WORLD INTELLECTUAL PROPERTY ORGANIZATION

3. Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights

Biotechnology

Denis Borges Barbosa and Karin Grau-Kuntz

01/01/2010

Table of Contents

I – Preliminary considerations

Purpose and areas of study

In the second tranche of our mandate, we are supposed to cover such "exclusions, exceptions and limitations where incentives through exclusive rights are unnecessary or incentives are provided by alternative protection mechanisms" related to biotechnology patents issuing, including plants, animals and other life forms.

The conditions related to strictly pharmaceutical or veterinary inventions, will not be covered by this study, except to the extent they have also *specific* biotechnological import. Information was gathered, however, with regards to human and animal treatment methods [1].

The disclosure requirements[2], relating specifically to biotechnological inventions, including the living material deposit in specialized institutions to provide access to genetic information. As they are not exclusions, exceptions or limitations, they are not covered hereby.

Exclusions, exceptions and limitations

Our purpose is to identify those exclusions, exceptions and limitations directed specifically to such area of technology; therefore, we shall not deal on other aspects of patent law related to that field.

---

[1] The main discussion of this issue is covered in the sister article "Patent exclusions that promote public health objectives", by Shamnad Basheer, ShashwatPurohit and Prashant Reddy. A considerable number of domestic laws, however, cover methods of treatment of *animals* (other than humans), which shall not be necessarily contingent in the study concerning health issues. Furthermore, Section 3 of India's Patent Act, 1970 excluded from patentability "any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals *or plants to render them free of disease or to increase their economic value or that of their products"*. Here also, the biotechnological value surpassed the purely health issue. As shall be seen below, this extension of the exclusion to plants was eventually excised from Indian law.

[2] As to *disclosure of genetic sources* of the object of patents, see below. As further mentioned, this matter, being the subject of International discussions in course on very specific basis (the 1992 Biodiversity Convention) and included in a relatively small number of national laws, will not be extensively discussed in this study.

For the purposes of this study, we use the term "exclusion" to refer to subject matter exclusions and "exceptions" as encompassing not only exclusions of patentee's rights but also limitations on those rights[3].

[3] As to the interpretation of what are "exceptions, exclusions and limitations" in the field of biotechnology and its conditioning factors under TRIPs, *see* the recent EU Case of Monsanto Technology LLC v Cefetra BV, Case C-428/08,6 July 2010, "76. On the assumption that 'exceptions to rights conferred' could be regarded as encompassing not only exclusions of rights but also limitations on those rights, it should be pointed out that an interpretation of Article 9 of the Directive limiting the protection it confers to situations in which the patented product performs its function does not appear to conflict unreasonably with a normal exploitation of the patent and does not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties', within the meaning of Article 30 of the TRIPS Agreement".

II - Biotechnology protection: a precarious convergence?

A peculiar aspect of the current patent regime is the relative convergence of the standards of exclusions from patentable subject matter and exceptions and limitations to the rights in connection with biotech matter [4]. The basis here for evaluation of tendencies and variations is the model of TRIPs Art. 27.

Two trends could be discerned: a quite liberal pattern epitomized by the American patent system, and a more contained system as indicated by the European directive and to some extent EPO practice. The details of those two trends are voiced below [5]. All other national or regional systems could be to a certain extent affiliated to one of those trends.

What should be taken as a rather crucial consideration is that the patent system is only one aspect of the IP approach to the biotechnology protection; not only the neighboring plant varieties apparatus is a necessary adjunct to this analysis (though outside the scope of the present study) as many other extra-IP aspects impact directly on the effectiveness of this protection. The Convention of Biological Diversity (1992)[6] and the FAO Treaty

---

[4] UNCTAD-ICTSD. Resource Book on TRIPS and Development. New York: Cambridge University Press, 2005, p. 388: "Since the adoption of the Agreement, the differences in the treatment of biotechnological inventions among developed countries have been reduced, but not eliminated", noting "plant varieties and animal races are not patentable in Europe, while they are eligible for protection in the USA".

[5] Some inklings of a prospect of increasing divergent models could be discerned: organizations of the civil society in Europe and some developing countries are taking a more active role in constraining the further advancing of patent and plant varieties rights on biotechnological creations. *See* International Experts See Backswing In Pendulum Of Biological Patenting/By Monika Ermert for Intellectual Property Watch. 21 July 2010, found at http://www.ip-watch.org/weblog/2010/07/21/international-experts-see-backswing-in-pendulum-of-biological-patenting/. Even though some authors indicate a somewhat analogous trend in US current case law (based on macroeconomic efficiency), it would seem that the momentum in the two systems is not the same.

[6] As to the issue, *see* Communication from India. IP/C/W/195, 12 July 2000; "The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of Traditional knowledge", submission by Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe, IP/C/W/356, 24 June 2002; "Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement", Joint Communication from the African Group, IP/X/W/404, June 26, 2003; "Review of article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore. A concept paper", Communication from the European Communities and their Member States, IP/C/W/383, 17 October 2002; "The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge", submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru,

(2001)[7], to mention only two International instruments of broad import, incorporate provisions that condition the scope of protection (or subject its economic results) to some constraints [8]. Furthermore, this area is probably where more urgently new legal regimes to cover the periods (for instance, the research phases) should be sought in which it is not yet possible to obtain a patent or a Plant Variety Right[9].

Developing country systems have raised some marginal variations in these standards [10]. The issue of protection of selection or purification of objects found in nature has some importance in South America and other area, as in Pakistani and Thai Laws [11]. The disclosure requirements regarding origin and legal provenance of biological material would seem to be a very significant theme within the evolving International patent law,

---

Thailand, Venezuela, IP/C/W/403, June 24, 2003; "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.

[7] In addition, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), *see* http://www.planttreaty.org/. In its relevant provision, such treaty states: "Article 12.3 (d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System". On the issue of potential ITPGRFA/patent clashes, *see* Kathryn Garforth and Christine Frison, Key Issues for the relationship between the Convention on Biological Diversity & the International Treaty on Plant Genetic Resources for Food and Agriculture, July 2007, found at http://www.qiap.ca/pages/documents/OP2-Final_000.pdf, visited on 08/20/10.

[8] For the impact of those treaties to the issue under analysis, see Bertacchini, Enrico, Biotechnologies, Seeds and Semicommons. Available at SSRN: http://ssrn.com/abstract=960747visited on 08/20/10.

[9] Those issues are, among many other: (a) the blurring of the science/technology distinction (and the discovery/technical solution question); (b) the appropriation paradigm in connection with multi-party, public/private research environment; (c) the interference with environmental, biodiversity, health and food International and domestic legal systems (d) the raising of ethical issues. Some researchers and graduate candidates under the supervision of this author exploring specifically the question of pre-patent protection of developing biotech-related technologies, especially in connection with the prevailing model of joint research in this area, where public and private funding and initiative are particularly intertwined. See as to the multi-party issue Maria Ester Dal Poz and Denis Borges Barbosa, Incertezas e riscos no patenteamento de Biotecnologias: a situaçãobrasileiracorrente, *in* Vanessa Iacomini, Propriedade Intelectual e Biotecnologia, JuruáEditora, 2007, found at http://denisbarbosa.addr.com/arquivos/200/propriedade/esterdenis.pdf. As to the pre-patent appropriation issue, see Lessa, Marcus, Contracting Innovation (June 18, 2009). Available at SSRN: http://ssrn.com/abstract=1431469 and JENNEJOHN, Matthew C. Collaboration, Innovation, and Contract Design.Columbia Law and Economics Working Paper Series, no. 319, June 2007. SSRN: http://papers.ssrn.com/paper.taf?abstract_id=1014420, checked on January 13, 2009. As totheproblemof legal appropriationof exclusive rights in multiple-inventor contexts, see Denis Borges Barbosa, (org) Lélio Denicoli Schmidt, Elisabeth Kasznar Fekete, Letícia Provedel, Marissol Gómez Rodrigues, Reivindicando a Criação Usurpada (A Adjudicação dos interesses relativos à Propriedade Industrial no Direito Brasileiro), Editora Lumen Juris, Rio de Janeiro, 2010.

[10] Not necessarily towards a curtailment of protection. *See* Borges Barbosa, Denis and Lessa, Marcus, The New Brazilian Government Draft Law on Plant Varieties (Or… How a Developing Country May Want to Enhance IP Protection Because It May Actually Need It) (June 6, 2009). Available at SSRN: http://ssrn.com/abstract=1415406 .

[11] The relevant provision excludes both naturally found items "or extracts from animals or plants".

but would hardly be classifiable as an exception or limitation to the patent right under the scope of this study[12].

[12] See Doc. WIPO/GRTKF/IC/16/6 Prov. The specific Brazilian current situation is described in Doc. WIPO/GRTKF/IC/16/INF/9.

III - International law concerned

In this section, we will consider the multilateral and bilateral treaties concerning exclusions, exceptions and limitations of patent rights in the field of biotechnology. The regional treaties are dealt with in the pertinent section below.

\ Multilateral treaties

Subject matter exclusions

The Paris Union Convention for the Protection of Industrial Property does not include any restriction on (or obligation of) protection of biotechnological creations [13]. The area covered by biotechnology is within the "broadest sense" mentioned by the Convention.

It is obvious that such a provision did not oblige any country to include agriculture, or whatever, under the patent protection (Bodenhausen, 1968:26). Until the unification of substantive intellectual property through the "minimum criteria" of the WTO TRIPs Agreement, there was no requirement to include in the legislation of each country every object of what is considered proprietary, and each state had room under the Convention to choose what to protect via patent.

According to TRIPs 27.1, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. According to the art. 27.1 and 29, to all *inventions*[14]whether products or processes, in all fields of technology, must be granted a patent -provided that they are:

---

[13] Art. 1.3) “Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour”.

[14] What seems to preclude the patentability of *natural* or non-man made technical solutions. As noted elsewhere in this study, an important issue in this context is the status of elements isolated from nature. According to the UNCTAD Resource Book, "An important question is whether microorganisms as found in nature should be patented under this provision. It is generally accepted that ‘to be patentable, a microorganism cannot be as it exists in nature’. However, in some jurisdictions it is sufficient to isolate a microorganism and identify a use therefore to obtain a patent. Thus, in countries that are parties to the European Patent Convention a patent may be granted when a substance found in nature can be characterized by its structure, by its process of isolation or by other criteria, if it is new in the sense that it

1. new,

2. involve an inventive step,

3. capable of industrial application,

4. disclosed in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, and

5. disclosed in such a way to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application[15].

Those fields of technology in which patents *may* be denied by members are listed in Art. 27.2[16] and 27.3 [17].Art. 27.3 specific provisions also deal with biotechnological technologies (including the human medical field), allowing Members to exclude patents in the assigned areas [18].

TRIPs therefore allows for two kinds of subject matter exclusions:

---

was not previously available to the public. The European Directive on Biotechnological Inventions clarifies 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). In the United States, an isolated or purified form of a natural product is patentable. The concept of 'new' under the novelty requirement does not mean 'not preexisting' but 'novel' in a prior art sense, so that the unknown but natural existence of a product does not preclude the product from the category of statutory subject matter. Similarly, in Japan the Enforcement Standards for Substance Patents stipulated that patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance could not be detected without prior isolation with the aid of physical or chemical methods". UNCTAD-ICTSD. Resource Book, p. 392-393.

[15] Whenever those requirements are present in the examined body of law (or, at least, those referred to under (a) to (c)), they will be mentioned as the "general requirements of patentability".

[16]Article 27 "Patentable Subject Matter 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".

[17]Other exclusions of patenting may be noted at least from GATT 1947 art. XXI, especially in which is reflected in TRIPs art. 73 (essential security interests).

[18] "3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement".

(a) the one "necessary to protect *ordre public* or morality"[19], including when intended to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that *necessity*is at stake, and not just convenience[20];and

(b) a second group including: (i) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as (ii) plants and animals other than microorganisms[21], and (iii)plant or animal production essentially biological processes other than non-biological and microbiological processes[22].

[19] "Article 27.2 is concerned with the exclusion of particular inventions, not categories of inventions which are dealt with in Article 27.3 (discussed in Chapter 21 below). It is clear from the wording of the provision that the risk must come from the commercial exploitation of the invention, not from the invention as such. (...) An exception based on this Article can be applied only when it is necessary to prevent the "commercial exploitation" of the invention. Therefore, the condition non-commercial uses of the invention (e.g., for scientific research). There were debates whether the exception can only be applied when there is an actual prohibition on the commercialization of the invention, or when there is need to prevent it (even if still not done by the government concerned). According to one opinion, an effective ban should exist in order to make the exception viable. It has been held, however, that TRIPS "does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify an exclusion under Article 27 (2) TRIPS, a Member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the Member would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited". UNCTAD-ICTSD. Resource Book on TRIPS and Development. New York: Cambridge University Press, 2005, p. 377

[20] "Article 27.2 introduces a "necessity test" to assess whether protection of an overriding social interest is justified. Though TRIPS constitutes the *lexspecialis* for dealing with patent issues in the WTO framework, the GATT/WTO jurisprudence on Article XX of GATT is likely to play a role in the interpretation of said Article. Article XX (a) and (b) of GATT have a similar structure to Article 27.2, and it is clear that, for the purposes of these provisions exclusions must be objectively justified. These provisions permit Members to make exceptions to the basic GATT free trade principle on the ground (a) that it is necessary to protect public morals, and (b) that it is necessary to protect human, animal or plant life [emphasis added]. Thus, under GATT, quarantine, sanitary and similar regulations must not constitute arbitrary or unjustifiable discrimination or a disguised restriction on trade. A measure is justified only if no reasonable alternative is available to a Member which is not inconsistent, or at least less inconsistent, with GATT." UNCTAD-ICTSD. Resource Book on TRIPS and Development. New York: Cambridge University Press, 2005, p. 377.

[21] "A 'microorganism' is an organism that is not normally perceptible by the eye. The scientific concept of 'microorganism' refers to "a Member of one of the following classes: bacteria, fungi, algae, protozoa or viruses." UNCTAD Resource Book, p. 392.

[22] "The notion of 'essentially biological process' has been defined by the European Patent Office on the basis of the degree of 'technical intervention'; if the latter plays an important role in the determination of or control over the results, the process may be patentable. Under this notion, conventional breeding methods are generally not patentable. In contrast, methods based on modern biotechnology (e.g., tissue culture, insertion of genes in a plant) where the technical intervention is significant, would be patentable." UNCTAD Resource Book, p. 393.

A note on ordre public and morality

The two concepts of *ordre public*[23]and morality [24] come *in tandem* in TRIPs art. 27. Should they be distinguished for the purposes of this study? It has been noted that EPO's case law has made such distinction between *ordre public* and morality (Decision T.356/93) [25].

It might be relevant to say; however, that the rather sibylline distinction between those catchall expressions is not what seems relevant to the application of the exclusion in any particular case. The relevant filter would rather be an adequate balancing of the interests at play: in both cases, the societal interest at stake is the avoidance of public rejection to at the issuance of a patent, as an act of sate condoning some kind of technology, the use of which would be scandalous or publicly inacceptable[26]. As the EPO decision notes:

> Thus, under Article 53(a) EPC, the relevant question is not whether living organisms are excluded as such, but rather whether or not the publication or exploitation of an invention related to a particular living organism is to be considered contrary to "ordre public" or morality.

---

[23] "The term “ordre public”, derived from French law, is not an easy term to translate into English, and therefore the original French term is used in TRIPS. It expresses concerns about matters threatening the social structures, which tie a society together, i.e., matters that threaten the structure of civil society as such. "UNCTAD, op. cit., p. 375.

[24] “Morality” is “the degree of conformity to moral principles (especially good)”.The concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time. Some important decisions relating to patentability may depend upon the judgment about morality. It would be inadmissible that patent offices grant patents to any kind of invention, without any consideration of morality". UNCTAD, op. cit., loc. cit.

[25] See http://www.law.washington.edu/Casrip/Newsletter/default.aspx?year=1995&article=newsv2i2eu, visited on 20/08/10.

[26] "Patents represent a quid pro quo between the public and the inventor: in exchange for disclosing the invention, the inventor receives the right to exclude others from practicing her invention. They therefore serve as source technical information. Patents also communicate information to markets and companies that serve to reduce various transaction costs, allowing more efficient transactions and investment. Patents consequently communicate various types of information beyond the technical. There is no reason, however, that such messages must be limited to the technical or the pecuniary. (...) The grant of a patent could communicate a message of inferiority to groups whose identity is tied to their biology. (...) The grant of a patent on such technologies affords the government's imprimatur of such controversial technologies". Holbrook, Timothy R.,The Expressive Impact of Patents. Washington University Law Review, Vol. 84, p. 573, 2006; Chicago-Kent Intellectual Property & Technology Research Paper No. 08-008. Available at SSRN: http://ssrn.com/abstract=909581 or DOI: 10.2139/ssrn.702587, visited on 20/08/10.

Exclusions and limitations to the patentee's rights

There are no specific rules in the multilateral treaties dealing with the exclusions and limitations of patentee's rights on biotechnological inventions. Whatever limitations or exclusions shall be subject to the delimiting rules of art. 30 [27] and, as applicable, the standards provided by art. 31 and art. 31-A for uses without authorization of holder.

However, important considerations have been drawn as to the *exhaustion doctrine* as applied to such inventions, especially those that involve self-replicating material [28].

As it must be recalled, TRIPs does not provide obligations or restrictions as to the incorporation of first sale or exhaustion provisions in national laws [29]. It has been felt, however, that a straight application of this doctrine to seeds and other self-replicating material could inordinately stress the patent holders' rights [30].Even after the first sale,

---

[27] Article 30 "Exceptions to Rights Conferred Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

[28] Exhaustion or first-sale doctrine is not easily classifiable as a limitation to the rights of patentee and therefore arguably not subject to the three-step standard provided for art. 30. However, it would be at least prudent to check the extension of exhaustion to the confronting interests of trade and biotechnological innovation. An important case is Andean Decision 486 - Article 54.- [Exhaustion] (…) , which albeit assuring exhaustion of such material, ends by excepting… "... the material so obtained is not used for multiplication or propagation purposes".

[29] TRIPs Article 6 –"Exhaustion - For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights. Also, Paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: [. . .] (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

[30] "Regarding the impact on agricultural biotechnology and its ability to use patent law to prevent farmers from saving progeny seed for re-planting or sale, I don't think Quanta will be a substantial impediment, primarily because courts will find that patent exhaustion does not apply to progeny seed. The SG has expressed this view in a footnote in its amicus brief supporting Quanta, which states: 'This Court has never suggested that the patent-exhaustion doctrine applies to the products of a patented item that is capable of reproducing itself in the hands of the purchaser - e.g., newly-grown seeds that are identical to, and grown from, a patented genetically-modified seed that was purchased from the patentee or an authorized licensee'". See U.S. Amicus Br. at 14 & n.8, McFarling v. Monsanto Co., 545 U.S. 1139 (2005) (No. 04-31). "This case presents no opportunity to address that question. I think the SG is correct, and that courts will carve out an exception to the patent exhaustion doctrine for the progeny of self-replicating biotechnology products such as generically-modified seeds. This distinction between a product embodied by a patent vs. a copy of the product would also be consistent with the distinction the Supreme Court recently drew between a component of a patent invention under 271(f) and a copy of that component made outside the US (Microsoft v. AT&T)." Chris Holman, Quanta and Its Impact on Biotechnology, found at http://holmansbiotechipblog.blogspot.com/2008/06/quanta-and-its-impact-on-biotechnology.html, visited on 08/10/10.

the protected *physical* item may retain its full reproducible power, and therefore the buyer of such product may compete with the original seller on a free rider basis.

In some peculiar cases, seller may retain obligations as to the physical product sold [31],and the exhaustion doctrine would prevent him from exercising exclusionary powers towards buyer. Even the exercise of some contractual obligations extending a non-copy to buyer might be questionable under some public policy or trade-related considerations[32].

Even though the issue has not been yet solved in all the pertinent legal systems[33], it would appear that some further consideration should be given to such a problem [34].

---

[31] "In an effort to expand these categories and to allocate liability to the intellectual property owners of the biotechnology, many scholars have objected that these legal boundaries are too restrictive. A common objection is that the legal distinctions between physical and intangible property are Jesuitical ones when it comes to the sphere of biotechnology. The patented gene is inside the physical seed, so, critics argue, it is disingenuous and scientifically unsound to try to differentiate liability based on clear divisions between property rights or intellectual property rights." Elizabeth F. Judge, Intellectual Property Law as an Internal Limit on Intellectual Property Rights and Autonomous Source of Liability for Intellectual Property Owners, Bulletin of Science Technology Society 2007; 27; 301, at http://bst.sagepub.com/cgi/content/abstract/27/4/301, visited on 08/10/10.

[32] Todd Michael Leaven, The misinterpretation of the patent exhaustion doctrine and the transgenic seed industry in light of Quanta V. LG Electronics, North Carolina Journal Of Law & Technology Volume 10, Issue 1: Fall 2008, "In reversing Bizcom, Quanta signaled that the patent exhaustion doctrine still has teeth and industries cannot rely on patent law to enforce authorized post-sale restrictions. With the transgenic seed industry's sales models unchanged, the lack of patent law protection for post-sale restriction leaves the seed industry relying upon state contract law. Although contract law is still a viable option for the seed industry, it is evident from state legislation, such as the 2003 legislation in Indiana, that contract law is not as stable as patent law." "A concern surprisingly not mentioned in the Quanta amicus curiae briefs is recent action in state legislatures. Within the last seven years, state legislators in Missouri and Minnesota introduced bills allowing farmers to save their seeds regardless of what the seed patentee and the licensed distributor set forth in contract."

[33] The issue is however mentioned in Brazilian law and a small number of other statutes.

[34] The quite similar problem of self-replicating software, phonograms, DVDs and other expressive creations in digital environments was addressed by the WIPO Internet Treaties, by extending the coverage of copyright and software rights beyond the first sale, and including distribution rights within the scope of IPRs. It is not clear whether similar provisions in the patent system would fulfill the trade interests to be served under the exhaustion tag. See, for instance, Kevin E. Noonan, Supreme Court Fails to Grant Certiorari in Monsanto Co. v. McFarling, "2. Do the doctrines of patent exhaustion and patent misuse permit the purchaser of a patented good to use that good and dispose of its products as it sees fit, absent a valid contract? With regard to Question #2 of his Petition, McFarling argued that the infringing seed were a "natural product" of the seeds he had purchased, and that the doctrines of patent exhaustion and patent misuse precluded Monsanto from recovering for patent infringement. (In the District Court, Monsanto had abandoned its breach-of-contract claims under the Technology Agreement, and the damage award was based solely on patent infringement liability.) The Petition characterized replanting seeds as the "ordinary and expected use" of the patented seed product, and thus that a determination of infringement was contrary to settled principles of patent exhaustion (but see Rich, G.S., 6th Annual Conference on Intellectual Property Law and Policy, Fordham University, April 16, 1998, in Chisum et al., Principles of Patent Law: Cases and Materials, 2d Ed., New York: Foundation Press, 2001, pp. 1120-21)".Found at http://www.patentdocs.typepad.com/patent_docs/2008/01/supreme-court-f.html, visited 08/09/10.

A difficult protection to choose: alternative protection mechanisms for plant varieties

When each country accepted TRIPs' terms to conducting business, a Plant Variety protection – of some kind – came with the bundle. However, the treaty did not impose the choice of the UPOV model, as Josef Drexel notes:[35]

> As to the protection of plant varieties, the provision states an option for WTO Members. They can either provide for patent protection or "an effective *sui generis* system – thereby alluding to the concept of plant breeders' rights as provided for by the UPOV Convention,[36] without mentioning it – or protection by a combination of the two IP rights.[37] Developing countries have a strong interest in Art. 27.3(b) TRIPS, which is basically twofold. Firstly, developing countries want to make sure that the farmers' privilege of the UPOV Convention[38] according to which UPOV member states may allow farmers to use crop for bringing out new seeds on their own land can be considered part of an "effective" *sui generis* system of protection.

When TRIPs entered into force, the member countries could choose between the text of the 1978 UPOV Convention ("UPOV 1978"), and UPOV 1991 standards. The prior version was eventually closed to new entrants, and now only the later one is available. In a number of FTAs, the choice for the 1991 UPOV version was required, as noted below; the choice for non-UPOV systems is, therefore, prevented.

What are the distinctions between the 1978 and the 1991 versions? Aaron Cosbey so describes [39]:

> Scope of protection. Under UPOV 1978, commercial use of reproductive materials of the protected variety is not allowed. In other words, a farmer could not purchase a protected variety, and grow seed from it for subsequent sale, since it could be used to reproduce the protected variety. UPOV 1991 offers the same protection, but in some cases takes it further, to the products of the protected variety. According to this restriction, if permission has not been properly obtained for the growing of a protected variety, the products of the crop (e.g., fruit from protected tree varieties) are also accorded IP protection.

35Josef Drexl, The Evolution of TRIPS: Toward Flexible Multilateralism, published in French in KORS, J.; REMICHE, B. ADPIC, première décennie: droits d´auteur et accès à l´information. Perspective latino-americaine. L´Accord ADPIC: dix ans après. Belgica: LARCIER, 2007.

36 Convention for the Protection of New Varieties of Plants of 2 November 1961, revised in 1972, 1978 and 1991. The different versions are available at http://www.upov.int/en/publications/conventions/index.html. The Convention establishes an international organization, the so-called Union pour la protection des obtentions végétales (UPOV).

37 Such a dual system of patent and plant variety protection exists in the U.S.

38 See Art. 14(2) of UPOV Convention 1991.

39 The Sustainable Development Effects of the WTO TRIPS Agreement: A Focus on Developing Countries, Institute for Sustainable Development, Winnipeg, Canada.

> Duration of protection. UPOV 1978 provides for a minimum of 15 years of protection, while UPOV 1991 extends this to 20 years.
>
> Farmers' privilege. Farmers' privilege refers to the right of farmers using a protected variety to retain the seed from their crop for reuse, without paying royalties again to the breeder—a burden which would be particularly difficult for poor farmers. UPOV 1978 allows for farmers' privilege, while UPOV 1991 leaves it at the discretion of the national government.
>
> Breeders' exemption. Breeders' exemption refers to the practice of allowing breeders free access to protected varieties for research purposes—a measure devoted to fostering increased innovation. UPOV 1978 allows for such an exemption. UPOV 1991 allows only a limited application of this exemption. If the resulting improved variety is deemed to be "essentially derived" from the original protected variety (i.e., sufficiently genetically similar) then, while the breeder of the new variety may be granted IPRs, IPRs over the new variety are also granted to the breeder of the original variety. It is not yet clear how "essentially derived" will be defined in practice. This last element of UPOV 1991 might be thought to benefit traditional farmers, since a number of improved commercial varieties might be deemed to be essentially derived from land races. However, since there is no protection for such land races in the first place under UPOV, this potential protection for varieties derived from them is not available either.

The arguments against PVPs

The arguments against the adoption of any protection whatsoever for plant varieties may be easily anticipated. In a nutshell: any exclusive protection introduces a synchronic economic inefficiency, in the sense that access to some portions of the germplasm is immediately restricted in favor of protecting a *private* investment in plant technology [40].

On the other hand, the lesser protection afforded by the UPOV system was exactly what made it preferable, as stated in an oft-quoted remark, contemporaneous to the TRIPs Agreement:

> The original UPOV Convention laid down the rules for PBR that would have to be included in national laws in order for countries to qualify for membership. In essence, plant breeders are given a limited monopoly over the reproductive material of the variety. Even if it may seem only a nuance, this entails an important difference with patents, since patent holders claim ownership to the germplasm, technology and industrial processes, while breeders - in the original UPOV concept - can only control multiplication and sale of seeds. UPOV has also provided - until the 1991 version discussed below - special protection for farmers and the continued free access to plant genetic resources. Farmers have been allowed to continue with their ancestral costume of saving seeds for the coming seasons and informally exchanging them with other farmers, even from protected varieties, and this right is called the farmers' privilege. Plant breeder and Netherlands genebank director, Jaap Hardon, described this free availability of germplasm once as a "constitutional right" in agriculture. "A right going back 12'000 years to the dawn of agriculture and the domestication of all these crops we grow or have

[40] The arguments against PVPs are listed in Paulino et allii (2005).

grown." For the same reason, breeders have been allowed to make use of protected varieties' genetic material to develop new lines without having to pay royalties or ask permission. This right is included in UPOV as breeders' exemption. Without the possibility to freely exchange germplasm there is maybe agribusiness but not agriculture.[41]

The review of TRIPs Article 27.3(b)

"The TRIPS Agreement requires a review of Article 27.3(b) which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties.

Paragraph 19 of the 2001 Doha Declaration has broadened the discussion. It says the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore.

It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account."

At its inception, TRIPs article 27.3(b) was subject to a revision by 1999. The revisional exercise was not accomplished to this date [42].

The issue has raised an inflamed discussion; not only dividing south and north positions [43], but also the conflicting positions within the OECD group in connection with the differing practices now prevailing in the various countries and regional treaties (see Section II above).

---

41 Grain, June 1996, UPOV: Getting A Free Trips Ride?, http://www.grain.org/seedling/?id=161.

42 The present status of the exercise is noted at http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm, visited on 08/20/10.

43 "With respect to the review of Article 27.3(b), some developing country Members, as mentioned above, interpret "review" as opening up the possibility of amending Article 27.3(b). (...) This proposal has been the basis of controversial debates within the Council in 2003 and 2004. Developed Members have rejected an amendment of Article 27.3(b) in the above sense, referring, inter alia, to their biotechnology industries. The EC, for example, has proposed that those Members seeking to avoid the patenting of natural materials could make use of the TRIPS flexibilities, i.e. to define narrowly the patentability criteria. In this vein, genetic resources occurring in nature would not be patentable (failing to meet the novelty requirement). The aim of some developed countries, if a revision did take place, would be to eliminate the exception for plants and animals, and to establish that the UPOV Convention as revised in 1991 should be the only means of protection available for plant varieties, excluding other sui generis systems. Thus, according to the United States, the TRIPS Council should consider "whether it is desirable to modify the TRIPS Agreement by eliminating the exclusion from patentability of plants and animals and incorporating key provisions of the UPOV agreement regarding plant variety protection." For many developing countries, in contrast, it would be important to maintain the exception for plants and animals, as well as the flexibility to develop sui generis regimes on plant varieties which are suited to the seed supply systems of the countries concerned". UNCTAD, op. cit., p. 397.

The complexities of the problem is composed by the need to harmonize the various International instruments in force dealing with the theme outside the patent environment [44], as well as with the various exercises in course within WTO and WIPO concerning the protection of traditional knowledge and folklore, as mandated by Doha Ministerial declarations.

While the mention of such extremely important considerations could not be eluded from this study, the extent and intricacy of the questions preclude full discussion of the review at this point [45].

\ Bilateral treaties

Bilateral treaties, especially Free Trade Agreements[46], have a clear import in this analysis. As it is noted in this section, a number of FTAs executed with the United States [47]provides for requirements for patents within the scope of this study, which

[44] At least with the CBD (Convention on Biological Diversity), UPOV, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). See UNCTAD, p. 379 and following pages.

[45] The listing of most of the issues in discussion at this moment may be seen at http://www.twnside.org.sg/title2/health.info/2010/health20100701.htm, visited on 08/20/10.

[46] We would not discuss here the Economic Partnership Agreements (EPAs) between the European Union (EU) and other 77 countries. See as to the current status (June 2010), http://trade.ec.europa.eu/doclib/docs/2010/june/tradoc_146263.pdf. The CARIFORUM EPA, found at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:289:0003:1955:EN:PDF, does not contain particular provisions covering biotechnological patents.

[47] Only those FTAs that include significant biotechnology provisions are considered. The complete list of FTAs at this moment is: "Peru-US Trade Promotion Agreement, signed 14 December 2007 (pending implementation); Korea-US FTA (KORA), signed 30 June 2007 (pending US Congress approval); Panama-US Trade Promotion Agreement, signed 28 June 2007 (pending US Congress approval); Columbia-US FTA, signed 22 November 2006 (pending US Congress approval); Oman-US FTA, signed 19 January 2006 (pending implementation); Bahrain-US FTA, signed 14 September 2004 (entered into force 4 August 2006); CAFTA-DR FTA, signed 5 August 2004 (entered into force between the United States and El Salvador on 1 March 2006, followed by Honduras and Nicaragua on 1 April 2006, Guatemala on 1 July 2006, and the Dominican Republic on 1 March 2007. The remaining partner country, Costa Rica, approved the agreement in a national public referendum on 7 October 2007, although entry into force is pending passage of necessary implementation legislation by the Costa Rican legislature); Morocco-US FTA, signed 15 June 2004 (entered into force 1 January 2006); Australia-US Free-Trade Agreement (AUSFTA), signed 18 May 2004 (entered into force 1 January 2005); Chile-US FTA, signed 6 June 2003 (entered into force 1 January 2004); Singapore-US FTA, signed 6 May 2003 (entered into force 1 January 2004). There are also FTAs implemented before the Doha Declaration: Jordan-US FTA, signed 24 October 2000 (entered into force 17 December 2001); NAFTA, signed 17 December 1992 (entered into force 1 January 1994); Israel-US FTA, signed 22 April 1985 (entered into force 1 September 1985)". According to Nasu, Hitoshi, Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement (2010). INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES, Thomas Pogge, Matthew Rimmer, Kim Rubenstein, eds., Cambridge University Press, 2010; ANU College of Law Research Paper No. 10-53. Available at SSRN: http://ssrn.com/abstract=1652501.

differ significantly among themselves [48]. One important aspect of using patents instead of PVPs is the exclusion of some limitations provided under UPOV 1978 and even UPOV 1991 [49].

(a) The agreement with Bahrain (US-Bahrain, Art 14.8(2)[50]indicates some trends to beprobably followed in further agreements [51], especially the provision of plant patents (not only PVPs);

(b) The Chilean Agreement(US-Chile FTA, Art 17.9 (2))[52] does not actually requires plant protection through patents but introduces a "best efforts" obligation to eventually grant such patents [53];

---

[48] Frederick M. Abbott, IP Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law, athttp://www.unctad.org/templates/Download.asp?docid=7059&lang=1&intItemID=1397, visited on08/08/10: "Each of the IPRs chapters of the FTAs differs. These differences arise from a number of factors. The United States was insistent that Australia and Singapore, as high-income countries, accept greater restrictions on compulsory licensing than other FTA partners. Chile was more successful in maintaining flexibilities than were the CAFTA countries". See also Pedro Roffe, David Vivas, Gina Vea, Maintaining Policy Space for Development, A Case Study on IP Technical Assistance in FTAs, April 2007 ICTSD Issue Paper No. 19, at http://ictsd.org/i/publications/3435/, on08/08/10.

[49] "US FTAs go even further, pushing for patents on plants. This is the strongest form of intellectual-property protection available for plants – not only limiting the rights of farmers to exchange or sell seeds, but also to save and reuse seed they have grown themselves. The US–Morocco FTA requires the patenting of plants and all other FTAs include a 'best effort clause' to develop plant-patent legislation"; "Under US FTAs including DR-CAFTA, US–Peru and US–Colombia FTAs, developing-country governments will no longer be able to reject a patent application because a firm fails to indicate the origin of a plant or show proof of consent for its use from a local community. Signing Away The Future, Oxfam Briefing Paper, March 2007, at www.oxfam.org.uk/resources/policy/trade/downloads/bp101_ftas.pdf, visited on 08/20/10. Note P. Roffe and C. Spennemann, The impact of FTAs on public health policies and TRIPS flexibilities, Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006: "In recent years, all four major economic players, i.e., the European Union (EU), Japan, the USA, and the countries of the European Free Trade Association (EFTA) have been active in the negotiation of FTAs (Abbott, 2004b). In the EU's FTAs, there are a number of TRIPS-plus obligations, but these are less relevant to the public health context, covering mainly the protection of plant varieties and biotechnological inventions (CUTS, 2004) or geographical indications (Vivas-Eugui and Spennemann, 2006). See also MUSUNGU, Sisule F., VILLANUEVA, Susan, BLASETTI, Roxana, Utilizing Trips Flexibilities For Public Health Protection Through South-South Regional Frameworks.

[50] ARTICLE 14.8: "PATENTS 1. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law. Each Party may also exclude from patentability animals and diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals. 2. Each Party shall make patents available for plant inventions. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including products to be used for particular medical conditions, subject to the exclusions provided in Article 14.8.1 and the conditions of patentability".

[51] Jean-Frédéric Morin, Tripping up TRIPS debates IP and health in bilateral agreements, Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006: "This new provision will likely serve as a model for subsequent FTAs. Given that the USTR seeks for consistency, once a new rule is incorporated in an FTA, it is usually maintained in subsequent FTAs."

(c) Dominican Republic and Central American Countries(US-CAFTA-DR, Art 15.9(2))[54], which replicates the same commitment [55];

(d) The Jordan FTA (US-Jordan Art 4.17)[56] leads a trend where an obligation to establish both plant and animal patents might be induced by implicit construction[57];

---

[52] Article 17.9: Patents 1. "Each Party shall make patents available for any invention, whether a product or a process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. For purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as being synonymous with the terms "non-obvious" and "useful", respectively. 2. Each Party will undertake reasonable efforts, through a transparent and participatory process, to develop and propose legislation within 4 years from the entry into force of this Agreement that makes available patent protection for plants that are new, involve an inventive step, and are capable of industrial application".

[53]Roffe, Pedro (2004). "Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement." TRIPS Issues Papers 4. Found at www.qiap.ca, visited on 08/20/10. "Chile protects plants through a sui generis system based mainly on the International Union for the Protection of New Varieties of Plants (UPOV) Convention, as revised in 1978; but, under the FTA, Chile committed to adhere to the 1991 Act of UPOV by 1 January 2009. The FTA does not contain an explicit obligation to protect plants under the patent system. However, it provides for a "best effort" clause in order for each Party to undertake reasonable efforts, through a transparent and participatory process, to develop and propose legislation – within four years from the entry into force of the Agreement – to make available patent protection for plants, which are new, involve an inventive step, and are capable of industrial application. This provision does not contain any limitation on the type of plants that should be protected under the patent system (sexually and/or asexually reproduced). According to this obligation, that in practice applies only to Chile, the latter is not obliged to consider plants as a patentable subject matter, but to engage in a process to legislate to that effect".

[54] Article 15.9: Patents 2. "Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection".

[55] "For example, recently concluded free trade agreements (FTAs) between the United States and almost half a dozen Latin American countries require all parties to join UPOV and make "all reasonable efforts" to allow patents on plants." The end of farm-saved seed?, found at http://www.grain.org/briefings/?id=202, visited on 08/20/10.

[56] 17. Subject to paragraph 18, patents shall be available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step and is capable of industrial application. 18. Each Party may exclude from patentability: (a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because the exploitation is prohibited by their law; (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

[57] "[Note 120] For example, the agreements with Jordan, Singapore and Australia allow only for the exceptions in Article 27.2 and 3(a), TRIPS, thus excluding the exceptions for plants and animals. The Morocco agreement in an ambiguous formulation allows for the exception in Article 27.2 and is silent on Article 27.3(a), TRIPS. It further provides for the protection of plants and animals through patents. Furthermore, the latter agreement provides that "patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals" Signing Away The Future, op. cit.

(e) The Morocco FTA(US-Morocco, Art 15.9(2))[58] actually provides for the obligation to protect plant and animal patents;

(f) The Oman FTA (US-Oman FTA, Art 15.8)[59] imposes patenting of plants, but allows for denial of animal patents;

(g) The Peruvian FTA (US-Peru FTA Art 16.9(2))[60] contains a best-efforts provision comparable to the Chile agreement, but without a time limitation. The application of the FTA in the internal legislation also includes a rule of three steps for the limitations provided in the Andean Directive [61]. It is also noticed that the FTA application law has modified the effects of the Decision 486 in Peru by eliminating the certificate of origin as a prerequisite for the granting of a patent.[62] The same statute eliminated the nullity resulting from non-compliance with such requirement[63];

---

[58] 2. "Each Party shall make patents available for the following inventions: (a) plants, and (b) animals. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals".

[59] Article 15.8: Patents 1. "Subject to paragraph 2, each Party: (a) shall make patents available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step, and is capable of industrial application; and (b) confirms that it shall make patents available for any new uses for, or new methods of using, a known product, including new uses and new methods for the treatment of particular medical conditions. 2. Each Party may exclude from patentability: (a) inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; (b) animals other than microorganisms, and essentially biological processes for the production of animals other than non-biological and microbial processes; and (c) diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals".

[60] Article 16.9: Patents 2. "Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, a Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available consistent with paragraph 1. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection".

[61] This country is essentially ruled by the Andean rules as modified by the 2008 legislation and further by Law 29316 of January 14, 2009, edited as a result of the Free Trade Agreement of the US. Follows Andean limits on biological matter, but Law Nº 29 316-Article 39-A exceptions to rights conferred states that when the limited exceptions provided for in Article 53 of Decision 486 of the Andean Community Commission unreasonably with the normal exploitation of the patent or causing unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of third parties, the patent holder may exercise the rights provided in Article 52 of that decision.

[62]According to the Comments of Sociedad Peruana de Derecho Ambiental: „ La nueva Ley Nº 29316 ha eliminado el certificado de origen como requisito esencial para el otorgamiento de una patente. Es decir, ha eliminado el requisito sustantivo de contar con un contrato de acceso a los recursos genéticos con el Estado Peruano o con un contrato de licencia con las comunidades indígenas para el uso de sus conocimientos tradicionales, como condición para poder obtener una patente que incluya el uso o aplicación de los mismos el proceso de de innovación. Con la nueva Ley, en el caso de que no se cuente con un certificado de origen, se penaliza con una sanción pero no con la validez y no es ya causal de

(h) The Australia FTA (US-Australia 17.9.1) [64] also implicitly compels the granting of plant and animal patents.

The full scope of those FTAs as measured to the TRIPs allowances might be questionable, as some provisions of the last treaty are liable to be construed as a maximum level standard[65].

nulidad. De esta forma, la nueva Ley Nº 29316 modifica la Decisión 486 en dos momentos fundamentales: solicitud de la patente y declaración de nulidad de una patente ya otorgada.“, found at http://www.spda.org.pe/portal/_data/spda/noticias/20090121120835_.pdf, visited on 08/10/10.

[63] La Ley Nº 29316 - Se incluye el Art. 8 A: Nulidad de la Patente - “Una patente podrá ser revocada o anulada únicamente en base a las razones que hubieran justificado el rechazo de su otorgamiento. Sin embargo, la Dirección de Invenciones y Nuevas Tecnologías podrá anular una patente otorgada cuando se haya incurrido en fraude, falsa representación o conducta inequitativa.”

[64] Article 17.9 : Patents 1. “Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms “inventive step” and “capable of industrial application” as synonymous with the terms “non-obvious” and “useful”, respectively. 2. Each Party may only exclude from patentability: (a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals”.

[65] See Borges Barbosa, Denis, Untoward Restrictions to Trade and Abuses of Intellectual Property Rights: A Brazilian Perspective to the ACTA Exercise (June 22, 2010). Available at SSRN: http://ssrn.com/abstract=1628744,visited on 08/10/10.

III - Specific cases: humans, animals and plants

\ Inventions concerning human beings (including genes and cells)

Such inventions concerning directly the human beings are products may be generally prevented base on the morality or *ordre public* issue, with some important particularities. On the other hand, humans are animals [66], therefore under the possible exclusion mentioned in TRIPs art. 27.3.

The literal prohibition of patenting humans as a product[67], or even of "processes for cloning human beings, the human body and its genetic identity, the use of human embryos for industrial or commercial purposes" as found in the Equatorial Law, or "human beings, and the biological processes for their generation", as found in Australian law [68], is by no means frequent [69].

No set of statutory language is as comprehensive as the EU Biotechnology Directive that, especially in the whereas preamble, clarifies a quite complete policy towards the human-related inventions [70]. The normative portion of the directive is as so worded:

---

[66] Tribe Hominini, Genus Homo, Homo sapiens, according to Groves, C. (2005). Wilson, D. E., & Reeder, D. M, eds. ed. Mammal Species of the World (3rd ed.). Baltimore: Johns Hopkins University Press. pp. 181–184. ISBN 0-801-88221-4. In the case of Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1382 (Fed. Cir. 2009), the court has declared that humans are animals for the purposes of patent law.

[67] See, however, Mexican Industrial Property Law, Article 16: "Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of: (…) IV. the human body and the living matter constituting it…"

[68] It would seem that a non-biological process for making humans could be patented, what curiously would create exclusivity rights on the created being.

[69]Equatorial patent Law, Art. 126.- "Se excluye de la patentabilidad expresamente: a) Las invenciones cuya explotación comercial deba impedirse necesariamente para proteger el orden público o la moralidad, inclusive para proteger la salud o la vida de las personas o de los animales o para preservar los vegetales o para evitar daños graves al medio ambiente o ecosistema; (...) Para efectos de lo establecido en el literal a), se consideran contrarias a la moral y, por lo tanto, no son patentables: a) Los procedimientos de clonación de seres humanos; b) El cuerpo humano y su identidad genética; c) La utilización de embriones humanos con fines industriales o comerciales".

[70] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213, 30/07/1998 P. 0013 - 0021(16) "Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be

Article 5

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

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

---

patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented; (17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system; (...) (19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission; (20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment; (21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself; (...) (26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law".

(c) uses of human embryos for industrial or commercial purposes.

Those cases falling under the morality or *order public* exclusions of the Directive are in substance replicated in the pertinent provisions of EPC 2000 [71].Without such detailed exclusions, and without making use of the *ordre public* or morality basis [72], even under US (otherwise permissive) practice, the patenting of humans by itself is denied[73].

Other considerations related to the patenting of human beings are the TRIPs allowed exclusion of purely biological processes, and also TRIPs-allowed exclusion of methods of treatment of humans (and other animals)[74].

Therefore, the cases where the human issue is raised in connection with patent granting may be so summarized:

(a) patenting of human beings as a whole - it seems to exist complete convergence in all legal systems to exclude such objects *as products*, upon various legal grounds[75];

(b) parts of the human body except infracellular elements - According to the EU Biotechnology Directive, the human body (in any developmental phase) is not

---

[71] EPC 2000 Article 52(a)/section 1(3). EPC 2000 Rule 28 excludes "(a)processes for cloning human beings; (b)processes for modifying the germ line genetic identity of human beings; (c)uses of human embryos for industrial or commercial purposes; uses of human embryos for industrial or commercial purpose".

[72] Jennifer McCallum, "The Reality of Restricting Patent Rights on Morally Controversial Subject Matter" (2005) 39 New En. L. Rev. 517.

[73] MPEP 2105 Patentable Subject Matter - Living Subject Matter [R-1] "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made", found at http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2105.htm#sect2105, visited 07/24/10. But for the mention of the case Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930. (Fed.Cir.1991), no specific statutory basis for such exclusion could be found. See Sander Rabin, The human use of humanoid beings: chimeras and patent law, Nature Biotechnology 24, 517 - 519 (2006); on the 13th. Amendment issue, see Peter K. Yu, Intellectual Property and Information Wealth: Patents and trade secrets, Greenwood Publishing Group, 2007, p. 325.

[74] The concept of invention excludes the creations involving only mental steps, which is necessarily a human attribute albeit not biotechnological; and also in the concept of industrial application there is an element of technical action that shall not be caused directly by human intervention. Either grounds may explain why "Methods for influencing human interactions or behaviours" are not patentable under Canadian Law (Chapter 12.04.02, Manual of Patent Office Practice) and under Brazilian Patent Examination Directive cosmetic treatments even when not covered by the "treatment" exclusion is also non patentable whenever the procedure is done on a one-to-one, personal basis by a human agent.

[75] We are not considering here chimerical human being inventions as proposed by John Rifkin in 1998.

patentable [76]; other statutes, mentioning the human or animal body, expressly exclude "or parts thereof"[77], what is equally mentioned in EPC 2000 rule 29. However, the EU Directive covers elements isolated [78]or "otherwise produced by means of a technical process[79]", even in cases where the isolated of technically produced element is structurally identical to the pertinent body element[80].There are some important issues related, for instance, the human embryonic stem cells (HESC) [81]It would seem that the same isolation or non-natural solutions would be protected under US Law[82].

(c) Infracellular elements pertaining to the human body - The EU Directive covers under the same case of the previous item [isolated or produced by technical means] "the sequence or partial sequence of a gene" pertaining to the human body, provided that its industrial application is cited[83].Other statutes just reproduce the TRIPs 27.3 wording on microorganisms, which requires patents issued for such an object once satisfied the general invention, novelty, inventive step and industrial application requisites; in this case, only the *ordre public/*morality filter would seem eventually applicable.

(d) Processes for cloning humans or modifying human genome -Under current US practice, only cloning of nonhumans is allowed[84]. EU Directive and EPC art. 52would oppose the cloning of humans as well as any processes for modifying the germ line

---

[76] The provision also mentions "discoveries" of other human body elements, which would be otherwise unpatentable by the general requirement of invention.

[77] In the field covered by this study, Brazil, Andean, Peruvian post-FTA, Chile, and India. Mexican Law art. 16 states that no patent shall be granted for "IV. the human body and the living matter constituting it".

[78] It should be called here to attention whereas 26 of the EU Directive, where "free and informed consent" whenever an element is used from a human body - possibly also in an isolation procedure.

[79] Gross, Ludwig, Sullivan, Biotechnology and Pharmaceutical Patents, Aspen, 2010, § 22.01(C) notes that "technical application" does not necessarily equal "industrial application".

[80] Gross, Ludwig, Sullivan, § 22.01(C) state that human totipotens or germ cells are unlikely to be patentable, except cells differentiating *ex vivo* not taken from embryos. The same authors note that French national Law would further limit the scope of this patent to "the extent necessary to the realization" of the particular use. On the other hand, such authors see the UK Law as a less restrained environment as to pluripotent cells as compared with the EPO one.

[81] Philip W. Grubb, Patents For Chemicals, Pharmaceuticals And Biotechnology: Fundamentals Of Global Law, Practice And Strategy, Oxford, 2004, p. 280.

[82] See Gross, Ludwig, Sullivan, § 1.02 (B). and (C).

[83] EPC 2000 Rule 29 (3), April 2010: "The examination of a patent application or a patent for gene sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology (EU Dir. 98/44/EC, rec. 22)".

[84] However, Gross, Ludwig, Sullivan, § 1.03 (d)3, mentions US Patent 6,781,030 as an instance where claims cover the cloning of mammals, without excluding humans.

genetic identity of human beings[85]. It is to be assumed that in the other jurisdictions covered by this study the *ordre public*/morality exception would be also arguable.

(e) Gene therapy -A large number of gene therapy patents were issued by USPTO [86]. Those cases would be probably refused under EU law [87]. There is no information in our present field of study to anticipate how this matter would be treated in other jurisdictions.

(f) Processes for generating organs -It seems that at least some of such technologies would be acceptable under current US practice [88]. Art. 5.2 of the EU directive would likewise seem to accept the patenting of "an element produced by means of a technical process [for the human body], may constitute a patentable invention, even if the structure of that element is identical to that of a natural element…"; *a fortiori*, the related process would seem patentable[89].

f) Use of embryos -The EU Directive declares non patentable "uses of human embryos for industrial or commercial purposes"[90]; the exclusion does not cover necessarily

---

[85] The European Council stated its opposition the human cloning on May 29, 1997. Ratifications of the Council of Europe Human Rights and Biomedicine Convention were also called subsequently by the EU Parliament. According to EPC 2000 Rule 28 (a) April 2010, "For the purpose of this exception, a process for the cloning of human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being (EU Dir. 98/44/EC, rec. 41)".

[86] Gross, Ludwig, Sullivan, § 1.03 (d) 5.

[87] Philip W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy, Oxford, 2004, p. 280: "thus germ-cell gene therapy is regarded as unethical".

[88] Gross, Ludwig, Sullivan, § 1.03 (d) 4 mentions US patent 6.211,429 in this context, where transgenic mammals (preferably pigs) could be built up to generate organs bound to be used in humans.

[89] The present set of information would not permit to predict the patenting of processes directed to generating organs in other jurisdictions.

[90] On 25 November 2008, the Enlarged Board of Appeals (EBA) of the European Patent Office issued the Decision G 0002/06. According to https://www.aippi.org/enews/2009/edition07/epo-uspto.html, visited July 21, 2010, "... as a matter of fact the restriction to patentability shall not apply to inventions concerning human stem cells (or cell cultures) in general, but only to those obtained by the use and destruction of human embryos. Consequently, inventions concerning human stem cells, not obtained by means of destruction of human embryos, are not excluded from patentability in accordance with Rule 28(c) EPC." Here the principle of "free and informed consent" of the donor of the embryo should probably be also raised. In its late 2010 5th. Edition, Grubb (now Grubb and Thonsen) notes that the decision seems curious as in the majority of European countries it is legal to use "blastocysts than would in any event be discarded".

therapeutic purposes[91]. What is the extent of such exclusion? Only the employ of embryo itself is excluded, or also uses of products derived from human embryos, e.g., hESCs? At this moment the issue was not clarified [92]. In other jurisdictions, a similar position could be discerned[93]. However, US current procedure diverge in this context from the European choice [94].

\ Inventions concerning (non human) animals

As noted, TRIPs art. 27.3allows members to exclude animals *as a product* from patent granting, both single and as a race, including those animals resulting from genetic transformation [95]. Many countries in the roster under study take full profit from this allowance. US practice has been following other track, and a number of higher animals have been patented as products [96].

As reported below, in Canada, even though statutory provisions would deny patenting *as products* of higher life forms, similar economic effect could result of patenting of genes defining the higher life form as such [97];it should be considered whether the same result would not occur in other jurisdictions including the plant or animal exclusion, but allowing for gene protection in the same fashion of Canada.

---

[91] EPC 2000 Guidelines Rule 28 (c) April 2010: "The exclusion of the uses of human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it (EU Dir. 98/44/EC, rec. 42)".

[92] Gross, Ludwig, Sullivan, § 22.01(C), p. 22-31.

[93] Brazilian Directives state: "2.31.2 However, it considers as not patentable processes for cloning human beings, processes for modifying the human genome and the uses of human embryos for industrial or commercial purposes".

[94] Mentioning the US side of the patent family examined under G 0002/06 by EBA, the same AIPPI source notes: " On 26 June 2008, after a re-examination procedure, the USPTO confirmed the issuance of two WARF patents, of the same family as the EP patent application. The former (US 5,483,780) refers to primate's cells and to a method for obtaining them from primate's blastocyst (the cell organization stage during embryogenesis before the differentiation between embryo and nutritive tissues and implantation takes place), the latter (US 6,200,806) refers to human embryonic stem cells in pre-implantation phase", see https://www.aippi.org/enews/2009/edition07/epo-uspto.html, visited July 21, 2010

[95] UNCTAD/ICTSID, op. cit., p. 392. "They may also exclude animals (including transgenic) and animal races".

[96] Gross, Ludwig, Sullivan, § 1.02(E) - Higher Animals. The first patent was granted on April 12, 1988 for the so-called Harvard Mouse. The European patent of the same family is discussed at length later in this study. The Canadian version of the same patent family was granted on 10/07/03 ref. 1,341,442 CA.

[97] Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902.

European current practice, on the other hand, has been accepting animal patents (other than human), provided that the invention is not confined to a single animal *variety*[98], and subject to a morality/*ordre public* filter balancing, that takes into account the possible *medical* advantage the technology might have for man, as compared with eventual animal suffering [99]. This position would encounter echo in other jurisdictions under the same morality/*ordre public* analysis[100].

Processes - at least non essentially biological ones - for obtaining animals (or animal *varieties*) are not excludable under the specific TRIPs Art. 27.3 exemption but may find some objections under the morality/*ordre public* filter.

\ Inventions concerning plants

As noted above, TRIPs art. 27.3 allows for the exclusion of patents for plants, but required at least some non-patent system for protecting plant *varieties*. This system might be the UPOV one, but not specific requirement exists[101]. The analysis of this non-patent system shall not be covered by the present study.

However, there is no obligation to exclude plants or plant varieties from the scope of regular patents. As noted below in the specific section, the US system provides for three concomitant patent and PVP systems to cover those creations.

There is, therefore, no need under TRIPs to have plant patents. Patents would do under the TRIPs standards, even though meeting grant requirements could prove too hard to cover the multiple interests at stake. Furthermore, the level of protection could also be too high for a regimen supposed to be soft enough to accommodate farmers' interests. PVP rights, even by UPOV 1978 standards, would satisfy international legal requirements, at least for the time being. One must bear in mind, however, that UPOV 1991, while establishing a higher standard (from a holder's standpoint), still does not

---

[98] Whatever an "animal variety" may be: EPO board of appeal decision T 19/90 of October 3, 1990.

[99] Gross, Ludwig, Sullivan, § 22.01 (C). The authors identify a trend to protect only animals that may have laboratory importance, like mice.

[100] For instance, the Brazilian Guidelines: "2.31.1 The PTO adopted the criterion to be regarded as patentable only those processes for modifying the genetic identity of animals that do not bring suffering to these animals, and those that even bringing some kind of suffering for the animal, produce any substantial medical benefit to human or animal".

[101] A number of FTAs has provisions is inducing the adoption of the UPOV 1992 version in the national legislation of the target countries.

reach the same level afforded by patents. There are, therefore, no international legal constraints to *enhancing* the level of protection by modifying PVP rights.

When there is *patent* protection two specific problems shall be considered: (a) the effects of conflicting or reiterating protections and (b) the extent of some special limitations, namely, the so-called farmers' privileges and breeders exemptions[102] might be extended to patents.

PVPs provide a *product* protection. Even though some national or regional systems may exclude *product* patents concerning plants (i.e., vegetal items over the microbiological level) probably all of them would comply TRIPs by granting patents on *processes* related with plants. Even though UPOV 1971 stated that PVP protection excluded a second non-PVP one, the current version of the treaty does not deal with the matter. Therefore, not only there may be in theory a patent plus a PVP over the same plant as a product, but also the effects of a process patent may encompass a plant that is protected by a PVP [103].Recent European case law has however enlightened some constraints of this process-to-product protection [104].

---

[102] "The original UPOV Convention laid down the rules for PBR that would have to be included in national laws in order for countries to qualify for membership. In essence, plant breeders are given a limited monopoly over the reproductive material of the variety. Even if it may seem only a nuance, this entails an important difference with patents, since patent holders claim ownership to the germplasm, technology and industrial processes, while breeders - in the original UPOV concept - can only control multiplication and sale of seeds. UPOV has also provided - until the 1991 version discussed below - special protection for farmers and the continued free access to plant genetic resources. Farmers have been allowed to continue with their ancestral costume of saving seeds for the coming seasons and informally exchanging them with other farmers, even from protected varieties, and this right is called the farmers' privilege. Plant breeder and Netherlands genebank director, JaapHardon, described this free availability of germplasm once as a " constitutional right" in agriculture. "A right going back 12'000 years to the dawn of agriculture and the domestication of all these crops we grow or have grown." For the same reason, breeders have been allowed to make use of protected varieties' genetic material to develop new lines without having to pay royalties or ask permission. This right is included in UPOV as breeders' exemption. Without the possibility to freely exchange germplasm there is maybe agribusiness but not agriculture". June Grain, UPOV: Getting a Free Trips Ride? Seedling, June 1996, http://www.grain.org/seedling/?id=161, last visited on 5/22/2009.

[103] According to TRIPs Article 28.1, a patent would prevent anyone from using, offering for sale, selling or importing for those purposes the product obtained directly by that process.

[104] Monsanto Technology LLC v Cefetra BV, Case C-428/08,6 July 2010, which held: "1. Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism."

\ The complex relation between patents and PVPs

The coverage of plant-related technologies by at least two different systems of protection brings complex issues to analysis. The patent system in this area must not defeat the PVP system, and the latter's exceptions and limitations are not to frustrated by any double protection [105].

The interaction among the three kinds of patents/PVP applicable to plants under US practice is indicated below. The EU Directive provides for some guidance as to the relation between the two systems:(a)by indicating areas where a patent is not to extend to fields covered by PVP [106]; (b) where the breeder's or farmer's exceptions should be

[105] "Broadly speaking, part (b) of paragraph 3 (i.e. Article 27.3(b)) allows governments to exclude some kinds of inventions from patenting, i.e. plants, animals and "essentially" biological processes (but microorganisms, and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible for protection either through patent protection or a system created specifically for the purpose ("sui generis"), or a combination of the two (…)The review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement. The topics raised in the TRIPS Council's discussions include: - how to apply the existing TRIPS provisions on whether or not to patent plants and animals, and whether they need to be modified - the meaning of effective protection for new plant varieties (i.e. alternatives to patenting such as the 1978 and 1991 versions of UPOV). This has included the flexibility that should be available, for example to allow traditional farmers to continue to save and exchange seeds that they have harvested - how to handle moral and ethical issues, e.g. to what extent invented life forms should be eligible for protection - how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications - how to ensure that the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) support each other. The 2001 Doha Declaration made it clear that work in the TRIPS Council under the reviews (Article 27.3(b) or the whole of the TRIPS Agreement under Article 71.1) and on outstanding implementation issues should cover: the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD); the protection of traditional knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPS Agreement. It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account.". Found at http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm, visited on 26/01/06. See also IP/C/W/369/Rev.1, revised 03/09/06, found at http://www.wto.org/english/tratop_e/trips_e/ipcw369r1.doc, visited on 1/26/2006.

[106] EU Directive whereas: "(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety; (30) Whereas the concept 'plant variety` is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties; (31) Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants; (32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;".

extended to the patent environment [107]; and (c) where a dependent compulsory license should be issued to allow for the exploitation of a plant variety that could clash against a dominant patent or vice versa [108].

Those are the relevant provisions:

> Article 4 (...) 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
>
> Article 11 1. By way of derogation from Articles 8 and 9, the sale or other form of commercialization of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.
>
> Article 12
>
> 1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

---

[107] EU Directive whereas: "(47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorize the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (6); (48) Whereas only the fee envisaged under Community law relating to plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer; (49) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against a breeder who has developed a plant variety incorporating the protected invention if the latter fails to adhere to his commitments; (50) Whereas a second derogation from the rights of the holder of the patent must authorize the farmer to use protected livestock for agricultural purposes; (51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;".

[108] EU Directive whereas: "(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent; (53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;".

> 2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.
>
> 3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
>
> (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
>
> (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.
>
> 4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

No similar provisions were verified in the other jurisdictions (outside the EU Directive-covered domestic statutes) reported in this study. As such, solutions would require most probably a specific legal language, and it may be assumed that no other jurisdiction has such an elaborate conciliation system.

The issue of Knowledge at Research-level

The issue here is the access level to the "industrial utility" requirement [109].A number of inventions within the biotechnology field purport to cover technologies addressed to research or at least not-yet-industrial problems[110]. The European directive model

---

[109] Whereas such a requirement is explicitly not considered within the scope of this analysis, some remarks are inevitable whenever discussing biotechnological inventions. See Kevin C. Hooper, Utility and non-operability standards in biotechnology patent prosecution: CAFC precedent versus PTO practice. IDEA: The Journal of Law and Technology, 1996. According to PhaneshKoneru, To Promote the Progress of Useful Articles? An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools 1998 38 IDEA 625, concerning the state of the US law before In Re Fischer: “[the] application of Brenner v. Manson, where the Supreme Court held that an invention must offer "specific benefit in currently available form" to satisfy the statutory utility requirement. Accordingly, a chemical process that produces a chemical intermediate has no patentable utility and thus is not patentable if that intermediate is useful only as a research tool".

[110] Expressed sequence tags (EST) are possibly an adequate example, as indicated in the case In Re Fischer alluded below. According to Gross, Ludwig, Sullivan, § 22.01(C) 2, Chinese and Indian current procedure would only accept EST patents in case they state a specific function, in the Indian case "properly and sufficiently disclosed in order to establish inventive step and industrial applicability".

requires that in new genetic material no patent shall issue except by disclosing its specific use, what may be convergent with the law declared in the American case of *In re* Fisher [111].

This issue should be considered within the exclusions to patent scope theme, as the peculiar intimacy that biotechnology displays between research level knowledge and patentable level invention is quite a sensible problem [112].

[111] The holding of Association for Molecular Pathology et al. v. United States Patent and Trademark et al., 09 Civ. 4515 (S.D.N.Y. 2010) would seem to be an isolated understanding.

[112] "The widespread view in scientific circles is that patenting ESTs may give disproportionate rewards for routine effort that constitutes a minor step on the road to developing a useful product, and would thus impede research. Biotech companies were concerned that EST claims that are cast in broad terms could preclude the patenting of subsequent claims for the gene and the protein for which the gene encodes, due to a lack of novelty. The reasoning was that if a scientist subsequently isolated and sequenced the full-length gene, he or she could only patent the portion of the gene that was not included in the EST because the section of the gene that corresponds to the EST would not be novel." Howlett, Melanie J. and Christie, Andrew F., An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs). Australian Intellectual Property Journal, Vol. 15, No. 3, pp. 156-162, 2004. Available at SSRN: http://ssrn.com/abstract=667202.

IV- A developmental analysis of biotechnological exclusions, exceptions and limitations

Examining the developmental effect of biotechnological exclusions, exceptions and limitations of the present International Patent System requires two vestibular clarifications: *which* development we are considering and the relative role of the patent system in attaining such purposes[113].

The notion of development that would guide us in this context was defined in the Barbosa, Chon and Von Hase study on the issue. According to such text,

> The contrasting, and indeed often clashing, understandings of development lead to very different normative visions of international intellectual property. The freedom model of development emphasizes not just the innovation mandate of intellectual property, but also its relation to other human capability-enhancing social welfare measures, such as access to education or health, which in turn build national capacities for innovation and growth. The growth model of development, on the other hand, ties intellectual property unilaterally to its capacity to encourage innovation through technology transfer, irrespective of intellectual property's function in other economic and social sectors.

The "freedom" model of development means, particularly in connection with biotechnologies, better access to food and health, and possibly more localization-prone technologies [114]. The relative irrelevance of Intellectual Property considerations in those studies indicating the developmental role of biotechnologies shows clearly the problem

---

[113] *See* Graham Dutfield, Lois Muraguri e Florian Leverve, Exploring the flexibilities of TRIPS to promote biotechnology capacity building and appropriate technology transfer, Final Report IPDEV Work Package 7, 2006.

[114] Here, emphasizing the importance of PVP for the expansion of localization biotechnologies, see Borges Barbosa, Denis and Lessa, Marcus, op. cit. In this context, Mia et al., Editors, *The Brazil Competitiveness Report 2009*, Geneva, World Economic Forum, 89 (2009) "One of the foundations of innovation in agriculture consists of the idea that the sector is location-specific in its technologies and its products. There are few opportunities where one can copy or directly transfer technologies and products from one country to another without adaptation and without considering differences in climate, soil, vegetation, and culture. This idea is even more relevant for technologies developed for countries with temperate climates that one wants to apply in tropical countries. This was the case of Brazil in the conquest of the cerrados (Brazilian savannahs). There was no technology specific to agriculture in the cerrados; the solution was to adapt forms of agriculture being used elsewhere to this large system. This idea is mirrored in the expression tropical technology".

facing us in this section [115]. Other studies seem to indicate that non-IP considerations (like clustering of innovative agents, Government support, and importance of pre-IP contracting)are much more relevant for the generation of developmental-type biotechnologies[116].

On the other hand, a series of analysis stress the importance of free access to biotechnological knowledge - both a *growth* concept of development as well as in a *freedom* one [117]. This line of thought does not preclude by any means the importance of the patent system but only suggests that an inclusive, not an excluding model of usage of patents or PVPs would improve the impact of biotechnologies to the developmental purposes [118]. It must be noticed that those considerations are not extraneous to the present WIPO mandates [119].Further analysis indicates that a proper balancing of both the patent appropriation model and the public access one could serve the interests of developing countries [120].

In this perspective, the ensemble of biotechnology-specific patent exclusions, exceptions and limitations must be screened cautiously. TRIPs took a prudent step allowing the exclusion of higher life forms patents; the idea that a fast reexamination of such allowance could lead to a general International obligation to patent "everything

---

[115] Borges Barbosa, Denis, Chon, Margaret and Moncayo von Hase, Andres, Slouching Towards Development in International Intellectual Property. Michigan State Law Review, Vol. 2007, No. 1, 2008. Available at SSRN: http://ssrn.com/abstract=1081366.

[116]Thorsteindottir, Halla, Singer, Peter A., Saenz, Tirso and Daar, Abdallah S., Different Rhythms of Health Biotechnology Development in Brazil and Cuba. Journal of Business Chemistry, Vol. 2, No. 3, pp. 99-106, 2005. Available at SSRN: http://ssrn.com/abstract=887286; Hobohm, Daniel, Frameworks for the Development of Innovative Industries Biotechnology in Taiwan, South Korea and Thailand (October 4, 2004). Available at SSRN: http://ssrn.com/abstract=1295122; Aerni, Philipp, Mobilizing Science and Technology for Development: The Case of the Cassava Biotechnology Network (CBN) (2006). AgBioForum, Vol. 9, No. 1, pp. 1-14, 2006. Available at SSRN: http://ssrn.com/abstract=1493805; Unyauni, Pushpa and Joshi, Manoj, Impact Making Biotechnology Firms in India (January 8, 2010). Available at SSRN: http://ssrn.com/abstract=1533275.

[117] Hope, Janet E., Open Source Biotechnology (December 23, 2004). Available at SSRN: http://ssrn.com/abstract=755244.

[118] Copyright is an essential instrument to prevent unwanted singular appropriation of open-model software creations; patents and are liable to take similar role in any open-access technologies at industrial-applicability level.

[119] Included in the forty-five recommendations proposed by the WIPO member states and later adopted by the General Assembly is the mandate to "consider the preservation of the public domain within the WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain".

[120] For instance, Maria Ester Dal Poz and Denis Borges Barbosa, op. cit.

under the sun that was made by man" was soon dispelled [121]. The significant differences between the American and EU biotechnology current regimes indicated above suggest that the time for review of such allowances is not reached.

Our contention is that the present International, TRIPs-based system of biotechnology-specific patent exclusions, exceptions and limitations has been almost universally utilized and incorporated in the domestic legislations within the present scope of study. Minor divergences [122] do not seem to detract from this conclusion. Even though the continuance of the present extension of such exceptions could be attributed to the imperfect harmonization of the developed economies' patent system, at this moment the TRIPs model would appear to have been at least nominally succeeded.

However, it is not within the purview of the present section to evaluate whether those exclusions, exceptions and limitations are in practice effective to improve developmental drives, at least of the *freedom* kind. The empirical data on the eventual *growth* aspect of patenting or providing PVP protection would likewise seems lacking improvement. Such empirical studies would de certainly required.

On the other hand, the various parallel initiatives concerning biodiversity preservation, food access, origin of genetic resources and traditional knowledge, not only in its technical or distributive sense, but also by its rhetorical value, are closely intertwined

---

[121] In connection with this review, *see* ABBOTT, Frederick, CORREA, Carlos, et allii, Resource Book on TRIPS and Development, Cambridge University Press, 2005, p. 395. "TRIPS entered into force on 1 January 1995. Though the review should have taken place in 1999, there has been no agreement at the Council for TRIPS on the meaning of "review". Developed countries have held that a "review of implementation" is what is called for, while for developing countries a "review" should open the possibility of revising the provision itself. The review of Article 27.3(b) was also one of the TRIPS issues dealt with at the Ministerial Meeting at Doha in 2001. In this respect, the Doha Declaration "19. We instruct the Council for TRIPS, in pursuing its work program 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." Implementing this mandate, the Council for TRIPS has been discussing, inter alia, the following agenda items: (a) the review of the provisions of Article 27.3(b); (b) the relationship between TRIPS and the Convention on Biological Diversity (CBD); (c) the protection of traditional knowledge (TK) and folklore. The Council has addressed these items together, due to their interrelated character. Despite consultations held by the Chair, Members have so far not been able to remove their substantive differences over these issues."

[122] For instance, the Brazilian Biosafety law provision directly targeted to Monsanto "terminator" Roundup Ready technologies and overly broad Indian exclusion methods of agriculture or horticulture.

with the efficacy of the set of biotechnology-specific patent exclusions, exceptions and limitations. However, as already indicated, those factors are not in our field of study.

III - A Regional analysis

\ South America

The exclusion of abstract creations and discoveries from the scope of a patent is general in the area[123]. However, there was no specific guidance found in case law or practice as to the application of such rules in regard to the patenting of research-level technologies, that is to say, not yet capable of application on a strictly industrial level.

Isolation of biological material is explicitly excluded in the Brazilian and Andean laws; but Peruvian law consequent to the US-FTA seems to include isolation within the patent scope. The Argentinean examination guidelines [124] also provide for such exclusion.

There are no reported cases or practice as to the use of the *ordre public* standard to prevent patenting in technologies where ethical issues may be raised. Only the Brazilian PTO has issued specific guidelines for biotechnological and pharmaceutical inventions [125], where this issue is addressed [126].

Mercosur Area

Exclusions to subject matter

In all four original countries, patents are granted for inventions that are new, useful [127]and with inventive activity.

---

[123] Venezuelan law, after the country left the Andean system, does not mention the abstract creations/discoveries exceptions. Is this change is relatively recent and the literature scarce if not nonexistent, there were no means to ascertain the status of law in this country.

[124] Found at http://www.inpi.gov.ar/pdf/DirectricesC.pdf.

[125] Found at http://www.denisbarbosa.addr.com/arquivos/diretrizes/diretrizes1.doc.

[126] Brazilian Patent Guidelines:"2.31.1 The PTO adopted the criterion to be regarded as patentable only those processes for modifying the genetic identity of animals that do not bring suffering to these animals, and those that even bringing some kind of suffering for the animal, produce any substantial medical benefit to human or animal. 2.31.2 However, it considers as not patentable processes for cloning human beings, processes for modifying the human genome and the uses of human embryos for industrial or commercial purposes. 2.33.2 Procedures for the use of cells of [human embryos] - are patentable, provided they include a method of treatment or a surgical method (...). The analysis should follow the guidelines dictated to processes that use biological material for a particular purpose"

[127] According to the Argentinean Guidelines, " 2.1.1. Discoveries, scientific theories and mathematical methods; a - Discoveries The products found in nature as they relate to findings of matter discoveries and as such are not considered inventions. The naturally occurring products *cannot be patented* by the fact

Surgery treatment, therapeutic or diagnosis methods applicable to the human body and regarding animals are excluded, as well as biologic and genetic material verified in nature(See Brazil) [128]; (See Argentina) [129]. In Brazil[130] and Argentina (here according to examination guidelines), those items are not patentable even though isolated from nature[131].

The national statutes do not distinguish entirely what is excluded because it is not an invention from what is simply an allowed statutory exclusion on account of public policy (those issues covered by TRIPs Art. 27.3). All countries in the sub-region exclude inventions offensive to *ordre public* or public health, and the whole or part of living bodies. Brazil, however, does not exclude inventions liable to harm the environment, and does not clarify that the *ordre public*/health exclusions only apply

---

that been isolated or purified in the form properly characterized as that in such cases there is no invention".

[128] According to the Brazilian Guidelines, "2.37.2 According to relevant literature, diagnostic methods consist of three distinct stages, namely, (1) examine the patient observing, feeling and listening for various parts of your body, (2) the patient undergo numerous clinical trials, and (3) to compare the data from these tests were normal, noting significant deviations, and assign the deviations to a particular disease state - medical deductive phase. If this last phase is not present, there is no way to speak of a diagnostic method, since no conclusion about the state of health of the patient, but rather a method of data collection that may be used in a method diagnosis. 2.37.3 In general, methods of obtaining information from human or animal body are patentable, provided that the data collected represent only an intermediate result, which alone are not sufficient for a decision regarding the appropriate treatment. For example, methods for measuring blood pressure, X-ray, blood tests, etc.. On the other hand, for example, methods of determination of allergic conditions, where the outcome is observed in the body of the patient, methods are not patentable because it is a diagnosis (is conclusive as to the allergic state or not). : 38 Surgical methods - Any method that requires a surgical step, i.e. a stage of invasive human or animal body (e.g. implantation of embryos fertilized artificially, cosmetic surgery, surgery, therapy, etc...), is regarded as the surgical method, focusing on what the Article 10 (VIII) says it is not invention. "

[129] According to the Argentinean Guidelines, "Finding a substance as existing in nature would be a mere discovery and therefore not would be patentable. If, however, to obtain the substance is developed process, this process could be patentable. For example, the discovery of a nucleotide sequence that encodes a certain protein, it is not likely to protection since it is a discovery and therefore not considered invention within the meaning of art. 4 LP.)".

[130] According to the Brazilian Guidelines, "2.4 compounds found in nature (including those of unknown constitution and extracts from animals / plants) are not granted under Section 10 (I) or (IX).2.4.2 Statements include, except in very rare cases, several compounds between active and not active yet, since it merely isolated from nature, are not considered invention by Article 10 (IX). 2.4.3 Synthetic chemical compounds having corresponding naturally occurring, without distinguishing them as such, are not regarded as an invention in accordance with the provisions of Section 10 (I) - they are not organic - or (IX) - if they are organic."

[131] Brazil and Argentina, as the Andean IP rules, discussed below, exclude from patenting material isolated from nature under the non-invention filter. This denial is referred by some commentators as detrimental to the interests of a diversity-rich country.

when commercial exploitation should be necessarily prevented to protect the indicated values; these constraints are stated in the other laws.

"Essentially biological processes" are excluded either as not being an invention (Brazil)[132] or as statutory exclusion. Microorganisms resulting from genetic engineering are protected [133].

Country-by-country analysis

The Paraguay Law considers not patentable “the plants and animals *except microorganisms*, and the procedures essentially biologic for production of plants or animals that are *not microbiologic or non biologic”*.

The same text is found in Paraguayan and Uruguayan Laws, solely with difference that while the first repeats the disposal for TRIPS listing it as “non patentable”, the Uruguay repeats the disposition in the list of what is not an invention.

The Brazilian law denies patents to “all or part of the living beings, *except* the *transgenic microorganisms* that fulfill the three patentability requirements, which are novelty, inventive activity and industrial application – established in art. 8th of the Applicable Law and that are not just mere discovery. An administrative level provision submits the filing of the patent of invention whose object has been obtained as a result of access to samples of components of the national genetic patrimony to a reporting obligation.

The Argentinean Law, on its hand, simply does not mention microorganisms. In Art. 6, g, states that all living material and substances preexisting in nature are not inventions, and in Art, 7 b disposes: “the totality of the biological or genetic material existing in nature or its reproduction in biologic implicit procedures of animal, vegetable and reproduction, including the genetic procedures regarding material capable of conducting its own duplication in normal and free conditions, as occurs in nature”.

---

[132] According to the Brazilian Guidelines, "2.28.2 It is understood by "natural biological process" any process that does not use artificial means to obtain organic products or that, even using an artificial medium, it would be likely to occur in nature without human intervention, consisting entirely of natural phenomena . For example, a process of improvement of an animal that consists of selecting the players and put them in contact so that there is coverage. Another example would be a pollination process, which uses a cotton swab to move pollen from one plant to another. In this case, the use of an artificial medium (cotton swab) merely accelerates or limits what would occur naturally".

[133] In Brazil " *through direct human intervention in their genetic composition"*.

According to Cabanellas[134]

> "Based on the dispositions on the Argentine patent legislation, we can establish which inventions are patentable and which are not in the biotechnology area. Such division includes the following elements:
>
> -The living material preexisting in nature does not constitute themselves as inventions but discoveries, in the methodology of the patent law, and are not, as so, patentable. The possibility of patenting a living material not preexistent in nature is then open.
>
> -The prohibition of patenting extends not only to plants, animals and microorganisms preexisting in nature, but also the remaining biologic and genetic previously existing in nature, but also in this case you are facing a discovery and not an invention.
>
> -Plants and animals never are patentable, except if they include the conditions of novelty, inventive activity and industrial applicability.
>
> -The essentially biologic process in animal, vegetable and human production are not patentable.
>
> -Microorganisms are only patentable (VIII, § 4g) if they gather the usual positive patenting conditions".

An important decision by the Argentinean Federal Appeal Court, dated May 15, 2003 provided on the issue of "essentially biological processes"[135], as an exclusion of patentability for lack of invention concluding that a human intervention involved in an induced mutagenesis procedure was sufficient to assure patent [136].

Exceptions and limitations of patentee's rights

The only biotechnologically-oriented limitations found in the area are in Brazilian Law, which allows (a) for free use of the patented (living material) product, without economic

---

[134]CABANELLAS, op. Cit., p. 830:

[135] According to the Argentinean Guidelines, "Regarding item 2.1.7.5 2.1.7.2 c) essentially biological processes are those that cover phases that concluded with obtaining or reproduction of plants or animals that are met mainly or significant degree by the action of their own and of existing phenomena in nature. Thus, to determine whether procedures for the production or reproduction of plants or animals is essentially biological assess the technical aspect of the process. If the technical intervention of man plays an important role in determining the outcome or whether their influence is decisive, then the process is deemed to have a technical nature and therefore be patentable (see Section 2.1.7.1). 2.1.7.6 Under this concept, the classic procedures for breeding or improvement are not patentable. For example, a method of crossing or selective breeding involves crossing horses with certain characteristics, which involves the selection, would essentially biological and therefore not patentable. In contrast, methods based on genetic engineering (e.g. production of a transgenic plant), where the technical intervention is significant, may be patentable."

[136] KORS, J. Et allii, Patentes de Invención, La Ley, 2004, P. 142.

purpose, as an initial source of variation or propagation in order to obtain other products and(b) (in exception to the rule of national exhaustion applicable for patents[137]) also allows for free use "in case of patents related to living matter, use, place in circulation, or market a patented product that has been lawfully placed on the market by the owner of the patent or his licensee, provided that the patented product is not used for the commercial multiplication or propagation of the living matter concerned".

General limitations also applicable in biotechnological area

Limitation: private acts

The right to patenting is a right with economic nature; e.g. does not extend to acts without commercial purpose. This affirmation is in the Argentine, Brazilian and Uruguayan Law and Decision 486 of the Andean Pact. This limitation of the patenting right is linked to the nature of the act, and not its dimension, but some national or regional provisions make explicit the TRIPs three-step rule.

For instance, in Brazil, Art. 43 disposes to be free the private use (and, therefore without commercial purposes) of the invention, and adds to this a condition, *as long as it does not generate economic damages to the patent owner*.

Research or academic use

The right granted to the patent owner does not produce effects with research-intended acts. The fact that the invention is free for research purposes aims to serves as means to develop innovation and the state of the arts, which, for its term, achieves the goal of the patent system. The patent right cannot, thus, go so far in a way to refrain studies, researches, etc.

Following such guideline, the laws of the countries members of the Mercosur and the Andean Pact (Decision 486) dispose in appropriate laws that the use of patented

[137] Art. 68 § 4 of the Brazilian Law, which deals with compulsory licensing, provides that in case of importation to exploit a patent and in the case of import under paragraph art. 68 § 3 (license due to abuse of economic power), will also be allowed to any third-party to import product manufactured according to patent a process or product, provided that it has been placed on the market (without discriminating whether internal or external) directly by proprietor or with his consent. When occurs such general permission? When there is no exploitation of the subject of a patent in Brazilian territory for failure to manufacture or incomplete manufacture of the product, or even non-use of a patented process. This follows the caption and art.68 item I. It should be understood that such permissive is applicable especially in those cases where it is not economically feasible to manufacture the product in Brazil, what it is presumed by the fact that the holder of the patent is not making such a fabrication, either directly or licensee. For utilizing, there is no need for a specific declaration or compulsory license granted by the Brazilian authorities.

inventions for research and merely experimental scientific investigation purposes is allowed.

Limits: exhaustion of rights

One of the main IP concepts is that exclusivity effect must last until, but not after, the moment when investor has the opportunity to recover his investment [138]. However, the unapplied Trademarks Protocol of the Mercosur established that the trademark registration could not stop the free product circulation if the introduction to the market was legal. As so, rules must to assure this exhaustion of rights application in Mercosur.

In which regards specifically patents, the owner or with his consent placing the patented product in the market, concludes the right to commercialization. In other words, with the first placement at the market, the exclusive right to commercialization of the invention is completed. In this sense, all future utilization is free.

In Argentina and the countries of the Andean Pact, the exhaustion is international. The same occurs in Paraguay and Uruguay. In Brazil, on the other hand, exhaustion is national [except in the case of certain biological material], subject however to the special provision of Art. 68 § 4 [139], whereby whenever a patent holder exploits its patent by importing the products related, international exhaustion then applies. There is no recorded case where this provision was actually utilized.

With what regards to living material exhaustion in Brazil the legislation decided for a solution in separate. According to Art. 43 VI of the mentioned Law, the owner may not prohibit the use and commerce of patents regarding living material, when they have been legally placed for commerce, and as long as it is not used for multiplication or commercial propagation of the living material in hand.

---

138 Completion of rights X parallel import. In the latter, the country where the owner has such right may have the product manufactured by a third party. In the completion of rights, the product shall have already been paid in the initial market placement. In the import situation, there is no payment to the holders of rights. See As importações paralelas na Lei nº 9.279, de 14 de maio de 1996, and Mercosul, Henry K. Shernill. (25): 23-26, nov.-dez. 1996.

139 Art. 68. "(3) In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent. (4) In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent".

Here it may seem, in the first moment, an exception to the exhaustion rule, when reproduction seems not considered in the exhaustion rule. In truth, however, the reading expresses an adequate exhaustion principle application to the special characteristics of biotechnology. In case of commercial reproduction, it is, in fact, a patented microorganism production, and this right is not subject to exhaustion.

Andean Area

South American legal systems are generally divided in three zones: the expanding Mercosur area, the eroding Andean Pact area, and jurisdictions not aligned to any of those pacts. As aforesaid, Mercosur has not as yet a common IP regimen, and however somewhat interconnected, the legal systems remain national. The recent divorce of the Venezuelan IP system from the Andean uniform system is noted below; but the lack of practice and case law concerning the revival of a 1955 law must also be noticed.

Andean supranational legislation provides the basic IP legal system to the countries under the Pact (Bolivia, Colombia, Ecuador, and Peru), to which ancillary domestic provisions may be added as supplementary law. Colombia has relinquished to provide such domestic counterpart. Venezuela in 2008 abandoned the Pact and revived the 1955 IP domestic law then quiescent.

Andean law shall prevail on domestic law [140]

According to Andean Decision 689 of 2008 [141], countries may provide in their national laws more enhanced protection than the one provided under general Andean standards

[140] PROCESO 14-AN-2001 "... it is necessary to point out that the legal system of the Andean integration prevails in its application to internal and national standards, being essential feature of Community law, as a basic requirement for building integration. This was recognized by the Cartagena Agreement Commission composed of the plenipotentiaries of the Member Countries, in the declaration adopted at its Twenty-Ninth Ordinary Session (Lima, May 29-June 5, 1980), when he declared the "full validity" of following concepts: a) the law of the Cartagena Agreement has identity and autonomy, is a common law and is part of the national legal systems, b) the law of the Agreement prevails, within the framework of its powers, the rules national, but they may oppose him unilateral measures or the Member Countries, c) the decisions which create obligations for member countries enter into force on the date indicated or otherwise, on the date of the Final Act of the meeting respectively, in accordance with Article 21 of the Rules of the Commission. Accordingly, those decisions are binding and acquire the required compliance from the date of its validity. "

[141] Found at http://www.comunidadandina.org/normativa/dec/D689.htm.

[142], thus allowing that supranational rules work in a supplementary and minimum level role whenever the domestic laws apply, and not anymore as principal body of law. This was needed as result of the Andean jurisprudence stating that legislation not in conformity with Andean Decision 486 was to be held invalid [143].

It is generally held that the Andean IP statutes and especially its case law is the most important body of law throughout the region [144].

---

[142] In which it relates to our field of analysis: „1. By introducing an exception to article 9, it allows countries to establish conditions to reinstate priority rights on a patent or utility model, industrial design or trademark, for a term not more than two months beyond the established initial period. 2. It allows amendment of article 28 to introduce additional regulations related to divulgation of the invention, in sense of requiring applicant greater clarity in the description and sufficiency in such divulgation, so that there is no need for a person having knowledge of the state of the art to conduct undue experimentation. 3. It clarifies article 34 by establishing that reporting on omissions on the Spanish text of description and claims, will not be considered an extension of the invention if the new matter was contained in the priority application, if claimed. 4. Except in the case of patents for pharmaceutical products and processes, it grants rights to the members countries to compensate for undue delays in the grant of the patents, undue delays being those delays exceeding five years from filing date or three years from the date a petition for examination was filed and where such delays can only be attributable to the Patent Office. 5. Introduce a clarification to article 53, allowing countries to pass new legislation limiting patentee's rights, so to introduce a provision equal to the Bolar Exception. (...)". According http://www.barredamoller.com.pe/store/publicaciones/78/September_2008.pdf, visited on 15/4/2010.

[143] For instance, in DICTAMEN Nº 07-2007, República del Perú – Reclamo de THE REGENTS OF THE UNIVERSITY OF CALIFORNIA. For all the above, the Secretary General considers that the Republic of Peru has committed a breach of Article 26, letter k) and 32 of Decision 486, establishing through internal regulations (Legislative Decree 823 and Decree Law 807) formal requirements additional to those contained in Decision 486 for the filing of patents. Similarly, the Republic of Peru has also violated the provisions of Article 4 of the Treaty Creating the Court, by which the Member Countries of the Andean Community made a commitment to take the necessary measures to ensure compliance Andean Community (obligations to do), and the commitment not to take any action or use would be contrary to the Andean system or in any way hinder its implementation (obligations not to do). Indeed, "the breach of any rule of law, originating in or derived from a member country inevitably leads to violation of Article 4 No ...."

[144]Helfer, Laurence R., Alter, Karen J. and Guerzovich, M. Florencia, Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community. American Journal of International Law, Vol. 109, 2009; Vanderbilt Law and Economics Research Paper No. 08-53; Vanderbilt Public Law Research Paper No. 08-53; Northwestern Law & Econ Research Paper No. 08-22; Northwestern Public Law Research Paper No. 08-41. Available at SSRN: http://ssrn.com/abstract=1306318"The Andean Community - a forty-year-old regional integration pact of small developing countries in South America - is widely viewed as a failure. In this Article, we show that the Andean Community has in fact achieved remarkable success within one part of its legal system. The Andean Tribunal of Justice (ATJ) is the world's third most active international court, with over 1400 rulings issued to date. Over 90% of those rulings concern intellectual property (IP). The ATJ has helped to establish IP as a rule of law island in the Andean Community where national judges, administrative officials, and private parties actively participate in regional litigation and conform their behavior to Andean IP rules".

Andean IP rules

As most of the post-TRIPs South American statutes, Decision 486[145] (Common Intellectual Property Regime) of The Commission of the Andean Community indicates that:

> Article 14.- The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable

In art. 15 [146], the Decision states what is not to be deemed an invention. Discoveries and material existing in nature (including that specified from nature through selection, etc.), non technical even though useful creations, literary and aesthetic creations, methods for presenting information and computer programs and software, *as such*, are excluded. The denial of patenting of elements isolated from nature, found also in the Brazilian text, is here indicated.

On the other hand, the supranational rules exclude from patenting the inventions even though new, non obvious and industrially useful [147] where prevention of the commercial exploitation within the territory of the respective Member Country is necessary to:a) protect public order or morality, or else, necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment, provided that such exclusions are not merely because the exploitation is prohibited or regulated by a legal or administrative provision; b) plants, animals, and plant or animal production

---

[145] http://www.comunidadandina.org/normativa/dec/D486.htm.

[146] Article 15.- "The following shall not be considered inventions: a) discoveries, scientific theories, and mathematical methods; b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing; c) literary and artistic works or any other aesthetic creation protected by copyright; d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities; e) computer programs and software, as such; and, f) methods for presenting information".

[147] Article 20.- "The following shall not be patentable: a) inventions, the prevention of the commercial exploitation within the territory of the respective Member Country of the commercial exploitation is necessary to protect public order or morality, provided that such exclusion is not merely because the exploitation is prohibited or regulated by a legal or administrative provision; b) inventions, when the prevention of the commercial exploitation within the respective Member Country of the commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment, provided that such exclusion is not made merely because the exploitation is prohibited or regulated by a legal or administrative provision; c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes; d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals".

essentially biological processes other than non-biological or microbiological processes; and c) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals [148].

Therefore, the last exclusion follows the TRIPs art. 27 standards, not the also common trend of deeming it not an invention.

On the other hand, the Decision declares that new applications of known solutions, in any field of technology, are excluded from patenting[149]; therefore, not only second medical uses but also any use is void. Case law from the Andean Court confirms this understanding [150].

In a very significant provision, the Decision conditions the issuance of patent (and provides for nullity in case of non compliance[151]) related to those technologies:

> The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or

[148] The Manual for the Examination of Patent Applications for Invention in the Industrial Property Office of the Countries of the Andean Community (Prepared jointly by the General Secretariat of the Andean Community (CAN), the European Patent Office (EPO) and the World Intellectual Property Organization (WIPO). Second Edition, year 2004, p. 49) states: "With regard to the treatment methods is important to note that they involve not only curing diseases or malfunction of the body , but also include prophylactic or preventative (e.g., immunization against diseases, removal of plaque from the teeth, etc.).. In this sense, we must consider carefully whether what you're trying or preventing, by the method claimed is or is not a disease."

[149] Article 21.- "Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent".

[150] Tribunal de Justicia de la Comunidad Andina en el Proceso 89-AI-2000, publicada en la Gaceta Oficial N. 722 del 12 de octubre de 2001: "No puede desprenderse del texto de este artículo la posibilidad de patentamiento de otra clase o naturaleza de creaciones distintas a las invenciones, como por ejemplo los usos o concretamente, los segundos usos".

[151] Artículo 75.- "La autoridad nacional competente decretará de oficio o a solicitud de cualquier persona y en cualquier momento, la nulidad absoluta de una patente, cuando: g) de ser el caso, no se hubiere presentado la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen; h) de ser el caso, no se hubiere presentado la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades indígenas afroamericanas o locales de los Países Miembros, cuando los productos o procesos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que cualquiera de los Países Miembros es país de origen".

> that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.
>
> The Member Countries recognize the right and the authority of indigenous, African American, and local communities in respect of their collective knowledge.

It is argued that this provision would have the intent of favoring the region's economic agents in face of foreign competition for mega diverse resources[152].

Country-by-country exclusions of patentability

Ecuador

Codificación 2006-013 [153] provides for the applicable domestic provisions under Andean rules and pertinent treaties. All inventions satisfying the novelty, technical and industrial utility shall be patentable (art. 121).

However, discoveries, scientific theories and principles; and substances that exist in nature (art. 125)[154] are not considered inventions.

Even though satisfying the general patentability requirements, patents are denied to inventions - the commercial exploitation of which must be prevented as necessary to protect morality. Specifically: processes for cloning human beings, the human body and its genetic identity; use of human embryos for industrial or commercial purposes; and

---

[152] MORALES, Diana Carolina Leguizamon, MIPLC, Patent Protection of Biotechnological Inventions in Colombia: Present Issues and Perspectives, found at http://www.miplc.de/research/master_theses/2005_2006/abstracts/abstract_dl.pdf: "However, a closer look to the Community law suggests that the intention of the law is not to exclude completely biological matter from patentability but rather that the exclusion is to be applied in a restrictive manner, probably only applying to biological or genetic material found or present "as such" in nature. The question arises whether the inclusion of these limitations or the adoption of these rigid schemes of interpretation are an effective measure to protect the natural resources of a nation, thus generating aggregate value, or if on the contrary, what is sought is simply to weaken the international and powerful competitor to allow the local competitor to participate in a business."

[153] http://www.wipo.int/clea/docs_new/pdf/es/ec/ec031es.pdf

[154] Art. 125.- "No se considerarán invenciones: a) Los descubrimientos, principios y teorías científicas y los métodos matemáticos; b) Las materias que ya existen en la naturaleza; c) Las obras literarias y artísticas o cualquier otra creación estética; d) Los planes, reglas y métodos para el ejercicio de actividades intelectuales, para juegos o para actividades económico-comerciales, así como los programas de ordenadores o el soporte lógico en tanto no formen parte de una invención susceptible de aplicación industrial; y, e) Las formas de presentar información."

procedures for modifying the genetic identity of animals when they cause suffering without obtaining any substantial medical benefit to humans or animals (art. 126) [155].

Patents are also denied on absolute grounds to inventions - the commercial exploitation of which must be prevented as necessary to protect public order – including: to protect the health or life of humans or animals or plant life or to prevent serious damage to the environment or ecosystem; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and plants and animal varieties and plant or animal production essentially biological processes.

Bolivia

The Industrial Property Law of December 12, 1916 stays in force as adjunct to the Andean rules and subject to them.

According to Art.3 of such law [156], patents are denied to inventions that are in public domain; the mere use of substances or newly discovered natural forces; scientific principles or discoveries that are purely speculative; and the invention or discovery whose exploitation would be contrary to law, public safety, or decency or morality.

Peru

After the revocation of the Decreto Legislativo 823 of 1996, the prior Intellectual Property Law, by the Legislative Decree Nº 1075, on June 28, 2008[157], the country is essentially ruled by the Andean rules, as modified by the 2008 legislation and further by

---

[155] Art. 126.- "Se excluye de la patentabilidad expresamente: a) Las invenciones cuya explotación comercial deba impedirse necesariamente para proteger el orden público o la moralidad, inclusive para proteger la salud o la vida de las personas o de los animales o para preservar los vegetales o para evitar daños graves al medio ambiente o ecosistema; b) Los métodos de diagnóstico, terapéuticos y quirúrgicos para el tratamiento de personas o animales; y, c) Las plantas y las razas animales, así como los procedimientos esencialmente biológicos para obtenciones de plantas o animales. Para efectos de lo establecido en el literal a), se consideran contrarias a la moral y, por lo tanto, no son patentables: a) Los procedimientos de clonación de seres humanos; b) El cuerpo humano y su identidad genética; c) La utilización de embriones humanos con fines industriales o comerciales; y, d) Los procedimientos para la modificación de la identidad genética de animales cuando les causen sufrimiento sin que se obtenga ningún beneficio médico sustancial para el ser humano o los animales."

[156] Artículo 3º.- "Son impatentables: 1. La invención o descubrimiento que por ejecución o publicidad dentro o fuera de La república haya caído en dominio público. 2. El simple uso o aprovechamiento de sustancias o fuerzas naturales recién descubiertas. 3. El principio o descubrimiento científico que sea puramente especulativo. 4. Los planes o combinaciones de crédito o de hacienda. 5. La invención o descubrimiento cuya explotación sea contraria a la ley, a la seguridad pública, o a las buenas costumbres o a la moral. 6. Los productos químicos o composiciones farmacéuticas o terapéuticas, sin perjuicio de poder patentarse de nuevos procedimientos para poder producirlos, o sus nuevas aplicaciones industriales."

[157] At http://www.indecopi.gob.pe/repositorioaps/0/10/par/leg_nornacio/decretolegislativo1075-c.pdf.

Law 29316 of January 14, 2009 [158], edited as a result of the Free Trade Agreement with the United States [159].

The new legal environment provides for a clear enunciation that all fields of technology must be patentable, even though not diverging from the Andean text [160].

Colombia

Colombia applies the Andean rules.

Exceptions to patentability

The Andean Community IP Directive states that:

> Article 14.- The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable[161]

Exception - Limitations applicable exclusively to biological matter

Andean rules (applicable to Bolivia, Ecuador, Colombia and - subject to US FTA provisions - Peru):

> Decision 486 Article 53.- A patent owner may not exercise the right referred to in the previous article with respect to the following acts: (...)
>
> e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

Exception - Exhaustion of self-replicating material

> Decision 486 - Article 54.- [Exhaustion] (…) Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or

---

[158] Found at http://www.indecopi.gob.pe/repositorioaps/0/10/par/leg_nornacio/Ley29316.pdf.

[159] „Ley que modifica, incorpora y regula diversas disposiciones a fin implementar el Acuerdo de Promoción Comercial suscrito entre el Perú y los Estados Unidos de América. Publicada en el diario oficial El Peruano el 14 de enero de 2009. “

[160] Art.25A Patentabilidad. “Sera patentable toda invención, ya sea de producto o de procedimiento, en todos los campos de la tecnología, siempre que sea nueva, tenga nivel inventivo y sea susceptible de aplicación industrial.”

[161] The post-FTA Peruvian law excludes any living being existent in nature, as a whole or in part, thus suppressing the denial of patenting of elements isolated from nature.

propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes.

South America - not in regional groups

Venezuela

Venezuela withdrew from the Andean block in 2006, having been from 1973 until revocation. Now, subject to the 1955 law on Industrial Property, Venezuelan patents are issued for inventions, improvements and the introduction of foreign patents not yet in public domain (art.5). Art. 14 lists the allowable inventions. On the other hand, Art. 15 has a series of exclusions to patentability, including both areas that more recent South American laws deem to be not inventions and those that are now classified as public policy exclusions.

Therefore, chemical, pharmaceutical, food and drink products and chemical preparations, reactions and combinations are excluded. New applications of known products, industrial secrets, and the standard non-invention cases are also excluded.

The retroaction to the pre-Andean law seems to be part of a Venezuelan policy to effectively exclude patenting particularly in the pharmaceutical and biotechnology areas, as reconsideration of patents issued under Andean law to the razor of the 1955 statute is considered[162].

Chile

The Chilean IP statute was amended in 2006 [163] in order to assimilate new International obligations. Patents are obtainable for all inventions that are new, non-obvious and susceptible of industrial application (art.32).

Are deemed as non inventions: discoveries or other abstract knowledge [164]; plants and animals (but microorganisms may be patentable whenever fulfill the general patent requirements) and essentially biological processes for the production of plants and

[162] See http://iptango.blogspot.com/2009/12/venezuela-to-examine-all-pharmaceutical.html.

[163] Ley Nº 19.039, as resulting from amendments from a Codifying Decree published in March 9, 2006.

[164] Artículo 37.- "No se considera invención y quedarán excluidos la protección por patente de esta ley: a) Los descubrimientos, las teorías científicas y los métodos matemáticos (...)"

animals (but microbiological processes are patentable) [165]; surgical, diagnostic or therapeutic methods and for human or animal body (but products intended to implement those methods are patentable) [166].

Are likewise not considered inventions the new applications or formal changes introduced in known products[167]; but there is an invention whenever the new application of a known product solves a technical problem not hitherto solved on an equivalent manner, and furthermore is required to effect formal changes or changes in material of the known product to solve such technical problem. To obtain this new application patent it necessary to evidence in the patent filing the experimental data proving the new application.

Also excluded from the notion of invention are the parts of living beings as found in nature, natural biological processes and biological material found in nature even though isolated therefrom, including genome or germplasm[168]. However, processes utilizing such natural materials as well as the resulting products, provided that the general

---

[165] Artículo 37.- "No se considera invención y quedarán excluidos la protección por patente de esta ley: (...) b) Las plantas y los animales, excepto los microorganismos que cumplan las condiciones generales de patentabilidad. Las variedades vegetales solo gozarán de protección de acuerdo con lo dispuesto por la ley Nº 19.342, sobre Derechos de Obtentores de Nuevas Variedades Vegetales. Tampoco son patentables los procedimientos esencialmente biológicos para la producción de plantas y animales, excepto los procedimientos microbiológicos. Para estos efectos, un procedimiento esencialmente biológico es ll que consiste íntegramente en fenómenos naturales, como los de cruce y selección."

[166] Artículo 37.- "No se considera invención y quedarán excluidos la protección por patente de esta ley: (...) d) Los métodos de tratamiento quirúrgico o terapéutico del cuerpo humano o animal, así como los métodos de diagnóstico aplicados al cuerpo humano o animal, salvo los productos destinados a poner en práctica uno de estos métodos."

[167] Artículo 37.- "No se considera invención y quedarán excluidos la protección por patente de esta ley: (...) e) El nuevo uso, el cambio de forma, el cambio de dimensiones, el cambio de proporciones o el cambio de materiales de artículos, objetos o elementos conocidos y empleados con determinados fines. Sin perjuicio de lo anterior, podrá constituir invención susceptibles de protección el nuevo uso de artículos, objetos o elementos conocidos, siempre que dicho nuevo uso resuelva un problema técnico sin solución previa equivalente, cumpla con los requisitos a que se refiere El artículo 32 y requiera de un cambio en las dimensiones, en las proporciones o en los materiales del artículo, objeto o elemento conocido para obtener la citada solución a dicho problema técnico. El nuevo uso reivindicado deberá acreditarse mediante evidencia experimental en La solicitud de patente."

[168] Artículo 37.- "No se considera invención y quedarán excluidos la protección por patente de esta ley: (...) f) Parte de los seres vivos tal como se encuentran en la naturaleza, los procesos biológicos naturales, el material biológico existente en la naturaleza o aquel que pueda ser aislado, inclusive genoma o germoplasma. Sin embargo, serán susceptibles de protección los procedimientos que utilicen uno o más de los materiales biológicos antes enunciados y los productos directamente obtenidos por ellos, siempre que satisfagan los requisitos establecidos en El artículo 32 de la presente ley, que el material biológico esté adecuadamente descrito y que La aplicación industrial del mismo figure explícitamente en La solicitud de patente."

patentability requirements are satisfied, there is sufficient description of the biological material and the industrial application is explicit in the patent filing.

On the other hand, inventions even satisfying the general patentability requirements are not patentable where the commercial exploitation must be prevented either: to protect public order, national security, morals and good customs, health or life of humans or animals; or to preserve plants or the environment. Such exclusion must not only be because there is a legal or administrative provision that prohibits or regulates such exploitation[169].

Suriname

Suriname applies the Patent Act in force in Holland.

Effects of Bilateral Treaties

As mentioned previously, when discussing Free Trade Agreements, Peru and Chile FTAs have specific provisions covering biotechnology.

\ Europe[170]

We concentrate our analysis on the European system, including the Biotechnological Directive 44/98 and the European Patent Convention. Whenever relevant, some remarks on the national systems are offered, especially the UK 1977 Patents Act, as amended.

The Biotechnology Directive was formally adopted by the Council and the European Parliament on 6 July 1998. The Biotechnology Directive deals with the patentability and scope of protection conferred on biotechnological inventions. As well as introducing special defenses, the Directive also establishes a scheme for compulsory licences and cross licences to deal with the overlap between patent and plant variety protection. In addition, it also provides for the deposit of biological material.

---

[169] Artículo 38.- "No son patentables las invenciones cuya explotación comercial deba impedirse necesariamente para proteger El orden público, la seguridad del Estado, la moral y las buenas costumbres, la salud o la vida de las personas o de los animales, o para preservar los vegetales o el medio ambiente, siempre que esa exclusión no se haga sólo por existir una disposición legal o administrativa que prohíba o que regule dicha explotación."

[170] Considerable portion of the *wording* of this section was provided by Brad Sherman's analysis of European law under this same study. The authors are, however, responsible for the use of the text and its restructuring.

Exclusions from patent rights

European Patent Convention (EPC) states that for an invention to be patentable it must be capable of *industrial application*; patents shall be granted for *any* invention in *all* fields of technology.

There is no general bar on the patenting of biological material or biotechnological inventions. Indeed, as the EPC 2000 and the UK 1977 Act (as revised) are clear, an invention shall not be considered unpatentable solely on the ground that it concerns a product consisting of or containing biological material or a process which by which biological material is produced. More specifically, the EPC 2000 and the 1977 Act explicitly state that it is possible to patent inventions for plants and animals, as long as they comply with the general requirements of patentability.

Abstract creations

This is especially important in biological research: unless there is a useful purpose for newly discovered genes or any other biotechnological invention, patent is deniable by either lack of invention or (as the case may be) lack of industrial application. In connection with biotechnological inventions, both the EU Biotechnology Directive and the UK Patent act specify that the industrial application of a sequenced or a partial sequence of a gene must be disclosed in the application. It is not actually a disclosure requirement, but an invention or industrial applicability one.

For some time it has been indicated as a problem that while a patentee *only has to disclose one specific use* of a gene to show industrial applicability, once this threshold is satisfied they are given control over *all* uses of the patented gene: even those uses which they had not discovered or even imagined. This has led some authors to argue that protection should be *limited to what is actually disclosed in the application*. Despite its importance, this issue was only solved in the July 6, 2010 decision of the case Monsanto Technology LLC v Cefetra BV and Others[171], having the court stated that the text of the

[171] "The Advocate General of the Court of Justice (the renamed European Court of Justice) has published the first-ever opinion on the extent of protection that European patents should give to biotech patents. This controversial opinion proposes that the full Court should give a narrow interpretation to the Biotechnology Directive, which was implemented to harmonize EU laws on the patentability of biotech inventions. Although now implemented in all Member States, there are major differences in how the Directive has been implemented. This is the first time the Court of Justice has been able to consider the scope of the protection of biotech inventions, particularly DNA sequence patents, in the ten years the Directive has been in force. This opinion is therefore significant for a number of reasons: the Advocate

Directive prevent the national laws from assuring to patentee any rights on such technologies beyond the purposes disclosed in the request.

Methods of medical and veterinary treatment

EU law, as most other laws within the scope of this study, excludes from patent *methods* of medical and veterinary treatment. As such, it *does not prevent the patenting of surgical, therapeutic, or diagnostic substances and compositions* (such as drugs), or apparatuses or products (such as ECG machines, prosthetic ball and socket joints, or pacemakers).

Following European practice, to determine whether or not an invention is excluded from patentability one must determine whether the invention falls within the definition of surgery, therapy or diagnosis.

Surgery has been defined as the branch of medicine concerned with the healing of disease, accidental injury or bodily defects by operating on the living body.There are two analytical paths in this context: the first approach focuses on the *nature* of the physical intervention; the second approach focuses on the *purpose* of the intervention.

Therapy has been interpreted broadly as the curing of a disease or malfunctions of the human or animal body and includes *prophylactic* treatments with a view to maintaining health by preventing ill effects that would otherwise arise.

Methods of diagnosis typically consist of four subsidiary steps. These are:

(1) *Examination*: involving the collection of data (recording the case history);

(2) *Comparison*: of the data with normal values;

(3) *Identification:* of any significant deviation from the norm (i.e. symptom); and

(4) *Diagnosis*: the deductive medical or veterinary decision.

General recommended that traditional patent protection should not be applied to DNA sequence patents. The protection given by such DNA patents should instead be 'purpose-bound". Nabarro, UK: Biotech patents – Cutting the scope of protection, found at http://www.mondaq.com/article.asp?article_id=105008, visited on 08/14/10. In its decisions of the case (Monsanto Technology LLC v Cefetra BV and Others, C-428/08), the court accepted the Advocate General advice, stating that "2. Article 9 of the Directive effects an exhaustive harmonization of the protection it confers, *with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.*", see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62008J0428:EN:NOT, visited on 08/14/10

The exclusion of methods of medical or veterinary treatment *only applies to methods of treatment that are practiced on or in the human or animal body*. The ambit of this provision has been interpreted broadly to include 'any interaction with the human or animal body, necessitating the presence of the later'. The four steps mentioned above can either be invasive processes (which require physical contact with the body), or non-invasive ones that are practiced at 'a certain distance to it'. The key factor is that the step *requires interaction with the body*. This means that exclusion does not apply to methods practiced on substances that are removed from the body.

One example would be: the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is *not* excluded. In contrast, a treatment of blood by dialysis, where the blood returns to the same body, *would* be excluded.

Naturally occurring material

Patent law traditionally distinguishes between naturally occurring substances (unpatentable discoveries) and the products and processes which result from the human effort in isolating those substances from their natural environment (patentable inventions).

Therefore, under the European law and practice a patent shall not be granted for 'any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or other technical process or the product of such a process'. On the other hand, if an invention is 'a microbiological process or other technical process ***or*** the product of such a process', the invention may be patented.

According to the rule that excepts from patent naturally occurring material, the finding of a substance freely occurring in nature is a mere discovery and, as such, is unpatentable[172]. On the other hand, if a developed *process* enables a substance found in nature to be isolated and obtained from its surroundings, the *process* may be patentable.

---

[172] `To find a substance freely occurring in nature is mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining is developed, that process is patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is `new' in the absolute sense of having no previously recognized existence, then the substance per se may be patentable. An example of such a case is that of a new substance which is discovered as being produced by a microorganism.' (EPO Guidelines.)

If a natural substance that has been *isolated* from its surroundings can be properly characterized either by its structure, by the processes by which it is obtained, or by other parameters, the substance *per se* may be patentable[173].

Subject matter exclusions: plant and animal varieties

European law and practice excludes from patenting *'animal varieties'*[174] and '*plant varieties'*. It is to be noticed that plants and animals by themselves are not excluded (see the discussion of the onco-mouse case below), but only *varieties*.

Subject matter exclusions: essentially biological processes

Also excluded from protection are those inventions, regarded as 'essentially biological processes for the production of animals and plants'. Defining "essentially biological processes" we can state about the exclusion that it: (a) only applies to processes, having no application to a product claim or a product-by-process claim; (b) only applies where the process is for the 'production of animals or plants';(c) as such, may not apply if the process results in the death or destruction of animals or plants; and (d) only applies where the process is 'essentially biological'.

According to the Biotechnology Directive, a process for the production of plants and animals is said to be essentially biological if 'it consists entirely of natural phenomena such as crossing or selection'.

The question of the degree of technical intervention needed for a process to fall outside the scope of the exclusion was also considered in the *Novartis* decisions. The Board added that there were three possible approaches when answering this question.

> (1) Under the first approach, an invention would be excluded if it included an aspect or step that was biological. To fall outside the exclusion, the claimed processes would have to be exclusively made up of non-biological process steps.
> (2) The second approach, which was taken from *Lubrizol*, requires the tribunal to weigh up the overall degree of human intervention in the process. Under this approach, the decision as to whether an invention was essentially biological would be judged on the basis of

[173] This is verified in the Relaxin decision, which concerned claims relating to DNA sequences of a naturally occurring substance that relaxes the uterus during childbirth, which was obtained from the human ovary. The Opposition Division of the EPO held that the invention was not a discovery and, as such, was not excluded from patentability. Relaxin Decision - Opposition Division, OJ EPO 1995, 308.

[174] For example, in the UK, paragraph 3(f) of Schedule A2 to the 1977 Patent Act/Article 53(b). For other domestic laws, see below.

> the essence of the invention, taking into account the totality of human invention and its impact on the result received.
> (3) The third option, which was the most liberal, provides that the mere presence of a single artificial (or technical) element in the process might be enough to prevent its being classified as an essentially biological process.

Therefore, processes where there is no human intervention—are essentially biological. One question that remains is whether processes that only have a trivial or minimal amount of human intervention are classified as essentially biological processes. While trivial interventions may mean that a process is not 'purely' biological, it does not mean that it is not essentially biological. Such a process may, therefore, still be excluded[175].

Biological processes: Remarks on the legislative history of article 53(B) of EPC

As part of its deliberations, the technical board of appeal provided a general history of article 53(b) noting that the drafters regarded 'biological' as opposing 'technical' and that they had deliberately chosen the adverb 'essentially' to replace the narrower term 'purely'. The board also noted that the legislators intended for the exclusion to apply to processes such as the selection or hybridization of existing varieties. This was the case even if, as 'a secondary feature, "technical" devices were involved (use of a particular type of instrument in a grafting process, or a special greenhouse in growing a plant).

EPC 1973 Rule 23(b) (5) says that processes will only be considered essentially biological where they consist entirely of biological processes for the production of plants. At the same time, the rule also says that crossing and selection, which clearly involve human (technical) intervention, are examples of natural phenomena.

- This seems to be contradictory to the extent that 'the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man'.
- The Board then went on to say that Rule 23(b) (5) [EPC 2000 Rule 26(5)] suggests that Article 53(b) should be read narrowly. In particular, the Board said that Rule 23(b) (5) meant that a process which contains an additional feature of a technical nature would be outside the ambit of the process exclusion.

[175] Compare that with the case decided by Argentinean Federal Appeal Court, dated May 15, 2003, mentioned above, where just the human intervention is held to justify the non-biological nature of the process.

- This would not be the case, however, in relation to 'natural phenomena' (which covered crossing and selection by way of a legal fiction).The Board of Appeal noted that on this reading of the exclusion, the use of molecular markers as part of a breeding process (which required the removal and in vitro analysis of plant tissues) would lead to the conclusion that the invention would fall outside the ambit of the exclusion.

- The Board also noted that this narrow reading of Article 53(b) would be contrary to the earlier decisions of T320/87 and T 356/93. Faced with the uncertainty about the scope of Article 53(b), the Technical Board of Appeal in *Plant Bioscience/Broccoli* decided to refer the matter to the Enlarged Board for deliberation. In particular, the Technical Board of Appeal asked the Enlarged Board of Appeal to consider the question:

  - 'Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?'. The Technical Board of Appeal also asked the Enlarged Board to identify the criteria that should be used to determine whether an invention fell within Article 53(b).The outcome of this decision will hopefully provide important guidance on these vexed issues.

  - microbiological processes refer to processes in which microorganisms or their parts are used to make or to modify products.[176]

  - A process [is] not a microbiological process simply because a microbiological step was involved. Instead the process ha[s] to be judged as a whole.

Exclusions from patent rights due to ordre public/moral requirements

The Biotechnology Directive became a focal point for public concerns about the ethical and social dimensions of biotechnology generally, as well as specific concerns about the patenting of the products of such activities.

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

  (a) Processes for cloning human beings;

  (b) Processes for modifying the germ line genetic identity of human beings;

[176]Microbiological processes do not fall within the exclusion.

(c) Uses of human embryos for industrial or commercial purposes;

(d) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes'.

Furthermore, there are a number of specific types of biological inventions that are deemed to be immoral or contrary to "ordre public" according to the EPC [177]: 'processes for cloning human beings'[178]; processes for modifying the germ line genetic identity of human beings (Article 52(a)/section 1(3)); uses of human embryos for industrial or commercial purpose(Article 52(a)/section 1(3)); and 'processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes'.

The Onco-mouse case and its meaning

Settled by the EPO (*T19/90)* decision, the case concerned the patentability of genetically modified mice to develop cancer: a result that the applicants hoped would be useful in cancer research. Initially, the Examining Division declined to consider Article 53(a), taking the view that it was inappropriate for people who were essentially qualified as technicians to consider such issue. On appeal, the Technical Board of Appeal took a very different view. It observed that the genetic manipulation of mammalian animals is 'undeniably problematical in various respects', particularly in circumstances where the modifications 'necessarily cause suffering'. Moreover, the release of the mice into the environment might 'entail unforeseeable and irreversible adverse effects'. Consequently, it was necessary to consider the application of Article 53(a).

The Technical Board of Appeal, remitting the case to the Examining Division for reconsideration, explained that the application of Article 53(a) 'would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand and the invention's usefulness to mankind on the other'.

---

[177] These are to be found in EPC 2000 Rule 28 [formerly EPC 1973 Rule 23d]. They are also covered by paragraph 3, Schedule A2 of the 1977 UK Patents Act. Article 53(a) EPC 2000 provides that European patents 'shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality …'.

[178] EPC 2000 Rule 28(a) [EPC 1973 Rule 23d(a)]/Schedule A2, par. 3(b) 1977 Act.

Applying this ***utilitarian balancing test***, the Examining Division held that the subject matter was patentable. It reasoned that finding a cure for cancer was a highly desirable end, and that the mouse would assist in achieving that end. In contrast, the Examining Division played down the harm caused by the invention. The Examining Division suggested that given that the research would take place anyway, and that it would require vast numbers of mice to locate some which had 'naturally' developed cancer, the invention produced a benefit to mouse-kind in that large numbers of healthy mice would no longer need to be bred and then destroyed.

Exceptions from patentee's rights

Exhaustion of biological patents

According to the Directive (and the domestic laws following it), the protection conferred by a patent shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the owner of the patent (or with his consent), where the multiplication or propagation necessarily results from the application for which the biological material was marketed.

Farmer's Privilege:

In debates surrounding the Biotechnology Directive, one of the fears raised was that patent protection over biological inventions would have a negative impact on traditional farming practices. In particular, it was feared that *patent protection would mean that farmers would not be able to use the seeds that they harvested from their crops to resow crops, nor would they be able to breed patented animals.*

Section 60(5) (g) provides a defense regarding the farmer use of a harvest product for propagation or multiplication on the farm, where there has been a sale or other form of commercialization of plant-propagating material to the farmer by the patent owner for agricultural use. *In effect, the defense enables farmers to save seeds from one year's crop to sow crops in the following year.*

Section 60(5) (h) provides farmers with a defense in relation to the breeding of animals. More specifically, it provides that 'the use of an animal or animal reproductive material by a farmer for an agricultural purpose ... of breeding stock or other animal reproductive material which constitutes or contains the patented invention' is non-infringing.

Switzerland

Switzerland has a unique exception related to the biological material obtained in the field of agriculture by chance or by means of an inevitable technical step. Besides that, the law excludes new varieties of plants or animal breeds, or for essentially plant producing or animals breeding biological processes; inventions whose implementation would be contrary to public order or morality; and methods of surgical or therapeutic treatment and of diagnosis applied to the human body or to the bodies of animals. [179]

Limitations in national laws of European countries related to Biotechnology

The same limitation of exhaustion of biotechnological products found in Brazilian law is also included in Denmark, Estonian, Finish and Sweden statutes.

Farmer's exception exists in Denmark, Finland, France, Sweden, Switzerland and United Kingdom. Use of biological material for breeding new varieties is found at the national laws of Germany and Switzerland. Switzerland also has a very peculiarly worded research exception[180].

In compliance or in harmony with the EU Biotechnology Directive, Belgium has created compulsory cross licensing of certain biotechnological inventions [181], covering patents and PVPs[182]. The same happens with:

---

[179] "Art. 1a Patents shall not be granted for new varieties of plants or animal breeds, or for essentially biological processes for producing plants or breeding animals; microbiological processes and products obtained by such processes shall be patentable, however. **Art. 2** The following shall not be patentable: (a) inventions the implementation of which would be contrary to public order or morality; (b) methods of surgical or therapeutic treatment and of diagnosis applied to the human body or to the bodies of animals." Available at http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/switzerland/pl/chap1.htm#secB. Access on 08/12/2010.

[180] "Switzerland(2008 Patents Act): Exception includes experiments «on» patented substance even with commercial objective, provided main objective is generation of new knowledge; Exception does not include experiments « with » patented substance (=research tool), but provides mandatory license against compensation; some countries allow for the patentability of research tools (utility of relaxed industrial criteria application)" In Vivas□Eugui, David, TRIPS Post□Grant Flexibilities: Key Exceptions to Patent Rights, www.ictsd.net. The text is: *Art. 40b*Quiconque entendutiliserune invention biotechnologiquebrevetéecomme instrument oucommeaccessoire de recherche a droit à unelicencenon exclusive.

[181] " Belgium modified its patent law in 2005, creating a new compulsory cross-license for biotechnology inventions, and also a new compulsory license for public health purposes", LOVE, James Packard, Recent examples..., op. cit.

[182]"Article 31 § 1er. Le Ministre peut octroyer, conformément aux articles 32 à 34, une licence d'exploitation d'une invention couverte par un brevet : (...) 3. Lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété représente un progrès technique important d'un intérêt économique considérable par rapport à l'invention

- Bulgaria [183],

-Latvia [184],

-Lithuania [185],

-Malta [186],

---

revendiquée dans le brevet et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national; 4. Au titulaire d'un droit d'obtention végétale, lorsque le titulaire d'un brevet concernant une invention biotechnologique a, conformément aux dispositions de la loi sur la protection des obtentions végétales, obtenu une licence obligatoire pour l'exploitation non-exclusive de la variété végétale protégée par ce droit d'obtention végétale parce qu'il ne peut exploiter l'invention biotechnologique sans porter atteinte à ce droit d'obtention végétale antérieur et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national.]"

[183] Compulsory Cross-License Article 32a "(1) Where a breeder cannot obtain or use the right in a plant variety without infringing an earlier patent, he may apply for a compulsory license for non-exclusive use of the invention enjoying patent protection, in so far as the license is required for using the plant variety for the purposes of its legal protection, subject to the payment of a respective remuneration. Where such a license is granted, the patent owner shall be entitled to a cross-license for using the protected plant variety under fair conditions. (2) Where the owner of a patent for a biotechnological invention cannot use it without infringing an earlier plant variety right, he may apply for a compulsory license for non-exclusive use of the protected plant variety, subject to the payment of a respective remuneration. Where such a license is granted, the protected variety owner shall be entitled to get a cross-license for using the invention under fair conditions. (3) The person applying for the grant of a compulsory license according to paragraphs (1) and (2) shall prove that: 1. he has tried unsuccessfully to get a contractual license from the patent or plant variety owner; 2. the plant variety or the invention represents significant technical progress of great economic importance compared to the patented invention or the protected plant variety."

[184] LATVIA (EU) : Section 54 of the Patent Law of 15/02/2007, Section 54. Compulsory Licence. "(2) If the proprietor of the patent of a biotechnological invention is not able to use it without violating the prior rights to the plant variety, he or she may apply for a compulsory licence for the use of such plant variety, which is protected by the referred to rights, and pay a compensation to the proprietor, determined by the court. In the case of a grant of such licence, the proprietor of the plant variety is entitled to qualify for a cross-licence with substantiated requirements for the use of the protected invention."

[185] LITHUANIA (EU) : Articles 38-39 of the Patent Law No. I-372 of 18/01/1994 as last amended by Law No. X-1119 of 10/05/2007, Article 38. "Compulsory Cross-licensing when an Invention is Related to the Protected Plant Variety, Where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent owner will be entitled to a cross-licence on reasonable terms to use the protected variety. Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention."

[186] MALTA (EU): Articles 39-40 of the Patents and Designs Act, Chapter 417, of 01/06/2002, as amended by Acts IX of 2003 and XVIII of 2005. (9) "Where a breeder cannot acquire plant variety protection or exploit a plant variety without infringing a prior patent, he may apply to the Civil Court, First Hall, for a compulsory licence for non-exclusive use of the invention protected by the patent in so far as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety: Provided that an applicant for a licence referred to in above shall demonstrate that: (a) he had applied unsuccessfully to the holder of the prior patent to obtain a contractual licence; (b) the plant variety constitutes significant technical progress of

-Romania [187],

-Russian Federation [188],

-Slovakia [189],

-Sweden [190],

---

considerable economic interest compared with the invention claimed in the prior patent. (10) Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention: Provided that an applicant for a licence referred to in above shall demonstrate that:(a) he had applied unsuccessfully to the holder of the prior plant variety right to obtain a contractual licence;(b) the invention constitutes significant technical progress of considerable economic interest compared with the plant variety protected by the prior plant variety right.(11)With regard to plant variety protection sub articles (9) and (10) shall only come into force when the relevant form of plant variety protection comes into force as provided in article 4(5)(e).'

[187] ROMANIA (EU): Articles 46-47 of the Patent Law no. 64 of 1991 as republished in the Official Gazette of Romania, Part I, No. 456/18.VI.2008. "When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent. When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory license for the exploitation of the plant variety protected by said patent."

[188] Compulsory Licence Granted to Plant Breeders Article 68 "Where a plant breeder cannot obtain or exploit a plant variety right without infringing a prior patent concerning a biotechnological invention, he may file an application with the competent authority for a non-exclusive compulsory licence for the use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the protected plant variety, subject to payment of an appropriate royalty. If such a licence is granted, the owner of the patent shall be entitled to a compulsory cross-licence to use the protected plant variety on reasonable terms. Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may file an application with the competent authority for a non-exclusive compulsory licence for the use of the plant variety protected by that right, subject to payment of an appropriate royalty. If such a licence is granted, the holder of the variety right will be entitled to a compulsory cross-licence to use the protected biotechnological invention on reasonable terms. The compulsory license referred to in paragraphs 1 and 2 of this Article cannot be exclusive. An applicant for the compulsory licence referred to in paragraphs 1 and 2 of this Article must prove that: 1) he has unsuccessfully made efforts to obtain a contractual licence; 2) the plant variety or the biotechnological invention constitutes significant technical advance of considerable economic interest compared with the invention claimed in the patent or the protected plant variety."

[189] SLOVAKIA (EU) : Article 27 of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended by Act No. 402/2002 Coll., Act No. 84/2007 Coll. and Act No. 517/2007 Coll.(5) "Notwithstanding presuppositions pursuant to paragraph 1 and conditions pursuant to paragraph 2, a court shall be entitled to grant a compulsory non-exclusive licence for utilization of a biotechnological invention on request, if a cultivator shall not be able to exploit or acquire right to a plant variety without infringing earlier right to a patent, if the plaintiff proves that a) before filing a request he has offered to a patent owner a proper conclusion of a licence agreement, whilst this offer was not been accepted by a patent owner within three months from its filing , and b) plant variety represents an important technical progress of a considerable economic importance comparable with an invention which is a subject-matter of a request for granting a compulsory licence. (6) In case of granting a compulsory licence pursuant to paragraph 5, a patent owner shall have right for granting a cross compulsory licence for utilization of a plant variety pursuant to a special regulation.(7) If a patent owner has granted a compulsory licence for utilization of a plant variety pursuant to a special regulation, 13b) an owner of a cultivator certificate shall have right for granting a cross compulsory licence for utilization of a biotechnological invention."

- UK [191];

And, in general, all countries subject to the Directive.

\ African and Arab Countries

Exclusions from patentability

Algeria

The national law excludes: principles, theories and scientific discoveries; methods of treating human or animal body by surgery or therapy and diagnostic methods; plant or animal varieties and plant or animal production essentially biological processes; inventions whose implementation on the Algerian territory, would contrary public order or morality; and inventions whose exploitation in Algeria would undermine human, animal or plant health and lives or would seriously undermine environment protection[192].

---

[190] SWEDEN (EU) : Sections 44-49 of the Patents Act No. 837 of 01/12/1967 as last amended by Law No. 159 of 01/04/2004. 46a. “A plant breeder who cannot obtain or exploit a plant breeders' right without infringing a prior patent, may obtain a compulsory license to exploit the invention which is protected by the patent, inasmuch as such a license is necessary for the plant variety to be exploited. Such a license may be granted only if the applicant proves that the plant variety constitutes a significant technical progress of considerable economic interest compared with the invention. If a holder of a patent obtains a compulsory license in a plant breeders' right, the holder of the plant breeders' right is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the invention of the holder of the patent. Provisions on the possibility for the holder of a patent on a biotechnical invention to obtain, under certain conditions, a compulsory license to exploit a protected plant variety are contained in Chapter 7, Article 3a, of the Act on the Protection of Plant Breeders' Rights (1997:306).”

[191] "Following the passage of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, the United Kingdom amended its patent law to provide for mandatory compulsory cross-licenses of certain biotechnology inventions used for agriculture. The license is available to plant breeders who demonstrate a technical advance. The December 6, 2006 UK Gowers Review noted the British Society of Plant Breeders complained the provision is “ineffective in the UK at least”, because to prove an advance the product must actually be created, thereby infringing the patent, in calling for an expanded research exception, to permit broader use of the compulsory license", LOVE, James Packard, Recent examples of the use of compulsory licenses on patents, KEI Research Note 2007:2, Knowledge Ecology International 8 March 2007, revised 6 May 2007A.

[192]Ordonnance n° 03-07 du 19 Joumada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention.Article 7: - „Au sens de la présente ordonnance, ne sont pas considérés comme inventions : 1°) les principes, théories et découvertes d'ordre scientifique ainsi que les méthodes mathématiques ; 4°) les méthodes de traitement du corps humain ou animal par la chirurgie ou la thérapie ainsi que les méthodes de diagnostic ; Article 8: - En vertu de la présente ordonnance, les brevets d'invention ne peuvent pas être obtenus pour : 1) les variétés végétales ou les races animales, ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux ; 2) les inventions dont la mise en oeuvre sur le territoire algérien, serait contraire à l'ordre public ou aux bonnes moeurs ; 3) les inventions dont l'exploitation sur le territoire algérien nuirait à la santé et à la vie des personnes et des animaux ou à la préservation des végétaux ou porterait gravement atteinte à la protection de l'environnement.“

Bahrain

The national law excludes: any invention that inhibits the protection of public order or morality Principles (including the protection of human life or health or that of animals or plants or to avert causing serious harm to the environment, animals); and diagnostic, therapeutic, and surgical methods necessary for the treatment of humans and animals. Such exclusion is not applicable to products used in any of these methods. See the FTA section on the effects of such bilateral treaty.

Egypt

The national law excludes: inventions whose exploitation is likely to be prejudicial to the environment or human, animal and plant life or health; discoveries, scientific theories, mathematical methods, programs and schemes; diagnostic, therapeutic and surgical methods for humans and animals or plants and animals, regardless of their rarity or peculiarity; plant or animal production essentially biological processes, other than microorganisms, non-biological and microbiological processes for the production of plants or animals; as well as organs, tissues, live cells, natural biological substances, nuclear acid and genome.

Ethiopia

The law contains exclusions: to plant or animal varieties or plant or animal production essentially biological processes; discoveries, scientific theories and mathematical methods; methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body. The exclusion is not applicable to products for use in any of the methods of treatment of the human or animal body by surgery or therapy, or diagnostic methods practiced on the human or animal body.

Ghana

The law excludes: discoveries, scientific and mathematical theories; plant or animal varieties or plant or animal production essentially biological processes, other than microbiological processes and the products of such processes; surgery or therapy methods for humans or animals, as well as diagnostic methods, but not products for any of these methods.

Jordan

The law excludes: inventions threatening the life and health of humans, animals and plants, or severe damage to the environment; discoveries, scientific theories and mathematical methods; diagnostic, therapeutic and surgical methods necessary for the treatment of humans or animals; plants and animals other than microorganisms; as well as biological methods for the reproduction of plants and animals (other than non-biological and microbiological methods).

Kenya

The law excludes: discoveries, scientific theories and mathematical methods; methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced in relation thereto (not applicable to products used in any such methods); public health related methods for use or uses of any molecule or other substance whatsoever applicable in the prevention or treatment of any serious health hazard or as a life threatening disease (as designated by the Minister responsible for matters of health); plant varieties, as provided for in the Seeds and Plant Varieties Act, but not parts thereof, or products of biotechnological processes; and inventions contrary to principles of humanity and environmental conservation.

Lebanon

The law excludes scientific discoveries and theories and absolute mathematical methods that are not industrially applicable and methods of medical diagnosis or treatment related to humans or animals, but not products or utilities for use in such methods.

Morocco

The law excludes: inventions whose publication or exploitation would be contrary to public order or morality; plant varieties which are subject to the provisions of Law # 9/94 on Protection of New Plant Varieties; methods for surgical or therapeutic treatment of the human or animal body; and diagnostic methods practiced on human beings or animals. This provision does not apply to products, in particular substances or compositions, for the implementation of these methods. [193]

[193]Article 24 « Ne sont pas brevetables : a) les inventions dont la publication ou la mise en oeuvre serait contraire à l'ordre public ou aux bonnes moeurs; b) les obtentions végétales qui sont soumises aux dispositions de la loi N° 9 / 94 sur la protection des obtentions végétales. Article 25 Ne sont pas considérées comme des inventions susceptibles d'application industrielle au sens de l'article 22 cidessus,

Mozambique

The law excludes: scientific theories and mathematical methods, including discoveries aimed to make public or revealing something which already exists in nature, notwithstanding the heretofore unknown to man; methods of surgical, therapeutic or diagnostic treatment, applicable to the human body or animals (although the products, substances or compositions used in any of such methods shall be patentable); and all or part of living beings (although microbiological processes and products obtained from such processes are patentable).

Nigeria

The law excludes plant or animal varieties, or plant or animal production essentially biological processes (other than microbiological processes and their products) and scientific Principles and discoveries.

OAPI

The countries within the OAPI purview will not patent inventions: whose exploitation is contrary to public policy or morality (provided that the exploitation of the invention shall not be considered contrary to public policy or morality merely because it is prohibited by law or regulation);discoveries and scientific theories; inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals (other than microbiological processes and the products of such processes); and surgery or therapy methods for humans or animals (including diagnostic methods)[194].

Qatar

The law excludes scientific theories; exercise of pure intellectual activities; plant and animal research; plant or animal production essentially biological processes other than

---

les méthodes de traitement chirurgical ou thérapeutique du corps humain ou animal et les méthodes de diagnostic appliquées au corps humain ou animal. Cette disposition ne s'applique pas aux produits, notamment aux substances ou compositions, pour la mise en oeuvre d'une de ces méthodes. »

[194]Article 6 –« Objets non brevetables . Ne peuvent être brevetés : a) l'invention dont l'exploitation est contraire à l'ordre public ou aux bonnes mœurs, étant entendu que l'exploitation de ladite invention n'est pas considérée comme contraire à l'ordre public ou aux bonnes mœurs du seul fait que cette exploitation est interdite par une disposition légale ou réglementaire; b) les découvertes, les théories scientifiques et les méthodes mathématiques; c) l'invention qui a pour objet des variétés végétales, races animales, procédés essentiellement biologiques d'obtention de végétaux ou d'animaux, autres que procédés microbiologiques et produits obtenus par ces procédés;(...) e) les méthodes de traitement du corps humain ou animal par la chirurgie ou la thérapie ainsi que les méthodes de diagnostic; (...)

microbiological processes and its productions; and diagnostic, therapeutic and surgical methods for the treatment of humans or animals and its productions.

Saudi Arabia

The law excludes: inventions whose commercial exploitation is harmful to life, to human, animal or plant health, or is substantially harmful to the environment; discoveries, and scientific theories; plants, animals and processes - which are mostly biological - used for the production of plants or animals, with the exception of microorganisms, non-biological and microbiology processes; surgical or therapeutic methods for human or animal bodies; and methods of diagnosis applied to human or animal bodies - with the exception of products used in any of these methods.

South Africa

The law excludes: discoveries, scientific theories, any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process; and any human or animal treatment method, including surgery, therapy or diagnosis. Such methods shall not be capable of being used or applied in trade, industry or agriculture, but the law would grant a patent to a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture, even though it was invented for use in any such method.

Tanzania

The law excludes: discoveries, and scientific theories; plant or animal varieties or plant or animal production essentially biological processes, other than microbiological and the products of such processes; and methods for the treatment of the human or animal body by surgery or therapy, as well as diagnostic methods. The exclusion does not apply to products for use in any of those methods.

Tunisia

The law excludes: discoveries and scientific theories; treatment methods and surgical therapy of the human body or animal and methods of diagnosis applied to human or animal body; all kinds of living substances occurring in nature. These provisions do not apply to processed products and in particular to compositions used for the application of any of these methods. A patent *can* be issued for plant varieties, animal breeds or plant

or animal production essentially biological processes; however, there would not be allowed medical and biological processes or the products such processes and inventions the publication or implementation would be contrary to morality, public order, public health or environmental protection.[195]

Uganda

The law excludes discoveries and scientific theories; plant or animal varieties or plant or animal production essentially biological processes, other than biological processes and the products of those processes; and methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods. The exclusion does not apply to products for use in any of these methods.

Zambia

The law excludes substances capable of being used as food or medicine which are a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients, or claiming as an invention a process to produce such substances by mere admixtures.

Zimbabwe

The law excludes substances capable of being used as food or medicine which are a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients or claiming as an invention a process producing such a substance by mere admixture.

---

[195] Art. 2. «Le brevet est délivré pour les inventions nouvelles impliquant une activité inventive et susceptibles d'application industrielle. Ne sont pas considérées comme inventions au sens de l'alinéa premier du présent article, notamment: a. les créations purement ornementales ; b.les découvertes et les théories scientifiques ainsi que les méthodes mathématiques (...) d. les méthodes de traitement thérapeutique et chirurgical du corps humain ou de l'animal et les méthodes de diagnostic appliquées au corps humain ou à l'animal. Ces dispositions ne s'appliquent pas aux préparations et notamment aux produits et compositions utilisés aux fins de l'application de l'une de ces méthodes. (...) ; e. toutes sortes de substances vivantes existant dans la nature. Les exceptions des dispositions de l'alinéa 2 du présent article concernant la brevetabilité des éléments énumérés ne s'appliquent qu'aux dits éléments considérés en tant que tels. Art. 3. - Le brevet ne peut être délivré pour : Les variétés végétales, les races animales ou les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux. Toutefois, cette disposition ne s'applique pas aux procédés biologiques médicaux et aux produits obtenus par ces procédés; Les inventions dont la publication ou la mise en oeuvre seraient contraires aux bonnes mœurs, à l'ordre public, à la santé publique ou à la sauvegarde de l'environnement. La mise en oeuvre du brevet ne pouvant être considérée comme telle du seul fait qu'elle est limitée par une disposition légale ou réglementaire ».

Exception: limitation for scientific research

The following countries also make exceptions to patent protections for the purpose of scientific research: Egypt, Ethiopia, Ghana, Kenya, Mozambique, Saudi Arabia and Uganda.[196]

Exception: limitation for non commercial/ nonprofit making purposes:

The following countries make exceptions to patent protections for non-commercial/ non profit-making purposes: Bahrain, Ethiopia, Ghana, Kenya, Morocco, Nigeria, Saudi Arabia and Tunisia.

\ Asian and Pacific Countries

Exclusions of patent right

Australia

The law excludes inventions contrary to law; substances or processes related to substances that are mere admixtures capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use); human beings, and the biological processes for their generation. For *innovation* patents (as distinguished from standard patents), the law excludes from patent plants and animals, and the biological processes for the generation of plants and animals (but such exclusion does not apply if the invention is a microbiological process or a product of such a process) [197].

---

[196]**EGYPT (**activities carried out for scientific research purposes);**ETHIOPIA (**the use of the patented invention solely for the purposes of scientific research and experimentation);**GHANA (**extends only to acts done for industrial and commercial purposes and in particular not to acts done for scientific research);**KENYA (**only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research);**MOZAMBIQUE (**acts related to a patented invention for the purposes of scientific research);**SAUDI ARABIA (**exploiting his invention in non-commercial activities relating to scientific research); and **UGANDA** (acts done in pursuance of scientific research).

[197] Patents Act 1990 39 50 (1) "The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent: (a) for an invention the use of which would be contrary to law; or (b) on the ground that the specification claims as an invention: (i) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or (ii) a process producing such a substance by mere admixture.(...) Section 19 Patents Act 1990 17 (2) Human beings, and the biological processes for their generation, are not patentable inventions. Certain inventions not patentable inventions for the purposes of an innovation patent (3) for the purposes of an innovation patent, plants and animals, and the

China

According to the national law (Article 25), no patent right shall be granted for: scientific discoveries; methods for the diagnosis or treatment of diseases; and animal and plant varieties. For processes used in producing these products, patent right may be granted in accordance with the provisions of this PRC Law.[198]

India

The national law excludes as not being inventions: the creations; what could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment (the primary or intended use or commercial exploitation of); the mere discovery of a scientific principle or the formulation of an abstract theory discovery of any living thing or non-living substance occurring in nature[199]; a method of agriculture or horticulture; any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar animal treatment to render them free from diseases or to increase their economic value or that of their products[200]; and plants and animals in

---

biological processes for the generation of plants and animals, are not patentable inventions. (4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process."

[198] Cui, Guobin, A Review of the Status Quo of Genetic Resources and Traditional Knowledge Protection in China (August 21, 2009). Available at SSRN: http://ssrn.com/abstract=1458890 indicates that a series of non-patent laws have special import in biotechnological technologies, as the Forestry Law(1984, latest revision 1998), the Grassland Law(1985, latest revision .2002), the Fishery Law(1986, latest revision 2004), the Wild Animal Protection Law(1988), the Environmental Protection Law(1989), the Seed Law (2000, latest revision 2004), the Stock-breeding Law(2005), the Regulation on Nature Reserve(1994) , the Regulation on the Protection of Wild Plants(1997), the Regulation on the Protection of Wild Medicinal Resources(1987), the Regulation on the Import and Export of Endangered Wild Fauna and Flora(2006), the Interim Regulation on Human Genetic Resources(1998), and specially the Regulations on Protection of Traditional Chinese Medicines (1992).

[199] According to the case Speaking Roses International Inc. v. Controller General of Patents and Anr. 2007 (109) Bom L R 630: There is no bar to the grant of a patent for making an image of an organic product by a non-biological process.

[200] The prior statute included here "plants". As to the issue of actual seed patents, see Wani, Tabasum, Patenting Seeds in India: Boon or Bane for Indian Farmers (2008). Available at SSRN: http://ssrn.com/abstract=1114522: "Thus, by comparing both the TRIPS agreement and the Indian law we find that the Indian law in Section 3 (i), by the amendment of 2002, omitted the word "or plants" from the purview of Section 3 and with it methods of agriculture was also excluded from patentability in the Indian Patent Act to ensure that the seed, which is the first link in the food chain, was held as a common property resource in the public domain. This amendment was a bolt from the blue for the Indian Farmers on their inalienable right to save, exchange and improve upon the seed. Thus, patents can now be granted for a process for treatment of plants, a GM seed which renders them free of disease or increases their economic value.".

whole or any part thereof other than microorganisms, but including seeds, varieties and species; and plant and animal production or propagation essentially biological processes[201].

The Indian biotechnological patent system, even though considering the peculiar nature of some exceptions and exclusions, does not seem to have impacted negatively in the country's economy [202]. It is noted that case law has expanded the interpretation of Indian patent rules in order to cover biotechnology processes even before the 2005 application of TRIPs provisions[203].

On the other hand, there is a set of provisions meant to exclude from the field of patent the whole Traditional Knowledge area[204].

---

[201] The PVP protection is provided under the Protection of Plant Varieties and Farmers' Rights Act, 2001, No. 53, Acts of Parliament, 2001, available at http://indiacode.nic.in/fullact1.asp?tfnm=200153..

[202] "As for attracting FDI, India is becoming more successful with life science corporations setting up research and development facilities in the country. Since India's patent system is still considered by many transnational corporations to be inadequate, the existence of a large number of well-qualified and inexpensive-to-hire Indians able to do the research and the enormous growth potential of such a high population market are likely to be far more significant factors than the patent regime however it may be designed. That is not to say that a more expansive patent regime would not necessarily spur accelerated biotech research-oriented FDI. We have no evidence to counter such a scenario, and therefore cannot rule it out. Nonetheless the growth of such investment has so far not been directly influenced by changes to the patent regime and has more to do with the relative cheapness of doing high quality research in India compared to Europe and North America". Graham Dutfield, Lois Muraguri e Florian Leverve , Exploring the flexibilities of TRIPS to promote biotechnology capacity building and appropriate technology transfer, Final Report IPDEV Work Package 7, 2006.

[203] " On January 15, 2002, the Calcutta High Court held in Dimminaco A.G. v. Controller of Patents, Designs & Trade Marks193 that a process for preparation of a vaccine, the end product of which contained a live virus, was an "invention" eligible for protection under the Patents Act. By its decision, the Dimminaco court overturned a long-standing policy of the Indian Patent Office to refuse such process claims, thus opening the door to biotechnology patenting in India much as the Chakrabarty decision did in the United States." Mueller, Janice M., Biotechnology Patenting in India: Will Bio-Generics Lead a 'Sunrise Industry' to Bio-Innovation?. University of Missouri-Kansas City Law Review, Vol. 75, No. 2, 2008; U. of Pittsburgh Legal Studies Research Paper No. 2008-02. Available at SSRN: http://ssrn.com/abstract=1087131.

[204]Mueler, op. cit.: "Section 3(p) excludes from patentability "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components." This exclusion is but one of several provisions inserted into the new Act in an effort to prevent the exercise of proprietary rights in India's genetic resources and indigenous knowledge. For example, the Act's disclosure requirements mandate inclusion of the source and geographical origin of biological material used in the claimed invention, and interested parties may oppose or petition to revoke an Indian patent on the ground that the invention claimed therein is anticipated "having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere . . . ."

Indonesia

The national law excludes (Article 7): any method of examination, treatment, medical care, and/or surgery, which may be applied on human beings and/or animals; theories and methods in the fields of science; all living creatures, except microorganism; as well as any biological process, which is essential in producing plant or animal, except non-biological process or microbiological process.

Japan

The national law states that any invention that is liable to injure public order, morality or public health shall not be patented (Article 32).

Malaysia

The law excludes (Section 13): discoveries of scientific theories and mathematical methods; plant or animal varieties or plant or animal production essentially biological processes, other than man-made living microorganisms, micro-biological processes and the products of such microorganism processes; and methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods to human or animal body. This exception shall not apply to products used in any such methods.

Pakistan

The national law excludes (Article 7(2)) discoveries of scientific theories and mathematical methods and substances that exist in nature or if isolated therefrom. Further, a patent shall not be granted (Article 7(4)) for: an invention whose commercial exploitation would contrary the “ordre public” or morality (including to protect human, animal or plant life or health or to avoid serious prejudice to the environment), provided that such exclusion is not made merely because the exploitation is prohibited by any law in force at the time; plants and animals other than microorganisms and plant or animal production essentially biological processes other than non-biological and microbiological processes; and diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

Philippines

The national law excludes (Section 22): discoveries, and scientific theories; methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body (this provision shall not apply to products and

composition for use in any of these methods); plant varieties or animal breeds or plant or animal production essentially biological processes. This provision shall not apply to microorganisms and non-biological and microbiological processes (provisions shall not preclude Congress to consider the enactment of a law providing *sui generis* protection of plant varieties and animal breeds and a system of community intellectual rights protection); and anything which is contrary to public order or morality.

South Korea

The national law excludes (Article 96) the effects of the patent right for inventions of medicines (namely, products used for diagnosis, therapy, alleviation, medical treatment or prevention of human disease: hereinafter referred to as "medicines") manufactured by mixing two or more medicines, or for inventions of processes for manufacturing medicines by mixing two or more medicines. It does not extend to the acts of manufacturing medicines in accordance with the Pharmaceutical Affairs Act or to medicines manufactured by such acts (Article 96(2)).

Thailand

The national law excludes (Section 9): naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants; scientific rules or theories; methods of diagnosis, treatment or cure of human and animal diseases; inventions contrary to public order, morality, health or welfare. Section 36(2) also states that the rights conferred by patents *do not extend* to creations necessary for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items[205].

[205] **"**Section 9- The following inventions are not protected under this Act: (1) naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants; (2) scientific or mathematical rules or theories; (3) computer programs; (4) methods of diagnosis, treatment or cure of human and animal diseases; (5) inventions contrary to public order, morality, health or welfare. PATENT ACT B.E. 2522 As Amended by the Patent Act (No.2) B.E 2535 And the Patent Act (No.3) B.E. 2542", available http://www.thailawforum.com/database1/patent.htmlvisited on 08/20/10.

Limitations of patentee's rights

India

The complex system of limitations provided by Indian Law includes two specific cases that might impact biotechnology patents: the research limitation, essential to high technology pursuits [206] and an enhanced bolar provision[207].

India has introduced by the entry in force of TRIPs in 2005 a specific compulsory license in favor of prior users of the newly patented items, which might cover some aspects of biotechnologically oriented medical inventions[208].

\ North America[209]

The *North American Free Trade Agreement(NAFTA)* is a multilateral agreement between Canada, the United States and Mexico that came into force on January 1, 1994. Part VI of *NAFTA* contains provisions pertaining to intellectual property

Provisions specifically pertaining to patents are found in article 1709. These provisions include the ability to exclude certain subject matter from patentability (diagnostic,

---

[206] "India's statute provides an explicit experimental use exemption from patent infringement liability. Section 47(3) specifies that uses of patented inventions "for the purpose merely of experiment or research including the imparting of instructions to pupils" are not actionable as patent infringement", Mueller, op. cit.

[207]"For the purposes of this Act, . . . any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product... shall not be considered as an infringement of patent rights."

[208] Section 11 A of the Indian Patent Act read as follows:: "(7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application: Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted: Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent: Provided also that after a patent is granted in respect of applications made under subsection (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises34."

[209] As noted before as to the European section, considerable portion of the *wording* of this section was provided by Yann Joly and E. Richard Gold's analysis of North American law under this same study. The authors are however responsible for the use of the text and its restructuring.

therapeutic and surgical methods, plants and animals other than microorganisms, and essentially biological processes).

Even though the NAFTA provides a unified basis for the analysis of the exceptions and exclusions of patent, this section would focus on the national laws of the three concerned jurisdictions.

Exclusions to Patent rights

United States

The United States law fails to provide explicit *statutory* exclusions of patent rights[210]. The constructive exception for patenting of humans, noted before, is not stated in statutory language.

Particularly regarding *biotechnological* inventions, the Supreme Court Case of *Diamond v. Chakrabarty*[211],which describes patentable subject matter as "anything under the sun made by man," illustrates the extensive definition given to patentable subject matter. The case law, including *Chakrabarty*, makes clear, however, that phenomena of nature, mental processes, and abstract intellectual concepts are not considered subject matter.[212]

In a recent trial court decision (Association for Molecular Pathology et al. v. United States Patent and Trademark et al), in addition to invalidating the claims reading over isolated human genes, the District Court found that claims reading over the process of conducting a genetic test – essentially, copying and then reading the gene isolated from the patient in question against a reference – was an unpatentable process pursuant to the reasoning in *In Re* Bilski, 545 F.3d 943 (Fed. Cir. 2008), since it involves no transformation of matter and is not tied to a particular machine or apparatus [213].

---

[210] The nuclear-related inventions, however, have a special exclusion.

[211] 447 U.S. 303 (1980).

[212] Benson, 409 U.S. 63 (1972) at 67, *Parker v. Flook*, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67, 93 S.Ct. 253, 255, 34 L.Ed.2d 273 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 68 S.Ct. 440, 441, 92 L.Ed. 588 (1948); *O'Reilly v. Morse*, 15 How. 62, 112-121, 14 L.Ed. 601 (1854); *Le Roy v. Tatham*, 14 How. 156, 175, 14 L.Ed. 367 (1853).

[213] According to the decision of Bilski v. Kappos, rendered on June 28, 2010, the issue seems to be moot. According the subsequent decision of the US Supreme Court in Classen Immunotherapies, Inc. v. Biogen Idec (a biotechnology case dealing on the machine/apparatus issue) the fact that an isolated gene is not *necessarily* subject to the transformation of matter test seem to be established. See Kevin E. Noonan ,

Exclusive rights on Plants

Multiple forms of protection are available. Plants can be protected by utility patents (35 U.S.C. § 101), plant patents (35 U.S.C. § 161) and plant variety protection certificates (7 U.S.C. § 2321) [214].

Utility patents

Plants can be protected under the utility patent regime of 35 U.S.C. 101 U.S. "[…] as the *Plant Patent Act* (35 U.S.C. 161) [215] is not an exclusive form of protection which conflicts with the granting of utility patents to plants." According to USPTO examination manual, "Plants capable of sexual reproduction are not excluded from consideration if they have also been asexually reproduced." [216]

Asexual reproducible Plants

The special system under U.S.C. § 161 – 164 stem from the *Plant Patent Act* of 1930. Its purpose was to give a similar protection to utility patents for what was considered a product of nature at the time. F. Scott Kieff *et al.*, 4th ed. *Principles of Patent Law* (Foundation Press, 2008), 807-808. Not a *sui generis* system. The patent provided under 35 U.S.C. § 161 protects against unauthorized *asexual* reproduction

General conditions for patentability also apply to plant patents. However, the non-compliance with the description of the invention requirement of 35 U.S.C. § 112 does not invalid a plant patent (35 U.S.C. § 162).

The scope of protection provided is: "In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States." On the other hand, 35 U.S.C. § 161 prevents the patenting of plants "in an uncultivated state".

Bilski v. Kappos: What Effects on Biotechnology Patents?, at http://www.patentdocs.org/2010/07/bilski-v-kappos-what-effects-on-biotechnology-patents.html, visited 07/02/2010.

[214] Although the remaining sections of this study do not extend to the protection of plant varieties under specific (non-patent) system, the peculiarity of the U.S. law in this context led to the inclusion of such kinds of patent-like regimes.

[215] Such act confers protection to asexually reproducible plants.

[216] United States Patent and Trademark Office, Manual of Patent Examining Procedure (MPEP8 E8R7) (Alexandria, Virginia, 2008), ch. 1601.

Regime protecting sexually reproduced plants

Under 7 U.S.C. § 2321 & seq. (Plant Variety Protection Act) United States law provides for a different system aimed to protect sexually reproducible plant breeders. To be protected, a variety must be new, distinct, stable and uniform. The rights conferred essentially protects against unauthorized sexual reproduction and use of the plant. In 1994, new legislation was enacted in order to bring the PVPA into compliance with the 1991 Act of the UPOV Convention.

Canada

Whole plants and animals do not constitute patentable subject matter. This does not affect the patentability of components of whole plants or animals and does not limit the scope of claims over those components to less than the whole plant or animal. Thus, while *de jure*, whole plants and animals cannot be patented, *de facto*, they can through claims over genes or cells [217].

Canadian law expressly indicates that unicellular microorganisms are patentable as are processes to produce life forms [218]. Genes are patentable because they are considered chemical compounds. Claims reading over genes extend to the entire organism despite the non-patentability of higher life forms [219]. Methods of medical and surgical treatments are not patentable [220].

Higher Organisms

As mentioned, higher life forms (i.e., whole animals and plants) are considered unpatentable by the Supreme Court of Canada[221]. While referring to plants as being higher life forms, the Supreme Court says higher life forms are deemed unpatentable in the current Patent Act[222].

---

[217] Harvard College v. Canada (Commissioner of Patents) [2002], 4 S.C.R. 45.

[218] Re Application of Abitibi Co. [1982], 62 C.P.R. (2d) 81.

[219]Monsanto Canada Inc. v. Schmeiser [2004], 1 S.C.R. 34. See Chapter 17, Manual of Patent Office Practice, found at http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html, visited on 08/20/10.

[220] Imperial Chemical Industries Ltd. v. Commissioner of Patents, [1986] 3 F.C. 40. Tennessee Eastman Co. v. Commissioner of Patents, [1974] S.C.R. 111.See Chapter 17, Manual of Patent Office Practice

[221] See Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902.

[222] Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, paras. 165 - 166.

However, this general rule has one exception. In *Monsanto Canada Inc. v. Schmeiser*, (Par. 17) because "Monsanto did not claim protection for the genetically modified plant itself, but rather for the genes and the modified cells that make up the plant," a gene patent was deemed valid, even though it precluded the use of a type of plant or seed without the patent owner's consent. Therefore, though the patent system does not expressly protect plants as a whole, it does so effectively by conferring patents over specific genes or cells (Par. 21).

The Canadian Government has not taken an official stance against patents on plants and higher organisms generally. However, higher organisms are not patentable as a whole because the Supreme Court interpreted the definition of "invention" in the Patent Act as not including higher life forms, which include *inter alia* plants and animals. Nevertheless, patents on elements contained within higher organisms (e.g. genes) can provide the same protections conferred had the entire organism been patented.

Mexico

Mexican excludes from patenting: human body and its components [223]; biological elements found in nature, including naturally occurring DNA and proteins [224]; essentially biological processes for obtaining, reproducing and propagating plants and animals;[225] and plant *varieties* and animal *breeds* [226].

Also excluded are those inventions whose contents or form are contrary to public policy, morality or proper practice, or if they violate any legal provision [227]; methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals[228]; and discoveries and elements found in nature [229].

---

[223]Industrial Property Law Article 16, "Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of: (…) IV. the human body and the living matter constituting it…"

[224] Id., (...) II. Biological and genetic material as found in nature…"

[225] Id., (...) I. essentially biological processes for obtaining, reproducing and propagating plants and animals;

[226] Id., (…) III. animal breeds; (…) V. plant varieties

[227] Industrial Property Law, art. 4; "No patent, registration or authorization shall be granted… in respect of any of the legal devices or institutions regulated by this Law when their contents or form are contrary to public policy, morality or proper practice, or if they violate any legal provision."

[228]Industrial Property Law, Art. 19. "The following shall not be considered inventions for the purposes of this Law:(…) VII. methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals;"

Exceptions and limitations to patentee's rights

United States

Exemption for medical practitioners and their institutions

The patent portion of the United States Code contains a specific restriction of patent rights, which at least nominally is not an exclusion. Though patents are granted for the field of art, such patents are not opposable to certain designed users of the invention.

Section 287(c) provides *medical practitioners and their institutions* with immunity from patent infringement in "the performance of a medical or surgical procedure on a body." This immunity does not apply, however, with respect to "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent."

Section 287(c) intended to provide a similar level of protection for physicians in the US as the prohibition in other countries of methods of therapeutic treatment. Commentators suggest, however, that the level of protection offered by the immunity may be broader than that under the laws of other jurisdictions.

> In February 2010, The Secretary's Advisory Committee on Genetics, Health, and Society has recommended that this exemption be extended to medical practitioners providing gene testing.SACGHS, R*evised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, 2010.

Bolar Exception as applied in Biotechnology

Research that may result in information being filed under federal food and drug laws does not constitute infringement[230]. To qualify, the researcher needs only to intend the eventual filing of an application. The research does not need to be mandated by federal authorities.

The purpose of this provision is to allow generic drug companies to manufacture patented drugs. However, the provision was interpreted broadly by the Supreme Court

---

[229] Industrial Property Law, art. 19: "II. discoveries that consist in making known or revealing something that already existed in nature, even though it was previously unknown to man".

[230] 35 U.S.C. § 271 (e)(1) Merck KGaA v. Integra Lifesciences Ltd., 545 U.S. 193 (2005).

of the United States as allowing any research (including, possibly, biotechnological) where there is a legitimate belief that a filing will be made.

Farmer's privilege, breeder's exception and research exception

Under the Plant Variety Protection Act, there are three exemptions to the plant breeder's exclusive right:

(a) a compulsory license covering the "public interest in wide usage", whereby the Department of Agriculture may declare a variety free to use (provided an equitable remuneration to the owner). The issuance of the license is contingent to the finding that (i) two years (at most) is necessary to obtain an adequate supply of fiber, food, or feed; and (ii) the owner is unwilling or unable to meet public demand at a price, which may reasonably be deemed fair;

(b) a research exemption on the use and reproduction of a protected variety for plant breeding or other research[231];

(c) a farmer's exception, whereby the planter is allowed to save seed and to use such saved seed in the production of a crop. According to the current case law, it is not clear whether this right may be voluntarily relinquished in the licenses covering the protected varieties[232]. Since 1994, it is no more allowed to farmers to *sell* the seeds they grow [233].

Canada

Acts for obtaining regulatory approval

The Patent Act, R.S.C. 1985, c. P-4, s. 55.2 (1) exempts from patent infringement any use of an invention to file information to any federal, provincial or foreign regulator in respect of the sale of any product[234]. This provision is primarily, but not exclusively,

---

[231] Research exemption provided by 7 U.S.C. 2544, section 114: "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter."

[232] The Monsanto Co. v. McFarling case mentioned *at* note 34.

[233] "Growers may no longer legally sell seed of protected varieties for planting, yet growers may continue to replant seed of a [protected plant] variety for their own use without obtaining permission from the [patent owner]". Julian M. Alston & Raymond J. Venner, "The effects of the US plant Variety Protection Act on wheat genetic improvement" (2002) 31 Research Policy 527.

[234] "The Canadian exception is unrestricted as to subject matter of the patent, it applies to medicines, bicycles and anything patented, and unrestricted as to any country not just Canada or province in which regulatory approval may be sought.": Apotex Inc. v. Merck & Co. Inc. 2008 FC 1185 at par. 21. This exception is thus broader than that in the US as interpreted in Merck KG v. Integra Lifesciences Ltd. 545

aimed at assisting the generic pharmaceutical industry to obtain regulatory approval for the eventual sale of patented medicine.

This exemption applies to both pre-market and post-market activities undertaken to comply with regulation[235]. Further, the provision does not exempt only activity that actually results in submitted information. The section should not, therefore, be given a narrow interpretation but should be interpreted in the same way as provisions granting the patent itself[236].

US 1 (2005). "That United States statute is more restrictive as it speaks only of requirements under United States law and is limited to drugs." Merck & Co. Inc. v. Apotex Inc. 2006 FC 524 at par. 154.

[235] *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at par. 100.

[236] Section 55.2(1) is "not an exemption from the purpose of the Act, but is an integral part thereof by seeking to balance the rights of patentees with those of the public": *Merck & Co. v. Apotex Inc.*, [2007] 3 F.C.R. 588 at par. 102.

Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights - Biotechnology

Annex - Tables and Comparisons

\ Mercosur area

Brasil (MERCOSUR)	Argentina (MERCOSUR)	Paraguay (MERCOSUR)	Uruguay (MERCOSUR)
- patents are granted for inventions that are new, useful and with inventive activity	- patents are granted verified inventive activity and industrial application	- Patents are granted for new products and procedures that imply inventive activity and are subject to industrial application	-Patents are granted for new products and procedures that imply inventive activity and are subject to industrial application
- ***invention does not include*** surgical procedures and therapeutic methods for human & animal body - the whole or part of any living natural being and biological material found in Nature, including the genome or germplasm and the natural biological processes Excluded are the biological material found in nature, *even when isolated from the state of nature.* Law 972/1996 Law 11.105 x (Biosafety) of 03/24/2005 Article 6: It is forbidden: VII - the use, marketing, registration, patenting and licensing of genetic technologies that results in use restriction. Sole Paragraph: For the purposes of this Act,a Genetic technology results in restricting use whenever there is a procedure of human intervention for the purpose of generation or propagation of genetically modified plants to produce sterile reproductive structures, and any form of genetic manipulation aimed at the activation or deactivation genes related to fertility of plants by chemical inducers.	- ***invention does not include*** surgery treatment, therapeutic or diagnosis methods applicable to the human body and regarding animals - plants, animals and essentially biologic procedures are not considered patentable material The living material preexisting in nature does not constitute itself as an invention but discovery, in the methodology of the patent law, and are not, as so, patentable. The possibility of patenting a living material not preexistent in nature is then open.	-***Invention does not include*** diagnosis, therapeutic methods(for animals and humans)	-***Invention does not include*** - plants and animals except microorganisms and the essentially biologic process for production of plants and animals, excluding the non-biologic or microbiologic procedures. Also, biologic and genetic material verified in nature - Diagnosis, therapeutical and surgery methods of people and animals are not patentable

Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights - Biotechnology

-***Statutory Exclusions*** - Inventions offensive to public health, and the whole or part of living bodies [237] [Transgenic microorganisms that satisfy all of the patent requirements are acceptable as long as they fulfill the 3 patentability requirements (novelty, incentive activity and industrial application) [238]]	-***Statutory Exclusions*** - Inventions whose exploitation in the territory of Argentina are to be prevented to protect public order or morality, health or life of humans or animals or plant life or avoid serious environmental damage The totality of biological and genetic material existing in nature or a replica thereof in the biological processes involved in animal breeding, plant and human, including procedures relating to the genetic material capable of conducting its own replication in normal and free as in nature. -The essentially biologic process in animal, vegetable and human production is not patentable. -Microorganisms are only patentable (VIII, § 4g) if they gather the usual positive patenting conditions".	***Statutory Exclusions*** - Inventions whose commercial exploitation should be necessarily protected to protect health, people or animals lives and to preserve vegetables, avoid damage to the environment. Plants and animals other than microorganisms, and plant or animal production essentially biological processes other than non-biological and micro biological	***Statutory Exclusions*** - The following are not deemed patentable inventions: Diagnosis, therapeutic and surgical methods for the treatment of persons or animals. Those inventions contrary to public order, socially accepted manners, public health, population nutrition, security and environment.
Limitations Applicable exclusively to Biological Matter: Law 9.279/96 (Brazil): "Article 43 - The provisions of the previous article shall not apply (…) [variation] V - to other persons who, in the case of patents related to living matter, use the patented product, without economic purpose, as an initial source of variation or propagation in order to obtain other products, and [Exhaustion] **VI -** other			

[237] According to the Brazilian Guidelines, "Based on advice from consultants, the PTO considers viruses as chemical products. Thus, one must consider what was said above with respect thereto, including with regard to the issue of natural products".

[238] According to art. 18 of the Brazilian Law, transgenic microorganisms are organisms, except the whole or part of plants or animals that express, *through direct human intervention in their genetic composition*, a characteristic not normally attainable by the species under natural conditions. It must be noted that this is the only provision in the law that requires human intervention as a requirement for patentability; discoveries are defined by commentators as being simply knowledge that is not by itself capable of being a technical solution for solving a technical problem.

persons who, in case of patents related to living matter, use, place in circulation, or market a patented product that has been lawfully placed on the market by the owner of the patent or his licensee, provided that the patented product is not used for the commercial multiplication or propagation of the living matter concerned." [International]			

AndeanArea

Bolivia (ANDEAN)	Colombia (ANDEAN)	Ecuador (ANDEAN)	Peru (ANDEAN)
- Patents are denied to inventions that are in public domain; the mere use of substances or newly discovered natural forces;scientific principles or discoveries and chemical products or pharmaceutical or therapeutic compositions (new processes to produce them, or their new industrial applications are patentable)	-Applies the Andean rules (below)	- All inventions satisfying the novelty, technical and industrial utility shall be patentable - Substances that exist in nature are not deemed to be inventions - Patents are denied to inventions, the commercial exploitation of which must be prevented to protect morality. Specifically, processes for human cloning, the human body and its genetic identity, the use of human embryos for industrial or commercial purposes and procedures for modifying the genetic identity of animals when they cause suffering without obtaining any substantial medical benefit to humans. - Patents are also denied to inventions, the commercial exploitation of which must be prevented as necessary to protect the health or life of humans or animals or plant life or to prevent serious damage to the environment or ecosystem; diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and plants and animal varieties and plant or	- This country is essentially ruled by the Andean rules as modified by the 2008 legislation and further by Law 29.316 of January 14, 2009, edited as a result of the Free Trade Agreement of the US * Follows Andean limits on biological matter, but, Law Nº 29 316-Article 39-A. Exceptions to rights conferred. When the limited exceptions provided for in Article 53 of Decision 486 of the Andean Community Commission with the normal exploitation of the patent or causing unreasonably prejudice the legitimate interests of patentee, taking into account the legitimate interests of third parties, the patent holder may exercise the rights provided in Article 52 of that decision

Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights - Biotechnology

		animal production essentially biological processes	
Andean rules (Bolivia, Colombia, Ecuador, Peru)		**Peruvian Post FTA rules**	
Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing		Any living being existing in nature, as a whole or in part.[suppresses the denial of patenting of elements isolated from nature]	

South America - outside the regional groups

Venezuela	Chile	Suriname	Guiana
- Patents are issued for inventions, improvements and the introduction of foreign patents not yet in public domain -pharmaceutical, food, chemical and drink products and chemical preparations. Reactions and combinations are excluded. (No mention to biotechnological fields)	-Patents are obtainable for all inventions that are new, non obvious and susceptible of industrial application -Plants, animals and essentially biological processes are deemed not to be inventions. - Microorganisms may be patentable whenever they fulfill the general patent requirements -Microbiological processes are patentable; useful but non-technical creations as business methods and rules of games; surgical, diagnostic or therapeutic methods and for human or animal body products intended to implement those methods are patentable - Parts of living beings as found in nature, natural biological processes and biological material found in nature even though isolated from nature. This includes genome or germplasm - Inventions that satisfy the general patentability requirements are not patentable in cases where their commercial exploitation must be prevented to health or life of humans or animals or to preserve plants or the environment, provided that such exclusion is not made only because there is a legal or administrative provision that prohibits such exploitation	- applies Dutch Patent Act	-In the case of inventions relating to substances prepared or produced by chemical processes or intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and ascertained or by their obvious chemical equivalents: provided that in relation to a substance intended for food or medicine a mere admixture resulting only in the aggregation of the known properties of the ingredients of that substance shall not be deemed to be a method or manufacturing process

Quick Reference Table of Exclusions for the Following African Nations (Data absent for Algeria, Morocco)

Table with Original Text

	Inventions detrimental to the public health/well-being	Animals, plants, already existing species	Biological methods for the reproduction of plants and animals other than non-biological and microbiologic al methods	Diagnostic, therapeutic, and surgical methods necessary to treat humans and animals	Discoveries, scientific/ mathematical theories, etc.	
BAHRAIN	Any invention whose commercial use prohibition in of Bahrain is imperative for the protection of public order or morality Principles; including the protection of humans life or health or that of animals or plants or to avert causing serious harm to the environment	Animals Note: Required by Free Trade Agreement with the United States to offer patents for plants, US-Bahrain Art. 14.8(2)		Diagnostic therapeutic and surgical methods necessary for human and animal treatment. Not applicable to products used in any of these methods		
EGYPT	Inventions whose exploitation is likely to be…prejudici al to the environment human, animal or plant life and health	Plants and animals, regardless of their rarity or peculiarity	plant or animal production essentially biological processes, other than microorganis ms, non-biological and microbiologic al processes for plant or animal production	Diagnostic, therapeutic and surgical methods for humans and animals	Discoveries, scientific theories, mathematical methods, programs and schemes	Organs, tissues, live cells, natural biological substances, nuclear acid and genome
ETHIOPIA		plant or animal varieties	plant or animal production essentially biological processes	Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on	discoveries, scientific theories and mathematical methods	

				the human or animal body. (not applying to products for use in any of the methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body.)		
GHANA		plant or animal varieties	plant or animal production essentially biological processes, other than microbiologic al processes and the products of such processes	methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; this provision shall not apply to products for use in any of these methods	discoveries, scientific and mathematical theories	
JORDAN	Inventions whose non-exploitation is necessary to protect the life and health of humans, animals and plants or to avoid severe damage to the environment	Plants and animals other than microorganis ms Note: As per Free Trade Agreement to offer patents for plants, US-Bahrain Art. 14.17(implicit)	Biological methods for the reproduction of plants and animals other than non-biological and microbiologic al methods	Diagnostic therapeutic and surgical methods necessary for the treatment of humans or animals	Discoveries, scientific theories and mathematical methods	
KENYA	Inventions contrary to principles of humanity and to conserve the environment	plant varieties as provided for in the Seeds and Plant Varieties Act	*[but not parts thereof or products of biotech processes]*	methods for treatment of the human or animal body by surgery or therapy, as well as related diagnostic methods, except products for use in any such methods	discoveries, scientific theories and mathematical methods	public health related methods of use or uses of any molecule or other substance for the prevention or treatment of any disease which the health Minister designates as serious health hazard or as life threatening

						disease
LEBANON				Methods of medical diagnosis or treatment related to humans or animals but not products or utilities for use in such methods	Scientific discoveries and theories and absolute mathematical methods that are not industrially applicable	
MOZAMBIQUE		All or part of living beings	*[microbiological processes and products obtained from such processes are patentable]*	surgical, therapeutic or diagnostic treatment Methods applicable to the human body or animals, although products, substances or compositions used in shall be patentable	Scientific theories and mathematical methods; Discoveries aimed at making known or revealing something which already exists in nature, notwithstanding that it was heretofore unknown to man	Substances, materials, mixtures, elements or products of any type resulting from atomic nuclear transformation, and changes to physical and chemical properties and the respective obtaining or modifying processes
NIGERIA		plant or animal varieties	plant or animal production essentially biological processes (other than microbiological processes and their products)		Principles and discoveries of a scientific nature	
QATAR		Plants and animals research	plant or animal production essentially biological processes other than microbiological processes and productions	Diagnostic, therapeutic and surgical methods for the treatment of humans or animals and due productions	Scientific theories, mathematical methods, computer programs, exercise of pure intellectual activities, or practice of a specific game	
SAUDI ARABIA	In case the commercial exploitation is harmful to life, human, animal or plant health, or substantially harmful to the	Plants, animals	processes - mostly biological - used for the production of plants or animals, exception of microorganisms, non-	Methods of surgical or therapeutic treatment of human or animal body and methods of diagnosis applied to human or	Discoveries, scientific theories and mathematical methods	

	environment		biological and microbiology processes	animal bodies, exception to products used in these methods		
SOUTH		for any variety of animal or plant	essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process	An invention of a human or animal body treatment method by surgery or therapy or of diagnosis practiced on the human or animal body shall be deemed not capable of appliance or use in trade, industry or agriculture (not preventing) a product consisting of substance or composition being deemed capable of appliance or use in trade, industry or agriculture merely because it is invented for use in any such method	- discoveries; -scientific - mathematical methods	
TANZANIA		plant or animal varieties	plant or animal production essentially biological processes, other than microbiologic al and the products of such processes	methods for the treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; but shall not apply to products for use in any of those methods	discoveries, and scientific and mathematical theories	
UGANDA		plant or animal varieties or	plant or animal production essentially biological processes, other than biological processes and the products	methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods, but the restriction	discoveries and scientific and mathematical theories	

			of those processes	under this paragraph shall not apply to products for use in any of these methods		
ZAMBIA						a substance capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients, or a process producing such a substance by mere admixture
ZIM **BABWE**						a substance capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients or that it claims as an invention a process producing such a substance by mere admixture

	Inventions detrimental to the public health/well-being (including morality, protection of human/animal/environmental life)	Animals plants already existing species	Biological methods for the reproduction of plants and animals other than non-biological and microbiological methods	Diagnostic therapy, and surgical methods necessary to treat humans and animals	Discoveries, scientific/mathematical theories, etc.	Simple mixes of already known ingredients	Miscellaneous
BAHRAIN	X	X[1]		X			
EGYPT	X	X	X	X	X		*
ETHIOPIA		X	X	X	X		
GHANA		X	X	X	X		
JORDAN	X	X[1]	X	X	X		
KENYA	X	X	Parts, products, biotechnological processes MAY be patented	X	X		†
LEBANON				X	X		
MOZAMBIQUE		X	Microbiological processes and related products ARE patentable	X	X		‡
NIGERIA		X	X		X		
QATAR		X	X	X	X		
SAUDI ARABIA	X	X	X	X	X		
SOUTH		X	X	X	X		
TANZANI		X	X	X	X		
UGANDA		X	X	X	X		
ZAMBIA						X	
ZIMBABWE						X	

\ Ásia

China	India	Indonesia	Japan
For any of the following, **no patent right** shall be granted (**Article 25**): Scientific discoveries; Methods for the diagnosis or treatment of diseases; Animal and plant varieties; [For processes used in producing these products, patent right may be granted in accordance with the provisions of this PRC Law]	The following are not inventions within the meaning of the Act and hence cannot be patented (**Section 3**): an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment[239]; the mere discovery of a scientific principle or the formulation of an abstract theory discovery of any living thing or non-living substance occurring in nature; a method of agriculture or horticulture; [240] any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;	Patent shall not be granted to an invention of (**Article 7**): a method of examination, treatment, medical care, and/or surgery which may be applied on human beings and/or animals; Theories and methods in the fields of science and mathematics; all living creatures, except microorganism; any biological process which is essential in producing plant or animal, except non-biological process or microbiological process.	Any invention that is liable to injure public order, morality or public health shall not be patented (**Article 32**).

[239] See http://www.patentoffice.nic.in/ipr/patent/manual-2052005.pdf

[240] As this exclusion might seem extraneous to the TRIPs pattern, some case law addition is required: "A method of producing a new form of a known plant even if it involved a modification of the conditions under which natural phenomena would pursue their inevitable course is not patentable. (N.V. Philips Gloeiammpenfabrieken's Application 71 RFC 192)". "A method of producing improved soil from soil with nematodes by treating the soil with a preparation containing specified phosphorathioates was held not patentable" (Virginia Carolina Chemical Corporation application 1958 RFC 38). "A method of producing mushroom plant and a method for cultivation of an algae" (264/Cal/79) were held not patentable [445/Del/93).

	Cases: *Speaking Roses International Inc. v. Controller General of Patents and Anr. 2007 (109) Bom L R 630?:* There is no bar to the grant of a patent for making an image of an organic product by a non-biological process		

Malaysia	Pakistan	Philippines	South Korea	Thailand
The following inventions are not patentable (**Section 13**): Discovery of scientific theories and mathematical methods plant or animal varieties or plant or animal production essentially biological processes, other than man-made living microorganisms, micro-biological processes and the products of such microorganism processes; methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body: this paragraph shall not apply to products used in any such methods.	The following are not regarded as inventions and therefore, not patentable (**Article 7(2)**):Discovery of scientific theories and mathematical methods substances that exist in nature or isolated therefrom. Further, a patent shall not be granted (**Article 7(4)**): prevention of commercial exploitation necessary to protect "*ordre public*" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Such exclusion is not made merely because the exploitation is prohibited by any law for the time being in force; for plants and animals other than microorganisms, and plant or animal production essentially biological processes other than non-biological and microbiological processes; diagnostic, therapeutic and surgical methods for treatment of humans or animals	The following shall be excluded from patent protection (**Section 22**): Discoveries, scientific theories and mathematical methods Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods; Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes (Provisions under this subsection shall not preclude Congress to consider the enactment of a law providing *sui generis* protection of plant varieties and animal breeds and a system of community intellectual rights protection) Anything which is contrary to public order or morality	Limitations on Patent Right:are stated under Article 96: The effects of the patent right for inventions of medicines (namely, products used for diagnosis, therapy, alleviation, medical treatment or prevention of human disease: hereinafter referred to as "medicines") manufactured by mixing two or more medicines, or for inventions of processes for manufacturing medicines by mixing two or more medicines, shall not extend to the acts of manufacturing medicines in accordance with the Pharmaceutical Affairs Act or to medicines manufactured by such acts (**Article 96(2)**).	The following inventions are not protected under this Act (**Section 9**): naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants; Scientific or mathematical rules or theories methods of diagnosis, treatment or cure of human and animal diseases; inventions contrary to public order, morality, health or welfare. **Limitations on Patent Rights: Section 36(2)** states that the rights conferred by patents do not extend to: for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items

North America - Exclusions on Patentable Subject Matter

United States

Biotechnology	Genes: In re Fisher, No. 04-1465 (Fed.Cir. September 7, 2005); In Re Kubin No. 09-667,859 (Fed. Cir. April 3, 2009). Association for Molecular Pathology et al. v. United States Patent and Trademark et al., 09 Civ. 4515 (S.D.N.Y. 2010).	Genes and microorganisms are patentable as long as they possess utility (In re Fisher), unless they were obvious to try (In Re Kubin). However, in Association for Molecular Pathology et al. v. United States Patent and Trademark et al., the District Court for the Southern District of New York held that isolated human genes were not patentable subject matter since they were phenomena of nature. In arriving at this decision, the Court held that genes have both a physical and informational quality: "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature . . . [its] existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes." It is widely expected that this portion of the District Court's decision will be overturned on appeal to the United States Court of Appeals for the Federal Circuit. A second aspect of the decision in Association for Molecular Pathology et al. v. United States Patent and Trademark et al may fare better on appeal. In addition to invalidating the claims reading over isolated human genes, the District Court found that claims reading over the process of conducting a genetic test – essentially, copying and then reading the gene isolated from the patient in question against a reference – was an unpatentable process pursuant to the reasoning in In Re Bilski, 545 F.3d 943 (Fed. Cir. 2008) since it involves no transformation of matter and is not tied to a particular machine or apparatus.
Higher Life Forms	*Ex parte Allen*, 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987).	The United States Patent and Trademark Office (USPTO) "now consider[s] non-naturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101": Manual of Patent Application Procedure, section 2105.
Morality	None	A patent application cannot be rejected on moral grounds. Please see: Jennifer McCallum, "The Reality of Restricting Patent Rights on Morally Controversial Subject Matter" (2005) 39 New En. L. Rev. 517.

Canada

Biotechnology	*Re Application of Abitibi Co*. [1982], 62 C.P.R. (2d) 81. *Monsanto Canada Inc. v. Schmeiser* [2004], 1 S.C.R. 34. *Harvard College v. Canada* (Commissioner of Patents) [2002], 4 S.C.R. 45.	Unicellular microorganisms are patentable as are processes to produce life forms: *Re Application of Abitibi Co.* [1982], 62 C.P.R. (2d) 81. Genes are patentable because they are considered chemical compounds. Claims reading over genes extend to the entire organism despite the non-patentability of higher life forms. See Chapter 17, *Manual of Patent Office Practice* for more info.
Higher Life Forms	*Harvard College v. Canada* (Commissioner of Patents) [2002], 4 S.C.R. 45.	Whole plants and animals do not constitute patentable subject matter. This does not affect the patentability of components of whole plants or animals and does not limit the scope of claims over those components to less than the whole plant or animal. Thus, while *de jure*, whole plants and animals cannot be patented, *de facto*, they can through claims over genes or cells.
Methods	*Re Application No. 2,246,933 (Amazon.com)* [2009], C.D. 1290. *Calgon Carbon Corporationv. North Bay (City)* [2005], FCA 410.	"Advances in the concepts" in non-technological fields are unpatentable. See *Manual of Patent Office Practice*. Tools related to methods are considered patentable. "Methods for influencing human interactions or behaviours" are not patentable. See Chapter 12.04.02, Manual of Patent Office Practice for more info.

Mexico

Human body and its components	Industrial Property Law Article 16.	"Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of: (…)IV. the human body and the living matter constituting it…"
Biotechnology	Industrial Property Law Article 16.	"Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of: (…)II. biological and genetic material as found in nature…" *N.B.* This includes naturally occurring DNA and proteins.
Higher Life Forms	Industrial Property Law Article 16.	"Inventions that are new, the result of an inventive step and susceptible of industrial application within the meaning of this Law shall be patentable, with the exception of: I. essentially biological processes for obtaining, reproducing and propagating plants and animals;(…)III. animal breeds;(…)V. plant varieties." *N.B.* Please note that plants have their own regime

[Annex IV follows]