

October 2009



منظمة الأغذية  
والزراعة  
للأمم المتحدة

联合国  
粮食及  
农业组织

Food  
and  
Agriculture  
Organization  
of  
the  
United  
Nations

Organisation  
des  
Nations  
Unies  
pour  
l'alimentation  
et  
l'agriculture

Продовольственная и  
сельскохозяйственная  
организация  
Объединенных  
Наций

Organización  
de las  
Naciones  
Unidas  
para la  
Agricultura  
y la  
Alimentación

**COMMISSION ON GENETIC RESOURCES  
FOR FOOD AND AGRICULTURE**

**TRENDS IN INTELLECTUAL PROPERTY RIGHTS RELATING TO  
GENETIC RESOURCES FOR FOOD AND AGRICULTURE**

by

**Carlos M. Correa<sup>1</sup>**

This document has been prepared at the request of the Secretariat of the FAO Commission on Genetic Resources for Food and Agriculture, to provide an overview of recent developments in intellectual property rights relating to genetic resources for food and agriculture.

**The content of this document is entirely the responsibility of the authors, and does not necessarily represent the views of the FAO, or its Members.**

<sup>1</sup> Carlos Correa is a Professor of Economics of Science and Technology at the University of Buenos Aires, Argentina.

**TABLE OF CONTENTS**

	<i>Page</i>
<b>I. INTRODUCTION.....</b>	<b>1</b>
<b>II. PATENT PROTECTION.....</b>	<b>2</b>
<b>1. PLANT GENETIC RESOURCES .....</b>	<b>2</b>
<i>1.1. Patentable subject matter.....</i>	<i>2</i>
<i>1.2. Scope of exclusive rights.....</i>	<i>6</i>
<b>2. MICROORGANISMS.....</b>	<b>11</b>
<b>3. ANIMAL GENETIC RESOURCES.....</b>	<b>11</b>
<b>III. PLANT VARIETY PROTECTION.....</b>	<b>13</b>
<b>IV. SOME DEVELOPMENTS IN INTERNATIONAL ORGANIZATIONS.....</b>	<b>14</b>
<b>V. CONCLUSIONS.....</b>	<b>17</b>
<b>LIST OF ABBREVIATIONS.....</b>	<b>20</b>

## INTRODUCTION

Intellectual property rights (IPRs) may be applied to genetic resources (GRs), including microorganisms, plants and animals. Four main modalities of IPRs may be relevant to the protection of different kinds of GRs:

- utility patents;<sup>2</sup>
- trade secrets;
- plant variety protection;
- other *sui generis* systems of protection for plants.

After the landmark decision by the U.S Supreme Court *in re Chakrabarty* (1980), which accepted for the first time a patent on a microorganism *per se*, the patentability of biotechnological inventions has expanded in many countries so as to include, on the one hand, cells and sub-cellular parts and, on the other, multi-cellular organisms. A few countries (e.g. United States of America (USA), Australia) also allow for the patentability of plant varieties as such.

However, plants, as well as animals (broadly defined or limited to animal races) are excluded from patentability in many jurisdictions<sup>3</sup>, consistently with article 27.3(b) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. This situation has partially changed in the last ten years as the result of commitments made in the context of free trade agreements (FTAs) signed by the USA with a number of countries, which obligate the parties to take actions in order to provide patent protection for plants and/or animals, including in some cases plant varieties.<sup>4</sup>

Trade secrets, which protect undisclosed information of commercial value, may be applied to different types of GRs, such as parent and grandparent breeding stock for poultry production (when only cross breeds are commercialized) and hybrid seeds (when parental lines are not disclosed).<sup>5</sup>

Plant variety protection is a *sui generis* form of protection that, as examined below, has gained growing acceptance in the last ten years as an option for the protection of plant varieties.<sup>6</sup> Although many proposals and analyses have been produced over the last fifteen years on *sui generis* options for plant variety protection, a small number of countries seem to have implemented such options so far.

This paper examines some of the legal developments relating to the protection of genetic resources that took place in the last ten years<sup>7</sup> in relation to patents and *sui generis* regimes for plant varieties. Section II presents issues relating to the patentability of plants (subject matter and scope of protection), animals and microorganisms. Section III refers to the *sui generis* regimes, other than plant variety protection (PVP),

---

<sup>2</sup> In the case of the USA a special type of patents (plant patents) are also available under the *Plant Patent Act* of 1930.

<sup>3</sup> The scope of the exception, however, varies under different laws. For instance, under the European Patent Convention plant varieties are excluded from patentability, but the Board of Appeals of the European Patent Office (EPO) has accepted patents over plants (e.g. on a transgenic trait) provided that an individual plant variety is not claimed. In accordance with article 4.2 of the European Directive on the Legal protection of Biotechnological Inventions (98/44/EC), '[I]nventions which concern plants or animals may be patented if the practicability of the invention is not technically confined to a particular plant or animal variety'.

<sup>4</sup> See, e.g. the FTAs US-South Korea, US - Republic of Korea; US - Sri Lanka; US - Nicaragua; CAFTA. See Mullapudi Narasimhan, Savita (2008), *Towards a balanced sui generis plant variety regime- Guidelines to establish a national PVP law and understanding of of TRIPS-plus aspects of plant rights*, UNDP, New York, available at [content.undp.org/go/cms-service/download/asset/?asset\\_id.](http://content.undp.org/go/cms-service/download/asset/?asset_id.), p. 24 .

For information on various FTAs, see <http://www.ustr.gov/trade-agreements/free-trade-agreements> and <http://www.grain.org/rights/tripsplus.cfm?id=68>.

<sup>5</sup> For instance, trade secret protection was enforced in relation to inbred lines by a US court in *Pioneer Hi-bred v. Holden*, 35 F.3d 1226, 31 USPQ2w 1385 (8th Cir. 1994).

<sup>6</sup> In accordance with article 27.3(b) of the TRIPS Agreement, such varieties may be protected by patents, an effective *sui generis* regime or a combination of both.

<sup>7</sup> Relevant earlier precedents, however, are mentioned where necessary to introduce or explain a particular issue.

established in a few countries. Section IV summarizes, finally, the developments in various international fora and organizations. There has been no attempt to be exhaustive in the analysis of national legislation. Given the lack of comprehensive and updated statistical studies on intellectual property rights granted to protect GRs for food and agriculture, quantitative information on the subject is only incidentally mentioned. The paper does not cover issues related to the protection of traditional knowledge associated to genetic resources nor to access and benefit sharing regulations, which would deserve separate treatment.

## I. PATENT PROTECTION

### 1. Plant genetic resources

#### 1.1. Patentable subject matter

Depending on national laws, patents may cover cells and sub-cellular parts, including genes, plants and plant varieties.<sup>8</sup> Processes for the production of plants may also be patented, under certain conditions.<sup>9</sup>

The significant number of patents granted in the area of plants, and the diversity of covered subject matter, has raised intense litigation and considerable concerns in agricultural circles about the scope of patent protection and its impact on the use of seeds and the access to germplasm for further research and breeding, particularly for the production of public goods. It has been noted in this regard that ‘[S]ince crop genetic improvement is a derivative process, each incremental improvement made through biotechnology now comes with a number of IP constraints, with new IP added with each transfer or further improvement... IP is used to protect biotechnology tools and reagents; genes and gene sequences; regulatory sequences; processes of transformation, regeneration and diagnosis; and, the resulting modified plants. It is in part to deal with this thicket of patents, and to gain “freedom to operate” (FTO), that the private sector is becoming greatly centralized through a large number of mergers, acquisitions and cross licensing agreements. The publicly-funded agricultural research community, for the most part, lacks FTO’.<sup>10</sup>

The development of new transgenic seeds would normally require the use of various patented methods, such as for gene isolation, transformation, culture of transformed cells, and regeneration of plants. Hence, developing a new transgenic plant may necessitate a careful analysis of the available ‘freedom to operate’ and possibly the negotiation of license agreements with several holders of patents that may be infringed in the process.<sup>11</sup>

While the first generation of genetically modified seeds essentially aimed at expressing individual traits in plants, genetic engineering techniques permit ‘stacking’ multiple genes to confer herbicide tolerance *and* insect resistance. Such techniques may also be used to control the levels of certain plant components.<sup>12</sup> Significantly, advances in science and technology<sup>13</sup> associated to the use of

<sup>8</sup> Most countries, however, do not grant patents on plant varieties but protect them under PVP only.

<sup>9</sup> Many laws exclude the patentability of essentially biological processes for the production of plants, but this exclusion has been interpreted in some jurisdictions as allowing the patentability of processes in which certain degree of human intervention is shown. A classical example was the *Lubrizol* patent (European application No. 44.723).

<sup>10</sup> Toenniessen, G. and Delmer, D. (2006), ‘The role of intermediaries in maintaining the public sector’s essential role in crop varietal improvement’, in *CGIAR research strategies for IPG in a context of IPR*, p. 49, available at [http://www.google.com.ar/search?q=cgiar+research+strategies+ipg&ie=utf-8&oe=utf-8&aq=t&rlz=1R1GGGL\\_es\\_AR344&client=firefox-a](http://www.google.com.ar/search?q=cgiar+research+strategies+ipg&ie=utf-8&oe=utf-8&aq=t&rlz=1R1GGGL_es_AR344&client=firefox-a).

<sup>11</sup> See, e.g., Krattiger, Anatole (2007), ‘Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options’, in *Intellectual property management in health and agricultural innovation. A handbook of best practices*, MIHR-PIPRA, Oxford, pp. 1317-1327.

<sup>12</sup> See, e.g. patent EP 0537178 on the use of nucleic acid fragments encoding soybean seed stearyl-ACP desaturase enzyme or its precursor to modify plant oil composition.

conventional breeding methods -which remain the main source of new plant varieties<sup>14</sup>- allow the expression of desired traits without the insertion of genes not naturally present in the plant.<sup>15</sup> Plants can, for instance, be modified to cope with climate change by enhancing their resistance to environmental stresses such as heat, cold, salinity and drought.<sup>16</sup>

In the light of these developments, some of the issues raised by the grant of patents in the area of plants include the following.<sup>17</sup>

*-Distinction between 'invention' and 'discovery'*: a basic question in the application of patent laws has been whether isolated genes and other biological materials may be deemed 'invented' and, hence, eligible for patent protection. A large number of patents have been granted, for instance, over genes that are engineered by mutagenesis or genetic engineering techniques, and even on isolated genes that had not been known to previously exist in nature. Although substances as existing in nature are not eligible for patent protection, a principle generally accepted under patent law is that the fact that an invention consist of, is based on or employs living matter, is not a sufficient reason to exclude patent protection.<sup>18</sup> Some countries, however, do not consider that an 'invention' exists where certain natural substance, such as a gene, has been isolated and its utility identified.<sup>19</sup>

*-Inventive step*: the level of inventive step required to grant a patent is crucial to determine the extent to which patents on genetic resources may be acquired. In some countries a relaxation of this criterion has been observed, which may explain the proliferation of patents with a low or inexistent inventive step.<sup>20</sup> In the case of the US law, recent court decisions point to a possible tightening of the 'non obviousness' requirement. In *KSR Int'l Co. v. Teleflex, Inc.* (550 U.S. 398, 2007), the Supreme Court indicated that 'A person of ordinary skill is also a person of ordinary creativity, not an automaton... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense...'.<sup>21</sup> In implementing the KSR doctrine, the

---

<sup>13</sup> Such as the use of fingerprinting, quantitative trait locus, targeting induced local lesions in genomes (TILLING), molecular marker-assisted selections (MAS), and Transcription Factor Stress-Related Proteins (TFSRP).

<sup>14</sup> See, e.g., Orlando de Ponti, Presidential Address, ISF Congress 2009 in Antalya, Turkey.

<sup>15</sup> Functional genomics permits the identification of gene sequences in the plant that can be over-expressed to obtain desired traits. Examples include patents US 7253000 and US 7161063. See, e.g., ETC Group (2008), *Patenting the 'climate genes'... And capturing the climate agenda*, available at [http://www.etcgroup.org/en/materials/publications.html?pub\\_id=687](http://www.etcgroup.org/en/materials/publications.html?pub_id=687). The application of 'cisgenetics', on the other hand, permits the improvement of cultivated plants using genes from wild relatives.

<sup>16</sup> ETC Group, op. cit.

<sup>17</sup> Several issues discussed in this and the following subsection, in particular, the distinction between discovery and invention, inventive step and coverage of patents on genes, are also relevant, *mutatis mutandi*, to the protection of microorganisms and animals dealt with below.

<sup>18</sup> The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996) stipulates that "biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature" (Article 3.2).

<sup>19</sup> For instance, the 1996 Brazilian Industrial Property Code (No. 9.279, 14 May 1996) excludes the patentability of 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>20</sup> See, e.g., Jaffe, Adam B. and Lerner, Josh (2004), *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press; Federal Trade Commission (2003), *To promote innovation: the proper balance of competition and patent law policy*, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

<sup>21</sup> Available at [www.supremecourtus.gov/opinions/06pdf/04-1350.pdf](http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf). A decision by the US Supreme Court is expected in the case *In re Bilski* (545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008, *en banc*)) which may have implications on the patentability of software tools used in agro-biotechnology as well as in cases where a patent claim preempts the use of natural phenomena or laws of nature, refers to methods of identifying mutations or to a process of analyzing data. See, e.g., Holman, Christopher (2008) *Applying Bilski to Biotechnology and the Life Sciences*, available at <http://www.patentlyo.com/patent/2008/11/applying-bilski.html>.

USPTO is requiring its examiners to apply a stricter criterion to grant patents.<sup>22</sup> The KSR doctrine is also influencing lower court decisions. For instance, *In re Marek Z. Kubin and Raymond G. Goodwin* (2008-1184, Serial No. 09/667859), the US Court of Appeals for the Federal Circuit determined the obviousness of a claim on a deoxyribonucleic acid (DNA) sequence of a gene associated with immune response.<sup>23</sup>

Questions about inventive step (or non-obviousness) arise when conventional methods, including hybridization,<sup>24</sup> and selection of plants for particular traits,<sup>25</sup> are used. An interesting example is provided by the 'enola patent'. US patent 5894079 was granted on April 13, 1999 on a 'new field bean variety that produces distinctly colored yellow seed which remain relatively unchanged by season' and a method for producing it. The patent was enforced against Mexican farmers selling yellow beans in the USA and seed companies and farmers growing or selling the Mexican yellow beans in the USA. The patentee had purchased a bag of commercial bean seeds in Mexico and selected the yellow seeds for several generations through conventional methods until he obtained a 'uniform and stable population' of yellow seeds.<sup>26</sup> The International Center for Tropical Agriculture (CIAT) filed a formal request for re-examination of the US patent in December 2000. After nine years of administrative and judicial procedures, the US Court of Appeals for the Federal Circuit ruled *in re* POD-NERS, LLC. that all the claims were obvious and, therefore, invalid. It reasoned that '[O]ne of ordinary skill in the art seeking to reproduce (and hopefully improve) the yellow beans that Proctor brought back from Mexico would have done what he did: plant the beans, harvest the resulting plants for their seeds, planting the latter seeds, and repeat the process two more times'.<sup>27</sup>

Similar questions arise out with regard to patents on minor changes to existing technologies. Claims on variants<sup>28</sup> of already known genetically engineered traits, if accepted by the patent offices, may affect the availability of *generic* versions of genetically modified plant varieties after the original patents have expired.<sup>29</sup> Regulatory issues may also erect *de facto* barriers for generic competition. Given the time and resources required to obtain marketing approval of a genetically modified organism (GMO), the potential benefits to society of the expiry of the patent term may be lost if, as it is the case in some jurisdictions, the marketing of generic versions of an GMO is not allowed after the end of the market authorization conferred to the original developer, if the latter.<sup>30</sup>

<sup>22</sup> The US Patent and Trademark Office (USPTO) *Examination training materials in view of KSR International Co. v. Teleflex Inc.* contains the following example of a patent claim that should be rejected: A transgenic corn plant that produces a Bt protein where the foreign DNA nucleic acid coding sequence has a G+C content of at least about 60%. In this case '[I]t would have been obvious to one of ordinary skill in the art to modifying the Bt DNA sequence by selecting codons for the Bt amino acid sequence that are rich in G+C with a reasonable expectation of improved expression of Bt in by the corn plant and optimizing the percentage G+C to produce desired expression' (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/ksr/ksr\\_training\\_materials.htm](http://www.uspto.gov/web/offices/pac/dapp/opla/ksr/ksr_training_materials.htm)).

<sup>23</sup> Available at <http://www.cafc.uscourts.gov/opinions/08-1184.pdf>.

<sup>24</sup> E.g. US [4143486](#) on hybrid wheat.

<sup>25</sup> E.g. US [4769512](#) on a plant genotype characterized by the expression of a low pod detachment force in *Phaseolus*.

<sup>26</sup> See, e.g., Shashikant, Sangeeta and Asghedom, Asmeret (2009), 'The 'Enola Bean' dispute: patent failure & lessons for developing countries', *TWN Info Service on WTO and Trade Issues* (Aug09/11) 12 August 2009, Third World Network, [www.twinside.org.sg](http://www.twinside.org.sg).

<sup>27</sup> US Court of Appeals for the Federal Circuit. 2008-1492. (Re-examination No. 90/005892). *In re* POD-NERS, L.L.C. (10 Jul 2009), available at [www.cafc.uscourts.gov/opinions/08-1492.pdf](http://www.cafc.uscourts.gov/opinions/08-1492.pdf). The ruling confirmed the *relative* novelty standard applied in the USA; it noted that 'being on sale, in public use, or known or used outside the United States' were not statutory bars to patentability.

<sup>28</sup> For instance, AR P040100492, which claims EPSPS tolerant to glyphosate by mutations of amino acids in positions 102 and 106.

<sup>29</sup> The so-called 'evergreening' of patents has been widely observed in the pharmaceutical sector. See European Commission (2009), *Pharmaceutical Sector Inquiry Report*, p. 10, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html><http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

<sup>30</sup> Lema, M. and Loewenstein, V. (2008), 'Tit for tat: agbiotech intellectual property and corporate social responsibility', *Environment and Natural Resources Programme*, ICTSD, *vol. 2, No. 3*, October, available at <http://ictsd.net:80/i/environment/31522/>.

Moreover, patent applications relating to 'native' traits and conventional breeding methods have become increasingly frequent in the last few years.<sup>31</sup> A study found that 'in 2008 nearly 25% 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'.<sup>32</sup> 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.<sup>33</sup>

-*Multiplicity of patents*: patent claims relating to genes, as mentioned, may cover different subject matter, such as the DNA sequence, whether comprising a complete or partial gene, promoters, enhancers, individual exons, expressed sequence tags (ESTs) or cDNAs, whole transcribed genes as cDNAs, cloning vectors, expression vectors, isolated host cells transformed with expression vectors, amino acid sequences (proteins), and nucleic acid probes.<sup>34</sup> Many patents may be found, hence, around a single genetically engineered trait. The patenting of components and methods for genetic engineering in plants (such as promoters, terminator sequences, sequences used for 'transportation' and 'reporter genes'<sup>35</sup>) may mean that, although a genetically engineered trait *as such* may be in the public domain, the commercialization of seeds containing it or directly resulting from a patented method<sup>36</sup> might be prevented on the basis of other patents in force.<sup>37</sup>

- *Misappropriation of genetic resources and traditional knowledge*: patents relating to plants have reportedly involved, in some cases,<sup>38</sup> genetic resources or traditional knowledge obtained without consent from the countries of origin or traditional holders, and without benefit sharing as prescribed by the Convention on Biological Diversity. Thus, the Peruvian government<sup>39</sup> identified several patents and patent applications relating to 'maca' (*Lepidium meyenii*), including claims on extracts, 'macamides', and therapeutic methods and uses of the plant.<sup>40</sup> The Peruvian government expressed its concerns about the extent to which the patents granted<sup>41</sup> and pending applications in the USA could prevent exports of maca extracts from Peru, and about the recognition of patent rights on genetic materials obtained 'unlawfully, contrary to the specific Decision 391 or even the rules in force for

<sup>31</sup> See, e.g., EP 1069819 on broccoli and EP 1211926 on tomatoes derived from conventional breeding (currently on appeal before the Enlarged Board of Appeal of the European Patent Office) and EP 0483514 on the use of fingerprinting in tree breeding.

<sup>32</sup> 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.

<sup>33</sup> *Idem*, p. 16.

<sup>34</sup> See Nuffield Council on Bioethics (2002), *The ethics of patenting DNA. A discussion paper*, London, p. 25. Although initially granted, patent applications on ESTs have been refused in the USA due to lack of utility.

<sup>35</sup> E.g. E.g. US 5097025 on promoter CaMv35s; EP 0507698 on an 'Isolated DNA sequence which can serve as terminator region in a chimeric gene capable of being used for the transformation of plants'; AR 256231 on DNA sequences of a transit peptide and chimeric gene for plant transformation; US 6174724 on chimeric genes suitable for expression in plant cells.

<sup>36</sup> In accordance with article 28.1(b) of the TRIPS Agreement, a process patent extends to the products directly obtained with its application.

<sup>37</sup> For instance patent AR 256231 has been enforced against local companies in Argentina that commercialized maize incorporating GA21 -which provides tolerance to glyphosate- despite the fact that GA21 is in off-patent in that country.

<sup>38</sup> A broad spectrum of materials and knowledge relating to indigenous peoples from different countries has been subjected to patent protection. See, e.g., Oldham, P. and Hall, S. (2009), *A European Patent Indicator for Access to Genetic Resources and Benefit-Sharing*, Report to the European Environment Agency EEA/BSS/08/012. ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) Lancaster University (abstract available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1397108](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1397108)), p. 72-79.

<sup>39</sup> See WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fifth session, Geneva, July 7-15, 2003, Patents referring to *lepidium meyenii* (maca): responses of Peru. Document submitted by the Delegation of Peru, WIPO/GRTKF/IC/5/13, available at [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_5/wipo\\_grtkf\\_ic\\_5\\_13.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_13.pdf).

<sup>40</sup> Oldham and Hall identified 107 patent documents containing the terms *Lepidium meyenii* in the Micropatent database (Oldham and Hall, op. cit. p. 77).

<sup>41</sup> Granted patents include US 6552206 "Compositions and methods for preparation from *Lepidium*"; US 6428824 "Treatment of sexual dysfunction with an extract of *Lepidium meyenii* roots"; US 6267995 "Extract of *Lepidium meyenii* roots for pharmaceutical applications"; US 6878731 "Imidazole alkaloids from *Lepidium meyenii* and method of usage".

collecting and exporting biological materials'.<sup>42</sup> The government also noted 'the enormous difficulty encountered by the country in its attempts to challenge or question, for administrative or legal reasons, in the United States or Europe, patents of this nature. Although the rules of the game are clear, the reality is that even where we wish to use them, the costs, time, and need for specialized advice make effective action in relation thereto and other similar patents very difficult. Any action taken after the event is prohibitively expensive'.<sup>43</sup> The use by patent offices of databases with information on genetic resources may contribute to reduce their appropriation through wrongly granted patents.<sup>44</sup>

In sum, trends relating to the subject matter of plant patents reflect the evolution of science and technology and, in particular, the possibility of applying a range of tools to increase the efficiency of conventional methods. In accordance with one report, the '[M]obilisation of biotechnologies in traditional plant breeding looks set to replace GMO, with the latter being developed only when the desired characteristic is expressed in too weak a way inside the species'.<sup>45</sup> In the next few years, however, patenting based on genetic engineering and other techniques are likely to coexist.

### 1.2. Scope of exclusive rights

Patents over genetic resources for food and agriculture have, given their peculiar nature and function, raised a set of specific issues relating to the scope of the exclusive rights conferred on the right holder, including with regard to possible restrictions to the use of protected materials for first and subsequent reproductions or multiplications, and for further research and breeding. Some of these issues are briefly reviewed below.

A matter of concern has been the breadth of patent claims. In some cases, claims covering a genetically modification in many field crops or throughout a whole species have been granted.<sup>46</sup> In addition, where functional claims<sup>47</sup> are allowed, all the potential means to solve a problem may be covered (for instance, the increase of the content of a given amino acid in the plant).<sup>48</sup>

In principle, a patent on a gene covers all its possible functions. However, a function of a patented gene not identified by the patentee may be subsequently found. Thus, the protection of a gene as such may hinder further research on it and its application for new uses. Some legislative reforms have addressed this issue. For instance, article L613-2-1 of the French Industrial Property Code, as amended in 2004, clarifies 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

<sup>42</sup> WIPO/GRTKF/IC/5/13, op. cit., para. 117. In accordance with Peru's submission, '[S]ix of the seven inventors mentioned in the patents of the United States of America and international applications analyzed recognize that they obtained dry maca roots from Peru in 1998' (idem. para. 118. X(ii)).

<sup>43</sup> Idem, para. 118. X(iii). In June 2007, Naturex, a French company that acquired in 2005 Pure World Botanicals Inc, the original owner of the patents on maca, , announced that it would grant 'free patent licenses to those companies that are 100 percent Peruvian-owned for the manufacture of [maca](#) extract and sale to end users' (<http://www.nutraingredients-usa.com/Industry/Naturex-eases-maca-patents-for-benefit-of-Peruvian-growers>).

<sup>44</sup> The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and the [International Center for Tropical Agriculture](#) ( CIAT), for instance, have made agreements with the European Patent Office, in 2008 and 2009, respectively, to ensure that prior art information available to patent examiners includes research results from those Centres. See [www.casipblog.wordpress.com](http://www.casipblog.wordpress.com).

<sup>45</sup> Trommter, Michel (2008), *Intellectual Property Rights in Agricultural and Agro-food Biotechnologies to 2030*, OECD, Paris, p. 29, available at <http://www.oecd.org/dataoecd/11/56/40926131.pdf>.

<sup>46</sup> For instance, in May 2007, the EPO revoked, after 13 years of procedures, a 'species-wide' patent (EP 0301749) on genetically modified soybeans, which was challenged by the ETC Group, an international civil society organization based in Canada, supported by Greenpeace and the "No Patents on Life! movement. See <http://lists.mutualaid.org/pipermail/sustainabletompkins/2007-May/002133.html>.

<sup>47</sup> Functional claims describe what an invention *does* rather than what an invention *is*.

<sup>48</sup> See, the classical example of the *Hibberd* patent, the first-ever issued patent for a plant in the United States, which disclosed an increase in tryptophan content.

be enforced against a subsequent claim on the same sequence that discloses another specific application thereof.<sup>49</sup>

Some laws make it clear that a plant or animal material may be multiplied or reproduced where it has been legally put on the market by the patent-holder or with his consent, where this was the purpose for which the material has been marketed. The obtained material, however, cannot be used for further reproduction or multiplication.<sup>50</sup> Provisions of this type determine the scope of the rights purchasers of materials subject to patent protection may have to utilize them in their normal farming activities.

A particularly important issue is the extent to which a farmer may save and re-use seed that incorporates a patented component. The possibility that farmers save seeds for further use in their exploitations (generally known as the 'farmers' privilege') has been a typical feature under PVP. While such a privilege is allowed under the 1978 version of the International Convention for the Protection of New Varieties of Plants (UPOV), it may be introduced as an exception, subject to some conditions, under UPOV 1991. The application of this exception is subject to payment of a compensation to the breeder in some countries.<sup>51</sup>

Patent laws, however, do not generally provide for an exception of this kind: patents on plant genetic materials may be enforced to restrict the saving and replanting of seeds that contain patented subject matter. Illustrative was the *Monsanto Canada Inc. v. Schmeiser* case, where the priority of patent rights over the right of the physical owner of a seed to save and replant it was affirmed by Canadian courts. Monsanto sued Schmeiser, a canola breeder and grower in Saskatchewan, who had harvested and saved canola seed from one of his fields containing Monsanto's patented transgene that conferred resistance to glyphosate. The Supreme Court of Canada held that 'the issue is not property rights, but patent protection. Ownership is no defence to a breach of the *Patent Act*'. It did not find as sufficient defense against infringement 'the ancient common law property rights of farmers to keep that which comes onto their land'. 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 defense 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'.<sup>52</sup> The Supreme Court ([2004] 1 S.C.R. 902, 2004 SCC 34) confirmed 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.<sup>53</sup>

In a decision by 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 in a case involving saved seeds. A farmer was condemned to pay US\$ 40 per bag of saved seed. In determining this amount the Court considered that

---

<sup>49</sup> In Germany, a similar limitation on gene patents was introduced in connection with human genes (*Patent Act* of December 16, 1980, as last amended by the Law of February 28, 2005). The *European Parliament resolution on patents for biotechnological inventions* of 26 October 2005 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), available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN>.

<sup>50</sup> See, e.g. French patent law, article L613-2-4 (as incorporated in 2004).

<sup>51</sup> See, e.g. the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, available at <http://www.cpvo.europa.eu/documents/lex/394R2100/EN394R2100.pdf>.

<sup>52</sup> See <http://csc.lexum.umontreal.ca/en/2004/2004scc34/2004scc34.html>.

<sup>53</sup> Decision available at <http://csc.lexum.umontreal.ca/en/2004/2004scc34/2004scc34.html>.

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.<sup>54</sup>

Some patent laws, however, have carved out a special exception in order to allow farmers, under certain conditions, to save and re-use seeds obtained in their exploitations with the cultivation of seeds containing patented materials. This exception mirrors the 'farmers' privilege' under PVP regimes. For instance, article 11 of the European Directive on the Legal Protection Biotechnological Inventions (Directive 98/44/EC) included an exception of this kind, subject to the same conditions and limitations applicable under the European Community Regulation (EC) n° 2100/94 on plant variety rights.

In order to protect a farmer against legal actions based on an unintentional presence of a patented material in a planted variety (as in the Schmeiser case), the Swiss patent law introduced a specific exception. In accordance with article 9(f), as amended in 2007, 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.

Innovation in agriculture is dependent on the use of existing genetic materials for further research and breeding. Concerns have been raised about the space left where plant materials are protected by patents, for developing new varieties or undertaking other research aimed, for instance, at assessing the materials' safe and effective use, or using them for education and extension.<sup>55</sup>

PVP regimes allow the use by breeders of a protected plant variety for research and breeding (the 'breeders' exception'). This is a mandatory exception under the UPOV Convention<sup>56</sup> and a key feature of PVP regimes. Under this exception, the outcome of the research and breeding can be freely commercialized by its developer, unless it is an 'essentially derived variety' the commercialization of which is, in accordance with the applicable law, subject to authorization of the breeder of the initial variety.<sup>57</sup>

The application of the breeder's exception may be constrained, however, when a patented material is present in a plant variety: [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

---

<sup>54</sup> See <http://www.cafc.uscourts.gov/opinions/05-1570.pdf>. A bill was submitted in California (USA) to exempt from infringement a farmer who did not know he was planting an infringing patent, when he acted *bona fide*, or when a patented GMO was found at insignificant levels. See <http://www.infogm.org/spip.php?article3705>.

<sup>55</sup> See 'A seed is planted: new dialogue makes significant progress in addressing independent seed research', American Seed Trade Association, [http://www.amseed.org/news\\_enews081209.asp](http://www.amseed.org/news_enews081209.asp), 12.08.2009.

<sup>56</sup> In accordance with UPOV, 'plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society' (UPOV, *Access to genetic resources and benefit-sharing. Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)* (adopted by the UPOV Council in its session number 37, on 23rd October 2003), available at [http://www.upov.int/export/sites/upov/en/news/2003/pdf/cbd\\_response\\_oct232003.pdf](http://www.upov.int/export/sites/upov/en/news/2003/pdf/cbd_response_oct232003.pdf)).

<sup>57</sup> The concept of 'essentially derived variety', incorporated by UPOV 1991, does not apply in PVP regimes modelled in accordance with UPOV 1978.

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>58</sup>

Under patent laws, an experimentation or research exception is generally provided for, but its scope varies considerably among national jurisdictions.<sup>59</sup> A few patent laws have included *specific* exceptions for research on biological materials.

For instance, article 22.V of the Mexican Law on Industrial Property (of June 25, 1991, as last amended by the Decree of May 17, 1999) provided 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).

Article L613-5-3 of the French law (as amended in 2004) provided 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. The Swiss law, as amended in 2007, stipulated in article 9(e) that the rights conferred by a patent do not extend to the use of biological material for selection or discovery with the purpose of developing a plant variety.<sup>60</sup> This kind of exceptions, strictly interpreted, however, would not be fully equivalent to the breeder's exception under PVP since, where a patent is in force, the breeder may not be free to commercialize the new variety he has developed, to the extent that the patented invention is still expressed in the new variety.<sup>61</sup>

A breeder may not be entitled to legally commercialize a new plant variety that contains one or more genes or other components covered by third parties' patents; 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.

---

<sup>58</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, October 25, 2002, WIPO-UPOV/SYM/02/2, para. 12 and 26.

<sup>59</sup> In Europe, research *on* (as opposed to *with*) a patented invention is generally permissible, even for commercial purposes. In *Madey vs Duke* (64 USPQ2d 1737 (Fed. Cir. 2002) the US Court of Appeals of the Federal Circuit ruled that the experimental use is not permitted, whether or not it is done with the intent to make a profit, but in pursuance of a business purpose and not 'solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry' (available at <http://cyber.law.harvard.edu/people/tfisher/2002Madeyedit.html>). However, in the case of plant patents granted in the USA it is interpreted (based on *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560, 36 USPQ2d 1673, CAFC 1995) that a protected variety can be used by a third party without authorization as a parent in a commercial breeding program, since infringement will only exist when the accused variety was derived *asexually* from the protected variety. See Henson-Apollonio, Victoria (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>60</sup> Any agreement that limits or nullifies the exception would be deemed null and void.

<sup>61</sup> Under this kind of exception a license from the patent owner would presumably be needed only at the time the new variety is commercialized, and not necessarily at the time when experimentation or crossing with a variety that contains a patented trait takes place. However, a breeder is unlikely to undertake the development of a new variety in a context of uncertainty about the possibility of obtaining a license after several years of breeding. Plantum NL (the Dutch seeds association) has recently proposed to create under patent law the same 'balance' found under PVP between rewarding breeders and allowing for 'continual improvement of varieties by other breeders', 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' (*Plantum NL position on patents-and plant breeders' rights* adopted 6 May 2009). In a letter of June 29, 2009, HM/MO/09-022, Crop International argues 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' ([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)).

A few national laws<sup>62</sup> have specifically sought to provide a legal solution to the problem of accumulation on the same material of PVP and patent rights belonging to different parties. Article 12 of the European Directive on the Legal Protection of Biotechnological Inventions provides for the grant of a compulsory license (subject to a cross-license) when a patent owner or a plant breeder cannot use their rights without infringing a breeder's right or a patent, respectively.<sup>63</sup> The possibility of effectively obtaining a compulsory license of this kind is limited, however, by the conditions that should be met for their grant. The breeder (or patentee) would need to show that his variety (or invention) represents an important advance of certain economic interest with regard to the patented invention (or protected plant variety). This proof may be hard to produce given the different nature of the subject matter protected by PVP and patents. More recently, the 2007 amendment to the Swiss patent law (article 36a) introduced the right of a breeder to request a compulsory license when he cannot obtain or exploit his title without infringing a patent, under conditions similar to those established in the referred to European Directive.

The introduction into patent laws of exceptions equivalent to the breeders' exception and the farmers' privilege under PVP, as well as of compulsory licenses are, some of the 'flexibilities' allowed by articles 30 and 31 of the TRIPS Agreement. Such exceptions may be necessary even where a country opts not to grant patents on plants, to the extent that the patentability of plant components (e.g. gene constructs) is permitted. Significantly, the debates about the use of such flexibilities have largely focused on the measures that may be adopted to protect public health,<sup>64</sup> and have only incidentally addressed their use to ensure a sustainable agriculture and food security.

The scope of protection conferred by patents on seeds in relation to derivative products has also generated some controversy and litigation. Monsanto requested and obtained border measures in several European countries to detain the importation into Europe of soya meal produced in Argentina, based on the alleged violation of European patents (EP)<sup>65</sup> over a gene construct that confer plants resistance to glyphosate. Some European importers of the Argentine meal were sued on this ground. 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. Sesostri 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.<sup>66</sup> In a third case, the District Court in The Hague, Civil Law Sector, on 28 September 2008, requested the Court of Justice of the European Communities to reach a decision, *inter alia*, on whether article 9 of Directive 98/44/EC<sup>67</sup> on the protection of biotechnological inventions (OJ EC L 1998, no. 213 pp. 0013-0021)

---

<sup>62</sup> In accordance with article 31 of the TRIPS Agreement, national laws may determine the grounds for the grant of compulsory licenses. These may include the protection of public health or the environment, food security or broader public interests. Article 31(l), in particular, refers to the situation of patents' dependency, that is, when a patent cannot be used without infringing another patent.

<sup>63</sup> It is to be noted that modern techniques, such as, molecular marker-assisted selection may avoid this type of conflict as they allow to by-pass products resulting from crossing in which the patented gene is present (Trommter, (2008), op. cit. p. 14).

<sup>64</sup> Such debates led to the adoption, in November 2001, of the referred to Doha Declaration on the TRIPS Agreement and Public Health by the 4th WTO Ministerial Conference.

<sup>65</sup> Patents EP 218571 and EP 546090. Equivalent patents had not been obtained by Monsanto in Argentina.

<sup>66</sup> The referred to judicial decisions have been appealed.

<sup>67</sup> One of the main issues at stake in the countries where the Directive was applicable has been the interpretation of its article 9, which provides 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'. On August 9, 2006, the DG Internal Market and Services of the

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’.<sup>68</sup>

## 2. Microorganisms

Although under article 27.3(b) of the TRIPS Agreement patents may not be granted, as noted above, for plants and animals, the same provision obligates World Trade Organization (WTO) Members to grant patents over microorganisms when the patentability requirements are met. A “micro-organism” is an ‘organism’, that is, an organized body with connected interdependent parts sharing common life, which is not visible to the naked eye.<sup>69</sup> However, in some countries, the concept of ‘micro-organism’ has been expansively understood as encompassing all kinds of microscopic biological materials, including cells and genes.<sup>70</sup>

There are important differences in national laws regarding the patentability of natural microorganisms, even if isolated, for which a particular function has been found. While in some countries they would be a ‘discovery’, not eligible for patent protection, in others an ‘invention’ may be deemed to exist.<sup>71</sup> On the other extreme, the application of a patent covering a novel bacterium entirely made up of synthetic DNA has been reported.<sup>72</sup>

Under the TRIPS Agreement, countries may apply a strict definition of microorganism, as indicated above, and determine how the disclosure of the invention is to be made. The Agreement does not oblige WTO Members to apply any particular requirement to deal with the disclosure of inventions involving microorganisms. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of patent procedure (1977, amended in 1980) has established a mechanism for the recognition, for the purposes of the granting of a patent, of the deposit of a microorganism with a foreign depository authority. The number of contracting parties to this Treaty has significantly increased in the last fifteen years. The majority of contracting parties acceded to the Treaty after 1 January, 1995.<sup>73</sup>

## 3. Animal genetic resources

Patenting of animals has been highly controversial<sup>74</sup> and has motivated many challenges to patent applications and grants, including on moral grounds.<sup>75</sup> While in some countries patents on animals are

---

European Commission sent a letter to the Argentine government providing an interpretation of the referred to provision. It stated that, in accordance with article 9 of the Directive, the genetic information must perform its function in order to determine the existence of infringement, and that ‘patent protection cannot extend to derived products in which the genetic information is residual and does not performs its genetic function’ (author’s translation from the original in Spanish).

<sup>68</sup> The ‘enola patent’, was also reportedly used to prevent imports of enola beans from Mexico. See Shashikant and Asghedom (2009), op. cit.

<sup>69</sup> The *Concise Oxford Dictionary*, 1989, p. 639 and 719.

<sup>70</sup> See, e.g., Adcock, Mike and Llewelyn, Margaret (2000), *Micro-organisms, Definitions and Options under TRIPS and Micro-organisms, Definitions and Options under TRIPS: Supplementary Thoughts*, QUNO, Occasional Paper 2, Geneva.

<sup>71</sup> For instance, in the United States, a substance cannot be claimed as it exists in nature, but an isolated or purified form thereof is patentable. See also article 3.2 of the European Directive on the Legal Protection of Biotechnological Inventions.

<sup>72</sup> US application 20070122826.

<sup>73</sup> See [http://www.wipo.int/treaties/en/ShowResults.jsp?treaty\\_id=7](http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=7). The FTAs recently signed by USA and the EU have required the parties to adhere to the Budapest Treaty.

<sup>74</sup> The US government, for instance, self-imposed a moratorium on the grant of such patents that ended in 1993.

<sup>75</sup> The EPO, for instance, has applied a ‘balancing of interest’ approach to consider whether a patent on an animal would be immoral, taking into account whether the advantages for humanity of a genetically modified animal exceeded its eventual inconveniences. In the ‘Harvard onco-mouse’ case, the Board of Appeal held that patentability depended “mainly on a

not patentable in general –in line with the exception permitted by article 27.3(b) of the TRIPS Agreement- in others the ban on patentability is limited to animal races, excluding animals as such.<sup>76</sup> In a third group of countries, such as in the USA, animals and their parts are eligible for patents without limitations.

A study found that patent publications relating to animal cells and tissues multiplied about six times between 2000 and 2003 as compared to 1990-2000.<sup>77</sup> Patents have been granted in some countries in relation to stem cells.<sup>78</sup>

In countries where patents on animals are admissible, a significant number thereof has been granted on animals, which have been modified to mimic human conditions or diseases at the laboratory, a route opened by the Harvard University with the patenting in 1988 in the USA, of a genetically modified mouse for use in cancer research.<sup>79</sup> Patent claims have been made on animals infected with a virus, surgically altered, injected with a toxin, immunodepressed by chemicals and radiation,<sup>80</sup> or otherwise purposefully damaged.<sup>81</sup> Patents have included, *inter alia*, nematodes, avian species, rabbit, sheep, cats, cattle, chickens, chimpanzees, dogs, horses, macaque monkeys, Guinea pig, and fish. Some patent applications or grants cover methods of selection<sup>82</sup> or genetic improvement and production methods<sup>83</sup> that are relevant for food and agriculture.

As in the case of plants, an important issue is the extent to which farmers can use and dispose of the patented animals and their progeny. The specific legal exceptions found in national laws are rare and more limited than for plants. The French law, as amended in 2004, permits the farmer to use the cattle for an agricultural purpose, except sale for reproduction, eventually subject, however, to payment to the patent owner. The amended Swiss patent law (articles 35a.2 and 35a.3) recognizes the farmers' right to reproduce animals marketed by the patent owner but bans their transfer to third parties with a reproductive purpose.<sup>84</sup>

---

careful weighing up of the suffering of the animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other" (Decision T. 19/90, para. 5). In contrast, in the case of a transgenic hair growth mouse a patent was refused, since it was considered that the suffering of the animal outweighed the benefits of the cosmetics industry. See, e.g., Van Overwalle, G., (1997), *The legal protection of biotechnological inventions in Europe and the United States: current framework and future developments*, Centre for Advanced Legal Studies, Leuven University Press, Leuven, p. 28.

<sup>76</sup> See above article 4.2 of the European Directive on the Legal protection of Biotechnological Inventions (98/44/EC).

<sup>77</sup> See Paul Oldham (2004) *Global Status and Trends in Intellectual Property Claims: Microorganisms*, Submission to the Executive Secretary of the Convention on Biological Diversity, available at [www.twinside.org.sg/.../Intellectual\\_Property/.../microorganisms-Paul\\_Oldham.doc](http://www.twinside.org.sg/.../Intellectual_Property/.../microorganisms-Paul_Oldham.doc), Figure 3.

<sup>78</sup> Preliminary data for 2000-2003 found approximately 125 publications of patents and patent applications covering animal stem cells in the espacenet worldwide database. Idem, p. 36.

<sup>79</sup> This patent was granted in the USA and by the European Patent Office (EPO) but was rejected by the Canadian Supreme Court in 2002.

<sup>80</sup> An example is patent US 6444872 on a 'Large animal model of invasive pulmonary aspergillosis in an immunocompromised host' The patent claims covered, among other things, 'a canine model [of fungal lung infection], which covered methods used to induce a fatal lung infection in the beagle dogs (applicable also to pigs, sheep, monkeys, or chimpanzees).

<sup>81</sup> For instance, US patent 6924413 (revoked) covered a rabbit whose eyes have been damaged to mimic the 'dry eye' condition in humans.

<sup>82</sup> See, for example, US 2007105107 (A1) which 'provides methodologies for improved molecular genetic analysis of individual animals and animal populations. The invention includes methods and systems for identifying those animals in a population that are most likely to heritably pass on desirable traits. Provided are means for evaluating the estimated breeding values and increasing the average genetic merit for animals in a population'.

<sup>83</sup> See, for example, the international patent application WO 03096799 which 'comprises use of first and second, and optionally additional further, genetically and information-linked swine nucleus breeding herds to transmit genetic improvement from the first herd to each of the other herds which can be closed to live animal introduction to provide benefits in addition to genetic improvement to both the first and second and any additional herds'.

<sup>84</sup> The exceptions provided for in article 35.a.2 and 35.a.3 are mandatory; any agreement that limits or nullifies the exceptions would be deemed null and void (article 35.a.4)

## II. PLANT VARIETY PROTECTION

The need to implement the protection of plant varieties, as mandated by article 27.3(b) of the TRIPS Agreement, has triggered the adoption of PVP in the last fifteen years in many developing countries. The number of countries that apply PVP has grown significantly since 1995, as illustrated by the enlargement of UPOV membership.<sup>85</sup> Forty countries, that is, the majority of current contracting parties, adhered to UPOV after 1 January, 1995. Free trade agreements signed since the 1990's by the USA, the European Free Trade Association (EFTA) and the European Union with a number of developing countries, included the obligation to join UPOV. Some countries also made commitments to or indicated they had or intended to adhere to the UPOV Convention in the process of accession to the WTO.<sup>86</sup>

The room left by article 27.3(b) of the TRIPS Agreement to protect plant varieties created considerable interest in the development of regimes for the protection of plant variety different from those modeled on the basis of the UPOV Convention. Despite the numerous studies and proposals for the adoption of alternative *sui generis* models, however, a relative small number of countries have adopted so far such regimes. This is, in particular, the case of India, Thailand and Malaysia, whose legislation applies new or relaxed requirements for plant variety protection and combine the latter with benefit sharing provisions inspired by the Convention on Biological Diversity.

Under these regimes the conventional PVP requirements (novelty, distinctness, uniformity and stability) are modified to serve specific objectives.<sup>87</sup> For instance, the Indian *Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act)*<sup>88</sup> does not require novelty for the registration of extant and farmers' varieties, but the other requirements must be met (Article 15(2)). Similarly, under the Thai *Plant Variety Protection Act*<sup>89</sup> local domestic plant varieties need to comply with such requirements, except novelty (section 43) and the distinctness criterion has been modified.<sup>90</sup> In the case of the Malaysian *Protection of New Plant Varieties Act 2004*,<sup>91</sup> plant varieties bred or discovered and developed by a farmer, local community, or indigenous people, are protectable if they are new, distinct, and *identifiable* (Section 14.2). Hence, uniformity and stability are not required in these cases.<sup>92</sup>

There is so far no significant evidence about the impact of these *sui generis* regimes on the improvement, supply and diffusion of the various categories of protected plant varieties.

---

<sup>85</sup> International Convention for the Protection of New Varieties of Plants, adopted on 2 December 1961, available at <<http://www.upov.int/en/publications/conventions/index.html>> [UPOV Convention].

<sup>86</sup> See Abbott, F. and Correa, C., *World Trade Organization Accession Agreements: Intellectual Property Issues*, QUNO, Geneva, 2007, p. 20, available at [www.quono.org/geneva/pdf/economic/Issues/WTO-IP-English.pdf](http://www.quono.org/geneva/pdf/economic/Issues/WTO-IP-English.pdf)

<sup>87</sup> The *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (OAU Model Law)*, which was approved by the Organization of African Unity in 2000, has also proposed the granting of protection to plant varieties that may be identified without relying on the NDUS requirements. Ethiopia has enacted legislation on the basis of this model (Proclamation No. 482/2006, Access to Genetic Resources and Community Knowledge, and Community Rights).

<sup>88</sup> *Protection of Plant Varieties and Farmers' Rights Act*, [PPVFR Act], <http://agricoop.nic.in/seeds/farmersact2001.htm>.

<sup>89</sup> *Plant Variety Protection Act*, [PVP Act], available at [http://www.grain.org/brl\\_files/thailand-pvp-1999-en.pdf](http://www.grain.org/brl_files/thailand-pvp-1999-en.pdf).

<sup>90</sup> Section 12 (2) of the Act requires that distinctness be 'related to the feature beneficial to the cultivation, consumption, pharmacy, production or transformation, including the distinctness from the following plant varieties: (a) plant varieties already registered and protected, whether in or outside the Kingdom, prior to the date of filing the application; (b) plant varieties in respect of which application for registration has been made in the Kingdom and which will subsequently have been registered'.

<sup>91</sup> *Protection of New Plant Varieties Act 2004*, available at <http://www.grain.org/brl/?docid=657&lawid=1404>.

<sup>92</sup> However, the competent authority would reportedly restrict the application of this requirement to asexually reproducing crops, which have built-in uniformity and stability (Genetic Resources Policy Initiative (2006) *Exploring Legal Definitions of Farmers' Varieties in Strategies to Promote Farmers' Rights*, 26–28 October, Hanoi, p. 17–18).

### III. SOME DEVELOPMENTS IN INTERNATIONAL ORGANIZATIONS

*World Trade organization (WTO)*. Article 27.3 (b) of the TRIPS Agreement was the only provision in the TRIPS Agreement subject to an early review, due in 1999. Such a review, however, has been frustrated so far by substantial disagreement about the meaning of “review” in the context of that provision and about the scope and purpose of the work to be undertaken.<sup>93</sup> The Doha Ministerial Declaration - adopted at the 4<sup>th</sup> WTO Ministerial Conference in 2001- included a specific mandate,<sup>94</sup> still unfulfilled, on the subject.

A group of developing countries has proposed the introduction of an international obligation to disclose the origin of biological resources in patent applications,<sup>95</sup> in order to monitor the possible appropriation of genetic resources and associated traditional knowledge and non-compliance with access legislation.<sup>96</sup>

The arguments justifying the proposed amendment to the TRIPS Agreement (incorporation of a new article 29 *bis*) include that ‘...a legally binding obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in inventions will guide the patent examiners in ensuring that all relevant prior art information is available to the patent examiners. Disclosure will also be relevant in helping patent examiners determine whether the claimed invention constitutes an invention that is excluded from patentability under Article 27 paragraphs 2 and 3 of the TRIPS Agreement. Further, disclosure would serve as part of a process to systematise available information of biological resources and traditional knowledge that will continuously build the prior art information available to patent examiners and the general public’.<sup>97</sup>

<sup>93</sup> For some Members, the “review” should only deal with the *implementation* of the obligations under this article, while for others “review” means the *amendment*, as necessary, of such obligations. Several proposals were submitted, mainly by developing countries, to amend article 27.3(b), including banning patents on life, protection traditional knowledge and Farmers’ Rights, limiting the obligation to grant patents on microorganisms. For a summary of the positions, see WTO, *Review of the provisions of article 27.3(b). Summary of issues raised and points made. Note by the Secretariat*, IP/C/W/369/Rev.1, 9 March 2006.

<sup>94</sup> Paragraph 19: We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension (available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm)).

<sup>95</sup> See WTO document WT/GC/W/564/REV.2 TN/C/W/41/REV.2 IP/C/W/474, *Doha Work Programme – The outstanding implementation issue on the relationship between the TRIPS agreement and the Convention on Biological Diversity*, 5 July, 2006.

<sup>96</sup> A disclosure obligation of the type proposed, albeit with different formulations and effects, is contained in the legislation of some developing countries, such as the Indian Patent Act (as amended in 2002)<sup>96</sup> the Biodiversity Law No. 7.788 of Costa Rica (article 80), Decision 486 of the Andean Community (article 26(h)), the Brazilian Provisional Measure 2.186-16 (Article 31), and China patent law (article 27, as amended in December 2008), as well as in a few developed countries: Norway, Switzerland and Denmark. Article 150.4 of the Economic Partnership Agreement (EPA) between the CARIFORUM states and the European Union also contains a non-mandatory provision on disclosure (‘The EC Party and the Signatory CARIFORUM States may require as part of the administrative requirements for a patent application concerning an invention which uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention’). See also, generally, on this subject, J. Samoff and C. Correa (2006), *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, UNCTAD/DITC/TED/2005/14, Geneva, 2006, available at [http://www.unctad.org/en/docs/ditcted200514\\_en.pdf](http://www.unctad.org/en/docs/ditcted200514_en.pdf).

<sup>97</sup> See *Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention*, submission from Brazil, India, Pakistan, Peru, Thailand, and Venezuela, IP/C/W/429 of September 21, 2004, para. 4-5. For an opposite view, see WTO, *Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. Communication from the United States* (IP/C/W/469, 13 MARCH 2006), where it is noted, *inter alia*, that ‘it is clear that in order to achieve the objectives of PIC and equitable benefit sharing, national laws outside the patent system that directly and effectively regulate conduct are critical. The co-sponsors of IP/C/W/459 agree that “a national abs regime is necessary for the proper running of the benefit-sharing aspects of

On July 19 2008, a group of developed and developing countries presented 'draft modalities' regarding the TRIPS Agreement that would include negotiations on the proposed amendment on disclosure of origin, in conjunction with negotiations on an international register and the extension of geographical indications.<sup>98</sup>

*World Intellectual Property Organization (WIPO) and UPOV.* In 2002 the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established to deal with the protection of traditional cultural expressions/expressions of folklore, traditional knowledge and genetic resources and related issues. In respect specifically of genetic resources, WIPO Secretariat prepared analyses on the clauses on intellectual property rights typical in material transfer agreements and other contracts relating to the access to genetic resources and benefit sharing. It also developed a data base of examples and drafted guidelines on the matter. The Committee held fourteen sessions, the last one on June 29 to July 3, 2009.<sup>99</sup> Despite differences among members of the Committee on the issue of whether negotiations should be started to develop a binding instrument for the protection of traditional knowledge. However, the WIPO Assembly decided, on October 1, 2009, to renew the mandate of the Committee.

Regarding the proposed obligation to disclose the origin of claimed biological materials, Switzerland has proposed to incorporate a provision to deal with this subject as a non-mandatory requirement for patent applications in the Regulations of the Patent Cooperation Treaty (PCT).

The issue of disclosure of origin in relation to PVP was addressed by the UPOV's Council on the following terms: "UPOV encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination [for distinctness], but could not accept this as an additional condition of protection ... Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of the material used for breeding purposes". Equally "UPOV encourages the principles of transparency and ethical behaviour ...".<sup>100</sup>

*United Nations Environment Programme (UNEP).* The possible establishment of an obligation of disclosure of origin was addressed by the Panel of Experts on Access to Genetic Resources and Benefit Sharing,<sup>101</sup> by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing,<sup>102</sup> and

---

the system." As noted in previous submissions, the United States has proposed national contract-based systems to meet the demands of achieving appropriate access and equitable benefit-sharing (para. 7). See also WTO, IP/C/W/368/rev.1, 8 February 2006, *The relationship between the TRIPS Agreement and the Convention on Biological Diversity. Summary of issues raised and points made. Note by the Secretariat*, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art27\\_3b\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm).

<sup>98</sup> The relevant part of the agreed text reads as follows: '4. Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent applications. Patent applications will not be processed without completion of the disclosure requirement.

5. Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.

6. Text based negotiations shall be undertaken, in Special Sessions of the TRIPS Council, and as

an integral part of the Single Undertaking, to implement the above. Additional elements contained in members' proposals, such as prior informed consent (PIC) and access and benefit-sharing (ABS) as an integral part of the disclosure requirement and post grant sanctions, may also be raised and shall be considered in these negotiations'. See WTO document TN/C/W/52, 19 July 2008, *Draft modalities for TRIPS related issues*. Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group, TN/C/W/52, available at [http://trade.ec.europa.eu/doclib/docs/2008/september/tradoc\\_140562.pdf](http://trade.ec.europa.eu/doclib/docs/2008/september/tradoc_140562.pdf).

<sup>99</sup> See [http://www.wipo.int/meetings/en/details.jsp?meeting\\_id=17452](http://www.wipo.int/meetings/en/details.jsp?meeting_id=17452).

<sup>100</sup> See UPOV C/37/21, ANNEX III.

<sup>101</sup> See Report of the Panel of Experts on Access and Benefit-sharing, document UNEP/CBD/COP/5/8, paragraph 127, 2 November 1999.

by the 6<sup>th</sup> Conference of the Parties, which invited Parties and Governments to encourage the disclosure of the country of origin of the genetic resources and traditional knowledge in applications for intellectual property rights, where the subject matter of the applications concerns or makes use of genetic resources or such knowledge in its development, as a possible contribution to tracking compliance with PIC and the mutually agreed terms on which access to those resources and knowledge was granted.<sup>103</sup> The Conference of the Parties (COP) of the Convention on Biological Diversity (CBD), at COP 6 and 7 invited WIPO to prepare technical studies on the subject.<sup>104</sup>

*United Nations- General Assembly.* The Special Rapporteur on the Right To Food submitted in 2008, via the United Nations (UN) Secretary General, an interim report on the right to food to the UN General Assembly. He considered that the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement “will have considerable implications across the food system”.<sup>105</sup> He also argued that “[E]xtending patents to plant varieties in particular would accelerate the “verticalization” of the food production chain, as agricultural producers would become dependent on the prices set by companies for the seeds on which they have patents and would be denied the traditional right to sell and exchange seeds among themselves, as well as to save part of their crops in order to retain seeds for the next planting season — either as a consequence of the protection of patents<sup>16</sup> or by the use of “technology use agreements” by companies selling seeds. It would also lead to a decrease in biodiversity, since patents are granted on stable or fixed varieties, which, although they promise higher yields, encourage monocultural forms of agriculture”.<sup>106</sup>

In a later report, the Special Rapporteur stated that the ‘granting of intellectual property rights in the form of patents or plant breeders’ rights is primarily justified by the need to encourage such innovations, by allowing the patent-holder or the breeder to be rewarded for the investment made in the development of a new variety, following a model of commercial plant breeding typical of industrialized countries... Yet, at the same time, a number of concerns are raised by the development of intellectual property rights over the past few years. It will lead to transfers of resources from technology users to technology producers, both within States and between States. The oligopolistic structure of the input providers’ market may result in poor farmers being deprived of access to seeds productive resources essential for their livelihoods, and it could raise the price of food, thus making food less affordable for the poorest.<sup>107</sup>

*Food and Agriculture Organization of the United Nations (FAO).* The independent Panel of Eminent Experts on Ethics in Food and Agriculture established by the Director-General of FAO to advise the Organization and raise public awareness of ethical considerations associated to food and agriculture, addressed intellectual property issues in its third report. It noted that “[W]hile most innovation for food and agriculture does not depend on IPRs, the acquisition and exercise of IPRs in this field raise a variety of ethical concerns”.<sup>108</sup> These include the fact that in the context of poor societies, ‘IPRs protection may just mean the lack of access to innovations for the poor’ and the concerns raised by the

<sup>102</sup> See Recommendations adopted by the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, document UNEP/CBD/COP/6/6, Annex (31 October 2001).

<sup>103</sup> See Report of the Sixth COP, document UNEP/CBD/COP/6/20, PAGE 274 (27 MAY 2002).

<sup>104</sup> The studies submitted by WIPO are the following: Technical Study on Disclosure of Origin Requirements in Patent Systems Related to Genetic Resources and TK UNEP/CBD/COP/7/INF/17 (2004), available at [http://www.wipo.int/export/sites/www/tk/en/publications/technical\\_study.pdf](http://www.wipo.int/export/sites/www/tk/en/publications/technical_study.pdf); and Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications WIPO/IP/GR/05/3 (2005), available at [http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=44610](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=44610).

<sup>105</sup> Report of the Special Rapporteur on the right to food (2008), United Nations, General Assembly, A/63/278\*, available at [http://www2.ohchr.org/english/issues/food/docs/A.63.278\\_en.pdf](http://www2.ohchr.org/english/issues/food/docs/A.63.278_en.pdf), p. 13

<sup>106</sup> Ibidem.

<sup>107</sup> General Assembly, *The right to food. Seed policies and the right to food: enhancing agrobiodiversity and encouraging innovation*, A/64/170, 23 July 2009, available at <http://daccessdds.un.org/doc/UNDOC/GEN/N09/424/73/PDF/N0942473.pdf?OpenElement>, para. 26-27.

<sup>108</sup> For the full report see, Panel of Eminent Experts on Ethics in Food and Agriculture (2005), 3<sup>rd</sup> Report of Eminent Experts on Ethics in Food and Agriculture, available at <ftp://ftp.fao.org/docrep/fao/010/a0697e/a0697e.pdf>.

‘patenting of merely isolated genes, the basic building blocks of life’, which ‘are not invented, but are part of nature. Isolating them or discovering what their function is requires scientific competence, but does not involve an inventive activity’. The Panel called ‘on governments and relevant international organizations to adopt measures to correct distortions in the use of the IPR system and ensure that it rewards genuine creation and invention, while preserving genetic information and biological processes in the public domain and allowing legitimate trade in agricultural products’.<sup>109</sup>

*Consultative Group on International Agricultural Research (CGIAR)*. The Genetics Resources Policy Committee has elaborated a proposal for a ‘Policy of the Alliance of CGIAR Centres on Intellectual Assets’, which intends to provide guidelines for the management of the Centre’s intellectual assets. In accordance with this proposal, the Centres ‘will make their intellectual assets globally available without restriction’ except ‘when it is indispensable for the effective utilization or further improvement of Centres’ intellectual assets’. In these cases, ‘the Centres may grant limited exclusivity for commercialization in a defined market segment, for a limited period of time, provided they continue to make the intellectual asset available, for research and development in developing countries as well as for Advanced Research Institutions (ARIs) in support of the CGIAR mission. Likewise, the Centres may seek or assert intellectual property only rights over such assets for the same reasons and subject to the same condition about availability for further research. The Centres, finally, will not use their intellectual assets with the sole intention to raise income.’<sup>110</sup>

#### IV. CONCLUSIONS

Different modalities of intellectual property rights apply to various types of genetic resources. While the UPOV-based regime for the protection of plant varieties has gained growing acceptance, there has been a steady trend towards the patenting of plants and their parts and components. Microorganisms have also become the subject matter of patents, in many cases linked to their industrial application. Patents regarding animals, although in most cases relate to their use for laboratory experimentation, also cover in some cases their agricultural use.

The landscape of intellectual property on genetic resources for food and agriculture has become more complex and raises a set of new and delicate issues. In particular, patents on genetic resources may impede their use by third parties for further research and breeding during the term of protection, and thereby delay the development of new products and the capacity to address evolving demands (including those associated to climate change).<sup>111</sup>

Governments enjoy a great deal of room of maneuver to address these issues. Firstly, the TRIPS Agreement allows Members to exclude plants and animals (whether genetically modified or not) from patent protection. Secondly, the criteria under which patents are granted, may exclude materials found in nature (even if isolated) and refuse patents on subject matter that does not meet a strict standard of inventive step. Similar considerations apply to microorganisms, which must be patented in accordance with said Agreement when they meet the patentability requirements.

In addition, national laws may provide - consistently with article 30 of the TRIPS Agreement- a number of exceptions to the exclusive rights. They may permit farmers to save and re-use seeds where plant varieties, or certain components thereof, are subject to patent protection, in a way similar to the ‘farmer’s privilege’ under PVP. Patent laws may also allow third parties to undertake research and

---

<sup>109</sup> *Idem*.

<sup>110</sup> See the full text of the policy proposal at [http://cgiar.org/pdf/grpc\\_25th\\_meeting\\_minutes.pdf](http://cgiar.org/pdf/grpc_25th_meeting_minutes.pdf). See also CGIAR (2006), CGIAR Research Strategies for IPG in a Context of IPR. Report and Recommendations Based on Three Studies, available at [www.sciencecouncil.cgiar.org/.../Reports/IPR\\_Report\\_Web.pdf](http://www.sciencecouncil.cgiar.org/.../Reports/IPR_Report_Web.pdf).

<sup>111</sup> Training of patent examiners in assessing patent applications covering genetic resources for food and agriculture and the development of specific guidelines to orient and facilitate their work could prove useful to avoid obstacles emerging from wrongly granted patents. The International Seed Federation (ISF) has initiated training activities with that purpose with the European Patent Office.

breeding during the patent term.<sup>112</sup> Moreover, national laws may provide for compulsory licenses in cases a plant variety cannot be exploited without infringing a patent (and viceversa). The conditions for obtaining the license, however, should not put an excessive burden on applicants and effectively facilitate the access to and use of the protected materials.

Likewise, national laws may define particular situations in which infringement of a patent should not be deemed to exist, such as when there is unintentional presence of a protected trait in farmers' fields, or traces of such materials are found in derivatives. Where patents on animals are admitted, national laws may regulate the space available to farmers that acquire them to deal with patented animals and their progeny.

One of the objectives of the patent system is to facilitate the free use of the inventions after the expiry of a patent. This is one of the reasons why well defined claims and sufficient disclosure are key conditions for patent validity. As the patents on the first generation of transgenic plants are starting to expire, the availability of 'generic' versions of genetically modified materials after the expiry of the respective patents may be delayed or blocked if new patents over minor modifications of existing gene constructs or on some of their elements are granted. The application of loose patentability criteria or defective examination may lead to the 'evergreening' of patents as found in other fields.

The high concentration observed in the seed industry and the control of patent thickets by a small number of companies may call for the intervention of the relevant competition authorities to remedy abuses in the exercise of patent rights.<sup>113</sup> Since competition laws are weak or inexistent in many developing countries, other measures may need to be adopted to protect the public interest. For instance, governments may consider the formation of patent pools to facilitate access to patented technologies when multiple patents apply in relation to a single plant variety.<sup>114</sup>

A large number of proposals and studies on the development of non-UPOV based *sui generis* regimes for the protection of plant varieties, including farmers' varieties, has been made, notably in order to implement article 27.3(b) of the TRIPS Agreement. However, only a small number of countries have adopted such regimes, and little is known about their impact. Many developing countries have adhered, instead, to the UPOV Convention after 1995.

The small number of countries that has put in place *sui generis* regimes to support the farmers' role in the conservation, improvement and use of plant varieties, raises questions about the extent to which the value of traditional varieties for addressing the problems of hunger and the challenges posed by climate change has been recognized. Commercial varieties often are not adapted to poor farmers' needs (who have no or limited access to agrochemicals or irrigation). Agricultural models that support small-scale farming may present alternatives for increasing food security that need to be supported by an appropriate legal regime,<sup>115</sup> including on intellectual property.

---

<sup>112</sup> It is to be noted that so far no case has been decided under the WTO Dispute Settlement rules specifically discussing the conditions under which a research or experimentation exception is allowed under article 30 of the TRIPS Agreement. However, in *Canada- Patent Protection for Pharmaceutical Products* case (WT/DS114/R, 17 March 2000), the panel took as an illustration of 'one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement' (para. 7.69).

<sup>113</sup> On 5 August, 2009, the US Department of Justice has convened 'Public Workshops to Explore Competition Issues in the Agriculture Industry'. See [www.usdoj.gov/atr/public/press.../248797.htm](http://www.usdoj.gov/atr/public/press.../248797.htm).

<sup>114</sup> See General Assembly, op. cit. para. 57.

<sup>115</sup> See 'The Cordoba Declaration on the right to food and the governance of the global food and agricultural system. In this regard, it is also important to note that seed and other legislation (e.g. regarding labeling) may restrict the diffusion of farmers' varieties adapted to agroecological and other local conditions, available at [www.fian.org/resources/documents/.../the-cordoba-declaration/pdf](http://www.fian.org/resources/documents/.../the-cordoba-declaration/pdf).

The adoption of an international obligation to disclose the origin of genetic resources and associated traditional knowledge claimed in patent applications, may bring some relief to those concerned with the misappropriation of such resources and knowledge. However, further actions would be needed to ensure that the information gathered on the basis of that obligation could be effectively used in order to prevent such a misappropriation, as well as to ensure compliance with access and benefit sharing obligations, where applicable.

The review made above suggests, finally, that governments have used to a very limited extent the flexibilities available under the TRIPS Agreement to develop a balanced system of protection that rewards innovations and, at the same time, ensures a continuous flow of genetic resources for food and agriculture suitable to local needs and changing conditions. It is noticeable the contrast with the situation in the area of public health, where several measures have been debated at the international level and adopted by national laws to reconcile private and public interests. The issues at stake in the case of genetic resources for food and agriculture are not of lesser importance. They concern the livelihood of millions of small-scale farmers, the sustainability of agriculture and the global food security.

**LIST OF ABBREVIATIONS**

ABS	Access and Benefit-sharing
ACP	Africa, Caribbean and Pacific
ARI	Advanced Research Institution
CAFTA	Central American Free Trade Agreement
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on Agricultural Research
CIAT	International Center for Tropical Agriculture
COP	Conference of the Parties of the Convention on Biological Diversity
DNA	DeoxyriboNucleic acid
EC	European Community
EFTA	European Free Trade Organization
EP	European Patent
EPO	European Patent Office
EST	Expressed Sequence Tags
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FTA	Free Trade Agreement
FTO	Freedom To Operate
GMO	Genetically Modified Organism
GR	Genetic Resources
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ICTSD	International Centre for Trade and Sustainable Development
IP	Intellectual Property
IPR	Intellectual Property Rights
ISF	International Seed Federation
MAS	Molecular Marker-Assisted Selections
OAU	Organization of African Unity
OECD	Organisation for Economic Co-operation and Development
OJ EC	Official Journal of the European Community
PCT	Patent Cooperation Treaty
PIC	Prior Informed Consent
PVP	Plant Variety Protection
TFSRP	Transcription Factor Stress-related Proteins
TILLING	Targeting induced local lesions in genomes
TRIPS	Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
UPOV	International Convention for the Protection of New Varieties of Plants
USA	United States of America
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization