International Patent Law on Biotechnology and its relationship with Biodiversity

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ABSTRACT
In this paper, we describe the main trends of International Patent Law on Biotechnology and the nature of its relationship with biodiversity through examples of drugs and marine biotechnologies. This study highlights the need for a comprehensive and pluridisciplinary of living organisms at the international level.

Keywords
Patent Law, Biotechnology, Biodiversity, International Law, life, drugs, marine biotechnologies, CBD, TRIPS

1. INTRODUCTION
The term biotechnology is a paradoxical compound noun employing the words life and technology. In international environmental, it was defined for the first time in the umbrella Convention on Biological Diversity (CBD, 1992)

"Biotechnology means any technical application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (art. 2)

The creation of a biotechnology depends on the industrial or scientific processing of biological resources originally collected in nature. The term Biodiversity refers, to "the variability among living organisms from all sources, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of the ecosystems" (art. 2). Biodiversity and biotechnology are both linked with an emergent concept: that of

1 From the Greek term “bios” which means life or living
2 Besides this legal definition, there is a multitude of possible definitions. It could however be simply defined as any application of theoretical and practical scientific principles in the treatment of substances by biological agents to reproduce goods and services: Scriban, R., p. 82-83.
3 see Jacob, F., 354 p.
4 For example, article 16-1 (3) of the French civil code stipulates that human body, its parts and products can not be subject matter of a patrimonial right.
5 Beurier, J.P., Kiss, A., p. 273.
6 In opposition to traditional biotechnology, for example the process of fermentation or hybridization and their products.
7 The ecological dimension however can not be denied.
8 In spite of a visible terminological distinction, biological resources and genetic resources, which are any material of plant, animal, microbial, or other origin containing functional units of heredity of actual or potential value, are in practice synonyms. : Allem, A.C., p. 337.
9 Oceans cover 71% of the planet’s surface.
10 32 of the 34 phyla of life discovered on Earth are present within the marine environment: Kornprobst, J.M.
diverse\textsuperscript{12}, it constitutes a huge reserve of biodiversity and active substances\textsuperscript{13} which can be used in the field of biotechnologies\textsuperscript{14}.

In the international political, economic and scientific context, access to the technology is unequal. There exist mainly three groups of States\textsuperscript{15}: Firstly, the countries which are able to produce technology and grant patents (e.g. the US, the EU, Japan, etc.). They are the founders of and are favourable to the patent system as it stimulates innovation and investment. Secondly, the countries that can, through the payment of royalties, adapt existing technologies to their domestic use (e.g. emergent countries such as India, South Africa or Brazil). Thirdly, the group which is excluded from the production and the reproduction of technologies (e.g. the vast majority of African countries). The two last groups are reluctant to grant patent applications for biological resources. In contrast to Northern countries, they are rich in biodiversity and some belong to the group of Megadiverse Countries\textsuperscript{16}.

2. THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS UNDER INTERNATIONAL LAW

2.1 The progressive standardization of the patent system

Intellectual Property Law, more specifically Patent Law, has rapidly developed at the international level in order to set up an international protection standard and to adapt legal norms with evolving technologies. From 1883, the Paris Convention for the protection of industrial property\textsuperscript{17} established an Union of States so as to harmonize their industrial property rights (patents, industrial designs, marks, utility models, etc.). This Union is managed by the World Intellectual Property Organisation (WIPO), a specialized agency of the United Nations promoting creativity and a coherent worldwide intellectual property system created in 1967\textsuperscript{18}. The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)\textsuperscript{19} takes up the essential measures of the Paris Convention. It standardizes international property rules, insofar as they are closely linked with the global commercial system established by the World trade Organization (WTO)\textsuperscript{20}.

The TRIPS sets minimum standards for the national protection of intellectual property rights along with procedures and measures for their enforcement\textsuperscript{21}. Not every technological invention is necessarily patentable\textsuperscript{22}. According to article 27.b of the TRIPS, three substantial conditions must be met for an invention to be patentable\textsuperscript{23}. Firstly, it must be new. An invention already known in the scientific community can not be the subject matter of a patent. Secondly, the invention must involve an inventive step or must be non obvious. A simple discovery of an existing element of nature can not be patentable. Thirdly, an invention must be capable of industrial application or must be useful. An invention with no practical use or providing only a scientific theory can not be patented. One main formal condition must also be met, i.e. the disclosure of the invention to the relevant patent office. The
application must include a sufficiently detailed description for a person skilled in the art (biologist, scientist, engineer, etc.) to make and use the invention. Once the application procedure has been accomplished, the inventor is issued a patent, whose protection is limited in terms of territory and temporality. The classic philosophy of patents could be expressed by the phrase “give and take”: the inventor enriches the scientific or industrial domain through the invention. The description of the invention is published at the time of filing the contents of the research are then accessible to the public. In exchange, the owner of the invention is granted a 20 years monopoly24. When the patent term expires, the details of the invention become public domain.

2.2 The integration of life into patentability

Life, despite its sacred and inviolable character, has long been assimilated to the miscellaneous exchangeable and interchangeable corporeal things in the West25. The integration of life into patentability demonstrates nevertheless a new form of human control or appropriation26 over animate nature. Henceforth, the object of a control is more the ‘qualitative dimension’ of living organisms (genetic patrimony or heritage) than their ‘quantitative dimension’ (biomass). This new form of human control over life is principally the result of the exponential development of bioengineering during the 20th century and specifically since the 1970s27. It has also coincided with the expansion of the market of biotechnologies correlating to the progressive standardization of the patent system at the international level28. Nowadays, some life forms or living organisms can be subject matter of incorporeal rights such as patents or plant variety protection certificates29.

The mutation of the intellectual property rights regarding life has been essentially based on the US case law. In 1873, the US Patent and Trademark Office (USPTO) allowed a patent applied to the commercialization of a new species of yeast. Initial in 1977, a claim to a pure culture of microorganisms was rejected by the US Court of Customs and Patents Appeal, on the grounds that it was a « product of nature » not patentable under the Common Law regime. The court yet found that the fact the micro-organism was alive did not remove it from the field of patentable subject matter.

It was the first patent on a microorganism, even if this microorganism was not considered at that time as a living organism but rather as an “article of manufacture”. Almost a century later, the Supreme Court took an essential decision concerning life patenting in the case Diamond v. Chakrabarty31. After several years of judicial battle, Ananda Chakrabarty and his employer, the General Electric Corporation applied for and obtained a patent that included two new strains derived from the marine bacterium genus Pseudomonas, capable of breaking down crude oil32. From this decision, the United States opened the way to the patentability of higher life forms. In In ex parte Hibbard case33, the Board of Patent Appeals and Interferences (BPAI) allowed a patent on a variety of maize. In 1987, it extended the field of life patentability to multicellular organisms, recognizing in the case In re Allen34 that a triploid oyster fell within the bounds of patentable subject matter. In 1988, the USPTO granted a controversial patent to Harvard College for a mouse with a human oncogene35. It was the first patented transgenic mamal36. Western countries, lead by the US, have considerably affected the global vision of life in admitting the patentability of certain living forms. Article 27 of The TRIPS echoes this new vision. Microorganisms37 and non-biological and microbiological processes fell within the field of patentability. WTO members may exclude inventions contrary to public order or morality, “including to protect human, animal and plant life or health or to avoid serious prejudice to environment” (art. 27. 2). They also may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals, just as plants and animals and

28 See supra, 2.1. Article 1(3) of the 1883 version convention of Paris on industrial property rights already included into patentability “[...] natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour...”. This last theme is excluded from the present study.

29 Improvment in the manufacture of beer and yeast, US Patent No 141.072.
essentially biological processes for the production of plants or animals. These exclusions are however only simple possibilities offered to States. At the national and the regional levels, positions on life patentability are much more fragmented insofar as they depend on ethical, philosophical, moral or religious aspects. Regardless of this, it still remains that life has entered the field of trade in a unheard-of context of correlation between Science, Economy and Law and this, without taking in consideration the specific nature of biotechnologies that can reproduce and spread in the environment (Genetically modified organisms).

3. THE PROBLEMATIC RELATIONSHIP BETWEEN PATENT AND BIODIVERSITY LAWS

3.1 TRIPS and CBD: a synergy to create

Although the CBD and the TRIPS were signed in an interval of less than 2 years in almost the same international context and are focused on the same subject matter, i.e. life, they do not respond to the same ideology. The main divergences between these two texts are summarized in the table below.

Table 1. Divergences between TRIPS and CBD

<table>
<thead>
<tr>
<th>Objectives</th>
<th>TRIPS</th>
<th>CBD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotion of technical innovation</td>
<td>Transfer and dissemination of technology</td>
<td>Conservation of biodiversity</td>
</tr>
<tr>
<td>Mutual advantage of producers and users of technology (art. 7)</td>
<td>Sustainable use of its components</td>
<td></td>
</tr>
<tr>
<td>Status of research</td>
<td>Proprietary research</td>
<td>Mixed research (open and proprietary research)</td>
</tr>
<tr>
<td>Relationship with other international conventions</td>
<td>Does not recognize the earlier adopted CBD</td>
<td></td>
</tr>
</tbody>
</table>

However, it could be argued that the research promotion and technology transfer, the protection of the environment and sustainable development are considered by the WTO. Even if negotiations between the WTO and the CBD fora are in progress on such questions as genetic resources or traditional knowledge, the points of convergence remain weak. Whereas the Conference of the Parties of the CBD has repeatedly and early emphasized the interrelationship between the CBD and the TRIPS and the need to further explore this interrelationship, it was only at the Doha Ministerial Conference in 2001 that the TRIPS Council was instructed to examine the relationship between the TRIPS and the CBD and the protection of traditional knowledge and folklore. Additionally, the request of the CBD secretariat for observer status in the TRIPS Council is still pending.

3.2 The Debate on disclosure of the origin of biological resources used in biotechnological inventions

The “Country of origin of genetic resources” means the country which possesses those genetic resources in situ conditions, whereas source is a broader term which refers to any source from which a patent applicant has acquired the genetic resources, other than the country of origin such as a research center, a gene bank, or an aquarium. States’ positions concerning the condition of disclosure of the origin of biological resource and/or traditional

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38 For example, the 1995 Treaty for life forms patent-free Pacific and related protocols illustrates the opposition of indigenous peoples of the Pacific to the life patentability. For more informations on national and regional positions on life patentability, see review of article 27.3 b) TRIPS: http://www.wto.org/english/tratop_e/tribs_e/art27_3b_background_e.htm.

39 As a diverse entity for the CDB and the support of a technology for the TRIPS.

40 See for example art. 28 (rights conferred) and 66 (Least developed Country Members) TRIPS.
knowledge used in an biotechnological invention are multipolar, as are their general positions on biotechnologies and the conditions of their protection via Patent Law at regional or national level.

Table 2. Summary of States’ positions regarding the condition of disclosure of the origin of biological resources used in a biotechnological inventions

<table>
<thead>
<tr>
<th>Approach</th>
<th>US, Japan</th>
<th>Switzerland</th>
<th>EU</th>
<th>Megadiverse and African group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obligation of disclosure</td>
<td>National</td>
<td>National/Multilateral</td>
<td>Multilateral</td>
<td>Multilateral</td>
</tr>
<tr>
<td>Conformity between CBD-TRIPS</td>
<td>Contracts with the competent authorities</td>
<td>Impose WIPO Member States to modify their legislation</td>
<td>Binding Disclosure Requirement within TRIPS</td>
<td>Binding disclosure requirement within TRIPS</td>
</tr>
<tr>
<td>Content of disclosure</td>
<td>Source and country of origin</td>
<td>Source and country of origin</td>
<td>Source and country of origin</td>
<td>Source and country of origin</td>
</tr>
<tr>
<td>Sanctions</td>
<td>Formal condition</td>
<td>Not a condition of patentability</td>
<td>Condition of Patentability which can result in suspension or revocation of patent</td>
<td></td>
</tr>
<tr>
<td>Access and benefits sharing</td>
<td>Prescribed in contract</td>
<td>Transmission of disclosure to an organism which could inform States and verify that consent has been obtained</td>
<td>Evidence of prior informed consent and fair and equitable benefits sharing must be given at disclosure time</td>
<td></td>
</tr>
</tbody>
</table>

Some States or Community of States have already introduced into their Law a principle or a duty to divulgate the source and/or the country of origin of the genetic resources being used as the basis for a biotechnological invention. Negotiations are still in process within the WTO concerning a modification of the TRIPS to impose disclosure of the origin of the genetic material when filing a patent for a biotechnological invention. However, this modification would be difficult to enforce due to opposing positions. Other technical questions must also be addressed such as the degree of relation between the origin of the genetic material and the invention.

4. ACKNOWLEDGMENTS

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5. REFERENCES


48 The preambule (whereas No. 27) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological invention provides that the patent application should, where appropriate, include information on the geographical origin of such material, if known. This condition is nevertheless without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

49 The Andean Community took decisions (No. 391 : Common regime on access to genetic resources and No. 486 : Common intellectual property regime, notably article 26 (h)) permitting national offices to demand that the patent application contain the access contrant for the genetic resource. The Norwegian patent Act (Act No. 80 of June 29, 2007, Chapter 2, Section 8b requires patent applicants to state the country of origin if known and if different from the providing country and to specify, if prior informed consent has been obtained, if the national in the country of origin requires such a condition. The non conformity of this requirement does not cancel the patent but results in a penal sanction.