of biotechnological patents mentioned above specifically address the issue of claims covering sequences characterized 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.¹¹⁵ In *Consejo Superior de Investigaciones Científicas v. INPI* (2003)¹¹⁶ the appeal court 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.¹¹⁷

Functional claims, i.e. 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.

SUMMARY

WTO members have policy space to decide how the patentability standards are interpreted and applied in their country. Analysis of the patents and case law in the selected countries indicates that patent applications relating to plants have often been rejected due to non-compliance with the requirements for an inventive step and sufficient disclosure.



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. They have followed the European approach and exclude plant varieties and essentially biological processes for their obtention, rather than plants as such.

In these countries, patents on parts and components of plants may be used to control the production and commercialization of plant varieties under conditions that are more stringent than those generally applicable under plant variety protection 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, etc. used to genetically modify plants. 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, plants' parts and components 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 USA. 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 hybridization.

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. Non-compliance 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.

A detailed overview of the legal situation in the selected countries can be found in Annex 1 of this report.¹¹⁸ Briefly, the situation in these countries can be summarized 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, though. 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 commercialization 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 therefrom, such as food and feed. Despite the exclusion, in practice this broad coverage gives the patent owner legal tools to control the production and commercialization 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 towards 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* has clarified some aspects of the legislation, notably the non-patentability of essential biological processes and the products exclusively obtained with them, and that a claim over a nucleic sequence which is introgressed and hybridized into a transgenic plant falls under the exclusions of Section 3(j) of the Patents Act.

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.¹¹⁹ 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.

In countries where a broad coverage of patents is allowed, patent laws may be used to prevent farmers from saving and re-using seeds that incorporate patented materials, thereby curtailing an essential right of farmers and putting food security at risk.

Although planting of GMOs has been banned in Uganda, several patents covering genetic constructs have been identified.¹²⁰

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’. Although the available sample is insufficient to make an assessment, the patent office seems to apply flexible standards regarding patentability in this field.

In the case of OAPI, while Rule 7bis of the Bangui Agreement seems to provide for a broad exclusion of patentability, it has not been possible to obtain examples of patents granted nor administrative or judicial decisions to assess how the rule is interpreted and applied. The same applies to patent applications examined under the Harare Protocol (ARIPO).

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 commercialization of plant varieties that incorporate such parts, and eventually the products obtained therefrom, such as food and feed.

In countries where a broad coverage of patents is allowed (including plants and/or their parts and components, or plant varieties), patent laws may be used to prevent farmers from saving and re-using seeds that incorporate patented materials, thereby curtailing an essential right of farmers and putting food security at risk. Those countries should be encouraged to review their legislation and learn from the examples of others that, consistently with the TRIPS Agreement, have appropriately narrowed down the scope of patentability in this field.

ANNEXES

➤ **ANNEX 2**

Overview of the most relevant provisions in patent laws of countries in the Global South

➤ **ANNEX 3**

Sample of patents in selected countries

➤ **ANNEX 4**

Patent search methodology

AVAILABLE AT:

<https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth>

ANNEX 1: OVERVIEW OF THE LEGAL SITUATION IN THE SELECTED COUNTRIES

ANNEX 1A: ARGENTINA

Legislation

Argentina's legislation does not allow the patentability of plants, parts or components thereof. Nevertheless, genes, proteins or DNA constructs are allowed under the patent law, its regulation and the patentability guidelines.

Argentine Patent Law No. 24,481 contains a definition of 'invention' in Article 4 (a) which reads: 'For the purposes of this Law, any human creation that permits material or energy to be transformed for exploitation by humankind shall be considered an invention'. This means that any type of discovery is excluded. While discovery is the act, process or circumstance of acquiring knowledge or verifying the existence of something previously unknown or not recognized, invention is the result of the action of humans over the forces of nature, which necessarily implies a human contribution. This provision is complemented by Article 6, which establishes what will not be considered as an invention under Argentine legislation:

The following shall not be considered

inventions for the purposes of this Law:

- (a) discoveries, scientific theories and mathematical methods;*
- (b) literary or artistic works or any other aesthetic creation; scientific works;*
- (c) schemes, rules or methods for performing intellectual activities, playing games or engaging in economic and business activities; computer programs;*
- (d) forms of data presentation;*
- (e) methods of surgical, therapeutic or diagnostic treatment applicable to the human body or relating to animals;*
- (f) the juxtaposition of known inventions or mixtures of known products, changes in the shape, dimensions or constituent materials thereof, except in the case of combination or merging in such a way that the elements are unable to function separately or where the characteristic qualities or functions thereof are so altered as to produce an industrial result that is not obvious to a person skilled in the art concerned;*

(g) any kind of live material or substances already existing in nature.

According to this article, any kind of substance or living material occurring in nature will not be regarded as an invention. Therefore any plant, part or component will not be considered invention under the law. The same would apply to any gene or living organism or any matter that is found in nature and not transformed by man.

Article 7 refers to subject matter that may be deemed an 'invention' but which nevertheless is not patentable:

The following shall not be patentable: (a) inventions the exploitation of which on the territory of the ARGENTINE REPUBLIC is to be prevented in the interest of the public good or morality, the health or life of persons or animals, the conservation of plants or the avoidance of serious damage to the environment; (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.

The regulations of the patent law (Decree 260/96) clarify Article 6 by indicating that 'plants, animals and essentially biological procedures for their reproduction shall not be considered patentable material'.

Guidelines

In October 2001, Joint Resolution 810/2001 and 99/2001 of the Ministries of Agriculture and Production were enacted, in accordance with which a Permanent Working Group on Industrial Property (GTPPI) was established with technical staff of both ministries. The Joint Resolution instructed the GTPPI to elaborate Guidelines on Patenting to guide the examiner on resolving applications for patents, in particular in relation to living matter and natural substances.

The Joint Resolution noted that the definition of patentability criteria, in a manner consistent with international law, was a component of public policy, as systems for the protection of intellectual property rights have an intimate relationship with the objectives of development and technology transfer.

The guidelines issued by the INPI on December 2003 (Resolution P-243) incorporated the result of the work of the GTPPI in Chapter IV on 'Patentability'. They have been applied since then and updated in 2015. Regarding plants and living matter, Chapter IV of Part C, para. 2.17 established that:

2.1.7.1 All living matter and pre-existing substances in nature are not inventions for the purposes of [the patent law]. Living matter and pre-existing substances in nature that are still purified, isolated and/or characterized are discoveries and consequently are not patentable.

2.1.7.2 Plants, animals and essentially biological processes for their reproduction or production (procurement) shall not be considered inventions.

In this way they are excluded from protection because they are not inventions, under article 6 g) of the law and the regulation:

a) The plants, their parts and components that can lead a complete individual are modified or not. The species and plant varieties are included. The parts and components of the plants, whether modified or not, include, among others, buds, seeds, stems, cells, fruits, bulbs, tubers, buds, stakes, flowers, etc. and its cellular components such as organelles, membranes, DNA molecules, etc. This enumeration is enunciative and not exhaustive, and other elements may be incorporated after the present exemplary list. Claims with modified parts and components must specify their isolated state and that they are unable to lead to a complete organism.

b) The animals and their parts that can lead a complete individual are modified or not. It includes species and animal breeds. The parts of an animal - whether modified or not - encompass and are not limited to: organs, tissues, cells, cellular components such



as organelles, membranes, DNA molecules. Claims with modified parts and components must specify their isolated state and that they are unable to lead to a complete organism.

c) Essentially biological procedures for reproduction or production (procurement) of plants or animals. (see 2.1.7.5).

2.1.7.3 Vegetable varieties are not patentable and are protected by a "sui generis" system, which is the breeder's rights system established in Law No. 20,247 on Seeds and Genetic Phyto-Creations and the UPOV Convention, Act 78 approved by Law No. 24,376.

2.1.7.4 For the purposes of these guidelines, the cell is considered the smallest unit of living matter.

2.1.7.5 Regarding point 2.1.7.2 c) essentially biological procedures are understood as the series of phases that conclude with the obtaining or reproduction of plants or animals that are fundamentally or substantially fulfilled by the action of own and existing phenomena in the nature. Thus, to determine if a procedure for the production or reproduction of plants or animals is essentially biological, the technical aspect of the process will be evaluated. If the technical intervention of man plays an important role in the determination of the result or if its influence is decisive, then the process will be considered to have a technical nature and therefore it will be patentable (see point 2.1.7.1).

2.1.7.6 Under this concept, the classic procedures of breeding or improvement would not be patentable. For example, a method of crossing or selective procreation that consists of crossing horses with certain characteristics, which involves selection, would be essentially biological and therefore not patentable. In contrast, methods based on genetic engineering (e.g. the production of a transgenic plant), where technical intervention is significant, may be patentable.

2.1.7.7 A claim of a procedure for the production (procurement) or reproduction of a plant, shall not be excluded a priori from patentability because the resulting product constitutes or may constitute a plant. It is possible to patent biotechnological procedures that lead to the creation of transgenic plants if they meet the requirements of patentability.

2.1.7.8 The exclusion of art. 6 RLP, does not apply to microbiological procedures. The term "microbiological process" covers the industrial processes that use, apply to, or result from the intervention of microorganisms.

These procedures will be patentable, even when the microorganism used, the resulting product or both are already patented, provided that the aforementioned processes comply with the requirements established in art. 4 LP and do not fall within the exclusions contemplated by arts. 6 and 7 LP and RLP.

2.1.7.9 On the other hand, claims of plants or

animals will not be allowed even when they are produced through a biotechnological process. The exclusions to the patentability contemplated in art. 6 RLP, applies to plants and animals regardless of the way they are produced. For example, plants and animals that contain genes introduced through recombinant DNA technology and those obtained through micropagation, cloning or any other biotechnological technique or other reproduction method, but technical intervention, will be excluded from patentability.

In accordance with these guidelines, applications which claim a modified component of living material such as a modified organelle (which can be considered a substance) may be admitted as long as the modified component does not form part of an individual plant, animal or living matter and is not capable of generating an individual.

Case law

Argentina has so far only two important cases involving plants:

Cámara Nacional de Apelaciones en lo Civil y Comercial Federal, Sala III, 03/16/2006 de marzo de 2006 (Consejo Superior de Investigaciones Científicas c/I.N.P.I.s/denegatoria de patente); Corte Suprema de Justicia de la Nación, 03/05/2005.

The National Institute of Industrial Property rejected a claim over a 'sunflower seed that includes sunflower oil that has a higher content of stearic acid'. The Supreme Court ruled that the petitioner of a patent on an object already protected by Law 20.247 for the protection of seeds and phytogenetic creations (plant varieties) can not claim protection under the patent law because there is a prohibition of double protection (Article 2 of UPOV 1978). It also established that biological methods are excluded from patentability. *Cámara Nacional de Apelaciones en lo Civil y Comercial Federal, sala III (CNFedCivCom). Monsanto Technology LLC c. Instituto Nacional de la Propiedad Industrial s/ denegatoria de patente. 2015*

The court held: 'The harmonious interpretation of art. 27.3.b of TRIPS and art. 2.1. of the International Convention for the Protection of New Varieties of Plants (UPOV) approved in Argentina through Law 24,376, supports the claim that the former allows Member States to adopt a sui generis system of plant variety protection that relieves them to include them in the patent system, protection that is accorded by Law 20.247 on Seeds and Plant Genetic Creations and its Regulation No. 2183/91; in short, the legal regime integrated by UPOV-Act 1978- and Law 20.247 establishes an effective sui generis system, in terms of art. 27.3.b of TRIPS... noting that the Seed Law and its subsequent amendments do not conflict with it.'

ANNEX 1B: AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

The African Regional Intellectual Property Organization (ARIPO) has 18 member states: Botswana, eSwatini (formerly Swaziland), the Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, São Tomé and Príncipe, Sierra Leone, Sudan, Tanzania, Uganda, Zambia and Zimbabwe.

ARIPO is an intergovernmental organization that facilitates cooperation among member states in the field of intellectual property. ARIPO was established by the Lusaka Agreement, adopted at a diplomatic conference held in Lusaka, Zambia, on 9 December 1976. ARIPO has special protocols to regulate intellectual property rights such as the Harare (patents), Banjul (marks) and Arusha (plant varieties) protocols.

Unlike OAPI, where a single application automatically covers all member states and it is not possible to designate countries of interest, ARIPO applications specifically require the applicant to designate those member states where protection is sought.

The Harare Protocol regulates the grant of patents. By filing only one application, an applicant can designate any of the contracting states in which that applicant wishes the invention to be accorded protection. The protocol requires the filing of the application to be made with any one of the contracting states or directly with the ARIPO Office. On receipt of the application, the ARIPO Office undertakes a substantive examination to establish whether the invention is patentable. If the application is deemed admissible, copies are sent to each designated contracting state which may, within six months, indicate to the ARIPO Office – citing grounds specified in the protocol – that should ARIPO grant the patent, it would not have effect in its territory.

Concerning plants, Section 3 of the Harare Protocol establishes:

- (10)(a) Patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.*
- (b) An invention shall be considered to be new if it is not anticipated by the prior art.*
- (c) Everything made available to the public anywhere in the world by means of a written disclosure (including drawings and other illustrations), an oral disclosure or by use or an exhibition, shall be considered prior art, provided that such publication occurred before the date of filing of the application or, if priority is claimed, before the priority date claimed in respect thereof and further provided that a disclosure of the invention at an official or officially recognized exhibition shall not be taken into consideration if it occurred not more than 6 months before the date of filing of the application or, if priority is claimed, before the priority date claimed in respect thereof.*
- (d) An official or officially recognized exhibition is an exhibition recognized by a State or falling within the terms of the Convention on international exhibitions.*
- (e) An invention shall be considered as involving an inventive step if, having regard to the prior art, it is not obvious to a person skilled in the art.*

Regulations for implementing the protocol:

- Rule 7bis Guidelines on Transgenic Plants and Animals*
- 7bis. 1. Definitions For the purposes of these guidelines–*
- (a) ‘biological material’ means any material containing genetic information and capable of reproducing itself or being reproduced in a*

biological system;
 (b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material;
 (c) 'biotechnological invention' are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used;
 (d) 'genetic engineering' means the technology which manipulates gene recombination, cell fusion, etc. Inventions relating to genetic engineering include those of a gene or a DNA fragment, a vector, a recombinant vector, a transformant, a polypeptide or a protein, a fused cell, a monoclonal antibody, etc;
 (e) 'plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be – (i) defined by the expression of the characteristics that result from a given genotype or combination of genotypes, (ii) distinguished from any other plant grouping by the expression of at least one of the said characteristics and, (iii) considered as a unit with regard to its suitability for being propagated and changed;
 (f) a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

7bis. 2. Patentable Biotechnological Inventions

Biotechnological inventions shall be patentable if they concern – (i) 'biological material' which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature, (ii) 'plants or animals' provided that the technical feasibility of the invention is not confined to a particular plant or animal variety, (iii) 'a microbiological or other technical process,' or a product obtained by means of such a process other than a plant or animal variety, (iv) any element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element

is identical of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

7bis. 3. Exceptions to Patentability of Biotechnological Inventions

ARIPO patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- I. processes for cloning human beings,*
- II. processes for modifying the germ line genetic identity of human beings,*
- III. uses of human embryos for industrial or commercial purposes,*
- IIII. processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes,*
- V. an embryonic stem cell of an animal, an animal at the various stages of its formation and development such as a germ cell, a zoosperm, an embryo etc belong to the category of animal variety,*
- VI. a single plant and its reproductive material (such as seed, etc) which maintains its life by synthesizing carbohydrates and protein from the inorganic substances such as water, carbon dioxide and mineral salts and so on through photosynthesis belong to the category of plant variety,*
- VII. inventions that do not possess practical applicability, i.e. cannot easily be reproduced,*
- VIII. the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

Finally, ARIPO has adopted guidelines for the examination of patent applications. In particular, for section 3.10.j of the Harare Protocol and 7bis of the implementation regulations, the guidelines clarify:

3.3.7 Biotechnological inventions

3.3.7.1 General remarks and definitions

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. "Biological

material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Rule 7bis).

3.3.7.2 Patentable biotechnological inventions (Rule 7bis. 2)

In principle, biotechnological inventions are patentable under the Harare Protocol.

For ARIPO patent applications and patents concerning biotechnological inventions, the relevant provisions of the Harare Protocol are to be applied and interpreted in accordance with the provisions of Rule 7bis. Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:

(i) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature. Hence biological material may be considered patentable even if it already occurs in nature.

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

The examination of a patent application or a patent for gene sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology. The industrial application of a sequence or partial sequence must be disclosed in the patent application as filed.

(ii) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety. Inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety.

A claim wherein specific plant varieties are not individually claimed is not excluded from patentability even though it may embrace plant varieties. The subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties. In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is neither limited nor directed to a variety or varieties or (iii) a microbiological or other technical

process, or a product obtained by means of such a process other than a plant or animal variety.

3.3.8.6 Plant and animal varieties, processes for the production of plants or animals

The list of exceptions to patentability under Rule 7bis.3 also includes “plant or animal varieties or essentially biological processes for the production of plants or animals”.

3.3.8.6.1 Plant varieties

The term “plant variety” is defined in Rule 7bis.1. A patent is not to be granted if the claimed subject-matter is directed to a specific plant variety or specific plant varieties. However, if the invention concerns plants and animals and if the technical feasibility of the invention is not confined to a particular plant or animal variety, the invention is patentable.

When a claim to a process for the production of a plant variety is examined, it is not to be taken into consideration. Hence, a process claim for the production of a plant variety (or plant varieties) is not a priori excluded from patentability merely because the resulting product constitutes or may constitute a plant variety.

3.3.8.6.2 Processes for the production of plants or animals

A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved the essence of the invention is technical; the same could apply to a method of treating a plant characterized by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability.

ANNEX 1C: AFRICAN INTELLECTUAL PROPERTY ORGANIZATION (OAPI)

OAPI is a regional organization composed of 17 members (mostly French-speaking countries). It was created by the Bangui Agreement, signed in Central Africa in 1977. Members are bound by uniform legislation regarding intellectual property and have centralized all procedures for issuing industrial property titles such as patents and goods or service marks, which are valid in all member countries. This means that any deposit made with the administration of one member state or the organization shall be considered as a national deposit in each member state.

The Bangui Agreement established a uniform system of intellectual property rights protection with a common administrative procedure. OAPI also serves as a national intellectual property rights protection office for each of the member states. A title granted by OAPI gives rise to intellectual property rights in each member country. Nevertheless, actions regarding the infringement of intellectual property rights are the responsibility of the courts of each member state. Judicial decisions regarding the validity of titles in one member state are authoritative in all other states, with the exception of circumstances based on public order and morality.

The Bangui Agreement adopts legislation for patents as well for plant varieties. Article 6 excludes from patentability plant varieties, discoveries and essentially biological processes:

Article 6.

Non-Patentable Subject Matter

Patents shall not be granted for the following:

- (a) inventions the exploitation of which is contrary to public policy or morality, provided that the exploitation of the invention shall not be considered contrary to public policy or morality merely because it is prohibited by law or regulation;*
- (b) discoveries, scientific theories and mathematical methods;*
- (c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes;*
- (d) schemes, rules or methods for doing business, performing purely mental acts or playing games;*
- (e) methods for the treatment of the human or animal body by surgery or therapy, including diagnostic methods;*
- (f) mere presentations of information;*
- (g) computer programs;*
- (h) works of an exclusively ornamental nature;*
- (i) literary, architectural and artistic works or any other aesthetic creation.*

ANNEX 1D: BRAZIL

Legislation

Brazil's legislation does not allow the patentability of plants: its patent law and guidelines establish that all living matter, even if isolated, is not patentable. The Brazilian Industrial Property Law (Law No. 9279 of May 14, 1996) provides in Article 10(XI), that the following are materials not considered as inventions:

All or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

According to this article, naturally occurring plants are not patentable, because they are not considered as an invention; nor are naturally occurring DNA and RNA sequences including polynucleotides and polypeptides. This is complemented by Article 18 regarding non-patentable inventions. Using fully the flexibility under the TRIPS Agreement, Brazilian patent law excludes from patentability even transgenic living matter, with the exception of transgenic microorganisms:

Article 18. The following are not patentable:
I. anything contrary to morals, standards of respectability and public security, order and health;
II. substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus; and
III. 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.

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.

Concerning the rights conferred by patents, Brazilian patent law clarifies that:

Article 43. The provisions of the previous Article do not apply:

...

V. to third parties who, in the case of patents related to living material, use the patented product, without economic intent, as an initial source of variation or propagation to obtain other products; and

VI. to third parties who, in case of patents related to living material, use, place in circulation, or market a patented product that has been legally introduced into commerce by the patent holder or the holder of a license, provided that the patented product is not used for commercial multiplication or propagation of the living material in question.

Brazil has also enacted a law (No. 13.123, 20.5 2015) to protect genetic resources and cultural heritage. It makes the grant of intellectual property rights conditional on compliance with access and benefit conditions. The law provides that if access is made contrary to this regulation, patent rights may be void:

Article 47. The granting of an intellectual property right by the competent organ of the finished product or reproductive material obtained from access to genetic heritage or associated traditional knowledge is conditioned to the registration or authorization, in accordance with this Law.

Regarding plant varieties, the Plant Variety Protection Law (No. 9.456 of 1997) created

a sui generis protection for plant varieties (implemented through decree No. 2366 of November 5, 1997). Through further decrees (No. 28 of 19 April 1999; No 3109 of 30 June 1999), the International Convention for the Protection of New Varieties of Plants (UPOV) of 1978 was approved and put into force. Article 2 of No. 9.456 stipulated that:

The protection of the intellectual property rights in plant varieties is effected through the grant 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 and the rights therein that may be invoked against the free use of sexually or vegetatively propagated plants or parts thereof.

To summarize, under Brazilian legislation it is not possible to obtain patents for plants, plant varieties, transgenic plants, parts of plants or natural occurring processes for obtaining them. Nevertheless, it is possible to obtain patents for the processes to obtain a transgenic plant.

Guidelines

Since 2012 the Brazilian patent office has established several guidelines for the analysis of patent applications: Resolution 298/2012 – Establishing the utility model patent examination guideline; Resolution 124/2013 – Establishing guidelines for the examination of patent applications; Resolution 144/2015 – Establishing guidelines for the examination of patent applications in the area of biotechnology; Resolution 158/2016 – Establishing guidelines for the examination of patent applications involving inventions implemented by computer programs; Resolution 169/2016 – Establishing guidelines for the examination of patent applications – block II – ‘patentability’; Resolution 208/2017 – Establishing guidelines for the examination of patent applications in the field of chemistry.

Concerning the topic of plant patents, Resolution 144/2015 provides an interpretation

of the relevant articles of the Brazilian patent law:

4.2 Materials not considered as inventions (Article 10)

4.2.1 Natural biological products and processes (Article 10 (IX))

The art. 10 (IX) of the Industrial Property Law, as regards claims in the "product" category, provides that all or part of natural living and biological material found in nature, or isolated from it, including the genome or germplasm of any natural living being. For claims of the category "process", such as processes, methods, uses, applications, among others, art. 10 (IX) of the IPL refers only to natural biological processes, provided that these are not considered as inventions. As the art. 10 (IX) of the IPL deals with all or part of the natural and biological materials found in nature which are not considered as inventions, documents published after the date of priority / filing of the application under review may be used to show that the claimed matter is related to the provisions of art. 10 (IX) of the Industrial Property Law, provided that the information provided clearly and without doubt proves the existence in nature of the claimed matter.

Para. 4.2 clarifies Article 10(IX) of the Brazilian patent law, and confirms that essentially biological processes are not patentable because they are not regarded as inventions. The guidelines confirm the non-patentability of transgenic plants under Article 18 and address the possibility of patenting the processes for obtaining them. Product claims over plants and transgenic plants, hence, are not allowed:

7.2 Transgenic plants, their parts and their processes to obtain them

They are plants that had their genome modified by introducing a DNA manipulated by recombinant DNA techniques, and whose modification would not happen under natural conditions of crosses or recombination. Transgenic plants and their parts (e.g. transgenic cell, transgenic tissue and transgenic organ) are not considered as patentable materials according to art. 18

(III and single paragraph) of the Industrial Property Law.

Although the process of obtaining transgenic plants is patentable, it is important to note that the intermediate and/or final products of this process, that is, the transgenic plant and/or the parts of that plant constitute expressly prohibited substances of patentability according to art. 18 (III and single paragraph) of the Industrial Property Law.

However, there is no restriction on the patenting of the processes of obtaining these plants.

7.3 Process of obtaining plants by crossing

The art. 10 (IX) of the IPL states that natural biological processes are not considered to be inventions, and thus exclude the patenting of natural biological processes, including those for the production of plants. "Natural biological process" means any process which does not use technical means to obtain biological products or which, even using a technical means, would be capable of occurring in nature without human intervention, consisting entirely of natural phenomena. In this sense, biological processes will be considered unnatural when human intervention is direct in genetic composition and has a permanent character. Thus, processes involving the crossing of genetically modified plants by direct human intervention are passive of protection.

Regarding regulations about genetic resources, the guidelines indicate that obtaining intellectual property rights is conditional on the authorization of the authority governing genetic resources:

Applications for a patent of invention on a process or product obtained from a sample of components of the national genetic patrimony, deposited as of June 30, 2000, must comply with the standards in force established in MP [Medida Provisoria]

2186-16/01 of 08/23/2001, as well as CGEN Resolutions 34 of February 12, 2009 and INPI PR No. 69/2013, dated 03/18/2013.

MP 2186-16/01 provides, among other things, rights and obligations relating to access to a component of genetic heritage existing on national territory, the continental shelf and the exclusive economic zone? for scientific research, technological development or bioprospecting, as well as access to the traditional knowledge associated with the genetic heritage, relevant to the conservation of biological diversity, to the integrity of the genetic patrimony of the Country and to the use of its components (article 1, subsections I and II).

In art. 31, the MP provided that the granting of industrial property rights, on a process or product obtained from a component of the genetic heritage component, was conditional on compliance with the MP, and the depositor had to inform about the origin of the genetic material and associated traditional knowledge, when this was the case.

Case law

In *Bayer CropScience S/A v. Instituto Nacional da Propriedade Industrial (2010)*¹²² 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.

In a legal action by a group of farmers,¹²³ the court admitted the possibility of a 'dual protection' over plant varieties as a result of the cumulative effect of PVP and the patent protection over transgenic processes to modify a plant.

ANNEX 1E: CHINA

Legislation

The Chinese intellectual property system is relatively young. Patents, utility models and industrial design are covered by the Patent Law of the People's Republic of China, which was adopted by the Standing Committee of the National People's Congress and promulgated by the President on 12 March 1984, and amended on 4 September 1992, 25 August 2000, and 27 December 2008.

Article 25 clearly states that plant varieties are not protectable under the patent law:

Article 25 Patent rights shall not be granted for any of the following:
(1) scientific discoveries;
(2) rules and methods for intellectual activities;
(3) methods for the diagnosis or treatment of diseases;
(4) animal or plant varieties;
(5) substances obtained by means of nuclear transformation; and
(6) designs that are mainly used for marking the pattern, color or the combination of the two.

Nevertheless, patent rights may be granted for the production methods of animal or plant varieties. A substance found in nature and existing in its natural state is merely an object of discovery and should not be granted a patent right.

Along with the patent legislation, the People's Republic of China enacted implementing rules (promulgated by Decree No. 306 of the State Council of China on 15 June 2001, and revised on 9 January 2010 by the Decision of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China). These rules include a provision regarding genetic resources:

Article 26 (Newly added) The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-creation completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.

Plant variety protection in China is covered by the Regulations of the People's Republic of China on Protection of New Varieties of Plants, which indicates:

Article 2 The new plant variety referred to in these Regulations means a cultivated plant variety, or a developed one based on a discovered wild plant, which is new, distinct, uniform and stable, and whose denomination is adequately designated.

Guidelines

The State Intellectual Property Office of the People's Republic of China (SIPO) has published Patent Examination Guidelines to clarify the law and implementing regulations. They address the patentability of plants:

4.4 Animal and Plant Varieties
Animal and plant are living things. According to Article 25. 1 (4), no patent rights shall be granted for animal and plant varieties. Animal referred to in the Patent Law does not include human being, and it refers to the life form which cannot synthesize carbohydrate

and protein by itself but maintains its life only by absorbing natural carbohydrate and protein. Plant mentioned in the Patent Law refers to the life form which maintains its life by synthesizing carbohydrate and protein from the inorganics, such as water, carbon dioxide, and inorganic salt, through photosynthesis, and usually is immovable. Animal and plant varieties can be protected under other laws and regulations other than the Patent Law. For example, new plant varieties can get protection under the Regulations on the Protection of New Varieties of Plants. Moreover, according to Article 25.2, patent right may be granted for processes used in producing animal and plant varieties. The processes of production herein refer to non-biological processes, and do not include those for the production of animals or plants through essentially biological processes. Whether or not a process is an "essentially biological process" depends on the degree of human technical involvement in the process. If the human technical involvement is the controlling or decisive factor for achieving the result or effect of that process, the process is not essentially biological. For example, the method of raising high yield dairy cattle through irradiation and the method of producing lean meat pigs by improving raising approach are patentable subject matters. Microorganism inventions refer to those relating to producing a chemical substance (such as an antibiotics) or decomposing a substance by means of microorganisms such as various bacteria, fungi, and viruses. Microorganisms and microbial processes are all patentable. For examination of patent applications for invention concerning microorganisms, the relevant provisions of Chapter 10 of this Part shall apply.

According to these guidelines, all plants, including transgenic plants, would be excluded from patentable subject matter, whereas the protection of rights in new varieties of plants would be limited to the propagating material.

Section 9.1.2 clarifies Article 25 of the patent law:

9.1.2 Examination of Claimed Subject Matters According to Article 25

9.1.2.1 Microorganism

The term "microorganism" includes bacteria, actinomycetes, fungi, viruses, protozoa and algae, etc. Because a microorganism is neither an animal nor a plant, it is not listed in Article 25.1(4). A microorganism existing in the nature without the involvement of any artificially induced technical treatment is, however, a scientific discovery. Hence, it is unpatentable. Microorganism per se constitutes a subject matter of patent protection only when it is isolated into pure culture and has particular industrial use.

9.1.2.2 Gene or DNA Fragment

No matter it is a gene or a DNA fragment, it is, in substance, a chemical substance. The said gene or DNA fragment includes those isolated from microorganism, plant, animal or human body, as well as those obtained by other means. As stated in Section 2.1 of this Chapter, a gene or DNA fragment found in the nature and existing in its natural state is merely a discovery. It falls into "scientific discoveries" as provided for in Article 25.1 and is unpatentable. However, a gene or a DNA fragment per se and the process to obtain it are subject matters of patent protection if it is isolated or extracted for the first time from the nature, its base sequence is unknown in the prior art and can be definitely characterized, and it can be exploited industrially.

9.1.2.3 An Animal, a Plant and a Constitutive Part Thereof

An embryonic stem cell of an animal, an animal at the various stages of its formation and development, such as a germ cell, an oosperm, an embryo and so on, belong to the category of the "animal variety" said in Chapter 1, Section 4.4 of this Part, they are unpatentable in accordance with the provisions of Article 25.1(4).

A somatic cell of an animal as well as a tissue and an organ of an animal (except an embryo) are not in conformity with the definition of "animal" said in Chapter 1, Section 4.4 of this Part, so they do not belong to the subject matters excluded according to the provisions of Article 25.1(4). A single plant and its reproductive material (such

as seed, etc.), which maintains its life by synthesizing carbohydrate and protein from the inorganic substances, such as water, carbon dioxide and mineral salt and so on through photosynthesis, belong to the category of the "plant variety" said in Chapter 1, Section 4.4 of this Part, and they are unpatentable in accordance with the provisions of Article 25.1(4). If a cell, a tissue and an organ of a plant do not possess the above-mentioned characteristic, they cannot be regarded as "plant varieties", therefore, they do not belong to the subject matters excluded according to the provisions of Article 25. 1(4).

*9. 1. 2. 4 Transgenic Animal and Plant
Transgenic animal or plant is those*

obtained by biological method, such as DNA recombination technology of the genetic engineering. The animal or plant per se still belongs to the category of the "animal variety" or "plant variety" defined in Chapter 1, Section 4. 4 of this Part. In accordance with the provisions of Article 25. 1(4), no patent right shall be granted to them.

This section of the guidelines clarifies that claims on 'a single plant and its reproductive material (such as seed, etc.)' should be rejected, but claims on matters such as cell, tissue or organs might be acceptable, as well as the methods for producing them.

ANNEX 1F: INDIA

Indian patent law did not exclude plants or parts thereof before the TRIPS Agreement. Since then, the Indian Patent Act has undergone three amendments, the first being the Patents (Amendment) Act, 2002 (Act 38 of 2002). This introduced the new Patent Rules, 2003, which replaced the earlier Patents Rules, 1972, and came into force on 20 May 2003. The second amendment was the Patents (Amendment) Ordinance, 2004, later replaced by the Patents (Amendment) Act 2005. Along with the Patent Act, India has rules for implementing the Act and regulating patent administration. The last amendment of the rules was in 2006.

Legislation

Chapter II, Section 3 of the Indian Patent Act determines what are not inventions and hence not patentable. This includes mere discoveries as well plants or animals and their parts:

Section 3. The following are not inventions within the meaning of this Act,—

- (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;*
- (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*
- (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;*
- (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or*

employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

[(g) is omitted]

(h) a method of agriculture or horticulture;
(i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;

(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;

(k) a mathematical or business method or a computer programme per se or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation

or duplication of known properties of traditionally known component or components.

India adopted a sui generis protection for plant varieties under the Protection of Plant Varieties and Farmers' Rights Act, 2001. India has also protected genetic resources associated with living matter through the Biological Diversity Act, 2002, which provides a mechanism for access to genetic resources and benefit sharing. Section 6 provides that obtaining IPRs related to the utilization of biological resources in India is subject to the approval of the National Biodiversity Authority:

Section 6.1. No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the granting of the patent by the patent authority concerned:

Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

6.2. The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

6.3. The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

6.4. Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Guidelines

India has approved guidelines for examining patent applications, which supplement the practices and procedures followed by Patent Office as published in the Manual of Patent Office Practice and Procedure. In particular, the biotechnology guidelines have clarified issues relating to the patentability of plants, parts and essentially biological processes:

16. Section 3 (j): plants & animals in whole or any part, seeds, varieties, species other than microorganisms & essentially biological processes are not patentable subject matter According to Section 3 (j) of the Act.

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 are not patentable inventions. Although, microorganisms are excluded from non-patentability list, a conjoined reading with Section 3 (c) of the Act implies that only modified microorganisms, which do not constitute discovery of living thing occurring in nature, are patentable subject matter under the Act.

Claims relating to essential biological processes of growing plants, germination of seeds, of development stages of plants and animals shall be objected under Section 3 (j) of the Act.

ILLUSTRATIVE EXAMPLE 1: Claims: A therapeutic composition for treating an immune-related disorder in a mammalian subject, the composition comprises as an effective ingredient ex vivo educated autologous NK T cells capable of modulating Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells and optionally comprising pharmaceutically acceptable carrier, diluent, excipient and/or additive. Analysis: The claimed subject-matter falls within the scope of Section 3 (j) of the Act for claiming ex vivo educated autologous NK T cells in the form of therapeutic composition. Although the claim is directed to a composition, but there is nothing like a composition; in fact the educated autologous NK T cells alone

would be treated as a final product, because other ingredients are kept as optional. Just by wording a claim as a composition claim comprising additional one or more routine ingredients (for example pharmaceutically acceptable carriers) has no effect on the final product and it does not exclude the claim from falling within the scope of Section 3 (j) of the Act.

ILLUSTRATIVE EXAMPLE 2: Claim: A method of producing at least one of substantially pure hybrid seeds, plants and crops, comprising the steps of (i) producing a male parent which is male fertile, (ii) breeding the male parent with a female parent which is substantially male sterile, and (iii) harvesting seeds from the female parent which contain pure hybrid seeds. Analysis: The claimed method involves the step of cross breeding for producing pure hybrid seeds, plants and crops. Thus, it is an essentially biological process and not allowable under Section 3 (j) of the Act.

Case law

A recent case – Nuziveedu Seeds Ltd. And Ors vs Monsanto Technology Llc And Ors, on 11 April 2018 – relates 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. In response, the defendants filed a counter-claim for the revocation of the plaintiff's patent. 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.

Subsequent correspondence between the Patent Office and Monsanto resulted in exclusion of plants, plant cells, tissues and progeny plant containing the nucleic acid sequence as well as plants created through an essentially biological process (excluded on account of Section 3(j)). This narrowing of the patent claims, in the opinion of the court, is relevant, because ultimately what was granted was not a patent over the product, or even the method, but of identification of the 'event' i.e. the place in the genetic sequence of the DNA where the CryAB2 protein, in the plant cell.

In May 2018, the Supreme Court of India declined to stay the high court order that invalidated Monsanto's patent.

ANNEX 1G: PERU

Peru is part of the Andean Community – along with Bolivia, Colombia and Ecuador – which has enacted several decisions on patents that are mandatory for state members.

Articles 15 and 20 of Decision 486, issued by the Commission of the Andean Community (also called the Commission of Cartagena) on 14 September 2000, establish the non-patentability of living matter and plants:

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 germ plasm of any natural living being;*
- (c) literary and artistic works or any other work protected by copyright;*
- (d) plans, rules and methods for the pursuit of intellectual activities, the playing of games or the conduct of economic and business activities;*
- (e) computer programs or software as such; and*
- (f) methods of presenting information.*

Article 15 states that all living matter, even when isolated, will not be considered as an invention. Article 20 complements this by specifically excluding from patentability plants, their parts and the essentially biological processes:

20. The following shall not be patentable:
(a) inventions the commercial exploitation of which on the territory of the member country concerned has necessarily to be prohibited in order to protect law and order or morality. To that end the commercial exploitation of an invention shall not be considered contrary to law and order or morality solely owing to the existence of a legal or administrative provision

that prohibits or regulates such exploitation;
(b) inventions the commercial exploitation of which in the member country concerned has necessarily to be prohibited in order to protect the health or life of persons or animals, or to preserve plants or the environment. To that end the commercial exploitation of an invention shall not be considered contrary to the health or life of persons or animals or liable to prejudice the conservation of plants or the environment solely on account of the existence of a legal or administrative provision that prohibits or regulates such exploitation;
(c) plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes;
(d) therapeutic or surgical methods for the treatment of human beings or animals, and also diagnostic methods applied to human beings or animals.

Article 53 limits the rights of the patent holder on biological material other than plants that it is possible to reproduce:

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:
(a) acts performed in a private circle for non-profit-making purposes;
(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;
(c) acts performed solely for the purposes of teaching or scientific or academic research;
(d) acts referred to in Article 5ter of the Paris Convention for the Protection of Industrial Property;
(e) where the patent protects biological material, that can be reproduced, other than plants, using that material as the basis with which to obtain viable new material, except where to do so requires repeated use of the patented subject matter.

Article 54 explicitly establishes the reach of rights over biological material:

54. The patent shall not give the right to prohibit a third party from engaging in commercial acts in relation to a product protected by the patent after that product has been brought on to the market in any country by the owner of the patent, or by another person who has obtained his consent or is economically associated with him.

For the purposes of the foregoing paragraph, two persons shall be considered economically associated where one can directly or indirectly exercise a decisive influence on the other concerning the working of the patent, or where a third party can exercise such an influence on both. Where the patent protects biological material, that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in accordance with the first paragraph above, provided that the reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market, and provided that the material derived from such use is not used for multiplication or propagation purposes.

Peru has enacted legislation complementing the Decision, including Law No. 29316 of 13 January 2009 which incorporates provisions of the Trade Promotion Agreement between Peru and the United States. It includes Article 25-B, regarding what is not considered an invention:

Article 25-B. No inventions

The following are not considered inventions:

- a) Discoveries, scientific theories and mathematical methods.*
- b) Any living being, existing in nature, in whole or in part.*
- c) Biological material, existing in nature, in whole or in part.*
- d) Natural biological processes.*
- e) Literary and artistic works or any work protected by copyright.*

- f) Plans, rules and methods for the exercise of intellectual activities, games or economic-commercial activities.*
- g) Computer programs or software, as such.*
- h) Ways to present information.*

The Andean Community has also enacted legislation concerning the protection of genetic resources. Decision 391 establishes a requirement to disclose the origin of a genetic resource in order to obtain an intellectual property right:

The Decision 391. Complementary provisions
Second. The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

Third. The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

Law No. 28216 of 30 April 2004, on the Protection of Access to Peruvian Biological Diversity and Collective Knowledge of Indigenous Peoples, harmonizes Decision 391 with established mechanisms to identify and follow patent applications:

*Article 4.- Functions of the Commission
The Commission shall have the following functions:*

- (a) Establishing and maintaining a register of biological resources and collective knowledge of Indigenous Peoples of Peru.*
- (b) Providing protection against acts of biopiracy.*
- (c) Identifying and following up patent applications filed or patents granted abroad that relate to biological resources or the collective knowledge of indigenous peoples of Peru.*
- (d) Carrying out technical evaluations of the above-mentioned patent applications filed and patents granted.*
- (e) Issuing reports concerning cases studied, making recommendations for action in the competent State authorities.*
- (f) Lodging objections or instituting actions for annulment concerning patent applications filed and patents granted*

abroad that relate to biological or genetic resources, or the collective knowledge, of indigenous and native peoples of Peru.

- (g) Establishing permanent information and dialog channels with the industrial property offices of other countries.*
- (h) Promoting links with State and civil society regional participatory bodies.*
- (i) Drawing up proposals for the defense of the position of the State and of indigenous and native peoples of Peru in different international fora with a view to preventing and avoiding acts of biopiracy.*

Peru also protects plant varieties through a sui generis regime established by Decision 345 on a Common Regime on the Protection of the Rights of Breeders of New Plant Varieties, and Law No. 28126 of 13 December 2003 to Regulate Infringements to the Rights of Breeders of Protected Plant Varieties.

ANNEX 1H: SOUTH AFRICA

South Africa's patent act was enacted in 1979 and amended by the Patents Amendment Act, No. 14 of 1979; Patents Amendment Act, No. 67 of 1983; Patents Amendment Act, No. 44 of 1986; Patents Amendment Act, No. 76 of 1988; Patents Amendment Act, No. 10 of 2001; and Patents Amendment Act, No. 58 of 2002. Alongside the law, the South African patent system includes regulations (Patent Regulations, No. R6247 of December 15, 1978, as amended by Government Notice No. R1181 in Government Gazette No. 29413 of 1 December 2006).

Section 25 of the Patent Act defines what is not patentable, including discoveries, plant varieties and essentially biological processes:

25. Patentable inventions.

(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

(2) Anything which consists of— (a) a discovery; (b) a scientific theory; (c) a

mathematical method; (d) a literary, dramatic, musical or artistic work or any other aesthetic creation; (e) a scheme, rule or method for performing a mental act, playing a game or doing business; (f) a program for a computer; or (g) the presentation of information, shall not be an invention for the purposes of this Act.

(3) The provisions of subsection (2) shall prevent, only to the extent to which a patent or an application for a patent relates to that thing as such, anything from being treated as an invention for the purposes of this Act.

(4) A patent shall not be granted— (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

There is, to date, no significant case law providing a substantive definition of 'essentially biological process'.

ANNEX 11: UGANDA

Uganda has regional as well as national regulations because of its membership of ARIPO (see Annex 1b): it has signed the Banjul Protocol and Harare Protocol. Uganda's Industrial Property Act 2014 modifies its Patent Act to regulate the granting, registration and protection of patents. Part II defines invention, excluding discoveries, plants and essentially biological processes.

8. Meaning of "invention".

(1) For the purposes of this Part, "invention" means a solution to a specific problem in the field of technology.

(2) Subject to subsection (3), an invention may be, or may relate to, a product or a process.

(3) The following shall not be regarded as inventions and shall be excluded from patent protection—

(a) discoveries, scientific theories and mathematical methods; (b) schemes, rules or methods for doing business, performing purely mental acts or playing games;

(c) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(d) mere presentation of information;

(e) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes; and

(f) pharmaceutical products and test data until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade Organization;

(g) natural substances, whether purified, synthesized or otherwise isolated from nature; except the processes of isolating those natural substances from their original environment; and

(h) the human body and all its elements in whole or in part.

The Industrial Property Act also specifies which inventions are not patentable, including plant varieties:

13. Non-patentable inventions.

The following are not patentable—

(a) plant varieties as provided for in the law providing for the protection of plant varieties;

(b) inventions contrary to public order, morality, public health and safety, public policy, principles of humanity and environmental conservation.

Uganda has implemented regulations on access to and benefit from genetic resources. The 2007 Guidelines for Accessing Genetic Resources and Benefit Sharing in Uganda include conditions, such as prior informed consent (PIC), on obtaining intellectual property rights from genetic resources and associated traditional knowledge:

3.5 Access to Indigenous Knowledge

Uganda recognises and protects the rights of local communities and indigenous populations to benefit from their traditional knowledge collectively, and to receive compensation for the conservation of genetic resources, by means of payments in money, goods, services, intellectual property rights or other mechanisms.

The application of the principle of PIC to the rights of indigenous peoples and other local communities is mandatory. PIC is indeed central to securing the rights of these communities in the context of access to genetic resources activities. Holders of traditional knowledge have the right to be asked and to be informed about requests from other parties to access their knowledge, and to extend or refuse their approval for such access.

Such holders must be actively included in the negotiation of benefits on the basis of a full disclosure of potential benefits and risks arising from the use of the resources. Any

benefit sharing arrangements that may be entered into shall not negatively interfere with traditional knowledge systems and practices of indigenous peoples and local communities. The relevance of PIC is particularly significant due to concerns about companies, research institutions, other entities, and individuals acquiring and using genetic resources and traditional knowledge from communities without the knowledge and permission of the rightful owners and holders. The UNCST shall therefore not issue an access permit to an applicant who has not obtained PIC from a holder of traditional or indigenous knowledge. The UNCST is required to maintain a national reference file, where local communities or indigenous populations, and any other interested parties may deposit records of knowledge associated with genetic resources. The local communities and indigenous populations have exclusive rights over their traditional knowledge, and they alone are entitled to surrender it to the UNCST. Every record deposited in the national reference file shall be submitted to an ethnologic appraisal, and shall be used as a basis for decisions concerning the terms of the contract of access. These records are not mandatory, and their non-existence is not a condition for, neither does it preclude the exercise of any access rights negotiated under the Regulations. Intellectual property rights with respect to products or processes related to traditional

knowledge associated with genetic resources or derived products shall not be recognised if the access has not taken place in accordance with the provisions of the Regulations and these Guidelines.

Local communities that create, develop, hold or preserve indigenous knowledge associated with management or use of genetic resources are guaranteed the right to:

1. have the origin of the access to the indigenous knowledge mentioned in all publications, uses, exploitation and disclosures
 2. prevent unauthorised third parties from using or carrying out tests, research or investigations relating to associated indigenous knowledge
 3. prevent unauthorised third parties from disclosing, broadcasting or re-broadcasting data or information that incorporate or constitute associated indigenous knowledge
 4. derive profit from economic exploitation by third parties of associated indigenous knowledge the rights in which are owned by the community as provided in for under Ugandan laws and international legislation
- For the purposes of the Regulations and these Guidelines, any traditional knowledge associated with management and use of Uganda's genetic resources may be owned by the community, even if only one single member of the community holds that knowledge.

ANNEX 1J: VIETNAM

Vietnam has several regulations, decrees and laws on intellectual property. Regarding patentability of plants, law No. 50/2005/QH11 establishes which subject matter is not considered as an invention: a natural plant genetic trait can be considered as a discovery and not patentable, in accordance with Article 59; the same could be said of a essentially biological process for producing such plant, though there is no definition of essentially biological process:

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;*
- 2. Schemes, plans, rules and methods for performing mental acts, training domestic animals, playing games, doing business; computer programs;*
- 3. Presentations of information;*
- 4. Solutions of aesthetical characteristics only;*
- 5. Plant varieties, animal breeds;*
- 6. Processes of plant or animal production which are principally of biological nature other than microbiological ones;*
- 7. Human and animal disease prevention, diagnostic and treatment methods.*

Vietnam also has protection for plant varieties by way of a sui generis regime, enacted by an ordinance in 2004.



Notes

- ¹² 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.
- ¹³ Monsanto Canada Inc. v. Schmeiser. Retrieved from <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2147/index.do>.
- ¹⁴ 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.
- ¹⁵ United States Congress – Office of Technology Assessment. (1989). *New Developments in Biotechnology: Patenting Life – Special Report*. Washington DC: U.S. Government Printing Office. Retrieved from http://www.wws.princeton.edu/~ota/ns20/pubs_f.html. See also e.g. J. H. Barton. (1991). 'Patenting life'. *Scientific American*, 264, 40–46; P. Dacor. (1998). *Patenting the Recombinant Products of Biotechnology and Other Molecules*. London, The Hague, Boston: Kluwer Law International.
- ¹⁶ See e.g. C. H. Agris. (1999). *Patenting plants: What to claim?* *Nature Biotechnology* 17 (7) 1999, 717–18; M. Parvin. (2009). *Patentability of plants: technical and legal aspects*. *Journal of Intellectual Property Rights*, 14, 203–13.
- ¹⁷ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
- ¹⁸ *Ex parte Hibberd*, 227 USPQ 443 [Bd. Pat. App. S. Inter. 1985].
- ¹⁹ *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001).
- ²⁰ The academic literature on US developments has extensively examined what was patentable subject matter under US law and many questions about the reach of biotechnology patents that the courts needed to settle. See e.g. M. D. Janis. (2001). *Sustainable Agriculture, Patent Rights, and Plant Innovation*, *Indiana Journal of Global Legal Studies*, Volume 9, Issue 1, Article 6. Retrieved from <http://www.repository.law.indiana.edu/ijgls/vol9/iss1/6/>
- ²¹ See e.g. J. M. Dunwell. (2005). *Review: intellectual property aspects of plant transformation*. *Plant Biotechnology Journal*, 3: 371–84, doi:10.1111/j.1467-7652.2005.00142.x.
- ²² S. J. R. Bostyn. (2004). *Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation*. Luxembourg: European Communities. S. J. R. Bostyn. *Patentability of Plants: At the Crossroads between Monopolizing Nature and Protecting Technological Innovation?* *The Journal of World Intellectual Property*, 2013, 16, 105–49.
- ²³ M. Llewelyn. (2000). *The patentability of biological material: continuing contradiction and confusion*. *European Intellectual Property Review*, 22(5), 191–7.
- ²⁴ See e.g. V. Santaniello et al. (2000). *Agriculture and Intellectual Property Rights: Economic, Institutional, and Implementation Issues in Biotechnology*. CABI Publishing. E. Binenbaum et al. (2003). *South–North trade, intellectual property jurisdictions, and freedom to operate in agricultural research on staple crops*. *Economic Development and Cultural Change*, 51, 309–35.
- ²⁵ See e.g. S. C. Price. (1992). *The economic impact of novel genes in plant biotechnology: not without strong intellectual property rights*. San Diego: Academic Press. R. P. Adams and J. E. Adams. (1992). *Conservation of plant genes: DNA banking and in vitro biotechnology*. San Diego: Academic Press.
- ²⁶ J. Wijk. (1996). *How does stronger protection of intellectual property rights affect seed supply? Early evidence of impact*. *Natural Resource Perspectives* No. 13. London: Overseas Development Institute. Retrieved from <http://www.odi.org.uk/nrp/index.html>
- ²⁷ See e.g. R. McNally and P. Wheale. (1996). *Biopatenting and biodiversity: comparative advantages in the new global order*. *The Ecologist*, 26(5), 222–8.
- ²⁸ See e.g. A. Harfouche et al. (2012). *Intellectual property rights of biotechnologically improved plants*. In *Plant Biotechnology and Agriculture*. San Diego: Academic Press, 525–39.
- ²⁹ See A. Max Jarvie. (2016). *Productivity and Diversity in Research and Agriculture: Improving the IPR Landscape for Food Security*, *William & Mary Environmental Law & Policy Review*, 40, 849–892.
- ³⁰ See e.g. K. Singh. (2016). *Intellectual property rights in agricultural biotechnology and access to technology: a critical appraisal*, *Asian Biotechnology and Development Review*, 18(3), 3–23. M. C. Gomes da Silva d'Ornellas and J. Tonello. (2013). *Intensificação de proteção da propriedade intelectual na área da biotecnologia agrícola e impactos no desenvolvimento da agricultura nacional*. In *Direito, Inovação e desenvolvimento: tópicos de propriedade intelectual e concorrência*, 123–65.
- ³¹ The selected countries and regional organizations are Argentina, ARIPO, Brazil, China, India, OAPI, Peru, South Africa, Uganda and Vietnam.
- ³² Samples were obtained from public databases from Argentina, Brazil, China, India and South Africa. Online information was not obtainable from Peru, Uganda, Vietnam, ARIPO and OAPI. These samples are included in Annex 3, which can be found online at: <https://www.sdhspgrom.org/publications/statusofpatentingplantsintheglobalsouth>
- ³³ The research also looked into FTAs signed with the European Union, but these do not include an obligation to grant or endeavour to grant patents on plants.
- ³⁴ 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).
- ³⁵ The Convention currently has 177 contracting parties. See http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=2.
- ³⁶ The rest of this section is substantially based on C. M. Correa. (2014). *Patent Protection for Plants: Legal Options for Developing Countries*. Research Paper 55. Geneva: South Centre.
- ³⁷ Article 15.9(2): 'Each Party shall make patents available for the following inventions: (a) plants, and (b) animals...'
- ³⁸ It has been interpreted in this regard that '(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'. P. Roffe. (2004). *Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement*. TRIPS Issues Papers 4, QIAP, 21. Retrieved from http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_other_Topics/Chile-USAFTAP.Roffe.pdf
- ³⁹ See article 37(b) of Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3), retrieved from <http://www.leychile.cl/N?i=250708&f=20070104&p=>
- ⁴⁰ See also article 16.9(2) of the US FTA with Peru.
- ⁴¹ 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.'
- ⁴² Article 27.2: 'Members may exclude from patentability inventions, the prevention within their 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 their law'. Article 27.3: 'Members may also exclude from patentability:...[a] diagnostic, therapeutic and surgical methods for the treatment of humans or animals;...'
- ⁴³ Article 15.8: Patents 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.'

⁴⁴ Now renamed as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

⁴⁵ See M. Geist. (2017). *Rethinking IP in the TPP: Canadian Government Plays Key Role in Suspending Unbalanced Patent and Copyright Rules*. Retrieved from <http://www.michaelgeist.ca/2017/11/rethinking-ip-in-the-tp/>

⁴⁶ Annex 2 can be found online at <https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth>

⁴⁷ As further discussed below, the exclusion of plants may be deemed to encompass gene constructs, cells and other parts and components.

⁴⁸ 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. In India, for instance, there are no judicial decisions yet on issues relating to the patentability of plants and plant materials, but some cases are pending before the High Court of Delhi. In Vietnam no decision has been identified.

⁴⁹ For instance, Monsanto filed lawsuits in courts of Brazil and Argentina contesting patent offices' decisions denying patents over transgenic modifications.

⁵⁰ Information on granted patents (based on the International Patent Classification) is not always readily accessible in developing countries. The study 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.

⁵¹ In accordance with 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 recognized, while 'invention' is the result of the action of humans on the forces of nature, which necessarily implies a human

contribution.

⁵² Article 52(2)(a) of the European Patent Convention.

⁵³ The European Directive on Biotechnological Inventions (98/44/EC of 6 July 1998) 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).

⁵⁴ 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 Arabidopsis thaliana diacylglycerol acyl 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.

⁵⁵ Association for Molecular Pathology v. Myriad Genetics, 569 US 12-398 (2013).

⁵⁶ However, as noted below, the court considered that cDNA (a form of DNA artificially synthesized used in genetic engineering to produce gene clones) was patentable.

⁵⁷ See e.g. W. Li and L. Cai. (2014). *The Scope of patent protection for gene technology in China*. *Nature Biotechnology*, 32, 1001-3.

⁵⁸ B. Ravi. (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, 323-29.

⁵⁹ 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.

⁶⁰ This decision established, inter alia, that a claim over a nucleic sequence which is introgressed and hybridized into a transgenic plant falls under the exclusions of section 3(j) of the Patents Act. See <https://indiankanoon.org/doc/96804771/>

⁶¹ A possible modification of the genetic material is the so-called complementary DNA or 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 US 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 e.g. A. Liptak. (2013). *Supreme Court Rules Human Genes May Not Be Patented*, retrieved from <http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html>

⁶² For instance, patent AP3098 (2005) granted to Monsanto Technology Ltd. in Uganda covers chloroplast transit peptides for efficient targeting of DMO and uses thereof.

⁶³ INPI Resolution No. 44, 2015, retrieved from http://www.inpi.gov.br/menu-servicos/patente/consultas-publicas/arquivos/resolucao_144-2015_-_diretrizes_biocologia.pdf/view

⁶⁴ Fourteen patents were granted in Brazil in relation to Monsanto's RR1 technology, the last of which expired in 2010. See C. de Avila. (2016). *Da expectativa de direitos da Monsanto no Brasil sobre os pedidos de patente da 'tecnologia' Intacta RR2 PRO: onde está de fato a inovação?* (231) and *A antinomia jurídica da intercessão entre patentes e cultivares* (177). In D. Borges Barbosa and M. Wachowicz (eds). *Propriedade Intelectual. Desenvolvimento na Agricultura*. Curitiba: GEDAI.

⁶⁵ Bayer CropScience S/A v Instituto Nacional da Propriedade Industrial (Recurso Especial No. 1.201.981 - RJ 2010/0120977-6).

⁶⁶ See e.g. *How plants grow and develop*, retrieved from <https://www.wur.nl/en/newsarticle/How-plants-grow-and-develop.htm>

⁶⁷ 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 to 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 (LKR), which consequently allows a greater accumulation of the amino acid lysine in the transgenic maize plant.

⁶⁸ Monsanto Technology LLC c/ Instituto Nacional de la Propiedad Industrial s/ denegatoria de

- patente, Causa n° 8.044/07/CA1, 26-11-2015.
- ⁶⁹ Reportedly, the guidelines on biotechnological patents adopted in 2015 in Argentina (Resolución INPI P283, 25-9-2015) has led to the rejection of most examined patent applications relating to plants.
- ⁷⁰ Resolución No. 000765-2012/DIN-INDECOPI, 22-06-2012.
- ⁷¹ It is worth noting that GMO crops and food were banned in Peru with the passing of a law on the subject in 2011. See K. Michaelis. Peru Bans Monsanto and GMOs, retrieved from <https://www.foodrenegade.com/peru-bans-monsanto-gmos/>
- ⁷² Resolución No. 001241-2013/DIN-INDECOPI, 23-9-2013.
- ⁷³ Resolución No. 000983-2015/DIN-INDECOPI, 31-07-2015.
- ⁷⁴ Resolución No. 002176-2016/DIN-INDECOPI, 28-12-2016.
- ⁷⁵ See *Monsanto Technology Llc And Ors. vs Nuziveedu Seeds Ltd. And Ors.* on 11 April, 2018, paragraph 82, retrieved from <https://indiankanoon.org/doc/96804771/>
- ⁷⁶ Annex 2 can be found online at <https://www.sdhprogram.org/publications/statusofpatentingplantsintheglobalsouth>
- ⁷⁷ In accordance with Article 27.3 b) of the TRIPS Agreement, plant varieties can be protected by an effective sui generis system, patents or a combination of both.
- ⁷⁸ 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.'
- ⁷⁹ Consejo Superior de Investigaciones Científicas v. INPI, Cámara Federal Civil y Comercial, sala III, 16-3-2016.
- ⁸⁰ 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.
- ⁸¹ For instance, in Decision 62/07 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 realization of the stages of sexual crossing of all the genome of the plants or later wing selection of plants.'
- ⁸² Notably, the experts' opinion is that these countries have no definition of 'essentially biological processes'.
- ⁸³ *Guidelines for Examination of Biotechnology Applications for Patent*. [2013]. Retrieved from http://www.ipindia.nic.in/writereaddata/Portal/IP0GuidelinesManuals/1_38_1_4-biotech-guidelines.pdf
- ⁸⁴ 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 program 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'.
- ⁸⁵ 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'.
- ⁸⁶ Resolución No. 000765-2012/DIN-INDECOPI, 22-06-2012.
- ⁸⁷ Resolución No. 002176-2016/DIN-INDECOPI, 28-12-2016. Native to Central America, this plant is used as a source of biofuel.
- ⁸⁸ Cámara Federal Civil y Comercial, sala III, 16-3-2016.
- ⁸⁹ The court said: 'There is no universally valid scientific concept but that the definition varies according to the criteria of the different national legislations and of the national patent offices of the different countries, a concept which, moreover, varies with time. Therefore, and until the legislator expresses a contrary will, I must follow the concept used by the national patent office of my country, in the conviction that it is not for me to make a merit or convenience judgment. Especially, in the field of biotechnology applied to plants, the legislator has established a sui generis protection through the regime of plant variety rights'.
- ⁹⁰ 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 Cível 1º Juizado.
- ⁹¹ 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.
- ⁹² This type of claim describes what an invention does rather than what it (structurally) is.
- ⁹³ See the decision of the Tribunal de Justicia de la Comunidad Andina en el Proceso 89-AI-2000, Gaceta Oficial N° 722 del 12-10-2001. In other jurisdictions use claims are considered equivalent to and admitted as process claims. See e.g. *Guidelines for Examination*, retrieved from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_4_16.htm
- ⁹⁴ Resolución N° 001230-2017/DIN-INDECOPI, 21-06-2017.
- ⁹⁵ 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 *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* [2016, 8 November].
- ⁹⁶ 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.
- ⁹⁷ S. Thambisetty. [2013]. *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology*, LSE Legal Studies Working Paper No. 20/2013, 24, retrieved from <http://ssrn.com/abstract=2328173>
- ⁹⁸ See e.g. *Report of the Secretary of the International Treaty on Plant Genetic Resources for Food and Agriculture*, IT/GB-5/13/4, Muscat, 2013, para. 7.
- ⁹⁹ 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. S. Webb *Plants in the CRISPR. Future Sciences – BioTechniques*, 63(3), retrieved from <https://www.future-science.com/doi/10.2144/000114583>
- ¹⁰⁰ See e.g. *Patents on CRISPR-related technology are going to become a lot harder to obtain, expert predicts* [2018, 9 March], retrieved from <http://www.iam-media.com/Blog/Detail.aspx?g=0ac5038f-9fdd-472a-ab87-1c91f9149ff6>; Valea Technology and Law. [2018]. *Revocation of a European patent relating*

to CRISPR technology [sic], retrieved from <http://www.valea.eu/en/news/2018/revocation-european-patent-relating-crisp-technology>

¹⁰¹ 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, characterized 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’.

¹⁰² 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’.

¹⁰³ See also Brazilian patent PI 0418683-4 (Dow Agrosciences LLC (US), 2016) that covers a method to detect insect-resistant genetically modified cotton.

¹⁰⁴ Monsanto Technology LLC c/ Instituto Nacional de la Propiedad Industrial s/ denegatoria de patente (Causa no. 8.044/07/CA1, 26-11-2015).

¹⁰⁵ Mycogen Corporation e Outros v. INPI-Instituto Nacional de Propriedade Industrial (CNJ: 0001996-10.2013.4.02.5101, 2013.51.01.001996-4, 25-08-2016).

¹⁰⁶ C. de Avila, *Da expectativa de direitos da Monsanto no Brasil sobre os pedidos de patente da ‘tecnologia’ Intacta RR2 PRO: onde está de fato a inovação?*, op. cit.

¹⁰⁷ Farming Brasil. (2018, 18 January). INPI pede nulidade da patente da soja Intacta da Monsanto, diz Aprosoja, retrieved from <https://sfagro.uol.com.br/soja-intacta-monsanto/>

¹⁰⁸ A. Mano. (2017, 9 November). *Produtores de MT pedem na Justiça nulidade da patente da soja Intacta da Monsanto*, retrieved from

<https://br.reuters.com/article/topNews/idBRKBN1D91AJ-OBRTPI>

¹⁰⁹ Processo 187-IP-2016, on 24 April 2017.

¹¹⁰ See for more information on this approach, see e.g. *Guidelines for Examination*, retrieved from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm

¹¹¹ 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.

¹¹² In several of the decisions by INDECOPI (Peru) mentioned above, objections based on lack of clarity of claims have been raised.

¹¹³ For example, claim 1 of BR 0100752 A reads: ‘A DNA construct characterized 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.ara: CP4’.

¹¹⁴ For example, claim 1 of WO 2006/006956 A2 reads: ‘An isolated polynucleotide characterized 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.

¹¹⁵ Resolución INPI (Argentina) P283, 25-9-2015INPI, para. 1º; Resolución INPI (Brazil) No. 44, 2015, para. 6.2, retrieved from http://www.inpi.gov.br/menu-servicos/patente/consultas-publicas/arquivos/resolucao_144-2015_-_diretrizes_biotechnologia.pdf/view

¹¹⁶ Consejo Superior de Investigaciones Científicas v. INPI, Cámara Federal Civil y Comercial, sala I, 15-05-2003.

¹¹⁷ See Farming Brasil (2018, 18 January), op. cit

¹¹⁸ This Annex can be found online at <https://www.sdhsprogram.org/publications/statusofpatentingplantsintheglobalsouth>

¹¹⁹ South Africa is one of the few African countries where planting of GMOs is admitted.

¹²⁰ A Bill was adopted by the Parliament in December 2017 to create a regulatory framework for the development and release of GMOs in Uganda.

¹²¹ Monsanto’s patent 1-0014994-000.

¹²² Bayer CropScience S/A v. Instituto Nacional da Propriedade Industrial, Recurso Especial No. 1.201.981 – RJ 2010/0120977-6.

¹²³ 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 Cível 1º Juizado.



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