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**Research Report**

## Patent protection for plants: Legal options for developing countries

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October 2014

**55**

# **PATENT PROTECTION FOR PLANTS: LEGAL OPTIONS FOR DEVELOPING COUNTRIES**

Carlos M. Correa





## **RESEARCH PAPERS**

**55**

### **PATENT PROTECTION FOR PLANTS: LEGAL OPTIONS FOR DEVELOPING COUNTRIES**

**Carlos M. Correa**

**SOUTH CENTRE**

**OCTOBER 2014**



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## I. INTRODUCTION

Initiatives for the protection of plants through intellectual property rights emerged in the USA and Europe at the beginning of the Nineteenth Century. They eventually led to the adoption in 1930 of the Plant Patent Act in the USA, which allowed for the grant of patents for asexually reproduced plant varieties, different, however, from the ‘utility patents’. In response to the demands of nurseries and plant breeders, the non-obviousness standard was replaced by ‘distinctness’ and the disclosure requirement was drastically relaxed.<sup>1</sup> In Europe, concerns about the weakening of the patent system generated a strong resistance to the application of patents to plants.<sup>2</sup> A special regime for the protection of plant varieties was introduced in the Netherlands in 1942, followed by Germany in 1953.<sup>3</sup> Based on these precedents, in 1961 an international convention<sup>4</sup> for the *sui generis* protection of such varieties was adopted and the Union for the Protection of Plant Varieties (UPOV) set up.<sup>5</sup>

The US Plant Patent Act of 1930 was not emulated in other countries. The *sui generis* protection of plant varieties based on the UPOV model found new adepts, but remained limited for more than 30 years to a small number of countries, mostly from the developed world. Hence, plants and plant varieties, in particular, were outside the intellectual property system in the majority of countries in the world. This situation dramatically changed in the last 35 years as the result of technological and institutional changes.

On the one hand, advances in biotechnology permitted to genetically modify plants. Demands rose up to obtain patent protection on the genetic constructs and other tools used in the transformation of plants, as well as on the plants themselves. In the USA, the first utility patent relating to a plant was granted *in re Hibberd* in 1985 in relation to a variety of corn modified to contain a higher level of tryptophan. In Europe, the non-patentability of plant varieties – enshrined in the European Patent Convention (EPC) of 1973<sup>6</sup> – did not prevent the extension of patent protection to plants as such. In a landmark case, the Board of the European Patent Office (EPO) decided that ‘a claim wherein specific plant varieties are not individually claimed is not excluded from patentability (...)’.<sup>7</sup>

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<sup>1</sup> See, e.g., Cary Fowler, ‘The Plant Patent Act of 1930: A sociological history of its creation’, available at [http://ipmall.info/hosted\\_resources/lipa/PlantPatent\\_Act/82JPatTrademarkOffSocy621.pdf](http://ipmall.info/hosted_resources/lipa/PlantPatent_Act/82JPatTrademarkOffSocy621.pdf).

<sup>2</sup> The proponents of an amendment to that effect to the Paris Convention for the Protection of Industrial Property were defeated at the Lisbon Diplomatic Conference on the Revision of the Convention held in 1958. See, e.g., Dhar, Biswajit (2002), *Sui Generis Systems for Plant Variety Protection. Options under TRIPS*, available at <http://www.qiap.ca/documents/SGcoll1.pdf>, p. 4.

<sup>3</sup> See Van Overwalle, Geertrui (1999), ‘Patent Protection for Plants: A Comparison of American and European Approaches’, *IDEA- The Journal of Law and Technology*, Vol. 39, No. 2, p. 161. The German law of 1953 set an important precedent by exempting breeding activity from liability. See, e.g., Mark D. Janis and Jay Kesan, (2002). *U.S. Plant Variety Protection: Sound and Fury ...?*, University of Illinois Working Paper No. LE03–002, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=384140](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=384140), p. 739.

<sup>4</sup> The UPOV Convention was revised on three occasions, in 1972, 1978 and 1991.

<sup>5</sup> See, e.g., André Heitz, ‘The History of Plant Variety Protection’, in UPOV, *The First Twenty-five Years of the International Convention for the Protection of New Varieties of Plants*, Geneva, 1987.

<sup>6</sup> It is worth noting that the UPOV Convention in its 1961 and 1978 versions prevented UPOV members to simultaneously protect plant varieties under breeders’ rights and patents, in line with the approach followed in Europe. This ban was lifted in the 1991 revision of the Convention.

<sup>7</sup> See *Transgenic Plant/Novartis II* OJ EPO 2000, (Decision 12 G 1/98 of the Enlarged Board of Appeal) 141.

On the other, article 27.3(b) of the TRIPS Agreement mandated the protection of ‘plant varieties’ through patents, an effective *sui generis* system or a combination of both. This obligation prompted a large number of developing countries to join UPOV and to implement national laws modelled under the UPOV Convention, whose membership dramatically increased from 27 to 72 contracting parties since 1995. A few developing countries (e.g. Egypt, India, Malaysia, Thailand) enacted *sui generis* laws that, although are not UPOV-compliant, became subject to the disciplines of the TRIPS Agreement.<sup>8</sup> While the latter, as discussed below, allowed WTO members to exclude ‘plants’ from patentability, many countries limited such exclusion to ‘plant varieties’ (in line with the European approach) thereby allowing for the patenting of plants and their parts and components. The extension of patent protection to plants was also prompted in some cases by clauses introduced by the USA in free trade agreements entered into with a number of developing countries.<sup>9</sup>

Moreover, even in countries where the legislation excludes plants and plant varieties from patent protection, patents have been sought and granted on genetic constructs, cells and other parts and components of plants. In some cases, the expansion of the coverage of patents to those matters was the result of a misconception about the concept of ‘microorganism’. If they meet the patentability criteria, microorganisms must be patented in accordance with the TRIPS Agreement (article 27.3(b)). Although the ordinary meaning of ‘microorganism’ does not encompass cells or its components, the practice and jurisprudence of the EPO and of other patent offices<sup>10</sup> has extended that concept to include plant cells and sub-cellular parts.

As a result of these trends, in one way or another, currently patent laws apply to plants, including in some cases, plant varieties, or to cells, genes and other components of plants. In most countries, however, such laws have not introduced provisions to deal with the specific problems that the patenting of plant-related materials bring about, for instance, the fact that seeds may be self-reproduced or that a single plant may incorporate several patented gene constructs or components, eventually owned by different right-holders.

This paper is based on the premise that the best policy option is to exclude plants from patent protection. However, if plants or their parts and components are patentable, the applicable laws need to incorporate provisions that take the specific features of such materials (biological origin, reproducibility, etc.) into account.

The paper examines, first, the **exclusion** of patent protection for plants, including plant varieties, biological materials, and essentially biological processes for the production of plants. The legal implications of the right – recognized under the TRIPS Agreement – to exclude plants from patent protection are briefly discussed, as well as how the exclusion

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<sup>8</sup> In *United States – Section 211 Omnibus Appropriations Act of 1998*, AB-2001-7, WT/DS176/AB/R (2 January 2002), the WTO Appellate Body referred to the *sui generis* protection for plant varieties as an example of rights that, although not expressly mentioned in article 1(2) of the TRIPS Agreement (as it was also the case of trade names) were in fact a form of intellectual property protected by the Agreement (para. 335).

<sup>9</sup> Some of these clauses were crafted as ‘best endeavor’ obligations (see below).

<sup>10</sup> In accordance with the EPO Guidelines for patent examination, for instance, the definition of ‘microorganism’ encompasses ‘bacteria and other generally unicellular organisms (...), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells’ (EPO Guidelines, Part G, Chapter II, Section 5.5.1).

allowed by article 27.3(b) of said Agreement<sup>11</sup> has been implemented at the national level and, particularly, whether it can be extended to parts and components of plants.

Second, the paper describes the obligation to grant patents on plants imposed under several free trade agreements (FTAs) entered into between the USA and developing countries. Third, it analyses possible limitations to the **scope** of patents relating to plants. Fourth, possible **exceptions** to the exclusive rights normally granted by a patent are examined, including the question of whether introducing specific provisions on plant materials is compatible with the non-discrimination clause of article 27.3(b) of the TRIPS Agreement. Fifth, the paper briefly considers how to address the overlapping of plant variety protection (PVP) and patent protection and the issue of infringement and permanent injunctions. Finally, some conclusions and recommendations are made.

## II. EXCLUSIONS FROM PATENTABILITY

In accordance with article 27.3(b) of the TRIPS Agreement, WTO members ‘may’ 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’.

Despite this option to exclude plants from patent protection<sup>12</sup>, not all countries do provide for an exception of this kind. For instance, in the USA plants, including plant varieties, may be protected under utility patents; asexually reproduced plant varieties may also be protected under the referred to Plant Patent Act of 1930 which introduces a *sui generis* form of patent protection. As discussed below, countries that have signed FTAs with the USA have been obliged by these agreements to grant patents on plants.

Most countries, however, provide for exceptions relating to plants, with different scope, either in relation to ‘plants’ or ‘plant varieties’. Some laws also make ineligible for patent protection, in general, biological or genetic material, without specific reference to plants. A WIPO Secretariat study<sup>13</sup> found that the exclusions are framed under national laws with diverse wording, such as:

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<sup>11</sup> This paper does not address the exclusions from patent protection that may be implemented on the basis of article 27.2 of the TRIPS Agreement. See on the subject, e.g. Carlos Correa, *TRIPS-Related Patent Flexibilities and Food Security. Options for Developing Countries*, ICTSD-QUNO, Geneva, 2012, available at <http://www.quno.org/resource/2012/9/trips-related-patent-flexibilities-and-food-security-options-developing-countries>.

<sup>12</sup> Patents confer exclusive rights for the use of the invention, generally for twenty years from the date of filing of the application. They are characterized in many jurisdictions as legal ‘monopolies’. See, e.g., *Federal Trade Commission v. Actavis, Inc., et al* (2013) Certiorari to the United States Court of Appeals for the Eleventh Circuit No. 12-416; European Court of Justice *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE*, ([2008] ECR I-7139, § 64, ECJ, C-468/06 to C-478/06).

<sup>13</sup> WIPO, *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, Document prepared by the Secretariat, SCP/13/3, 2009, available at [http://www.wipo.int/edocs/mdocs/scp/en/scp\\_13/scp\\_13\\_3.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_3.pdf), p. 16.

“plants and animals except microorganisms”;

“plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species”;

“living materials and substances already existing in nature”;

“biological and genetic material occurring in nature or derived therefrom by reproduction”;

“natural biological materials”;

“living beings, in whole or in part, other than transgenic microorganisms”;

“natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom”.

The scope of the exclusion will significantly vary depending on the formulation of the relevant legal provision.

The exclusion of plants from patentability is the best option for countries willing to avoid the monopolization of plant genetic resources, including their parts and components, such as genes. WTO members are obliged to grant some form of protection to plant varieties but such a protection does not need to be on the basis of patent grants. The patent protection of plants may limit the use of plant materials for further breeding, prevent farmers from saving and re-using seeds obtained in their own fields, and significantly increase the cost of seeds for farmers.

It is worth noting that in the context of the unfinished review of Article 27.3(b), the African Group has demanded that Article 27.3(b) be amended to clarify that no life forms and living processes can be patented; moreover, the African Group submitted that a review of Article 27.3(b) should preserve the room existing at the national level to develop specific modalities of protection for traditional knowledge.<sup>14</sup>

More recently, Bolivia has proposed to amend article 27.3(b) to prohibit the patenting of all life forms, protect innovations of indigenous and local farming communities and their farming practices, prevent anti-competitive practices, protect the rights of indigenous communities and prevent any IPR claims over their traditional knowledge.<sup>15</sup>

Although these proposals are unlikely to be palatable to many WTO member countries, they point to the need to exploit the current flexibility under the TRIPS Agreement and provide for an exclusion from patentability of plants, including plant varieties in national laws.

It is important to note that if, despite the right recognized under the TRIPS Agreement to exclude plants or any taxonomic classification thereof (such as plant varieties) from patent

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<sup>14</sup> WT/GC/W/302 of 6 August 1999 and IP/C/W/206 of 20 September 2000.

<sup>15</sup> IP/C/W/545, February 2010. See also IP/C/W/554, March 2011, where Bolivia proposes to amend article 27.3(b) to prohibit the patenting of life forms and parts thereof.

protection, a WTO member decides to grant patents in the area of plants, they can **limit** the rights conferred in a manner that would not be permissible for subject matter that cannot be excluded from such protection. Provided that the national treatment and most-favoured clauses are complied with, such a limitation would be compatible with the TRIPS Agreement since *qui potest plus, potest minus*.

In effect, since a WTO member country can deny patent protection for plants altogether, *a fortiori*, it also has the option of granting patent protection but restrain the **rights** conferred in different ways. For instance, national laws might narrow down the **scope** of the exclusion so as to:

- allow for the patentability of plants for non-food crops but exclude it for food-crops in general or for those that are particularly important for food security;
- limit patentability to plants that are mainly exploited for exports, such as flowers;
- grant patents over genetically modified plants if they meet certain environmental requirements only, and exclude cases (such as the so-called ‘genetic use restriction technology’ or ‘Terminator’ technology).<sup>16</sup>

National laws may also *limit the rights* conferred by patents relating to plants (the protection could have been refused in the first place) and introduce, for instance, *special exceptions* in relation to the use of protected materials to develop and commercialize new plant varieties, as discussed below.

The following sub-sections examine how article 27.3(b) of the TRIPS Agreement provision can be interpreted in relation to the exclusion of plants from patentability, and how the permitted exclusion has been implemented in different countries.

## II.1 Plants

### (1) *Exclusion of ‘plants’*

In countries where the patentability of ‘plants’ is excluded – as literally allowed by the TRIPS Agreement – plants individually considered, whether claimed as found in the wild, or modified by conventional breeding or genetic transformation techniques, would not be eligible for patent protection. In the absence of any differentiation, the concept of ‘plants’ is broad enough to cover all possible forms in which they may exist. Thus, under a provision excluding ‘plants’ a genetically modified plant that, for instance, is resistant to a herbicide because of the introduction of a transgene<sup>17</sup> – or of an artificial transformation event<sup>18</sup> – would be non-patentable.

<sup>16</sup> Article 29(3) of the Indian Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act) prohibits the grant of plant variety protection where a technology is used to prevent the reproduction of plants.

<sup>17</sup> ‘Transgene’ is a gene that is taken from the genome of one organism and introduced into the genome of another organism with artificial techniques. See <http://www.merriam-webster.com/dictionary/transgene>. See, e.g., patent US 7888122 B2 on a ‘transgenic plant comprising in its genome a transgene encoding a member FLOWERING LOCUS C (FLC) gene family; having early timing of its flowering’, available at

Importantly, an exception applicable to ‘plants’ covers ‘plant varieties’, that is, a population of plants that share some features,<sup>19</sup> even in the absence of express wording relating to such varieties.

A further question is whether an exclusion of plants from patentability in accordance with the TRIPS Agreement may be interpreted as comprising of plant cells, genes and other sub-cellular components, whether claimed as they are found in nature, or artificially made.

The non-patentability of a plant may be irrelevant, in practice, if the patenting of parts and components of the plant is allowed. A patent owner will be normally entitled to prevent the commercialization and other acts relating to a plant that **contains** a patented material, even if the plant as such is not patentable. This might be the case even where **a single** transgene (or a transformation event) is incorporated into a plant made up of thousands of coding genes.<sup>20</sup> In one case discussed below, for instance, Monsanto, the US biotechnology company, attempted to prevent the commercialization in some European countries of soya meal produced in Argentina on the argument that it contained traces of a transformation event (commercially known as ‘Round Up Ready’) patented in those countries.

While the text of the TRIPS Agreement does not explicitly refer to parts and components of a plant as an excludable subject matter, WTO member countries can exclude them from patentability consistently with that Agreement.

Firstly, it would be illogical to authorize the exclusion of plants and, at the same time, deny the same treatment to their parts and components in a way that would frustrate the exclusion itself. A different interpretation would be at odds with the principle of effectiveness (*‘effet utile’*) recognized under international customary law as a basic corollary of the interpretive rules codified by the Vienna Convention on the Law of the Treaties.<sup>21</sup> Thus, in the *US-Gasoline* case the WTO Appellate body held that

[O]ne of the corollaries of the “general rule of interpretation” in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms

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[https://www.google.com/patents/US7888122?dq=transgene+plant&hl=en&sa=X&ei=7Lr1U\\_\\_3A8LRywO60IH4CA&ved=0CB4Q6AEwAA](https://www.google.com/patents/US7888122?dq=transgene+plant&hl=en&sa=X&ei=7Lr1U__3A8LRywO60IH4CA&ved=0CB4Q6AEwAA).

<sup>18</sup> See, for instance, US patent 6040497, which claims ‘Glyphosate resistant maize lines’ modified by an artificially constructed ‘transformation event’, available at <http://www.google.com/patents/US6040497>.

<sup>19</sup> A ‘plant variety’ is a grouping or population of plants that share certain characteristics. The UPOV Convention (article 1(vi), UPOV 1991), for instance, defines that concept taxonomically as ‘a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged’.

<sup>20</sup> For instance, the study of the genome of an inbred line of maize called B73, an important commercial crop variety, revealed the presence of more than 32,000 protein-coding genes spread across maize’s 10 chromosomes. See Elie Dolgin, ‘Maize genome mapped. Sequence should help corn breeders meet global demands for food and fuel’, *Nature*, 19 November 2009, available at <http://www.nature.com/news/2009/091119/full/news.2009.1098.html>.

<sup>21</sup> Available at [http://legal.un.org/ilc/texts/instruments/english/conventions/1\\_1\\_1969.pdf](http://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf).

of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.<sup>22</sup>

An interpretation that allows for the non-patentability of plants *and* their parts and components is the only one that guarantees a practical effect of the permitted exclusion.

Secondly, article 27.3(b) textually alludes to ‘plants... except microorganisms’. The negotiating parties were, hence, explicit about what was excluded from the exception. They could have excluded plant parts and components if they would have wished to. Importantly, cells and sub-cellular components, including genes, are not ‘microorganisms’, which are **organisms** not visible with the naked eye, such as bacteria, viruses, or fungi.<sup>23</sup>

Thirdly, although in a different context, article 12.3(d) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)<sup>24</sup> prevents recipients of plant materials under the ‘Multilateral System’ from claiming intellectual property rights over whole plants or ‘their genetic parts or components’.<sup>25</sup> The Preamble to the treaty clarifies that ‘nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements’, thereby suggesting that the referred ban is consistent with the TRIPS Agreement.

## (2) *Exclusion of ‘plant varieties’*

Following the approach adopted by the European Patent Convention (EPC) in 1973, many national laws only partially use the flexibility introduced by article 27.3(b) of the TRIPS Agreement and allow for the exclusion of ‘plant varieties’ only. Formulated in this way, the exclusion does not affect the possible patentability of individual plants, if the patentability standards are met. The exclusion of ‘plant varieties’ only is much narrower than one referring to ‘plants’ without any taxonomic reference.

Notably, there is nothing in the TRIPS Agreement requiring WTO members to limit the exclusion of patentability to plant varieties, nor a justification to do so at least in the case of developing countries. The grant of patents over plants is unlikely to promote biotechnological innovation in plants, which is highly concentrated in the hands of a few multinational companies.<sup>26</sup> In addition, the appropriation of plants under patents may prevent

<sup>22</sup> US-Gasoline, WT/DS2/AB/R, p. 23, DSR 1996:I, p. 3 at 21. In *Canada – Dairy*, the Appellate Body also stated that ‘... the task of the treaty interpreter is to ascertain and give effect to a legally operative meaning for the terms of the treaty. The applicable fundamental principle of *effet utile* is that a treaty interpreter is not free to adopt a meaning that would reduce parts of a treaty to redundancy or inutility’, WT/DS103/AB/R, WT/DS113/AB/R, WT/DS103/AB/R/Corr.1, WT/DS113/AB/R/Corr.1, para. 133. The European Court of Justice, similarly, ‘refers to the so-called *effet utile*, which means that amongst several possible interpretations the one will prevail which best guarantees the practical effect of existing community law’ (<http://www.zar.kit.edu/DATA/projektseiten/ECJ-ALAI/DATA/script/III1.htm>).

<sup>23</sup> See, e.g., Mike Adcock and Dr Margaret Llewelyn, *Micro-organisms, Definitions and Options under TRIPS*, QUNO Occasional Paper 2, Geneva, available at [http://www.iatp.org/files/Micro-organisms\\_Definitions\\_and\\_Options\\_under\\_.htm](http://www.iatp.org/files/Micro-organisms_Definitions_and_Options_under_.htm).

<sup>24</sup> Available at <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>.

<sup>25</sup> Article 12.3(d): ‘Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System’.

<sup>26</sup> In accordance with one estimate, Six biotech large companies account for 76% of total private R&D expenditures in both the seed and agrochemical sectors. See Hope Shands, ‘The Big Six: a profile of corporate power in seeds, agrochemicals and biotech’, *The Heritage Farm Companion*, 2012, available at

research and breeding with patented materials – and thereby deter rather than promote innovation – while food security may be negatively affected through the limitation of possible sources of supply of seeds.<sup>27</sup>

### (3) *Exclusion of living, biological or genetic materials*

Those laws that exclude biological materials in general, as per different formulations, may also lead to the non-patentability of plants and their parts and components, as well as of plant varieties. This will depend, however, on whether the exclusion applies to all such materials or to only those claimed as found in nature.<sup>28</sup> In the latter case, the exclusion would encompass wild plants and their parts and components, but may not cover genetically modified plants, transformation events, modified cells and plant varieties (which are also developed with human intervention).

Thus, a provision in national law of the type “living materials and substances already existing in nature” will not exempt from patent protection modified plants and their parts and components, nor plant varieties. This kind of provision spells out what is not an invention, rather than excluding from patentability subject matter that would be otherwise protectable.

Under European law, materials found in nature, including genes (DNA) may be deemed patentable:

Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.<sup>29</sup>

National laws and policies, however, may exclude DNA – which is not invented but just discovered – from patent protection. For example, the Brazilian Industrial Property Code (No. 9.279, 14 May 1996) excludes from patentability living beings or “biological materials found in nature”, even if isolated, including the “genome or germplasm” of any living being (article 10.IX). The Biodiversity Law of Costa Rica (1998) establishes the non-patentability of sequences of DNA per se.<sup>30</sup> In the USA, the patentability of ‘isolated’ DNA (as different from ‘natural’ DNA) was considered in *Association for Molecular Pathology v Myriad Genetics* 569 U.S. 12-398 (2013). The district court decision deemed such a differentiation as artificial. It ruled that patents over isolated DNA were ‘improperly granted’ since they involved a law of nature. The judge noted that the practice of patenting isolated DNA could be seen as a ‘lawyer’s trick’:

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[http://www.seedsavers.org/site/pdf/HeritageFarmCompanion\\_BigSix.pdf](http://www.seedsavers.org/site/pdf/HeritageFarmCompanion_BigSix.pdf). See also James F. Oehmke and Christopher A. Wolf, ‘Measuring Concentration in the Biotechnology R&D Industry: Adjusting for Interfirm Transfer of Genetic Materials’, *The Journal of Agrobiotechnology Management & Economics*, Volume 6 // Number 3 // Article 7, 2004, available at <http://www.agbioforum.org/v6n3/v6n3a07-oehmke.htm> (arguing that the concentration in plant biotechnology R&D is higher and more consistent over time than traditional concentration measures indicate);

<sup>27</sup> See, e.g., Carlos Correa, 2012, op. cit.

<sup>28</sup> For example, Decision 486 of the Andean Community and the Argentine patent law consider non-patentable substances that pre-exist in nature.

<sup>29</sup> Article 3.2, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13.

<sup>30</sup> See Carlos Correa, ‘Patenting Human DNA: What Flexibilities Does the TRIPS Agreement Allow?’, *The Journal of World Intellectual Property*, Vol. 10, no. 6, 2007, pp. 419-437.



Many, however, including scientists in the field of molecular biology and genomics, have considered this practice a "lawyer's trick" that circumvents the prohibitions on the direct patenting of DNA in our bodies but which, in practice, reaches the same result. The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.<sup>31</sup>

Interestingly, in an *amicus curiae* submitted in these proceedings, the US Department of Justice noted that

[T]he chemical structure of native human genes is a product of nature, and it is no less a product of nature when the structure is 'isolated' from its natural environment than are cotton fibres that have been separated from the cotton seeds or coal that has been extracted from the earth."

The US Supreme Court final decision on this case held that naturally occurring isolated DNA is not valid patentable subject matter.<sup>32</sup> This is an important conclusion that may change decades of a wrong policy by the US patent office and influence how the issue is tackled in other countries.<sup>33</sup> However, the court made a questionable distinction between DNA and 'cDNA', a synthesized DNA used in genetic engineering to produce gene clones, which contains the same information found in a natural DNA but omits portions within the DNA segment that do not code for proteins (introns). The court stated that cDNA could be patentable, thereby ignoring that a 'molecule housing the DNA of a naturally occurring protein is not "markedly different" from anything found in nature just as "isolated and purified DNA" is not. Both are artificial, but neither are 'inventions'.<sup>34</sup>

The change in the policy of the USA regarding patents on isolated genes provides a good example of the policy space left by the TRIPS Agreement to determine what an 'invention' is. However, national laws may exclude both DNA and cDNA from patentability, so as to prevent the appropriation of plant genetic materials even if claimed as isolated or in a synthesized form.

## II.2 Essentially Biological Processes

In accordance with article 27.3(b) of the TRIPS Agreement, WTO members 'may also exclude from patentability 'essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'.

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<sup>31</sup> United States District Court Southern District of New York, Case 1:09-cv-04515-RWS, available at <http://patentlyo.com/media/docs/2010/03/myriad-opinion.pdf>.

<sup>32</sup> Gostin LO, "Who Owns Human Genes? Is DNA Patentable?" (2013) *JAMA* 310: 791.

<sup>33</sup> See, e.g., Luigi Palombi, 'Patenting of naturally occurring 'isolated' biological materials, Asian Biotechnology and Development Review, vol. 15, No. 2, 2013, p. 27.

<sup>34</sup> Adam Liptak, 'Supreme Court Rules Human Genes May Not Be Patented' (2013), available at [http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?\\_r=0](http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?_r=0).

This provision of the TRIPS Agreement was unequivocally inspired by the EPC of 1973. Article 53(b) of the EPC reads:

European patents shall not be granted in respect of:...

(b) ...essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

While the TRIPS Agreement has literally followed this text, there are two important differences with the EPC. On the one hand, the exclusion under the latter is mandatory, while it is only facultative under the TRIPS Agreement. This is a key difference, since members of the EPC are obliged to respect the exclusion.

On the other, the TRIPS Agreement introduces the concept of ‘non-biological’ processes, absent in the EPC. This is a superfluous clarification, indeed. Any possible reading of ‘essentially biological’ excludes processes that are **not** biological, such as the use of irradiation to produce targeted transformations in plants.

Many patent laws have literally introduced the concept of ‘essentially biological process’ as a result of the implementation of the TRIPS Agreement or the earlier adoption of the EPC model. Most laws, however, do not define the concept<sup>35</sup> and have left its application to interpretations by patent offices and courts. In Europe and other countries much of the discussion surrounding this ambiguous concept has focused on the **degree of human intervention** required to consider that a process is “essentially” biological or not.

In *Hybrid Plants/Lubrizol* (T-320/87) of 1988 the EPO Board of Appeal provided an interpretation that basically set the standard for EPO’s future jurisprudence on the matter. The case concerned a process for rapidly developing hybrids and producing hybrid seeds based on the conventional steps of crossing and cloning, but applied in a reverse sequence. The Board observed:

This arrangement of steps is decisive for the invention and permits the desired control of the special result in spite of the fact that at least one of the parents is heterozygous. The facts of the present case under appeal clearly indicate that the claimed processes for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product in the present case show important technological character.

As further elaborated in other EPO decisions<sup>36</sup>, the determination of what is ‘essentially biological’ became, under EPO rules, dependent on the degree and impact of

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<sup>35</sup> An exception is article 37(b) of the patent law of Chile which states: ‘the words “an essentially biological process” shall mean one that consists entirely of natural phenomena, such as crossing and selection’ (Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3) available at <http://www.leychile.cl/N?i=250708&f=20070104&p=>. This wording reproduces EPC Rule 26 (5) mentioned below.

<sup>36</sup> See, e.g., *Plant Genetic Systems/Plant Cells*, 1995, EPOR 357.

human intervention, which is assessed case-by-case. In fact, the presence of one single technical step (if essential to the process) has sufficed to assert patentability.<sup>37</sup>

In accordance with EPC Rule 26 (5) '[A] process for the production of plants or animals is essentially biological if it consists **entirely** of natural phenomena such as crossing or selection'.<sup>38</sup> Under this definition **any** human intervention seems to transform a biological process for producing a plant (or animal) into patentable subject matter. Interestingly, the EPO Enlarged Board of Appeal found the wording in Rule 26(5) 'ambiguous, if not contradictory', and that it did 'not give any useful guidance on how to interpret the term "essentially biological process for the production of plants" in A 53(b).<sup>39</sup>

The EPO Guidelines for Examination attempted the following explanation of the meaning of 'essentially biological process' for the purpose of grant or refusal of a patent application:

A process for the production of plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is excluded from patentability as being essentially biological, even if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps (see G 1/08 and G 2/07). To take some examples, a method of crossing, interbreeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals (or their gametes) having certain characteristics would be essentially biological and therefore unpatentable. This method remains essentially biological and unpatentable even if it contains an additional feature of a technical nature, for example the use of genetic molecular markers to select either parent or progeny. On the other hand, a process involving inserting a gene or trait into a plant by genetic engineering does not rely on recombination of whole genomes and the natural mixing of plant genes, and hence is patentable. 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 an essentially biological process for the production of plants or animals since it is not based on the sexual crossing of whole genomes and subsequent selection of plants or animals; the same applies to a method of treating a plant characterised 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.<sup>40</sup>

The main effect of the exclusion of 'essentially biological processes' would be to prevent patents over traditional breeding methods, while preserving the possibility of obtaining protection on methods based, for instance, on cell manipulation or the transfer of genes.

However, the increase in the grant of patent applications relating to 'native' traits that apply conventional breeding (generally with the help of molecular marker-assisted selection)

<sup>37</sup> See, e.g., Abhinav Kumar, 'Towards Patentability of Essentially Biological Processes', *Journal of Intellectual Property Rights*, Vol.13(2) March 2008, p. 130.

<sup>38</sup> Emphasis added.

<sup>39</sup> Decision G 1/08.

<sup>40</sup> Available at [http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g\\_ii\\_5\\_4\\_2.htm](http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4_2.htm).

raised concerns about the scope of the exclusion.<sup>41</sup> Two patents granted by the EPO, EP 1069819 on broccoli<sup>42</sup> and EP 1211926 on tomatoes<sup>43</sup>, demanded the EPO to review whether the referred to Rule 26(5) EPC reduced the scope of the exclusion under Art. 53(b) EPC and rendered plant breeding processes patentable if they contained any technical step, or whether in line with previous precedents (notably the decision T 320/87<sup>44</sup>), such a technical step should not be a “classical” plant breeding step and have a decisive impact on the final result. While the decision of the EPO’s Enlarged Board of Appeal was against the patentability of the processes (which were deemed ‘essentially biological’) the question remained open as to whether the *products* obtained could be patented as such.

While the decision on this issue is pending, the EPO granted a patent for pepper obtained by conventional methods.<sup>45</sup> EP 2140023 covers insect-resistant sweet pepper plants obtained by crossing a wild pepper plant from Jamaica – resistant to various pest insects – with commercially grown pepper plants.<sup>46</sup>

It is to be noted that the extension of protection from the process to the directly obtained product required by article 28.1(b) of the TRIPS Agreement only applies if the process is patented. Such extension could not be alleged if a process is found to be ‘essentially biological’ and, hence, non-patentable. Otherwise, the non-patentability of such processes could be easily circumvented. This has been clarified by an amendment to the German patent law that entered into force in October 2013, in accordance to which patents shall not be granted for plants and animals ‘exclusively obtained’ by essentially biological processes (article 2a (1)1).

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<sup>41</sup> A study found that ‘in 2008 nearly 25 per cent of all patent applications at the European patent office (EPO) related to plants were directed at conventional breeding. Some years before, patent applications centered on conventional breeding processes had been the rare exception’. At least 500 identified patent applications concerned plant breeding without any reliance on genetic engineering, some encompassed a combination of genetic engineering and conventional breeding or included conventional breeding as an option. See Then, Christoph and Tippe, Ruth (2009), *The future of seeds and food under the growing threat of patents and market concentration*, available at [http://www.no-patents-on-seeds.org/images/documents/report\\_future\\_of\\_seed\\_en.pdf](http://www.no-patents-on-seeds.org/images/documents/report_future_of_seed_en.pdf), p. 14 and 16.

<sup>42</sup> A method for the production of *Brassica oleracea* (...) which comprises: (a) crossing wild *Brassica oleracea* species with *Brassica oleracea* breeding lines; and (b) selecting hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in *Brassica oleracea* breeding lines.

<sup>43</sup> A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of: 1) crossing at least one *Lycopersicon esculentum* plant with a *Lycopersicon* spp. to produce hybrid seed; 2) collecting the first generation of hybrid seeds; growing plants from the first generation of hybrid seeds; 3) pollinating the plants of the most recent hybrid generation; 4) collecting the seeds produced by the most recent hybrid generation; 5) growing plants from the seeds of the most hybrid generation; 6) allowing plants to remain on the vine past the point of normal ripening; and 7) screening for reduced fruit water as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.

<sup>44</sup> ‘Whether or not a (non-microbiological) process is to be considered as “essentially biological” within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved’, available at <http://xepc.eu/node/t870320>.

<sup>45</sup> Interestingly, this patent was granted to Syngenta, which had submitted an objection against the broccoli patent referred to above. See <http://www.jenkins.eu/pi-spring-2011/broccoli-and-tomatoes.asp>.

<sup>46</sup> The process claims describe an introgression of a *bemisia*-resistance gene into a prior non-resistant *Capsicum annuum* plant by backcrossing a *bemisia*-resistant line with the *Capsicum annuum* plant that did not show said resistance. A coalition of 32 NGOs, farmers and breeders organizations from 26 European countries have filed an opposition to this patent. See <http://no-patents-on-seeds.org/en/information/news/free-pepper>

Finally, the exclusion authorized by the TRIPS Agreement in respect of ‘essentially biological processes’ does not extend to microbiological processes, such as fermentation.<sup>47</sup> This broadly worded exception to the exception is present in the European legislation and in the laws of various other countries. Such a broad exception does not seem to be logically justified in the context of article 27.3(b) if, as suggested above, the reason for the exclusion of biological processes is that they are ‘natural’ or executed with minimal human intervention. Microbiological processes may also occur naturally. Naturally occurring microbiological processes should be excluded from patent protection on the same grounds as ‘essentially biological processes’: they are not inventions. As a result, the exception regarding microbiological processes needs to be read as only requiring the grant of a patent – if the patentability standards are met – when such processes are not naturally occurring but the outcome of an identifiable technical contribution.

### II.3 Free Trade Agreements: Imposing Plant Patentability

While the TRIPS Agreement, as mentioned, does allow WTO members to exclude plants from patentability, the USA has promoted the opposite approach through FTAs,<sup>48</sup> under three different modalities.

- (a) Some US-FTAs contain a **straightforward obligation** to grant patents on plants. For instance, article 14.8(2) of the agreement with Bahrain stipulates that ‘[E]ach Party shall make patents available for plant inventions’. The US FTA with Morocco also makes plant patents mandatory.<sup>49</sup>
- (b) Other US-FTAs include **best-endeavour obligations** to grant patents over plants. Such clauses are generally interpreted as placing upon the party the onus of making every reasonable effort (‘best effort’) to achieve the desired objective.

For instance, article 17.9.2 of the US FTA with Chile 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 ‘develop and propose legislation’, and provides for a deadline to that end, it may be argued that ‘reasonable efforts’ establishes a standard lower than ‘best efforts’ and that the only obligation the government has is to put a

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<sup>47</sup> EPC Rule 26(6) states that “[M]icrobiological process” means ‘any process involving or performed upon or resulting in microbiological material’. In accordance with the case Law of the EPO’s Boards of Appeal, this concept refers to processes in which micro-organisms (or their parts) are used to make or to modify products or in which new micro-organisms are developed for specific uses (T 356/93 (OJ 1995, 545). See [http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/c/r/\\_i/\\_b/\\_3/\\_4/\\_1.htm](http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/c/r/_i/_b/_3/_4/_1.htm).

<sup>48</sup> See, e.g., Jean-Frédéric Morin, Tripping up TRIPS debates IP and health in bilateral agreements, *Int. J. Intellectual Property Management*, Vol. 1, Nos. 1/2, 2006; Denis Borges Barbosa and Karin Grau-Kuntz, *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights. Biotechnology*, WIPO, SCP/15/3, Annex III, available at [http://www.wipo.int/edocs/mdocs/scp/en/scp\\_15/scp\\_15\\_3-annex3.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf).

<sup>49</sup> Art 15.9(2): ‘Each Party shall make patents available for the following inventions: (a) plants, and (b) animals...’.

legislative process in motion.<sup>50</sup> Although reciprocal in appearance,<sup>51</sup> the provision is irrelevant for the USA where patent protection for plants was already available at the time the FTA was signed.<sup>52</sup> At the same time, Chile does not seem to have introduced patent protection for plants, which are still legally excluded from patent protection.<sup>53</sup> Significantly, the government of Chile found strong resistance against the adoption of a bill implementing the standards of UPOV 1991, as also required by the US-FTA. As a result of the opposition from farmers, indigenous communities and other stakeholders, the government was forced to withdraw that bill from the Congress in March 2014, more than 10 years after the commitment to join UPOV 1991 was made in the US-FTA.<sup>54</sup>

Arguably, a 'best effort' 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).

- (c) Finally, some US-FTAs do not specifically refer to the patentability of plants, but these are not mentioned as subject matter for which exclusion from patent protection is allowed. This is the case, for instance, of the US-FTAs with Jordan, Singapore and Australia, which only allow for the exceptions provided for in Article 27.2 and 3(a) of the TRIPS Agreement, without any reference to plants (or

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<sup>50</sup> 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' (Pedro Roffe, *Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement*, 2004, TRIPS Issues Papers 4, QIAP, available at [http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_other\\_Topics/Chile-USAFTAP.Roffe.pdf](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_other_Topics/Chile-USAFTAP.Roffe.pdf), p. 21).

<sup>51</sup> It is worth noting that, although FTAs seems to be based on reciprocal treatment, the USA has not taken steps to implement internally obligations imposed in such agreements that are more stringent (or subject to no or narrower exceptions) than under the US law: '[the US] Congress has made a practice of expressly denying self-executing effect to the FTAs in its implementing legislation... [t]he FTAs do not change existing federal law unless specifically mandated by Congress. An individual may not directly invoke the provisions of an FTA in a court of the United States... To the extent that FTAs may impose obligations on the United States that are inconsistent with existing federal law, this is not relevant for domestic legal purposes (even if the United States may incur international legal liability' (Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, UNCTAD - ICTSD Project on IPRs and Sustainable Development, 2006, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1912621](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1912621), pp. 4-5).

<sup>52</sup> A similar best-effort obligation –although less detailed than in the US-FTA with Chile– can be found in the US-CAFTA-DR, but in this latter case the fact that plant patents were already granted in the USA is suggested in the text. Article 15.9(2) reads: 'Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection'. See also article 16.9(2) of the US-FTA with Peru.

<sup>53</sup> See article 37(b) of Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3) available at <http://www.leychile.cl/N?i=250708&f=20070104&p=>.

<sup>54</sup> See <http://newamericamedia.org/trending/2014/03/chile-derails-monsanto-law-that-would-privatize-seeds.php>. Although Chile remained in the 'Priority Watch List' in the USTR Report on the Special Section 301 in 2014, the report does not mention the lack of protection for plants among the issues of 'serious concern' for the USA. See Office of the United States Trade Representative, *2014 Special 301 Report*, available at <http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf>, p. 44.

animals).<sup>55</sup> The US FTA with Oman allows for the exclusion of patents in respect of animals, but does not mention plants.<sup>56</sup>

A question may arise as to whether the obligation to issue patents for ‘plants’ imply 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), for instance, distinguish between them and provide for a different treatment, although the introduction to the second sentence (‘However, Members...’) may support the thesis that ‘plants’ is an all-encompassing term that would include any taxa.

### III. LIMITATIONS ON THE SCOPE OF PLANT-RELATED PATENTS

In the case that patents on plant materials are admitted by the national law, a number of problems relating to the scope of the protection would need to be addressed.

#### III.1 Species-wide Patents

In some cases, a transformation event has been patented in such a way that its use in various field crops or throughout a whole species would be subject to the patentee’s exclusive rights. One example was EP 0301749 granted by the EPO to Agracetus. The patent covered **all** genetically modified soybeans:

The present invention relates to the general field of genetic engineering of plants and relates, in particular to the transformation of exogenous genetic material into the germ line of soybean plant lines by physically introducing the genetic material into regenerable tissues of soybean plant by particle-mediated transformation.<sup>57</sup>

This patent would prevent any third party from introducing a genetic modification, regardless of the particular transformation event. The validity of the patent was successfully challenged by some NGOs and Agracetus’ competitors (DeKalb, Pioneer, Sandoz, Ciba-Geigy

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<sup>55</sup> See, e.g., Barbosa, op. cit.

<sup>56</sup> 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”.

<sup>57</sup> EP 0301749, Description, para. 1, available at <https://www.google.com/patents/EP0301749B1?cl=en&dq=EP+0301749&hl=en&sa=X&ei=sALuU8z9FOmO4gSBjIHYCQ&ved=0CBwQ6AEwAA>.

and Monsanto). The patent was revoked by the EPO's Board of Appeal in May 2007,<sup>58</sup> but only after 13 years of legal proceedings.<sup>59</sup>

Patent offices and courts can limit the scope of plant patents to what has been actually invented and specifically disclosed in the patent claims. Broad patent claims can be disallowed. Importantly, the policy space to determine the admissible scope of patent protection has not been limited by the TRIPS Agreement. As noted above, in the particular case of plants, which in accordance with article 27.3(b) of said Agreement can be excluded from patent protection altogether, that policy space can be freely exercised to narrow down the reach of the protection to suit national policies on the matter.

### III.2 Functional Claims

Functional claims describe what an invention **does** rather than what an invention **is**. A classic example in the field of plant patents is the already mentioned first plant patent granted in the USA (the *Hibberd* patent), which disclosed an increase in tryptophan content. Another example is the EPO patent EP 1185160 B1 (High oleic and high stearic acid sunflower plants, seeds and oils), which claimed an invention that

...relates to plant seeds that contain an oil having an oleic acid content of more than 40 weight per cent and a stearic acid content of more than 12 weight per cent based on the total fatty acid content of said oil, and wherein a maximum of 10 weight per cent of the fatty acid groups in the sn-2 position of the TAG molecules constituting the oil are saturated fatty acid groups. The invention also relates to plants that can be grown from the seeds, oil that can be extracted from the seeds, and to methods for obtaining the seeds, plants and oil.<sup>60</sup>

Functional claims are not admitted by many patent offices and courts,<sup>61</sup> since the patent owner becomes entitled to control any technique that performs the described function, including those that the he completely ignores or has not invented. A report by the US Federal Trade Commission (FTC) noted that functional claiming is a 'source of vagueness',<sup>62</sup> and

<sup>58</sup> Case T 1165/03.

<sup>59</sup> See, e.g. No Patents on Seeds, *The Gene-Gun Case (Agracetus/Monsanto) .EP 0301749 Particle-mediated transformation of soybean plants and lines*, available at [http://www.alt.no-patents-on-seeds.org/index.php?option=com\\_content&task=view&id=23&Itemid=20](http://www.alt.no-patents-on-seeds.org/index.php?option=com_content&task=view&id=23&Itemid=20).

<sup>60</sup> EP 1185160, abstract, available at <https://www.google.com/patents/EP1185160B1?cl=en&dq=sunflower+patent+high+oleic+acid&hl=en&sa=X&ei=IAruU6SsMorb4QTwhIBA&ved=0CDEQ6AEwAw>.

<sup>61</sup> In *Halliburton v. Walker*, 329 U.S. 1 (1946) the US Supreme Court stated that a "claim which describes the most crucial element in a 'new' combination in terms of what it will do, rather than in terms of its own physical characteristics or its arrangement in the new combination, is invalid as a violation of [the indefiniteness requirement]." Lemley has noted that the US Patent Act as amended in 1952 adopted a compromise by allowing patentees to write their claims in functional terms, but the patent would not cover the goal itself, but only the particular means of implementing it (means-plus-function claims). This author also notes how functional claiming became, however, an accepted practice when the patenting of computer software was admitted. See Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, available at <http://web.stanford.edu/dept/law/ipsc/Paper%20PDF/Lemley,%20Mark%20-%20Paper.pdf>, p. 2. See also Dennis Crouch, *Functional Claim Language in Issued Patents*, January 23, 2014, available at <http://patentlyo.com/patent/2014/01/functional-language-patents.html>.

<sup>62</sup> Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition*, Washington DC, 2011, available from



recommended the courts to ‘require sufficiently detailed structure to inform the public of the means that fall within and outside of the claim’s scope’.<sup>63</sup> Certainly, there is nothing in the TRIPS Agreement obligating a WTO member to accept that type of claims in relation to plants or in other field of technology.

### III.3 Claims Covering Food/Feed

The already quoted EPO’s patents relating to tomatoes, broccoli and pepper suggest that the effects of patents may extend to food as such. Another example is Monsanto’s EP1962578, granted in May 2011, which claims melons with a natural resistance to certain plant viruses originating in India.

In many cases, patents relating to plants cover the products that can be obtained through processing of the grain or parts of plants. For instance, the European patent EP 1185160 B1, mentioned above, covers not only the plants and seeds, but also the oil that may be obtained therefrom.

#### Box 1

#### **Monsanto’s attempt to extend patent protection to soya meal**

Monsanto requested and obtained border measures in several European countries against importers of soya meal produced in Argentina, based on the alleged violation of European patents over a gene construct that confer plants resistance to glyphosate. The United Kingdom (UK) High Court of Justice, Chancery Division, Patents Court, ruled on 10 October 2007 in *Monsanto Technology LLC v. Cargill International and SA Cargill PLC* that the original transformed plant had not survived the process of production of the meal, and that the DNA present in the meal was ‘entirely irrelevant to the meal as an animal feedstuff’ since it was present ‘in small, variable, quantities and may not be present at all if processing conditions are changed. It is not in any serious sense genetic material. It is just the remains of the material which was in the soybeans from which the meal was extracted’. In *Monsanto Technology LLC v. Sesostris SA* that (*Juzgado Mercantil No. 6, 27 of Madrid, July 2007*), the court dismissed a similar action on the argument that practically the totality of the genetic material in the meal was degraded and did not supply any value added to it, as glyphosate resistance was only a valuable feature while the plant developed. In a third case (*Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV, Alfred C.*), the District Court in the Hague, Civil Law Sector, requested the Court of Justice of the European Union to reach a decision, inter alia, on whether article 9 of Directive 98/44/EC on the protection of biotechnological inventions should be interpreted in the sense ‘that the protection offered by this article can also be invoked in a situation ...in which the product (the DNA) constitutes part of a material (soya meal) imported in the European Union and is not performing its function at the moment of the alleged infringement, but did however perform the same (in the soy plant) or could possibly, after this has been isolated from the material and introduced to the cell of an organism, again perform its function’. In dismissing Monsanto’s claims, the European Court of Justice ruled that ‘Article 9 of the Directive [on the Legal Protection of Biotechnological Inventions] makes the protection

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<http://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf>, p. 84.

<sup>63</sup> Ibid., p. 11.

for which it provides subject to the condition that the genetic information contained in the patented product or constituting that product ‘performs’ its function in the ‘material ... in which’ that information is contained’ and that ‘the protection provided for in Article 9 of the Directive is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived’ (Case C-428/08, para. 34 and 38).

Source: based on Carlos Correa, *Trends in intellectual property rights relating to genetic resources*, Commission on Genetic Resources for Food and Agriculture, Rome: Background Study Paper No. 49, Rome, 2009, available at <ftp://ftp.fao.org/docrep/fao/meeting/017/k533e.pdf>.

Based on patents relating to a genetic transformation event commercially known as ‘Round Up Ready’, Monsanto sued importers of soya meal produced in Argentina (where Monsanto had failed to obtain patent protection for that event) alleging the violation of its patents (see Box 1).

Article 9 of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions<sup>64</sup> provides an example of how national patent laws may limit the scope of plant patents relating to genetic transformation events, and thereby prevent the extension of patent protection to derivative products, including food/feed. That article stipulates that

[T]he protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function’.

As interpreted by some European courts and the European Court of Justice, as noted in Box 1, the exclusive rights of a patent covering genetic information can only be exercised in relation to the biological material where that information is functional. In the case of a genetic transformation event that provides resistance to a herbicide – like Monsanto’s ‘Round Up Ready’ – such effect can only take place in the live plant itself. The European Court of Justice dismissed Monsanto’s argument that protection to that information was warranted on the sole ground that the DNA sequence containing the genetic information could be extracted from soya meal and perform its function in a cell of a living organism into which it has been transferred. The Court argued that soy meal was ‘a dead material obtained after the soy has undergone several treatment processes’ and that [I]n such a scenario, the function would be performed in a material which is both different and biological.<sup>65</sup> The Court concluded that

To allow protection under Article 9 of the Directive on the ground that the genetic information performed its function previously in the material containing it or that it could possibly perform that function again in another material would amount to depriving the provision interpreted of its effectiveness, since one or other of those situations could, in principle, always be relied on.<sup>66</sup>

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<sup>64</sup> OJ 1998 L 213, p. 13.

<sup>65</sup> Case C-428/08, para. 37 and 39.

<sup>66</sup> Ibid., para. 40.

### III.4 Gene Patents: Absolute v. Purpose-Bound Protection

A single gene can contribute to multiple phenotypic traits in a plant; for instance, the seed coat colour gene of pea plants is not only responsible for the seed coat colour, but also for flower and axil pigmentation.<sup>67</sup> If patents on genes are admissible under the applicable law, an important policy issue to be addressed is the scope of the protection conferred on the gene.

A patent on a gene may be understood as covering all its possible functions, even those not identified by the patentee but subsequently found. Such a broad protection may not only be considered unfair because it confers rights in relation to functions of a gene that were not known to the 'inventor'; it may have a serious detrimental on further research relating to the patented gene and its application for new uses:

Researchers naturally refrain from further investigating uses of genes when they know that these have already been patented by a third party. The perspective of being dependent on the patents or somebody else can be reason enough for a company to turn down research on the specific functions of a gene.<sup>68</sup>

Some legislative reforms have addressed this problem. Article L613-2-1 of the French Industrial Property Code, as amended in 2004, clarified that the scope of a claim on a gene sequence is limited to that part of the sequence directly linked to the function specifically disclosed in the specifications, and that such a claim cannot be enforced against a subsequent claim on the same sequence that discloses another specific application thereof. Said provision stipulates that

The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description.

The rights created by the grant of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L. 611-18 and if it discloses any other particular application of this sequence.

In Germany, a similar limitation on gene patents was introduced in connection with human genes:

Section 1a...

(3) The industrial application of a sequence or a partial sequence of a gene shall have to be specifically disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.

(4) Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, the use thereof, for which

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<sup>67</sup>. See, e.g., Ingrid Lobo, (2008), 'Pleiotropy: One gene can affect multiple traits', *Nature Education* 1(1):10, available at <http://www.nature.com/scitable/topicpage/pleiotropy-one-gene-can-affect-multiple-traits-569>.

<sup>68</sup> Nikolaus Thumm, 'Patents for genetic inventions: a tool to promote technological advance or a limitation for upstream inventions?', *Technovation*, Volume 25, Issue 12, December 2005, p. 1410.

industrial application is specifically described in subsection (3), shall have to be included in the patent claim.<sup>69</sup>

The European Parliament also called

on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection) (paragraph 5).<sup>70</sup>

In the already mentioned case *Monsanto Technology LLC v Cefetra BV*, *Cefetra Feed Service BV*, *Cefetra Futures BV*, *Alfred C*, both the EU Advocate General and the European Court of Justice argued in favour of the limitation of the scope of gene patents, specifically in relation to plants, to what the patent applicant has actually claimed. Both argued that, under the European Directive on the matter, only purpose-bound claims are admissible in the case of genes. The Advocate General, in particular, elaborated on the TRIPS-consistency of claims so limited. He stated that

...to grant absolute protection to an invention consisting in a DNA sequence, thereby conferring on the patent holder exclusive rights over that sequence, extending to all its possible uses, including those unspecified or unknown at the time when the application was lodged, would be in breach of that fundamental principle, in so far as it would confer on the patent holder a disproportionate level of protection.<sup>71</sup>

Nor are there problems of compatibility with Article 30 of the TRIPS Agreement, which concerns possible exceptions to the rights conferred on a patent holder. Above all, in fact, to recognise purpose-bound protection does not mean providing for *exceptions* from the scope of protection of a patent: what is defined in narrow terms rather, is the *extent* of the right itself, which is not recognised in respect of uses other than those described in the patent application. There is no obligation under the TRIPS Agreement to recognise that the protection accruing to DNA sequences is ‘absolute’ – that is to say, protection in respect of all possible uses, including even unforeseen and future uses.<sup>72</sup>

On its side, the European Court of Justice reasoned that

...it should be borne in mind that recital 23 in the preamble to the Directive states that ‘a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention’.<sup>73</sup>

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<sup>69</sup> See *Patent Act* of December 16, 1980, as amended by the Law of February 28, 2005.

<sup>70</sup> European Parliament resolution on patents for biotechnological inventions of 26 October 2005 available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN>.

<sup>71</sup> Opinion of Advocate General Mengozzi, delivered on 9 March 2010 (I), Case C-428/08, available at <http://curia.europa.eu/juris/document/document.jsf?docid=80052&doclang=EN>, para. 32.

<sup>72</sup> para 76.

<sup>73</sup> Case C-428/08, op. cit., para. 43.

Moreover, the import of recitals 23 and 24 in the preamble to, and Article 5(3) of the Directive is that a DNA sequence does not enjoy any protection under patent law when the function performed by that sequence is not specified.<sup>74</sup>

In summary, national laws can circumscribe patents grants over genes, if allowed, to the functions that the applicant has specifically disclosed in the claims.

## IV. EXCEPTIONS TO PATENT RIGHTS

Article 30 of the TRIPS Agreement allows for the establishment of a number of exceptions to the exclusive rights conferred by patents. Numerous countries have established exceptions for research or experimentation, early approval of medicines (known as the ‘Bolar exception’)<sup>75</sup> and use of an invention prior to a third party’s application thereon.

If patents over plants are admitted, the exceptions generally provided for by patents laws may not be adequate to allow activities that are important for food security and a sustainable agriculture. Unless it is otherwise provided for by the applicable law, the patent owner may, in principle, block farmers’ traditional practices of saving and exchanging seeds (the ‘farmers’ privilege’) and prevent a third party from using a plant variety that contains a patented material (e.g. a transformation event) to develop a new variety. These acts, however, may be deemed permissible under a PVP regime, including under the latest version of the UPOV Convention (amended in 1991).<sup>76</sup>

### IV.1 Can Specific Exceptions be Crafted for Plants?

It is often held that patent laws should be **neutral** and do not distinguish among sectors of technology.<sup>77</sup> In particular, article 27.1 of the TRIPS Agreement has been read as preventing such laws from making distinctions based on the field of technology. The relevant provision reads:

patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

‘Discrimination’, however, implies the unjust or prejudicial treatment of different categories of interests. The referred to article 27.1 cannot be read as banning any differentiation justified by diversity in the protectable subject matter. This is what a

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<sup>74</sup> Para. 44.

<sup>75</sup> The admissibility of this exception was confirmed by a WTO panel in *Canada–Patent Protection for Pharmaceutical Products*. See Report of the WTO Panel, WT/DS114/R (2000). Under such exception it is possible to start the procedures for the marketing approval of a medicine before the expiry of a patent covering it, in order to speed up the commercialization of a generic version of the medicine once the patent term is over.

<sup>76</sup> In the case of UPOV 1991, the ‘farmers’ privilege’ is subject to certain conditions and needs to be specifically introduced by the national law.

<sup>77</sup> See, e.g., Timothy A. Caulfield and Bryn Williams-Jones, *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues*, Springer Science & Business Media, Dec 31, 1999, p. 67.

WTO panel clarified in the EC case against Canada on the 'Bolar exception'.<sup>78</sup> The panel stated that

Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit *bona fide* exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose.<sup>79</sup>

In fact, current legislative practice in patent law shows that the treatment given to certain areas is differentiated. Thus, some national laws contain provisions specifically related to pharmaceuticals which have never been challenged under the WTO rules as discriminatory. For instance, the French industrial property law provides for the grant of compulsory licenses on patents relating to medicines (article L. 613-16). In Australia, an amendment to the US Free Trade Agreement Implementation Bill 2004 introduced – in order to prevent the abusive exercise of 'evergreening'<sup>80</sup> patents – an AU\$ 10 million penalty for drug patent litigation in bad faith.<sup>81</sup> Under US legislation (35 U.S.C. § 156) and in accordance with the FTAs signed by the USA with a number of countries, special provisions apply for the extension of the term of pharmaceutical patents to compensate for delays in the marketing approval of medicines. The same advantage is not conferred to other products that are also subject to marketing approval, such as agrochemicals.<sup>82</sup>

Differentiation is also made, de facto, by the US patent office and courts in relation to biotechnological and software inventions. While the level of inventive step is low for the former, software inventions are deemed patentable if not obvious for a highly skilled programmer; in exchange, DNA sequences must be disclosed under a stringent written description rule, while applicants need to disclose virtually nothing about the detailed workings of their invention in the case of software patents.<sup>83</sup>

As discussed below, several European laws have already introduced specific exceptions to the patent rights that only apply to plants.<sup>84</sup> None of these provisions has been challenged as being incompatible with article 27.1 or any other provision of the TRIPS Agreement.

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<sup>78</sup> See Report of the WTO Panel, op. cit.

<sup>79</sup> Ibid., para 7.92.

<sup>80</sup> 'Evergreening' is a strategy particularly common in the pharmaceutical based on the acquisition on new patents around an invention for which protection has or is about to expire, in order to prevent the entry into the market of competing products. See, e.g., Carlos Correa, *Tackling the proliferation of patents: how to avoid undue limitations to competition and the public domain*, Research Paper 52, South Centre, Geneva, 2014.

<sup>81</sup> The US government threatened Australia with a challenge of this penalty on the basis of the TRIPS Agreement non-discrimination clause, but it was never submitted. See Outtersson K (2005): 'Agony in the Antipodes: The Generic Drug Provisions of the Australia-US Free Trade Agreement', *Journal of Generic Medicines*, vol. 2, no. 4, July, pp. 316-326.

<sup>82</sup> See Carlos Correa, 'Is Section 3(d) Compatible with the TRIPS Agreement?', *Economic and Political Weekly*, vol-XLVIII No. 32, August 10, 2013.

<sup>83</sup> D Burk and M Lemley, 'Is Patent Law Technology-Specific?' (2003), 17 Berkeley Tech LJ p. 1155.

<sup>84</sup> See, e.g., Viola Prifti, 'The Breeding Exemption in Patent Law: Analysis of Compliance With Article 30 of the TRIPS Agreement', *The Journal of World Intellectual Property*, volume 16, issue 5-6, pp. 218-239, December 2013.

In summary, ‘discrimination’ as referred to in article 27.1 of the TRIPS Agreement must be distinguished from ‘differentiation’. WTO Members bound to observe the Agreement<sup>85</sup> can introduce different rules for particular fields of technology, provided that they are adopted for *bona fide* purposes.

(a) Breeder’s exemption

Innovation in agriculture is dependent on the use of **existing** genetic materials for further research and breeding. The preservation of this possibility is essential for food security and a sustainable agriculture. While PVP regimes allow, under what is generally known as ‘the breeder’s exception’<sup>86</sup> the use of a protected plant variety for research and breeding, this possibility may be excluded under the broader exclusive rights granted by patents. It was noted in this regard that

[T]he breeder’s exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders. However, it also helps to ensure that the genetic basis for plant improvement is broadened and is actively conserved, thereby ensuring an overall approach to plant breeding which is sustainable and productive in the long term...The rapid progress in the development of genetic engineering raises the prospect that, in the foreseeable future, an ever increasing number of plant varieties will contain patented inventions. Furthermore, the varieties may contain several patented genetic elements. The practical consequence of this development would be that the breeder’s exemption, which is an essential principle in the UPOV system of plant variety protection, would be lost or greatly weakened’.<sup>87</sup>

Patent laws generally allow third parties to do research or conduct experimentation **on** patented inventions including, in many jurisdictions, with commercial intent, but not to undertake such activities **with** the patented invention,<sup>88</sup> as it is inevitable in the case of plant breeding.

In the USA, the exception under the utility patent law has been interpreted in narrow terms; experimental use is permitted ‘solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry’, and disallowed when such use is done ‘in pursuance of a business purpose’ whether or not with the intent to make a profit.<sup>89</sup> However, in the case of plant patents granted under the US Plant Patent Act of 1930, it has been interpreted that to establish an infringement it is not enough to prove that the ‘alleged infringing plant has the

<sup>85</sup> Least Developed Countries (LDCs) are exempted from complying with the TRIPS Agreement, including article 27.1, until 1 July 2021, in accordance with an extension agreed upon in June 2013 of the transitional period they enjoy pursuant to article 66.1 of the TRIPS Agreement. See [http://www.wto.org/english/tratop\\_e/trips\\_e/ldc\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm).

<sup>86</sup> This is a ‘compulsory’ exception under the UPOV Convention, but in the case of ‘essentially derived varieties’ (EDVs) as defined in UPOV 1991, the exception is limited to the right to undertake breeding but not to commercialize the new obtained variety (see article 15.1(iii) of UPOV 1991).

<sup>87</sup> Rolf Jördens (2002), *Legal and technological developments leading to this symposium: UPOV’s perspective*, WIPO-UPOV Symposium on the co-existence of patents and plant breeders’ rights in the promotion of biotechnological developments, WIPO-UPOV, Geneva, 25 October 2002, WIPO-UPOV/SYM/02/2, paras. 12 and 26.

<sup>88</sup> See, e.g., Carlos Correa, *The International Dimension of the Research Exception* (2005) Advancing Science, Serving Society (AAAS), available at <[http://sippi.aaas.org/Pubs/Correa\\_International%20Exception.pdf](http://sippi.aaas.org/Pubs/Correa_International%20Exception.pdf)>.

<sup>89</sup> See *Madey vs Duke* (64 USPQ2d 1737 (Fed. Cir. 2002), available from <http://cyber.law.harvard.edu/people/tfisher/2002Madeyedit.html>).

same essential characteristics as the patented plant'. Hence, a patented variety could be used by a third party without authorization as a parent in a commercial breeding program, since infringement would only exist when the accused variety was derived asexually<sup>90</sup> from the protected variety.<sup>91</sup>

The need to take into account the characteristics of biological materials, and in particular, plants, with regard to the use of patented materials has been recognized in some patent laws, through the adoption of specific exceptions.

Thus, article 22.V of the Mexican Law on Industrial Property (of June 25, 1991, as amended)<sup>92</sup> provides that there will be no patent infringement in the case of patents relating to live material when a third party makes use of the patented product as an initial source of variation or propagation to obtain other products, except where such use is made in a repetitive manner.

The French law is more specific, as it refers to 'plant varieties'. Article L613-5-3 of the French Intellectual Property Code (as amended in 2004) stipulates that the exclusive rights conferred by a product or process patent on a biological material do not extend to the acts accomplished with a view to creating or discovering and developing other plant varieties.<sup>93</sup>

Section 11.2.a of the German Patent Act adopted in 2005, similarly provides that the effects of a patent shall not extend to 'the use of biological material for breeding, discovery and development of a new plant variety type'.<sup>94</sup>

The Swiss law is also specific. It stipulates in article 9(e), as amended in 2007, that the rights conferred by a patent do not extend to 'the 'use of biological material for the purpose of the production or the discovery and development of a plant variety'.<sup>95</sup>

Interestingly, article 27 of the recently adopted Agreement on a Unified Patent Court also incorporates an exception on 'limitations to the effects of a patent' that comprises of an exception regarding 'the use of biological material for the purpose of breeding, or discovering and developing other plant varieties'.<sup>96</sup>

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<sup>90</sup> 'Asexual reproduction... means the progeny of the patented plant via "grafting, budding, cuttings, layering, division and the like, but not by seeds." See *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560, 36 USPQ2d 1673, CAFC 1995).

<sup>91</sup> See, e.g., Victoria Henson-Apollonio, (2002), 'Patent protection for plant material', WIPO-UPOV Symposium on the co-existence of patents.

and plant breeders' rights in the promotion of biotechnological developments, Geneva, October 25, available at [http://www.upov.int/en/documents/Symposium2002/pdf/wipo-upov\\_sym\\_02\\_4.pdf](http://www.upov.int/en/documents/Symposium2002/pdf/wipo-upov_sym_02_4.pdf).

<sup>92</sup> The effects of a patent shall not extend against '[A] third party who, in the case of patents relating to living matter, makes use of the patented product as an initial source of variation or propagation to obtain other products, except where such use is made repeatedly' (article 22.V), available at <http://www.wipo.int/edocs/lexdocs/laws/en/mx/mx113en.pdf>.

<sup>93</sup> Article L613-5-3: 'Les droits conférés par les articles L. 613-2-2 et L. 613-2-3 ne s'étendent pas aux actes accomplis en vue de créer ou de découvrir et de développer d'autres variétés végétales', available at [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=322949](http://www.wipo.int/wipolex/en/text.jsp?file_id=322949).

<sup>94</sup> Available at [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=238776](http://www.wipo.int/wipolex/en/text.jsp?file_id=238776).

<sup>95</sup> Available at <http://www.admin.ch/ch/e/rs/2/232.14.en.pdf>.

<sup>96</sup> Article 27(c), Agreement on a Unified Patent Court (2013/C 175/01), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:EN:PDF>. The Netherlands' Parliament approved a similar exception in 2013, but its entry into force is subjected to a Royal decree.



An important question in relation to the described exceptions is whether they are fully equivalent to the breeder's exception under PVP, which (except in the case of EDVs in countries that apply UPOV 1991 or similar rules) authorizes the breeder not only to do breeding but also to **commercialize** the new variety he has developed. The reply to this question seems negative; the exception under patent law may be construed narrower than under a PVP regime.

To the extent that, for instance, one or more patented genes are expressed in a new plant variety, arguably the breeder may not be entitled to legally commercialize such variety.<sup>97</sup> The breeder of the new variety would presumably require an authorization from the patent holder at the time he intends to reproduce (except for private and non-commercial purposes), offer for sale, or sell the new variety, even though such authorization was not needed at the time the new variety was developed. As a result, the exception would be more limited than the one provided for under the UPOV Convention and most PVP laws.

Another relevant question from a legal perspective is whether such exception is compatible with the TRIPS Agreement. The reply seems to be clearly affirmative in this case, since the conditions set out in article 30 of the TRIPS Agreement would be complied with, even if this article were interpreted narrowly (as in the panel ruling in *Canada–Patent Protection for Pharmaceutical Products* mentioned above).<sup>98</sup> In fact, there has been so far no complaint submitted to the WTO arguing that such an exception – as adopted by the countries mentioned above – violates the TRIPS Agreement. The adoption of the exception by the European Union – a zealous guardian of TRIPS compliance<sup>99</sup> – under the referred to Agreement on a Unified Patent Court, is also indicative of a general understanding about the TRIPS-consistency of a breeding exception as framed in the legislation examined above.

Another important question is whether such a limited breeding exception may actually attain its intended purpose of creating a space for further breeding by third parties on existing protected materials. Under such exception, a breeder is unlikely to undertake the development of a new variety, since obtaining the authorization of the right holder may be uncertain, and the time and investment needed for developing a new variety may be wasted definitely or until the patent protection expires. A limited breeding exception, hence, may not be enough to promote continuous innovation in plant breeding.

For this reason, the Dutch seeds association Plantum NL has proposed to adopt what has been termed as a 'comprehensive breeding exception'<sup>100</sup> with effects comparable to those under PVP legislation, that is, an exception conferring third parties not only the right to do research and breeding but also the right to commercialize the new variety. Plantum NL has argued that the same 'balance' found under PVP between rewarding breeders and allowing for 'continual improvement of varieties by other breeders' should be found under patent law,

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<sup>97</sup> See, e.g., Michiel Rijdsdijk, 'A limited breeders exemption', *World Intellectual Property Review*, 01-12-2012, available at <http://www.worldipreview.com/article/a-limited-breeders-exemption>.

<sup>98</sup> See, e.g., Viola Prifti, op. cit.

<sup>99</sup> 'The EU continues to monitor the IPR situation in third countries, and to push for compliance with international agreements, in particular through dialogue and negotiation. WTO dispute settlement procedures can also be resorted to for breaches of the TRIPS Agreement', European Commission, *Trade, growth and intellectual property - Strategy for the protection and enforcement of intellectual property rights in third countries*, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, COM(2014) 389 final, 2014, available from [http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc\\_152643.pdf](http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152643.pdf).

<sup>100</sup> See, e.g., Viola Prifti, op. cit., p. 2.

through an exception stipulating that the use and exploitation of plant varieties protected by patent rights ‘should be free, in line with the ‘breeders’ exemption of the UPOV Convention’.<sup>101</sup>

While a ‘comprehensive breeding exception’ would be functional to policies aimed at ensuring food security and a sustainable agriculture, its possible inconsistency with the TRIPS Agreement has been voiced.<sup>102</sup> The extent to which the WTO Dispute Settlement Body would subordinate the patent holders’ interest to such public policies is doubtful,<sup>103</sup> particularly if the exception is provided for on a non-remunerative basis (that is, without payment of royalties or other compensation to the patent owner). In order to overcome that possible objection, one option would be to consider a liability regime under which the patent owner may be compensated through royalties calculated as a fixed percentage of his gross revenues.<sup>104</sup>

#### (b) The ‘farmers’ privilege

Under the PVP regimes, especially those in line with UPOV 1978<sup>105</sup>, as well as other *sui generis* regimes (such as those implemented in India<sup>106</sup>, Malaysia<sup>107</sup> and Thailand<sup>108</sup>), farmers can save seeds of protected varieties and use them for plantation in their own holdings, or even exchange them with other farmers without a commercial intent. Under the Indian law, non-branded sales of seeds are also permissible.<sup>109</sup>

The farmers’ right to save, re-use and exchange seed with other farmers (generally called ‘the farmers’ privilege’) may become illusory if the variety incorporates patented components, since the patent holder may prevent such practices, which are vital indeed for food security. Examples of the way in which such rights can be used to deny the farmers’ privilege are provided in Box 2.

<sup>101</sup> See *Plantum NL position on patents-and plant breeders’ rights*, adopted 6 May 2009, available at <https://www.plantum.nl/Content/Files/file/Standpunten/Plantum%20Position%20on%20patent-%20and%20plant%20breeders%20rights.pdf>.

<sup>102</sup> In a letter of June 29, 2009, Crop International (whose members include Monsanto, Syngenta, Bayer and BASF, among other biotech corporations) argued that such an exception would violate article 30 of the TRIPS Agreement, as it would conflict with “the normal exploitation of the patent” and “unreasonably prejudice the legitimate interests of the patent owner”, and would also conflict with the research exception under the Dutch patent law and with the European Directive 98/44/EC, since the proposed exception ‘would result in an inventor’s inability to exert his or her patent rights when the invention is contained in seed, contrary to Recital 46 of the Directive’ (Letter HM/MO/09-022, available at [http://www.nrc.nl/multimedia/archive/00242/Patentrecht\\_09-06-2\\_242607a.pdf](http://www.nrc.nl/multimedia/archive/00242/Patentrecht_09-06-2_242607a.pdf)).

<sup>103</sup> For an analysis of this subject, see Viola Prifti, op. cit.

<sup>104</sup> See, in this regard the Jerome Reichman, ‘Of Green Tulips and Legal Kudzu: Repacking Rights in Subpatentable Innovation’, *Vanderbilt Law Review*, 53, 2000, 1743-98. p. 1784; Viola Prifti, op. cit., p. 17.

<sup>105</sup> As noted above, in the case of UPOV 1991 the ‘farmers’ privilege’ may be introduced as an exception, subject to some conditions (article 15.2). The exercise of this exception is subject in some countries to payment of a compensation to the right holder. Under European law, small-scale farmers are exempted from this obligation. See the European Community Regulation (EC) n° 2100/94 on plant variety rights (article 14).

<sup>106</sup> Plant Varieties and Farmers’ Rights Act (PPVFR Act), 2001, available at <http://www.wipo.int/wipolex/en/details.jsp?id=2401>.

<sup>107</sup> Protection of New Plant Varieties Act 2004, available at [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=128880](http://www.wipo.int/wipolex/en/text.jsp?file_id=128880).

<sup>108</sup> Plant Variety Protection Act, 1999, available at <http://www.wipo.int/wipolex/en/details.jsp?id=3816>.

<sup>109</sup> See Article 39.1(iv) of the PPVFR Act.

## Box. 2

**Denial of the farmers' privilege under patent law**

In *Monsanto Canada Inc. v. Schmeiser*, Monsanto sued Schmeiser, a canola breeder and grower in Saskatchewan, Canada, who had harvested and saved canola seed from one of his fields containing Monsanto's patented transgene that conferred resistance to glyphosate. Schmeiser argued that he had not benefited from Monsanto's patented trait that confers resistance to a particular herbicide. The Supreme Court of Canada ([2004] 1 S.C.R. 902, 2004 SCC 34) found that 'the ancient common law property rights of farmers to keep that which comes onto their land' was an insufficient defence against infringement. The court ruled that 'where a defendant's commercial or business activity involves a thing of which a patented part is a significant or important component, infringement is established. It is no defence to say that the thing actually used was not patented, but only one of its components' and that '[W]hether or not a farmer sprays with Roundup herbicide, cultivating canola containing the patented genes and cells provides stand-by utility. The farmer benefits from that advantage from the outset: if there is reason to spray in the future, the farmer may proceed to do so'. The Supreme Court established that Schmeiser had infringed section 42 of the Patent Act, despite the fact that the presence of the patented gene in the defendant's field was deemed to be unintentional. The Court, however, did not impose damages on Schmeiser as the defendant had not made a profit directly resulting from the patented invention.

In another case litigated in the USA, the US Court of Appeals of the Federal Circuit in *Monsanto v. McFarling* (302 F.3d 1291, Fed. Cir., May 2007), a patent was also enforced against a farmer who was condemned to pay US\$ 40 per bag of saved seed. In determining this amount the Court considered that the 'technology fee' charged by Monsanto was US\$ 6,50 per bag (whose price was between US\$ 19-22) and that the savings per acre of the defendant were between US\$ 31 and US\$ 61.54.

Source: based on Carlos Correa, *Trends in intellectual property rights relating to genetic resources*, Commission on Genetic Resources for Food and Agriculture, Rome: Background Study Paper No. 49, Rome, 2009, available at <ftp://ftp.fao.org/docrep/fao/meeting/017/k533e.pdf>.

Patent laws generally do not include provisions mirroring the 'farmers' privilege' traditionally recognized under PVP regimes in order to allow farmers to save and re-use seeds obtained in their exploitations with plant varieties containing patented materials.

One noticeable exception is article 11.1 of the European Directive on the Legal Protection Biotechnological Inventions (Directive 98/44/EC), which includes an exception for that purpose, subject to the same conditions and limitations applicable under the European Community Regulation (EC) n° 2100/94 on plant variety rights.<sup>110</sup> The referred to article 11.1 stipulates:

By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of

<sup>110</sup> Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994R2100:EN:HTML>.

the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

In accordance with this provision, a patented material is put on the same footing as material protected under the European PVP regime, as provided for in Regulation (EC) No 2100/94. As noted by one commentator,

[M]ost interestingly, the EU Biotech Directive has created an identical exception under patent law and, in this respect, directly refers to the scheme of the CPVR regulation. Due to the legislative link, patents and PVRs completely converge in this particular respect.<sup>111</sup>

Under the Regulation (EC) No 2100/94, the farmers' privilege is limited to a list of species of fodder plants, cereals, potatoes and oil and fibre plants enumerated in its article 14 (a). Farmers are subjected to payment of 'an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area' (article 14.1), except in the case of 'small farmers' as defined in the same provision.

The transposition of the farmers' privilege from PVP to patent law is an interesting approach that other countries may adopt, for instance, by incorporating in their patent laws, *mutatis mutandi*, the exceptions contemplated in their PVP or *sui generis* regime. Notably, such a transposition does not need to provide for payment of royalties to the patent owner if this is not required under the PVP or *sui generis* regime.

Issues relating to the compatibility with the TRIPS Agreement of an exception under patent law equivalent to the farmers' privilege, have never been raised in the context of the WTO dispute settlement mechanism. Article 11 of the EC Directive on biotechnology has been adopted 16 years ago, and no complaint has been voiced in that respect. As noted, small farmers can save and re-use seeds containing patented materials without any additional payment, a solution that developing countries may extend to all their farmers (most of whom would probably fall under the EC definition of 'small farmer').

It is worth noting that despite the efforts made by developing countries to eliminate trade distorting measures in agriculture in the context of WTO negotiations, European farmers continue to receive massive State subsidies.<sup>112</sup> Hence, the negative impact that payment of royalties for the re-use of seeds may have on farmers is to some extent neutralized in Europe by the financial support they receive. A similar obligation on farmers in developing countries may put a burden on them that may endanger their very survival. Hence, the farmers' privilege on a non-remunerative basis would seem to be the best policy option in those countries.

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<sup>111</sup> Rainer Moufang, *The Interface Between Patents and Plant Variety Rights in Europe*, Paper presented at WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology, Geneva October 24 2003, available at [http://www.upov.int/export/sites/upov/en/documents/Symposium2003/wipo\\_upov\\_sym\\_06.pdf](http://www.upov.int/export/sites/upov/en/documents/Symposium2003/wipo_upov_sym_06.pdf), p. 6.

<sup>112</sup> The EU provided €83 billion in support of agricultural producers in 2012 – or 19% of total farm receipts – a rise of 1 per cent from the year before. See OECD, *Agricultural Policy Monitoring and Evaluation 2013*, Paris.

## V. OVERLAPPING OF PVP AND PATENT PROTECTION

In some situations, PVP and patent protection may overlap on the same variety. This may arise for instance when a patent protects:

- a non-essentially biological process for the production of plants, since the protection conferred by the patent will extend to the plants directly obtained by the process;<sup>113</sup>
- a DNA sequence, for example a gene or a vector, introduced and functional in a plant variety;<sup>114</sup>
- a plant as such, for instance, a genetically modified plant, where the protection is not restricted to one or more specific plant varieties.<sup>115</sup>

When PVP and patent protection overlap, a plant breeder may not be able to commercialize a variety that contains a patented component; conversely, a biotechnological company owning patents on a gene or other components may not be able to legally commercialize a third party's plant variety that incorporates such a gene or components. Although different solutions have been proposed,<sup>116</sup> in most countries this problem has not been legislatively addressed. With regard to Ethiopia, for instance, it was noted that:

There exists no single provision in the relevant laws that addresses this issue even implicitly. As the law stands now, it arguably appears that Ethiopia has adopted a “dual approach” in addressing the possible relationship between patent and plant variety protection over the same biological material. That is, both patent and plant breeders' rights can be concurrently created over the same subject matter even if plant variety protection as such is excluded from the patent law regime. However, this possible overlap is left ungoverned. The issue may be contractually resolved between the right holders when it arises, but the contractual approach may fail to solve the problem if an agreement cannot be reached.<sup>117</sup>

European law has addressed this issue and specifically sought a legal solution to the problem of accumulation, on the same material, of PVP and patent rights belonging to different parties.

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<sup>113</sup> See, e.g. article 28.1(b) of the TRIPS Agreement.

<sup>114</sup> The use of some techniques, such as molecular marker-assisted selection, may contribute to avoid a conflict of rights in these cases since they allow to by-pass products resulting from crossing in which a patented gene is expressed. See Trommetter, Michel (2008), *Intellectual Property Rights in Agricultural and Agro-food Biotechnologies to 2030*, OECD, Paris, available at <http://www.oecd.org/dataoecd/11/56/40926131.pdf>, p. 14.

<sup>115</sup> See, e.g. Moufang, op. cit. p. 4.

<sup>116</sup> See, e.g., Lenßen, Markus, 'The Overlap between Patent and Plant Variety Protection for Transgenic Plants: Problems and a Solution' (May 2006), available at <http://ssrn.com/abstract=924343>.

<sup>117</sup> Sileshi Bedasie, The Possible Overlap Between Plant Variety Protection And Patent: Approaches In Africa With Particular Reference To South Africa And Ethiopia, *Haramaya Law Review*, Vol. 1:1, available at <http://www.google.ch/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=3&ved=0CCoQFjAC&url=http%3A%2F%2Fwww.ajol.info%2Findex.php%2Fhlr%2Farticle%2Fdownload%2F98573%2F87839&ei=KhvzU6e1FOP8ygPXoIDgDg&usg=AFQjCNEBVJ9RfX5TpB1mtHuYswP1DPTuAw&sig2=tXL3L49gPuMf6qjxSrwwWg>, p. 130.

As noted above, in accordance with article. L. 613-5-3 of the French Industrial Property Code, the exclusive rights conferred by a patent relative to a biological material do not extend to the acts accomplished with a view to creating or discovering and developing other plant varieties. This provision has been interpreted as creating policy space for a breeder to use patented material, but to the extent that a new variety is developed where that material is not functional:

French legislation proposes to limit the breadth of protection by patent. Article L 613 5-3 aims to guarantee access to genetic diversity, including GMO varieties that integrate one (several) patented gene(s); the patent covering a gene in a GMO is no longer extended to the plant as a whole. There is thus free access to the genetic diversity of the GMO minus the patented gene(s).<sup>118</sup>

Article 12 of the European Directive on the Legal Protection of Biotechnological Inventions contemplates the situation where a new variety **does contain** a functional patented material owned by a third party. It provides for the grant of a compulsory license – subject to payment of ‘an appropriate royalty’ and a cross-license – when a patent owner or a plant breeder cannot use its rights without infringing a breeder’s right or a patent, respectively. The possibility of effectively obtaining a compulsory license of this kind is limited, however, by the stringent conditions that should be met for its grant. Applicants for a compulsory license must demonstrate that

- (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual license;
- (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.<sup>119</sup>

The conditions established in paragraph (b) of this provision are similar to those required under article 31(1)(i) of the TRIPS Agreement, which refers to ‘an important technical advance’ and ‘considerable economic significance’ of the second invention in relation to the invention claimed in the first patent. A major difference between the provisions in the quoted European Directive and in the TRIPS Agreement is, however, that while in the latter the comparison is made between two inventions, in the former it is done between two heterogeneous matters, a plant variety and an invention. It is unclear how a breeder (or patentee) could show that his variety (or invention) represents an ‘important advance’ of considerable economic interest’ with regard to the patented invention (or protected plant variety), given that the terms of the comparison are different in nature.

In the 2007 amendment to the Swiss patent law a similar provision (article 36a) was introduced, which allows a breeder to request a compulsory license when he cannot obtain or exploit his title without infringing a patent, under conditions comparable to those established in the referred to European Directive.

While the cross compulsory licensing seems to offer a possible way out to deal with the cumulative protection derived from PVP and patents, such licensing is unlikely to be

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<sup>118</sup> Trommter, op. cit., p. 14.

<sup>119</sup> European Directive on the Legal Protection of Biotechnological Inventions, article 12.3.

operative<sup>120</sup> if the conditions for the grant are not adapted to the particular features of a possible overlap in this field. Article 30(l) of the TRIPS Agreement is **not** applicable in this situation, since it establishes standards for the case of patent dependency only. PVP and patent dependency are not regulated in that Agreement; hence, WTO members have full policy space to seek their own solutions, consistently with other provisions of the Agreement.

## VI. INFRINGEMENT AND INJUNCTIONS

In order to protect a farmer against legal actions based on the unintentional presence of a patented material in a planted variety (as in the Schmeiser case mentioned above) the Swiss patent law has introduced a specific exception.

In accordance with article 9(f), as amended in 2007, of said law, a patent does not extend to biological material that was obtained in the agricultural domain by chance ('au hazard') or when it is technically inevitable.

The Swiss amendment provides an interesting example for the introduction of similar safeguards in national laws, which may protect farmers in cases of 'contamination' through out-crossing (the dispersal of pollen to sexually compatible plants) of patented transgenes or gene constructs.

In addition, article 44.1 of the TRIPS Agreement allows WTO members to deny a permanent injunction where the alleged infringer acted *bona fide*. It provides that

...in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

The refusal of permanent injunctions could also be considered in cases where restrains of competition<sup>121</sup> or food security considerations are involved. Such refusal is equivalent to the grant of a compulsory license, normally subject to payment of an adequate remuneration to the patent owner.<sup>122</sup> It is worth noting in this regard that, under the UPOV Convention, the exercise of the breeder's right can be limited for reasons of 'public interest'<sup>123</sup> through the grant of an authorization to a third party for exploiting a protected variety.

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<sup>120</sup> There is no record of compulsory licenses granted under the EC and Swiss provisions commented above.

<sup>121</sup> In the case *eBay, Inc. v. MercExchange* (LLC, 547 U.S. 388, 391, 2006) the US Supreme Court decided that a permanent injunction can be denied, in cases of patent infringement, based on 'equity' considerations. The US courts denied such injunctions in a number of post-eBay cases. See, e.g., Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition. A Report of the Federal Trade Commission*, Washington D.C., 2011, pp. 272-274.

<sup>122</sup> See article 31(h) of the TRIPS Agreement.

<sup>123</sup> See, e.g., article 17 of UPOV 1991.

## VII. CONCLUSIONS AND RECOMMENDATIONS

Patent laws in many developing countries have incorporated the ‘flexibilities’ allowed by the TRIPS Agreement (such as compulsory licenses, government use, parallel imports and the ‘Bolar exception’) to respond to public health needs relating to the access to affordable medicines. The extensive debates on the subject in academic circles<sup>124</sup> and other fora, the analysis and advice provided by several UN and other international organizations,<sup>125</sup> and the work of dozens of NGOs, contributed to integrate public health policies into patent laws.

Food security and a sustainable agriculture are not less important, from a public interest perspective, than public health. However, most patent laws in force have not been adapted to take the specific features of plant materials into account. Many developing countries, in particular, have not used the flexibilities left by the TRIPS Agreement to the full extent possible in order to safeguard such public interest. This is notably, the case of the possibility of excluding ‘plants’ and not just ‘plant varieties’ from patent protection. Nor have many patent laws in developing countries addressed the issues of the scope of plant and gene patents, or the interface with PVP. While there are in Europe, as examined above, some interesting examples of provisions aiming at ‘greening’ the patent regimes, developing countries may develop their own policies on the matter, in accordance with the local conditions of agricultural production, seeds supply and needs of local farmers.

The monopolization under patents of plant genetic resources, including their parts and components, such as genes, and plant varieties, may endanger food security and the livelihood of farmers in developing countries, particularly small-scale farmers. Although WTO members (with the exception of LDCs during the transition period) are obliged to offer some form of protection to plant varieties, they do not need to grant it on the basis of patent grants, nor to extend it to plants as such. The best policy would seem to exclude plants from patent protection altogether, while providing for other *sui generis* forms of protection for plant varieties, adapted to the agricultural practices and national policies of each country. Importantly, such *sui generis* protection does need to be consistent or be based on the UPOV Convention.

The exclusion of plants from patentability may encompass their parts and components in order to give full effect to the exclusion. Genes found in plants, even if isolated or synthesized, can also be excluded from patentability as they are not ‘inventions’.

**Recommendation:** patent laws should exclude from patent protection plants, including but not limited to plant varieties. The exclusion should be interpreted to extend to any part or component of a plant the patenting of which may allow the right-holder to control the reproduction or commercialization of the plant containing such part or component. National laws should, in particular, exclude both isolated DNA and cDNA from patentability.

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<sup>124</sup> See, e.g., Jean-Frederic Morin, ‘Paradigm shift in the global IP regime: The agency of academics’, *Review of International Political Economy*, 2014 vol. 21, no. 2, 275-309, available from <http://dx.doi.org/10.1080/09692290.2013.819812>.

<sup>125</sup> See, e.g., Germán Velásquez, Carlos Correa and Xavier Seuba, *IPR, R&D, Human Rights and Access to Medicines - An Annotated and Selected Bibliography*, South Centre, Geneva, 2012.



There has been a noticeable increase, at least in the case of the EPO, in the grant of patent applications relating to ‘native’ traits, where conventional breeding methods are used, generally with the help of molecular marker-assisted selection. The TRIPS Agreement allows WTO members to exclude from patent protection ‘essentially biological processes’. This ambiguous concept can be interpreted as excluding the patentability of particular applications of such methods and the products obtained with their use.

**Recommendation:** exclude ‘essentially biological processes’ from patentability as well as the products obtained with such processes. The application of modern methodologies in conventional breeding, such as molecular marker-assisted selection, should not be deemed to overcome that exclusion.

Countries that have entered into FTAs imposing an obligation to grant patents on plants, or to do their best efforts to achieve that objective, have dramatically narrowed down their policy space to legislate on the subject in accordance with their national conditions and needs. There might be, however, some room for the interpretation and implementation of such an obligation that mitigate their possible negative impact. A ‘best effort’ obligation would not be violated if a government finds opposition to the introduction of such protection, or other conditions are not met (e.g. lack of capacity to examine the patentability of plants).

**Recommendation:** countries in the process of negotiating FTAs should avoid obligations relating to the patentability of plants and thereby preserve a key flexibility enshrined in the TRIPS Agreement in this regard. Those countries that have assumed best efforts obligations may consider limiting patentability to plants **as such**, with the exclusion of plant varieties.

If the patentability of plant materials is allowed by the applicable patent law, a number of rules and policies may be adopted in order to prevent the grant of patents with exorbitant coverage and, in particular, to limit protection to what the patentee has actually contributed in terms of new knowledge.

**Recommendation:** patentability should be limited to what is disclosed in the patent claims. If patents on genes are granted, the scope of protection should not go beyond the functions specifically identified by the patentee (purpose-bound protection). The protection of genetic information should be limited to the material in which it performs its intended function, and do not extend to derivatives, including food/feed. No functional claims should be admitted.

Patent laws can introduce rules specific to particular fields of technology. This will not amount to ‘discrimination’ as referred to in article 27.1 of the TRIPS Agreement, to the extent that such rules are justified by the special nature of the protectable subject matter. If plant materials are patentable under the applicable law, specific exceptions can be crafted in relation to such materials.

An important element in a policy aimed at ‘greening patents laws would be the introduction of a breeding exception. An exception allowing a third party to use a patented material to develop a new variety can be regarded as compatible with the TRIPS Agreement. The extension of the exception to the right to commercialize the new variety (containing the patented material) would enter into a grey zone. Its admissibility under WTO rules would

depend on the extent that the public interests in food security and sustainable agriculture are deemed to prevail over the private interests of patent owners.

**Recommendation:** patent laws should stipulate that the exclusive rights conferred by a product or process patent on a biological material do not extend to the acts accomplished for developing new plant varieties. Patent laws may also provide that the breeder of a new variety containing the patented material may be authorized to commercialize such variety, eventually subject to a statutory established compensation.

Patent laws in general do not include provisions incorporating an exception comparable to the ‘farmers’ privilege’ traditionally recognized under PVP regimes, so as to allow farmers to save, re-use and exchange seeds obtained in their exploitations with plant varieties containing patented materials. Such an exception, however, may be of crucial importance to preserve traditional farming practices and as a matter of food security.

**Recommendation:** patent laws in developing countries should provide for an exception allowing farmers to save, re-use and exchange (for non-commercial purposes) seeds they have obtained in their own fields, on a non-remunerative basis.

In some cases, PVP and patent protection may overlap on the same plant variety, thereby generating a reciprocal blockage for the respective breeder and patent owner. In the absence of specific regulation on the subject, in particular, the diffusion of plant varieties that contain patented materials may be hampered.

**Recommendation:** in cases of overlapping of PVP and plant variety protection, patent (and/or PVP) laws should establish the right to obtain a compulsory license if a voluntary license has been refused, subject to the right of the other party to obtain a cross-compulsory license. No conditions regarding the relative technical or economic importance of the protected plant variety and invention should be imposed. The grant of such licenses should be ensured when the concerned plant varieties are important for food security.

The TRIPS Agreement allows for the refusal of permanent injunctions in cases of *bona fide* infringement. In accordance with the US case law, such injunctions can be refused for reasons of ‘equity’ as determined by the competent courts. In addition, provisions may be introduced to protect farmers against legal actions where an unintentional presence of patented materials is found in their fields.

**Recommendation:** a patent should not be considered infringed when a patented material is unintentionally present in plant varieties, for instance, as a result of out-crossing. In addition, permanent injunctions should not be granted where plant materials containing a patented component were acquired by prior to knowing or having reasonable grounds to know that dealing with such materials would infringe a patent. Such injunctions may also be refused when an anti-competitive conduct by the patent owner is established, or where the diffusion of a plant variety is important for food security.



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