Université de Genève
Institut Universitaire de Hautes Etudes Internationales

Towards a Reconciliation between the Convention on Biological Diversity and TRIPS Agreement

An Interface among Intellectual Property Rights on Biotechnology, Traditional Knowledge and Benefit Sharing

par

Gionathan CURCI STAFFLER

(Italie, Suisse)

Genève

Some substantial parts of the present study are mainly drawn from the following research paper: O. ACHIMUGU, J. CURCI STAFFLER and A. KHAN, "Patentability of Animal Life: Regional Current Practices and Legal Challenges on the International Level" published in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001, p. 1 ss.

Table of Contents

I. INTRODUCTION 5

A. Importance of Innovation in Agriculture 7

B. Importance of Biodiversity for Human Existence 8

C. The Phenomenon of "Biocide" while Intellectual Property Expands into Life Forms 9

D. Striking a Balance between Interests of Intellectual Property Right Holders and Indigenous Communities 11

PART I INTELLECTUAL PROPERTY AND BIODIVERSITY 14

II. **PATENTABILITY OF BIOTECHNOLOGY IN THE UNITED STATES AND EUROPE** 14

A. Discerning between the Concepts of Invention and Discovery in the United States Patent System 14

B. The European Approach to Patentable Biotechnological Subject-Matter in the European Patent Convention of 1973 16

C. The European Union Biotechnology Directive of 1998 and the Imitation Effect 17

D. Some Ethical and Environmental Challenges in the United States and European Case Law on Biotechnological Patents 19

E. Is the Traditional Patent System Valid for Biotechnological Inventions? 21

III. RELATIONS BETWEEN INTELLECTUAL PROPERTY RIGHTS ON BIOTECHNOLOGY AND PROTECTION OF BIODIVERSITY 23

A. Globalization of Patentability of Life Forms through the TRIPS Agreement 23

1. Article 27 and its Exceptions: Is there Any Way Out of Patenting Life? 24

Table 1. Patentability Subject-Matter of Article 27.3(b)

2. Article 27.3(b): *Sui Generis* Systems for Plant Variety Protection 25

3. General Critique on the Scope and Utility of Article 27 26

B. General Observations on the Legal Tensions between TRIPS and CBD 28

1. The International Regime of Genetic Resources: from “Mankind’s Heritage” to the Affirmation of State Sovereignty in the CBD 28

2. General Impact of TRIPS on the Obligations under CBD 29

3. Impact of TRIPS on the Access to Genetic Resources Provided by the CBD 30

4. The Phenomenon of “Biopiracy” and the Problem of Equitable Benefit Sharing Arising from the Utilization of Biological Resources 31

5. Absence in TRIPS of Safeguard Provisions on Traditional Knowledge Held by Indigenous Communities 33

6. Positive and Negative Impact of TRIPS on the International Transfer of Technology Promoted by the CBD 34

Table 2. Synopsis of the Points of Conflicts between CBD and TRIPS according to the Developing Countries Standpoint

C. Reviewing Article 27.3(b) of TRIPS 37

1. No Patents on Life 37
2. Full Discretion to Exclude Life Forms from Patentability 37
3. Maintenance of the *Status Quo* 38

D. Bilateral Treaties and Creation of a "TRIPS Plus" Regime 39

CONCLUSION OF PART I 41

PART II. IMPLEMENTING TRIPS AND BENEFIT SHARING OBLIGATIONS BETWEEN INTELLECTUAL PROPERTY RIGHT-HOLDERS AND INDIGENOUS COMMUNITIES THROUGH THE VALORIZATION OF TRADITIONAL KNOWLEDGE 42

IV. RECOGNITION OF FARMERS' RIGHTS IN AN "EFFECTIVE *SUI GENERIS* SYSTEM" FOR PLANT VARIETIES (ARTICLE 27.3(b) OF TRIPS) 43

A. Tightening the Monopolistic Restrictions in UPOV Convention 43

B. FAO International Treaty of Plant Genetic Resources and Agriculture and Legal Nature of Farmers' Rights 44

C. Plant Variety Protection and Safeguard of Farmers' Rights in Developing Countries 45
1. Negative Impact of Plant Breeders' Exclusive Rights under UPOV Regime on Farmers' Rights 48
2. Importance of a *Sui Generis* Protection System for Plant Varieties 51
3. Proposals for an Effective *Sui Generis* System in Developing Countries 52

V. CBD AND THE DUTY OF NEGOTIATION: FRAGILITY OF THE CONTRACTUAL SOLUTION 54

A. Are Contracts Adequate to Fairly Share Benefits Arising from Utilization of Genetic Resources and Related Traditional Knowledge? 55

B. Are National Laws Able to Create a Legal Framework to Enhance Benefit Flows to their Local Communities? 57

C. Bioprospecting Cartels among Developing Countries for Access to their Biological Resources 59

VI. PROTECTION AND VALORIZATION OF BIODIVERSITY RELATED TRADITIONAL KNOWLEDGE IN INTELLECTUAL PROPERTY SYSTEMS 60

A. A Working Definition of Traditional Knowledge 61

B. Using Existing Intellectual Property Rights to Protect Traditional Knowledge 63
1. Suitability of Low Cost Patents for Traditional Knowledge 63
2. Does Traditional Knowledge Lack the Patent Requirement of Novelty? 64
3. Common Characteristics to Geographical Indications and Trademarks Protection of Traditional Knowledge 64
i. Geographical Indications 65
ii. Trademarks 66

C. Proposals for a *Sui Generis* System of Protection of Biodiversity Related Traditional Knowledge in Developing Countries 69

1. Adapting the Traditional Knowledge Subject-Matter to the Proper Intellectual Property Protection: the Example of Traditional Medicine 71
i. Trade Secrets Spiritual Healing and Ritual Regimes 72
ii. *Sui Generis* Rights for Non-Spiritual Healing 72
2. General Constraints to Protect Traditional Knowledge by Intellectual Property Rights 73

D. Valorization of Biodiversity Related Traditional Knowledge in a Flexible Patent Law System 75
1. Implementing the Concept of Prior Informed Consent in Patent Law System 75
i. Is the Obligation to Submit a Certificate of Origin a Procedural or Substantive Patent Rule? 75
ii. Is the European Biotechnology Directive of 1998 in Breach of the CBD "Prior Informed Consent" Obligation? 77
2. How Traditional Knowledge Databases Can Improve the International Prior art search to be Performed by the Examiners 80
i. Importance of Publishing TK in Databases for an Effective International Prior Art Search 80
ii. Are Traditional Knowledge Databases Enough to Improve the Novelty- Destroying International Prior Art Search? 81
iii. Interaction between the Elaboration of Disclosure Requirements and the International Prior Art Search 83
3. Implementing the Existing Exception to Patent Law and Limiting the Rights Conferred 86
i. Compulsory Licenses 87
ii. International Exhaustion of IPRs and Parallel Imports 87
iii. Local Working Requirement as an International Patent Law Obligation Rights 90
iv. The Doctrine of Fair Use from Infringement 92

VII. FINAL OBSERVATIONS 92

BIBLIOGRAPHY 97

List of Abbreviations

CBD - Convention on Biological Diversity
CGRFA - Commission on Genetic Resources for Food and Agriculture
EPO – European Patent Office
EPC – European Patent Convention
FAO – Food and Agriculture Organization
FAO Treaty - FAO International Treaty on Plant Genetic Resources for Food and Agriculture
FFMs – Fact Finding Missions
GATT - General Agreement on Tariffs and Trade
ICJ – International Court of Justice
ILO- International Labor Organization
IPRs - Intellectual Property Rights
IPP – Intellectual Property Protection
NGO – Non Governmental Organization
PIC – Prior Informed Consent
TK- Traditional Knowledge
TRIPS – Trade-Related Aspects of Intellectual Property Rights
UPOV - Union for the Protection of New Varieties of Plant
UNESCO – United Nations Educational, Scientific and Cultural Organization

Law and Science: Toward a Happy Marriage

"Like all good marriages… that of Science and Law… are complementary to each other… Science seeks knowledge of facts, Law seeks justice which may rise from above and beyond the facts… Science rested on the material, Law on the moral and ethical and philosophical. Science analyses and predicts phenomena, Law clarifies and controls conduct. Science describes, Law prescribes. […] As in human marriages each partner brings an influence on the other. Science and Technology move the Law toward new fields and the need to change and grow. The Law tames, controls, and channels Science and Technology […] In a broader sense, unless law controls science, man will become, in Thoreau's phrase, "the tool of his tools". Thus Science and Law must be treated as legitimate lovers, not as living in sin". MARKEY H. T., *A Compilation of his Writings Opinion and Speeches*, ed. By the John Marshall, Chicago Illinois, Buffalo New York, 1984.

I. INTRODUCTION

In this era of fascinating developments, both positive and negative, nearly every discipline of human activity is going through a kind of challenge. Intellectual Property (IP) Law and Environmental Law are no exception. The rapid pace of advancement in the once mysterious field of biotechnology has raised various complex ethical questions which need to be answered. And these questions become more complex when we try to address them in the context of international trade and sustainable development.

In our new millennium, biotechnology will enable genetic engineering to yield very important breakthroughs. There is further possibility for thousands of novel organisms to be developed through genetic modification. The fact that myriad biotechnological applications[1] can be released in the environment for pharmaceutical, agricultural and medicinal purposes has generated transnational concerns that have posed an enormous challenge to the national and international communities. Especially developing countries denounce the phenomenon under which the genetic resources of the world, once modified, would be reducible to property rights resulting in few companies who can control access to food, medicinal and other resources essential to the health and welfare of mankind. Further concerns arise about the potential for genetic engineering to cause transnational harm, particularly by destabilizing a region's atmosphere through genetic pollution and in the long-run accelerating an irreversible process of decline in global biological diversity.

[1] Biotechnology concerns techniques for using the properties of living things to market products and services. These techniques include selecting natural strains of organisms that carry desirable traits: making hybrids by fusing cells from different parental sources; using chemicals and radiation to create mutant strains; or genetically engineering plants, animals, and micro-organisms to produce specific phenotypic characteristics.

In this short-thesis, we are more particularly concerned with the problem of sharing benefits arising from the exercise of IPRs over genetic resources under existing international law treaties, especially in the context of the interaction between companies from industrialized countries and indigenous communities in developing ones.

No abstract or sophisticated explanation can better illustrate this matter than a typical and vivid example. Let us imagine a natural sweetener preserved for several millennia in the interstices of a local farming micro-culture and which is able to perform its sweetening function without dietary and health shortcomings. A Western bioprospecting company is orientated in its research by the knowledge of the local farmers that breed and use the sweetener. They hold some samples of this local genetic resource and then, once in their comfortable labs, shrewd chemists map its genome and, with a few apt strokes of genetic engineering, the plant raises tenfold the yield of the modified species over the original one. Next, the modified plant, which is indeed novel and may well imply an inventive step, is patented. As a consequence of its commercialization, the total profits flow to the company patent holder and not even a farthing goes to the local farmers who preserved it for such a long time. But on top of that, since the patented plant is so markedly more productive, the original plant is dismissed from the market. Is it fair that the one who adds the final cherry to a pie is thereby entitled to eat off the whole cake? The answer is obvious but a lot is to be done to counter these *biopiracy* cases that many still think are isolated (see section III.B.4). On the contrary, some 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived by wild species and land races[2].

In spite of this, major industrialized States - having realized the potential gains flowing from this new technology for their national economies and being particularly spurred on by private industries – are promoting stronger intellectual property rights (IPRs) standards to be integrated in multilateral and bilateral treaties to which most of developing countries are parties. At the same time, industrialized countries have been accused of watering down the patentability requirements of biotechnology within their own national jurisdictions in order to accommodate corporate interests without precisely and carefully considering the issues involved and the consequences thereof. The transnational behavior in this field has been regulated by at least two major multilateral treaties which are both legally binding: the UN Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO). Since these issues are intrinsically complex and multifaceted, various international institutions – such as World Intellectual Property Organization (WIPO), Food and Agriculture Organization (FAO), United Nations Educational, Scientific and Cultural Organization (UNESCO), International Labor Organization (ILO) etc. - are becoming eagerly involved by producing guidelines or even new treaties on the subjects concerned.

It goes without saying that granting IPRs over plant and animal genetic resources modified after unauthorized appropriation raises anger in developing countries. Therefore one of our objectives is to try to formulate some suggestions that may increase their confidence in IP linked to living matter. To do this we intend to portray the legal debate on the articulation and compatibility

[2] See BLAKENEY M., *Intellectual Property Aspects of Traditional Agricultural Knowledge,* paper presented November 22nd 2001 at the WIPO-Torino Law School Specialization Course in Intellectual Property, at 2. For similar data see COTTIER Th., "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law", in ABBOTT F., COTTIER Th., GURRY F., *The International Intellectual Property System. Commentary and Materials*, Kluwer Law Int., The Hague, London, Boston, 1999, 1820 ff., at 1827.

of TRIPS and CBD in light of other relevant agreements pertaining essentially to benefit sharing arising from the exploitation of genetic resources, mainly between holders of IPRs based on biological diversity and indigenous communities in developing countries whose traditional knowledge (TK) is crucial for discovery development, preservation of a tremendous range of medicinal plants and health-giving herbal formulations. We will also observe, on the one hand, how existing IPRs are apt to valorize biodiversity related TK and, on the other hand, we will address the necessity of creating a new IP right able to protect TK.

A. Importance of Innovation in Agriculture

Human existence is basically dependent on plants and animals, because they provide the basic needs of the human being. Plants are essential for the production of food, clothing, and even fuel[3]. People have bred and used plants as an element for composing their traditional medicines. It goes without saying that pharmaceutical drugs are developed through modification of chemicals found in plants. The very development of pharmaceutical products is inspired by the structure and activities of plant compounds. "About three-quarters of the world population still uses plant-based preparations in primary health care"[4].

However, it is envisaged that the demand of human beings would be unable to be satisfied by the available plant resources of the world. It appears that the rapidly increasing population is one of the major causes of this problem. As a tragic result, hundreds of millions of people may be affected due to lack of food security over the next twenty-five years[5]. It goes without saying that this situation affects most prominently developing countries. As a matter of fact, statistical prospects alarmingly predict that global population is expected to reach 8 billion by 2020 and 11 billion by the year 2050; food production will need to double for an estimated world, with 90% of the additional need arising in developing countries[6]. This will further reduce the extent of cultivable land and water required for cultivation, particularly in densely populated countries in the South and South-East region. Consequently, the food security of the people of these countries may be greatly jeopardized[7].

---

[3] "The main food plants in North America are cereal grains. The major types of grain crops include corn, rice, oats, barley and rye. Next are legumes such as peas, beans, soy beans and peanuts. For centuries people have used the herbs and spices derived from plants as seasonings for their food. Pepper and nutmeg are two examples of seasonings derived from dried fruits, while others such as sage and rosemary come from leaves. A common baking spice, cinnamon, is found in the stem of the plant. Several beverages are extracted or originate from plant life. By steeping plants in hot water, coffee, tea and cocoa are produced. Amongst other naturally produced beverages are fruit juices, cider and milk of various nuts", P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, "International Convention On The New Varieties Of Plants UPOV Convention And Its Implementation For Developing And The Least Developed Countries", in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001, p. 458.

[4] *Ibidem*. See also GIRSBERGER M., *Biodiversity and the Concept of Farmers' Rights in International Law*, Peter Lang, Berne, 1999, pp. 82-83. "A long tradition, widespread availability, and low cost have made plant-based medicines (Ayurvedic) an integral part of health care for an estimated 4 billion people in developing countries", *Grant of Conservation of Medicinal Plants in Sri Lanka, Press Release*, The World Bank Group, 1997, p. 1. Available at: www.worldbank.org/extrd/extmc/1585.

[5] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 456.

[6] COTTIER Th., "The Protection of Genetic Resources", *op. cit.*, p. 1823. See also FAO, *Global meeting to assess progress on World Food Summit goals*, available at www.fao.org/news.

[7] "In 26 of the 40 low-income countries listed by the World Bank, and in 26 of the 50 reporting countries in the middle and higher income category, per capita food output sank in the period from 1979 to 1991. In most African countries, South of the Sahara and in the Middle East, the degree of self-sufficiency in grain, the most important staples of these

Further, the annual growth rates in yields per hectare of staple foods like rice and wheat fell off in the greatest production areas of cultivation in Asia. According to FAO, it is envisaged that this trend will continue for years. The developing countries which export their agricultural products at present may become importers by 2010[8].

As a consequence of increased population and urbanization, the cultivated lands are converted into settlement projects, particularly in the suburban areas of most of the developing countries. This situation aggravates the problem of food security to a greater extent in view of the lack of suitable land for cultivation.

It is the mere lack of variety of food substances that has been causing malnutrition. Although absolute productivity has generally increased over the past 30 years for both crops and livestock; the gains in cultivated area and productivity have been outweighed by rapid population growth so that millions of people have faced food shortages. "In 2000, these totaled 28 million in sub-Saharan Africa, in at least 16 countries"[9].

Most of the developing countries are currently encountering the serious problem of meeting the future food requirements of the rapidly growing population. Remedial measures in overcoming the problem are not obvious. The classical solution is to increase food production while controlling the population. We are indeed concerned with the methods of increasing food production with the available natural resources. The answer seems more and more to be given by the innovation process in terms of recent research in the field of biotechnology. The application of this science to horticulture and forestry can pave the way to increased production, to achieve economic and social development and welfare. Improved varieties of plants are a necessary and very cost-effective element in the quantitative and qualitative improvement of the production of foods, renewable energy and raw material[10].

For instance, new varieties of plants generating higher harvestable yield because they may be resistant to plant pests, diseases etc. These are crucial element in the process of productivity increase (both in qualitative and quantitative terms) in agriculture, horticulture and forestry.

B. Importance of Biodiversity for Human Existence

"Biodiversity" is the variety of all life forms; the different plants, animals and micro-organisms, their genes and the ecosystems of which they are a part. Hence, humans depend on the

---

regions, decreased", *Socio-political Impact of Biotechnology in Developing Countries,* NOVARTIS Foundation for Sustainable Development, 2001, p. 1, available at www.foundation.novartis.com.

[8] BLAKENEY M., *Protection of Plant Varieties and Farmers' Rights*, International Seminar on the Role of Intellectual Property in the Field of Biodiversity and Traditional Knowledge, Jointly Organized by the Brazilian National Institute of Industrial Property and the European Commission, Manaus/Amazonas/Brazil, 9-11 September 2001, p. 1. PISTRUP-ANDERSEN, PANDYA-LORCH R. and ROSEGRANT M. W., *World Food Prospects: Critical Issues for the Early Twenty First Century, International Food Policy Research Institute*, Washington, 1999, ch.1. See also SERAGELDIN I. and PURSLEY G. J., *Promethean Science. Agricultural Biotechnology, the Environment and the Poor,* CGIAR, Washington, 2000, p. 3.

[9] "Extent and Productivity of Cultivation and Livestock Production Systems", available at: http://www.grida.no/aeo/173.htm.

[10] "Without the availability of new varieties, the world food storage would be even more serious, than it is. In order to feed the growing world population, the further development of new and high performance varieties is a necessity"; speech delivered by KIEWIET B., *Interaction between Intellectual Property and Biodiversity, European Union Plant Variety Office,* 2001, p. 1 quoted in P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 457.

conservation of biodiversity for their survival and quality of life. Over the years, conservation has acquired many connotations; to some extent it has meant the protection of nature, nowadays it means more and more the sustained production of useful materials from the resources of the earth. The most widely accepted definition for conservation of biodiversity, presented in 1980 in World Conservation Strategy by the International Union for Conservation of Nature and Natural Resources, is "the management of human use of the biosphere so that it may yield the greatest sustainable benefit while maintaining its potential to meet the needs and aspirations of future generations"[11]. These were the original inspiring principles of the CBD.

This definition highlights the maintenance of essential ecological processes and life support systems, the preservation of genetic diversity and guarantee of sustainable use of species and ecosystems. In general, conservation involves practices that perpetuate the resources of the earth on which human beings depend and that maintain the diversity of living organisms that share the planet. These factors need to be taken into account when considering IP protection of plant varieties, particularly with regard to granting exclusive rights *(ius prohibendi)* to the plant breeders or even patents and their effects on biodiversity.

C. Phenomenon of "Biocide" while Intellectual Property expands into Life Forms

The IPR that is primarily sought in the field of biotechnology is the patent because it is meant to be a right concerning ideas and information, which are used in new inventions or processes. Patents enable the holder to exclude imitators from marketing such inventions or processes for a specified time; in exchange, the holder is required to disclose the formula or idea behind the product/process. After a patent is granted, the owner has a monopoly over commercial exploitation of the idea/information, for a limited period. The stated purpose of a patent is to stimulate innovation, by offering higher monetary returns than the market otherwise might provide[12]. The classical IP scholarship has crafted each protection according to the principle of "allocative efficiency" according to which the long term benefits flowing to society from the protection granted to a particular class of creators or innovators outweigh the – mainly short term – costs imposed by the monopolistic structure of the grant itself[13]. And the mainstream legal literature has applied such a standard IP question to the field of biotechnology as well[14].

---

[11] *Variety of Life,* Biodiversity Web, p. 2; available at: www.biodiversity.nl.biodiversity.htm.

[12] ABBOTT F., COTTIER Th. and GURRY F., *The Intellectual Property System; Commentary and Materials*, Part I, Kluwer Law International, 1999, p. 25.

[13] TORREMANS P., *Intellectual Property Law*, Butterworths, 2001, at 20 and 16. Carvalho says that patents are devices with a precise social goal — the measurement of the economic value of inventions. In other words, patents are measurement devices aimed at a more efficient allocation of resources. The patent system exists because it is the only known legal institution that allows the inventor to put a price on technology and at the same time permits society to measure the adequacy of such a price with relative efficiency. The cornerstone justification of the patent system is the reduction of transaction costs. Transaction costs include the costs of measuring and the costs of enforcing rights, CARVALHO N. P., "From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?", *Revista da ABPI*, 40, 1999, pp. 3-28. See also COASE R.H., *The Firm, the Market and the Law*, 1988, see particularly chapters one "The Firm, The Market, and The Law" and two "The Nature of the Firm".

[14] Which includes, in the EU literature, BOSTYN S.J.R., *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, European Patent Office, München, 2001; KAMSTRA G, SCOTT N., SHEARD A., DORING M., WIXON H., *Patents on Biotechnological Inventions: The EC Directive – Special Report*, Sweet & Maxwell, London, 2001; LLEWELYN M., "The Patentability of Biological Material: Continuing Contradiction and Confusion", *European Intellectual Property Review*, 22, 2000, pp. 191 ff.; BOSTYN S. J. R., "One Patent a Day Keeps the Doctor Away?

In industrialized societies, investment in the biotechnology industry has been so conspicuous that the benefits of innovation in this field have outweighed the costs of full monopolistic restrictions created by patents. They are now applicable not only to plant varieties but also to micro-organisms and genetically modified animals. Genetically altered animals, such as the infamous *Onco-mouse* of Harvard University (bred for cancer research), were also soon given patents[15]. Finally, several patent claims have been made, and some granted on human genetic material, including on material that has arguably been altered from its natural state.

If these trends were until recently restricted to some countries, six months after the entry into force of the CBD, the adoption of TRIPS Agreement of 1994[16] marked the commencement of a new era of globalization of IPRs by the introduction of IP "minimal" standards to all WTO member States[17]. With respect to biotechnological inventions, State Parties are bound, under Article 27, to accept: patenting of micro-organisms and "microbiological processes" and providing some "effective" form of IPRs on plant varieties, either patents or some *sui generis* (new) version. But, while the TRIPS Agreement requires that States grant exclusive private rights over biological material, CBD, on the contrary, affirms the sovereign rights of States to biological material. This is the "epitaph" that utters the core of the dichotomy that we will be apprehending throughout our study.

Broadly speaking, tensions between the sovereign rights of States and the expansion of IPRs to biological subject-matter has to be primarily seen in the framework of the resource allocation at the international level under the pressure of science and technological innovation within national economies. In this context, an audacious analogy can be drawn with the Law of Sea[18], i.e. the

---

Patenting Human Genetic Information and Health Care", *European Journal of Health Law*, 7, 2000, pp. 229 ff.; OSER A., "Patenting (Partial) Gene Sequences Taking Particular Account of the EST Issue", *International Review of Industrial Property and Copyright*, 30, 1999, pp. 1 ff.; SCHATZ U., "Patentability of Genetic Engineering Inventions in European Patent Office Practice", 29, *International Review of Industrial Property and Copyright*, 1999, 2 ff.; SCOTT A., "The Dutch Challenge to the Bio-Patenting Directive", *European Intellectual Property Review,* 1999, pp. 212 ff. In a similar perspective but in connection with U.S. law see EISENBERG R.S., "Re-examining the Role of Patents in Appropriating the Value of DNA Sequences", *Emory Law Journal*, 49, 2000, pp. 783 ff.; IWASAKA R.M.T., "From Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law", *Yale Law Journal*, 109, 2000, 1505 ff.; LONG C., "Proprietary Rights and Why Initial Allocation Matters", *Emory Law Journal*, 49, 2000, p. 823; DUCOR P., *Patenting the Recombinant Products of Biotechnology,* Kluwer, The Hague, 1997; DAVIS M.D., *The Patenting of Products of Nature*, *Rutgers Comp. & Tech. L.J.*, 21, 1995, pp. 331 ff.; GREENFIELD M.S., "Recombinant DNA Technology: a Science Struggling with the Patent Law", *Stanford Law Review*, 44, 1992, 1051ff.; KO Y., "An Economic Analysis of Biotechnology Patent Protection", *Yale Law Journal*, 102, 1992, 777 ff.
A more global outlook is to be found in GRUBB Ph. W., *Patents for Chemicals, Pharmaceuticals and Biotechnology. Fundamentals of Global Law, Practice and Strategy*, Oxford University Press, Oxford, 1999 and BOVENBERG J. A., "Should Genomics Companies set up Database in Europe? The EU Database Protection Directive Revisited", *European Intellectual Property Review*, 23, 2001, pp. 361 ff.

[15] Harvard University applied for a patent on a genetically modified mouse, which was granted 4 years later, causing a big bang of controversy which soon reached the shores of Europe and whose ripples are still very much in evidence. For this was the first time it was officially decreed that an animal could indeed be classed as an invention. Moreover, it was a mouse specifically engineered to have an increased probability of suffering malignant tumors - for use as a "model" for studying human cancers and carcinogens.

[16] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Article 27, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 1994, 22 *International Legal Materials*, 81, 94, 1994.

[17] 144 countries as of 1 January 2002.

[18] *United Nations Convention on the Law of the Sea*, December 10, 1982, U.N. Doc. A/Conf.62/122, U.N. Sales No. E.83.V.,5 1983, reprinted in 21 *International Legal Materials,*1261. See also *Convention on the Continental Shelf*,

evolution of the continental shelf, exclusive economic zone and the phenomenon of the "State's creeping jurisdiction" during the last 50 years[19]. This has been due to the invention of the combustion engine, other uses of oil and gas and mineral and the advancement of fishing technology. However, the first difference between international conventions on the allocation of sea zones and international protection of IPRs on biotechnology inventions is that the first concern mainly the rights of the State whereas the second concerns essentially private rights. A second difference, and a more complex one, is that the first kind of conventions deals with physical features of natural resources (land, airspace, fish, gas, oil), whereas IPRs deal with appropriation of ubiquitous information: in our case, genetically encoded, exclusive in nature and untouched by man.

The expansion of IPRs to living matter has to be interpreted also in light of a basic structural economic problem. If traditionally States assured the development of biodiversity, such as for plant varieties, governments no longer can take it for granted that their work will be financed by the tax-payer. Liberalism, which generally fosters privatization, handicaps the freedom of the decision making power of governments which have transferred it to profit driven private companies. The repercussion on the international law-making within institutions, such as WTO, have been evident to all: since the scope of IPR protection to be granted to specific subject-matters is one of the most important forms of revenue for companies, they were the ones who strongly encouraged their States to include TRIPS into WTO Agreements so to assure the respect of their IPRs also in all developing countries willing to become Members of WTO. And IPRs on living matter are no exception to this trend.

A dreadful paradox is hardly to be concealed by the glamour of the numerous patented genetic manipulations: while we experience this transformation of the international economic structures, the world is undergoing an unprecedented loss of biodiversity: one hundred species become extinct every day, alarmingly more than the creation of new species. And this *"biocide"* (neologism that stands for the “biological extermination”) is accomplished under our very eyes, at the same time that farmers, scientists and consumers in developing countries argue that a few transnational corporations will eventually control the world's food supply because of the disparity of means of research. Indeed biotechnology today is substantially driven by private company research which will be critical in achieving the future food security. And again the incentive for biotechnological inventions is stimulated by a financial investment that flows only if such an invention is protected by an appropriate kind of IPR.

D. Striking a Balance between Interests of Intellectual Property Right Holders and Indigenous Communities

The alleged incompatibility between TRIPS and CBD resides at the crossroad of stark contrasts of perspectives opposing, schematically said, North and South. The debate over IPRs on biological resources and international trade is embedded in a broad context with so many intertwined aspects and competing interests that it becomes somewhat confusing even to choose the approaches to study the same. The complexity of this debate is accompanied by its high-paced intensity to the extent that it is argued that the equation of North and South also opposes "haves" and “have-nots"[20]. As for us, we wish to go beyond this recurrent objection to the exercise of IPRs

---

1958, UNTS, 1964, pp.312-321. *Convention on the Fishery and the Conservation of Biological Resources in the High Seas*, 1958, in UNTS, 1966, pp. 280-296.

[19] See COTTIER Th., “The Protection of Genetic Resources”, *op. cit.*, p. 1823.

[20] BADIMBOLI ATIBASAY J.F., “The International Legal Regime for Biotechnology Patenting: an Appraisal from the Standpoint of Developing Countries”*, Revue générale de droit*, 31, 2001, p. 294.

on biotechnology by postulating solutions based on the comparative advantage that is potentially to be implemented between North and South. These solutions are primarily based on the very fact that while industrialized countries are empowered with technology able to yield important biotechnological inventions, developing countries are hugely endowed with biological diversity which is lacking in the first.

Focusing on the recent international law controversy between TRIPS and CBD particularly with regard to the sharing of benefits arising from the exercise of Intellectual Property Rights, will allow us to study out some useful solutions to be found in international IP law itself, by demonstrating how the latter can be instrumental to strike the balance between the monopoly restrictions created by IPRs and the economic expectations of the local and indigenous communities. Having chosen this clear approach, we are nevertheless aware that economic interests might not constitute either the only or the most important priority of such communities of people.

Our methodology being embedded in IP law, we need to progressively observe the main legal challenges posed by the bi-dimensional expansion of IPRs (i) from inanimate to inanimate matter and (ii) from industrialized countries to developing ones. Accordingly, in Part I, we will outline the question of patentability of biotechnological inventions. Since the burning issue of the alleged inconsistencies arising from TRIPS and CBD coexist with the lack of adequate ethical and the scarcity of environmental considerations in domestic and regional IP systems in industrialized countries, we will not overlook the approaches adopted by US and European administrative and judicial bodies towards CBD principles in their decisions on the patentability subject-matter of biotechnological inventions.

In chapter III, we will seek to highlight an underlying paradox: through the adoption of Article 27 of TRIPS Agreement, Northern countries have embarked on a rapid and spectacular race to engage Southern countries in international obligations on IP protection for biotechnology when they themselves are yet to set and define clear guidelines within their own IP systems in order to assure protection of biodiversity. By referring to the major options for the revision of this article within the TRIPS Council of WTO, we want to purport an overall message of extreme caution when we deal with the delicate question of monopolized private ownership of the building blocks of life.

In Part II, we will shed light on the IP methods of redistribution of benefits in the international trade context by using the allocative efficiency principles. To do so, we need to explore the proposals that have been put forward by governments at the relevant fora, by the international legal doctrine and by NGO sponsored studies in order to make the IP system more supportive of the CBD's benefit sharing provisions.

At this juncture, we will move into the more delicate issue of the applicability of certain TRIPS provisions precisely in light of the local and indigenous people needs and expectations. Chapter IV will be dedicated to the creation in developing countries of an "effective *sui generis* system" for plant varieties, in compliance with Article 27.3(b) of TRIPS. Matching this obligation with the exigency of defending "farmers' rights" will require stretching our range of observation to institutional mechanisms based upon the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty) and the institutional mechanism based upon UPOV the Convention.

After having verified, in chapter V, how contractual practice has been contributing to the objective of equitable benefit sharing arising from utilization of genetic resources and related TK, in chapter VI, we will delve into the efforts made by various UN Specialized Agencies, and primarily by WIPO, to effectively protect biodiversity related TK in the IP system. This protection can be attainable through existing IPRs such as low-cost patents, trademarks, trade-secrets and geographical indications, but also by shaping a new and *sui generis* IPR after registration of TK subject-matters in a database.

TK databases will also be crucial in improving the quality of the prior art international searches. Patent Offices should indeed undertake such international searches more seriously because they might result in patents based on an ambiguous appropriation of TK, that, if it is proven to constitute prior art, such patent application would be rejected on the ground that the novelty requirement is not satisfied. Biopiracy can also be prevented through the implementation of the *"prior informed consent"* (PIC) obligation under the CBD, i.e. the duty of bioprospecting companies to negotiate an agreement with the provider country concerning the conditions of genetic resources' utilization. PIC implementation can occur through the introduction of disclosure requirements and certification about the genetic resources issued by the country of origin during the application procedure at the Patent Office of the recipient State. Apparently a simple requirement, the submission of certificates of origin is surrounded by difficulties and inconsistent interpretations both within WIPO and in the EU.

The final part of this chapter will be dedicated to the discussion of the feasibility of some of the proposed measures and different types of exceptions (i.e. compulsory licences, international exhaustion and exceptions to exclusive rights on the ground of public health) to adapt the patent system required by TRIPS according to the needs and interests of developing countries, that are presently under time pressure to incorporate TRIPS in their national legislation.

PART I INTELLECTUAL PROPERTY AND BIODIVERSITY

II. PATENTABILITY OF BIOTECHNOLOGY IN THE UNITED STATES AND EUROPE[21]

[21] This chapter is mainly drawn from O. ACHIMUGU, J. CURCI STAFFLER and A. KHAN, "Patentability of Animal Life: Regional Current Practices and Legal Challenges on the International Level" published in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001. I especially thank the contribution made by Ojochide Achimugu.

Before entering into the merits of the relationship between TRIPS and CBD, it is expedient, in this opening chapter, to observe how biotechnological inventions have achieved patentability. When it comes to biotechnology, we cannot avoid facing the challenge under which animate or living matters cannot be patented simply because they exist in nature and any modification thereof amounts to a discovery and not to a patentable invention. Originally reposing on a rather shaky conceptual distinction between "discovery" and "invention", patenting biotechnological inventions has become a consolidated practice the economic reason for which industrialized society has eagerly extended the realm of patent over animate things as well[22].

The patentability of life forms, which meanwhile has spurred an imitation effect from the US to EU and to other industrialized countries, has also been withstood by a second objection that has been forcefully raised by opponents and skeptics arguing that the granting of patents on new life forms may run the risk of benefiting inventions which jeopardize the principles of life ethics and of the environment. While this argument may stop short of proposing that patentability of life forms should be *per se* excluded, its advocates generally call for an increased amount of caution in the procedure which leads to biotech-patenting and in the standards employed in it.

A. Distinguishing between the Concepts of Invention and Discovery in the United States Patent System

In the United States the protection of inventions, other than being enshrined in the constitution[23], is governed by Title 35 of the US Code section 101: "*whoever invents or discovers any new and useful process, machine, manufacture or composition or any new useful, improvement thereof may obtain a patent therefore, subject to the conditions and requirements of this title*". This title states the three technical requirements for patentability of inventions: novelty, to determine whether the invention is truly original; utility, in that it has an existing practical use[24] and non-obviousness involving the hypothetical judgement of a person with ordinary skill in the particular field. A written description setting forth the best known method so as to enable the skilled person to create and use the invention is also another requirement. The subject-matter patentability requirement most pertinent to the question before us defines subject-matter as "*any new useful process, machine, manufacture or composition of matter in any new or useful improvement thereof*". This provision is broad and general and the repetitive use of "any" illustrates the intent of Congress not to place restrictions on subject-matter for which a patent may be sought[25].

In the landmark decision of *Diamond v. Chakrabarty*[26] the US Supreme Court articulated a broad standard for subject-matter patentability holding that living organisms could be patented.

---

[22] DUTFIELD G. (in press), *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Aldershot, Ashgate; see also BOZICEVIC K., "Distinguishing 'products of nature' from products derived from nature", *Journal of the Patent and Trademark Office Society,* 69, 8, 1987, pp. 422-423.

[23] *Article* 1 section 8(8) of the US Constitution establishes the basis for the protection of the invention in the US and stipulates: *"to promote the Progress of Science and useful Arts by securing limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries".* The term "Discoveries" has been interpreted to refer to actual inventions requiring human innovation of some kind; *State Street Bank and Trust Co v. Signature Financial Cup Inc*. 47 USPQ.2d.1596, 1000 Fed/Circ. 1998.

[24] See *Brenner v. Manson* 148 U.S.P.Q. 698, 1966. The US Supreme Court stated: "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion".

[25] See *State Street bank and Trust Co v. Signature Financial Cup Inc*., 47 USPQ.2d.1596, 1000 Fed/Circ. 1998.

[26] *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty,* Supreme Court of the United States, 447 U.S. 303; 1980 U.S. LEXIS 112 (1980), in ABBOTT, op. cit., p. 29.

The Court took a rather liberal approach acknowledging that Congress intended the statutory patentable subject-matter include "*anything under the sun that is made by man"* thus encompassing both foreseeable and unforeseeable subject-matter. Such standard encompasses much inventive work of biotechnology and gene sequences. It need only be the product of human ingenuity and not "laws of nature, natural phenomena and abstract ideas"[27]. Objects which exist in nature are *per se* unpatentable because of the absence of some significant human intervention. The reason being that an object existing in nature is a *discovery* and not an *invention*, especially as it is already in the public "storehouse" of knowledge. Moreover, protection seeks to reward meaningful technological advance. The Supreme Court in *Diamond v. Charkrabarty* thus distinguished between human made inventions and "products of nature", so that an inventive process, machine a composition of matter employing a law of nature, natural phenomena or an abstract idea is considered patentable subject-matter even though a law of nature, natural phenomenon or abstract idea would not by itself be entitled to such protection. Provided of course that the invention produces a "useful, concrete, tangible result"[28].

Biotechnological inventions fall within this scope, since, in the above case, it was held that where genetic engineering results in novel life forms, they do not occur in nature, and thus are eligible for patent protection as new and useful, manufactures or compositions of matter. Genes or DNA sequences, processes, peptides and other material derived by living organisms and humans are such, thus identification of same is also not considered a discovery.

In the case of *Amgen Inc v. Chunghai Pharmaceutical*[29] the US Court of Appeals for the Federal Circuit indicated that genes and gene sequences were patentable. The liberal attitude toward the grant of biotechnology patents can also be seen in the grant of a patent to cover a transgenic mouse[30]. With respect to plants *Ex parte Hibberd*[31] shows that though plants are patented under the Plant Patent Act and the Plant Variety Protection Act, the Board of Appeals held that plant seeds and tissue cultures may still constitute patentable subject-matter, thus man-made life forms were patentable. In *Ex parte Allen*[32] non-naturally occurring non-human multicellular organisms and animals were also held to be patentable. Again, in *Moore v. Regents of the University of California*[33] human cell-lines were patented without the majority opinion ever reaching an ethical analysis. We can thus conclude by saying that in the US there is a consolidated practical experience of patentability of biotechnology.

Finally, if a substance found in nature is first isolated from its surrounding and a process for obtaining it is developed, that process is patentable. This process should characterise a substance by its structure that, in turn, should be “new” in the absolute sense of having no previously recognised existence. This has also become the patentability standard of EPC.

B. The European Approach to Patentable Biotechnological Subject-Matter in the European Patent Convention of 1973

[27] *Diamond v. Chakrabarty, op. cit.*; *State Street Bank*, *op. cit.*.
[28] *State Street Bank, op. cit*.
[29] 18 U.S.P.Q. 2d 1016, (Fed. Cir. 1991).
[30] *Harvard Onco-mouse,* 447 US p. 307.
[31] 227 U.S.P.Q.443, pp. 444 – 448.
[32] 2 U.S.P.Q. 2d 1425, 1427.
[33] 793 P. 2d. 479, 1991.

In addition to the national route for obtaining patents, there is also the European route, namely the European Patent Convention (EPC) established in 1973[34] granting regional patents coexisting with national patent rights in each contracting State. The key provision on patentability, Article 53, stipulates that patents are to be granted for any invention which is new, involves an inventive step (non-obviousness) and which is susceptible of industrial application (utility)[35].

Unlike US law, which identifies classifications that are patentable (i.e. process, machine, manufacture or composition of matter) the EPC does not provide a definitive, positive definition of classes of patentable inventions. In view of this, Article 53 explicitly stipulates the exceptions. It has to be considered as a basic principle that all technological innovations meeting the necessary requirements are patentable and as a result all the exceptions are construed narrowly.

The exceptions of Articles 52 and 53 of interest in the present context are: (i) inventions the exploitation of which is contrary to public order and morality; (ii) plant and animal varieties and essentially biological processes for the production of plants and animals; and (iii) discoveries.

The first applies to all fields of technology. As regards the second exception, the purpose was to avoid double protection of plant varieties as stipulated under the UPOV Convention[36]. The EPC however recognized the need for protection of micro-organisms and thus provided that micro-biological processes and products thereof are patentable. Whilst the US permitted subject-matter patenting with no concept of "essentially biological process" as being outside the remit of patent law, Europe created a dichotomy which is difficult to apply stemming from the preconceived idea of separating patent law from plant variety protection[37]. Indeed the fuzziness of this distinction between parts of biology was not of much practical concern until the (impact of plant) biotechnology impinged on the scene.

According to Article 53(b) of the EPC, essentially biological processes and products thereof were not patentable, regardless of whether produced by traditional breeding or genetic engineering[38]. With the advent of recombinant gene technology, problems of patenting this type of invention arose. Innovations in this field, not being limited to specific plant varieties, increased the need for patent protection as opposed to inadequate plant variety protection. Thus the European Patent Office had to consider their patentability holding that plants in general were not excluded from patentability[39]. Several years later a similar development occurred with animals and the

[34]The Community Patent Convention with aim of a centralized enforcement mechanism is yet to be ratified by all members of the European Union.

[35] In this respect, EU and US law both have expansive language and practices or tests defining the limits or extent of patentability requirements outside the scope of this study.

[36] It is not clear why animal varieties were included.

[37] The legal line drawn between microbiological and high biological for plants and animals is traceable to the Strasbourg Convention of 1963.

[38] The US patent law has always been more flexible thus breeding methods and products were patentable.

[39] *Onco-Mouse/Harvard II*, Technical Board of Appeal 3.3.2., 2 October, n. T 19/90, O.J.E.P.O., 1990. The Examining Division had initially held that the subject-matter of Harvard's patent application was non-statutory subject-matter and exempted from patentability by Article 53(b). The Headnote I on the Examining Division's decision reads as follows: "Article 53(b) EPC excludes patent protection of animals per se in general and not only if a particular variety is claimed".
The decision was later set aside by the Technical Board of Appeal reasoning that the "possibility that the reference to certain categories of animals rather than to animals as such was simply a mistake by the legislator can be ruled out". Furthermore, the Board stated that the EPO should provide "a proper balance between the interest of inventors in obtaining reasonable patent protection for their efforts and society's interest in excluding certain categories or animals from patent protection" and that it must be borne in mind that for animals, unlike plant varieties, no other industrial

Harvard *Onco-mouse* case confirmed the decision on the plant cases and thus established the legal principle under the EPC that animals in general could be patented but not "animal varieties".

C. The European Union Biotechnology Directive of 1998 and the Imitation Effect

In order to address the volatile issue of the patentability of biotechnology-related inventions and of patenting biological substances, the EU has also set out to regulate the area with the promulgation of the EU Directive on the Legal Protection of Biotechnological Inventions[40] whose main impact lies in its generally favorable approach towards patent protection[41]. The Directive upgrades the EU law to US and Japanese standards in that the basic principle underlying it is that no invention shall be refused patent protection on the sole ground that living matter is involved.

This trend is the consequence of an "imitation effect", borrowing an effective expression by Ricolfi. The principal economic players see their comparative advantage in striving for strong IP protection so as to maintain investment in their national economies. The principal goal of the patent system in the three most developed patent jurisdictions of Europe, US and Japan is not only to encourage the development of science and technology but ultimately to defend or expand their national industries and thus protect their economic growth[42]. We will later observe how the patent provisions of TRIPS allow this policy agenda which is reflected in the national practices of their patent system. Among industrialized countries, the “imitation effect” occurs when one actor strengthens its patent protection and others follow suit by integrating stronger standards of IP protection and widening the patentable subject-matter[43].

The Directive 98/44/EC on the Legal Protection of Biotechnological inventions is a clear example of this imitation effect as it seeks to upgrade EU law to US and Japanese standards. The recitals 1-5 of same emphasize that protection of biotechnological inventions of high risk investment require legal protection for investment, productivity and industrial development. Australia is also moving in the same direction as the United States in making no discrimination as to new technologies. It has for instance granted patent for a transgenic pig without discussing the ethical grounds or environmental consequences, social, ecological or political impact of same. The reason again, according to Blakeney, being to restructure Australia’s primary produce dependent economy to a higher technology country, the economic considerations being paramount.

Though the exclusion of "essentially biological process" is not mentioned in the Directive, it anticipates that such process is patentable if it does more than selecting available biological material and letting it perform inherent biological functions in natural conditions. Indeed, the result is that very broad patent protection is available for natural products/biological material.

---

property right was available. Finally, as we will see later, the EPO came to the conclusion that the exclusive provisions of Article 53(a) and (b) must be subjected to extremely narrow interpretation and that neither plants nor animals were generally excluded from patent protection.

[40] Directive 98/44/EC of the European Parliament on the Council of 6 July 1998, in O.J.L. 213, 1998.

[41] The purpose of Biotechnology Directive to provide minimum harmonized standard of Intellectual Property Protection for biotechnological inventions.

[42] Technology importers tend to favour low-level discriminating regimes whilst technology exporters favor high level non-discriminatory regimes, SUBRAMANIAM A., "The International Economics of Intellectual Property Rights Protection: A welfare-theoretic Trade Policy Analysis", in *World Development Journal*, 1991, pp. 1945-56.

[43] RAY BARELL and NIGLE PAN, "Foreign Direct Investment, Technological Change and Economic Growth within Europe", *The Economic Journal*, 107, 1997, pp. 1170-1786.

Article 3(1) states : "*for purposes of this directive, inventions which are new, involve an inventive step and which are susceptible even if they concern a product consisting of and containing biological material or a process by means of which biological material is produced processed or used*". *"Biological material*" is defined as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

In fact Article 3(2) permits "*biological material isolated from its natural environment in purified form or produced by means of a technical process*" to be patented even if the material previously existed in nature. Such invention is considered novel[44]. This provision relating to the isolation and synthetic production of naturally occurring substances is of vital importance. The differentiation between patentable inventions and mere discoveries is an elementary feature of all regimes of patent law (see also Article 27(1) TRIPS). Clearly, the Directive rejects the established philosophy that argues that isolation of such materials represents a discovery since the product already existed and that the mere characteristic of being isolated from its environment does not change the "naturalness" of the element or its purification. Accordingly, it is common to all types of opponents to patenting living matter to maintain that natural elements can only be discovered not invented, even if their discovery fulfils patent requirements, i.e. even if they fulfill the requirement of utility or industrial application, they should still remain unpatentable.

In spite of this rather minority position, inventions concerning plants and animals are considered patentable under Article 4(2) of the EU Directive if the technical feasibility of the invention is not confined to a particular plant or animal variety. As such, processes for arriving at plant or animal variety may be patentable, in this sense[45].

The protection of new plant and animal varieties has traditionally been ensured not under patent laws but rather through the operation of *sui generis* systems, due to the fact that these products do not typically satisfy the requirements of patents such as novelty, inventive step and industrial application. Yet breeders need to be protected. Notwithstanding the consolidation of this practice, many question whether it is appropriate to limit access of the community to a resource of such great importance, through a monopolistic restriction[46].

Finally, as regards the human body, explicit exceptions are provided on moral grounds for the patentability of same and the simple discovery of one of its elements including the sequence or partial sequence of a gene as it naturally exists in the body; however exception is limited in that if an element is isolated from the human body or otherwise produced by means of a "technical process" it may be patentable even if identical to a natural element of the human body. As a result, under certain circumstances, elements of the human body may also be considered patentable[47].

---

[44] SPRANGER, "Ethical aspects of Patenting Human Genotypes According to EC Biotechnology Directive", in *International Review of Industrial Property and Copyright Law,* 31, 2001, pp. 373, 378.

[45] SCOTT A., "Dutch Challenge to Biotechnology Patent Directive*",* in *European Journal of Intellectual Property,* 212, 1999. See also Opinion Advocate General Jacobs delivered on 14 June 2001, *Kingdom of the Netherlands v. European Parliament and Council of the European Union Case*, Case C-377/98.

[46] LLEWELYN M. "The legal Protection of Biotechnology Inventions : An Alternative Approach", in *European Intellectual Property Review*, 1997, pp. 115-17.

[47] See Recital 26 of the EU Directive says *"whereas, if an invention is based on biological material of human origin or if it uses such a 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".* This Recital takes place of a rejected amendment (proposing the insertion, in this case, of a second paragraph of Article 8-*bis*) and was introduced at the eleventh hour to obtain Denmark's favourable vote in the Council.

D. Some Ethical and Environmental Challenges in the United States and European Case Law on Biotechnological Patents

To begin with, we have to note that there is no express statutory requirement concerning morality in US Patent law[48]. There seems to be no ethical safeguards, the important ethical values being left unaddressed by US Patent law in this field. Indeed, in the case of *Moore*[49] a patent application was filed claiming a technique combining human and animal embryo cell to produce a single two specied embryo, theoretically to be implanted in a human animal surrogate mother to develop into a chimera. The US Patent Office rejected the Chimera patent application for failing to recite statutory subject-matter, including enablement and best mode of disclosure requirements and for anticipation but, rather surprisingly, not for lack of moral utility. Once the utility requirement is satisfied in that at least one scientifically plausible use is provided, the patent will be issued. The Chimera applicants could easily have demonstrated that they will produce transplantable organs to satisfy the utility requirement. This case law clearly suggests that there is more concern for economic and policy considerations, particularly in view of the free market capitalist philosophy.

It has been argued that US law has an implicit ethical component in that in determining inventions (i.e. examining the utility of an intervention), the patent examiner or the Court is required to make subjective determination of what society considers useful and that any such subjective analysis reflects morals, ethics and cultural influences as perceived by the decision maker[50]. Officially however, the attitude of the US is that the patent system is not the appropriate vehicle for regulating the use of particular technologies on ethical grounds or the place to exercise moral judgments about scientific activity[51]. Such conclusion on the question of morality is reached in light of the research which precedes the invention. It is the research that leads to an invention and it is the subsequent application that leads to the grant or refusal of a patent. In Article 53 of the EPC, the morality of doing research does not enter into the equation at all. But on general moral reasoning, it would be possible to argue that if the research is morally objectionable then to benefit from the grant of a legally protected position for example, would also be unacceptable. Hence, biological scientists on the whole might be uncomfortable with the idea of research being immoral. So far, there is no test case comparable to the *Onco-mouse* case bearing on transgenic farm animals.

In considering the ethical questions in connection with patentability, unlike in the US, Article 53(a) of EPC explicitly provides in part that European Patents shall not be granted in respect "*of inventions the publication or exploitation of which would be contrary to* ordre public *or merely because it is prohibited by law or regulation in some or all of the contracting States ".*

---

[48] The US Patent Office issued guidelines in 1995 making no mention of public policy or morality based issues. See MANGANI Th. A, "Chimeras: The Patentability of Human-Animal Chimeras", 14 *Berkeley Technology Law Journal*, 445, 1999.

[49] *Ibidem.*

[50] According to US Case law, as we have seen, one could question whether this is really the case in practice. It has also been further argued that ethical analysis is embedded in US law in that the subject-matter patentability requires moral analysis of what society understands to be its collective and therefore unpatentable possession so that though it is not specifically listed in the legal patentability determination, it still exerts a strong or subtle influence on the decision process in the US.

[51] See *US Commissioner for Patents Bruce Lehman*, Utility Examination Guidelines, 60 Fed. Reg. 26,263, 1995. For further research in this area see MERGES R. P., MENELL P. S., LEMLEY M. A., *Intellectual Property in the New Technological Age*, Aspen, Gaithesburg, New York, 2000.

Indeed the question is not whether the patenting itself is ethical or not but whether the exploitation of the invention is objectionable. The moral permissibility of this kind of technology or invention as such is not at stake in Article 53(a) of the EPC but the exploitation of it is. The question is thus whether the making or the use of the invented product would be contrary to *ordre public* or morality. In this respect, the Guidelines of the EPO merely explain that the purpose of same is to exclude inventions likely to induce riot or public disorder and thus cites the infamous case of the letter bomb and indicating that *Article 53(a)* is to be invoked in rare cases. In reality this safeguard therefore offers very little protection, as the ethical analysis may not be exercised quite as diligently as the regulation suggests[52].

The EPO is progressively developing its position on the subject of morality and *ordre public* with respect to biotechnology-related inventions through a certain number of disputed patent applications. Formal opposition proceedings on specific patents have provided and continue to provide occasions for the EPO Opposition Division and Appeals Boards to interpret *Article 53(a)* with reference to biotechnological inventions. We can say that the starting point for an analysis of the concept of morality and *ordre public* is represented by the decision of the Board of Appeal in the *Onco-mouse* case[53].

---

[52] The deficiency in case law makes it difficult to explore ethics as an explicit preclusion to biotechnology patentability in the EU.

[53] In the first instance of *Onco-Mouse*, the Examining Division alluded to the moral question in a very restrictive interpretation of the notion of *ordre public* of Article 53(a). According to the Examining Division, possible environmental harms arising from inventions within the competence of national jurisdictions; the patent is to be considered as a neutral instrument with respect to regulation of environmental risks coming from the commercialization of transgenic organisms. This purely technical vision of the role of EPO is based on the legal ground of the inherent right of the inventor to be protected by the very act of his invention. An opposite conception maintains that the patent system should serve the public policy as a "social and moral filter", see in this sense BEYVELD D. and BROWNSWORD R., *Mice, Morality, and Patents*, London, 1993, pp. 33-46.

In the formal *Opposition* started by certain special interest groups against the Harvard Onco-mouse patent, the primary moral question was whether the potential benefit to cancer research justifies the use of animals genetically engineered to possess increased sensitivity to carcinogens (the Biotech-Directive, by Article 6.2(d), denies patents for *"processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medicinal benefit to man or animal, and also animals resulting from such processes)*. Moreover, objections to the patentability of such an invention might raise in relation with Article 53(a) on the ground that the release of genetically manipulated animals in the environment might entail irreversible adverse effects and cause animal suffering (Onco-Mouse/Harvard II, Technical Board of Appeal 3.3.2., 2 October, n. T 19/90, O.J.E.P.O., 1990, p. 476, para. 5).

In this groundbreaking case the question of environmental protection is intertwined with the one of the rights of animals. It was the Board of Appeal that gave guidelines for considering morality in remitting the case back and ordering that the positive and negative aspects be determined with respect to patentability. In the Board's view, patentability depends on the careful "*weighing up*" of suffering of animals and the possible risks to the environment on one hand and the usefulness of the invention on the other (Onco-Mouse/Harvard III, para 4(iv). The origin of the cost-benefit balancing test can have several application in international environmental law, see NOLLKAEMPER, "What you risk reveals what you value" and Other Dilemmas Encountered in the Legal Assaults on Risks", *The Precautionary Principle an International Law,* Freestone and Hey, The Hague, 1996, p. 1009-1016). The Board concluded that the patenting of animals is not intrinsically unethical but may rather be regarded as morally acceptable provided that the balancing exercise leads to a positive result. In this respect the Examining Division, after carrying out the balancing exercise/cost-benefit analysis, concluded that the low risk connected to handling the animal and the reduction of animal testing/suffering was important enough for humanity to justify patenting.

As regards the possible risk to the environment, the Division considered the purpose of the invention, i.e. to provide animal test models, were to be used exclusively in the laboratory under controlled conditions by qualified staff and that no release into the environment was intended. The Division stated : "the mere fact that such uncontrollable acts are conceivable cannot be a major determinant for deciding whether a patent should be granted or not. Exclusion from patentability cannot be justified merely because technology is dangerous. The regulation of handling dangerous material is not the task of the European Patent office but is rather the business of specialized governmental authorities".

E. Is the Traditional Patent System Valid for Biotechnological Inventions?

The patent system has been used as an instrument of economic policy in providing an incentive for people to invest and innovate[54]. Cornish also argues that one of the theories behind the patent system is to provide a centralized information gathering system so that other inventors can gather new ideas to develop future inventions[55]. Empirical research suggests that the effect of the patent system on the rate of technological progress is ambiguous and differs from industry to industry in that patents can be invented around.[56] In the field of biotechnology, it has been seen that patenting does have an overall effect on stimulating biotechnological research and development[57]. Biotechnology industries seek to secure very broad claims to be of practical advantage. Innovation is rapid but competition is fierce. Hence the search for over-monopolistic protection for genetic material. Though it is generally recognized that the innovators deserve reward for their efforts and therefore an effective protection, it has not been universally accepted that the patent system is the best means of obtaining that protection. The patent system not having been designed to protect animate material, other methods, especially *sui generis* systems, exist so as to take into consideration the needs of producers and users.

For many, the legitimacy of patent law is based on the idea that it operates in a neutral way without discrimination or prejudice to reward and stimulate research. It is thus a paradox that one of the results of the interaction between patents and biotechnology is that it emphasizes the mistaken belief of those who advocate the neutrality of the system. By asking patent law to evaluate or assess biotechnological inventions, ethics also indirectly calls into question the status of

---

Some arguments are moved in the doctrine against the application *sic et simpliciter* of the cost-benefit analysis in disputes concerning biotechnology patents. Firstly, the subordination of the protection of the environment to international commerce means the subordination of invaluable or priceless elements of the environment to the commerce of simple products. GALLOUX would have been more satisfied in accepting the adoption of decision less favourable to the environment instead of avoiding the environmental issues and hiding behind this cost-benefit analysis, "Ethique et brevet ou le syndrome bioéthique", in *Recueil Dalloz Sirey*, 1993, p. 83 and pp. 87-88). Secondly, the evaluation method of the "cost-benefit analysis" constitutes a foreign element to those conceived for the patentability not foreseen in Article 53. Thirdly, there is no international *opinio juris* sufficiently affirmed in other international judicial institutions to achieve the status of a principle of international law. Finally its nature is eminently economical and not juridical.

Finally, the *raison d'être* of the cost-benefits analysis implies a price to be paid in terms of potential harms to the environment if we are to enjoy the benefits of new technology; for instance "if we want to enjoy the benefits of nuclear power we have to put up with the occasional Chernobyl", BEYVELD D. and BROWNSWORD R., *op. cit.* p. 110. It must be noted, however, that, according to these critics, the alternative to this pseudo-juridical method of decision is a genuine cost-benefits test of moral nature, which is consequently exclusively political or at least less juridical than the first.

[54] MAZZOLENI R. and NELSON R., "Economic Theories about the Benefits and Costs of Patents", in XXXII *Journal of Economic Issues*, 1998, 1031.

[55] CORNISH W.R., *Intellectual Property - Patents , Trademarks, Copyrights and Allied Rights*, London Sweet and Maxwell, 1999. See also BEIER F.-K., "The Patent System and its information Function – Yesterday and Today", in *Industrial Property Copyright Journal,* 8, 1977, p. 387.

[56] MOKYR B., *The Level of Riches: Technological Creativity and Economic Progress*, Oxford University Press, 1990, p. 247. Broad claiming has been criticised in the biotechnology field. See CRESPI R., "Biotechnology, broad claims and the EPC", *European Intellectual Property Review,* 1995, p. 267.

[57] VAN den GRAAF E.S., *Patent Law and Biotechnology , A Comparative Study about the Requirements and Scope of Protection,* Gouda Quinta, p. 427.

all inventions and thus of the patent system itself. As Lord Hoffman has stated[58] the nature of patent law's "specialized epistemology" has to be determined and redefined. From current judicial decision and administrative practices, the trends, we observe, lean toward the reduction of traditional patent law requirements especially that of "inventive step" and that of "non-obviousness"[59].

Indeed, the debate spawned by the development of genetic engineering and the attempts to patent products of such research, and particularly the globalization of patent law, have highlighted the political, cultural and economic nature of patent law itself, as we further examine in Part II.

In Europe, we must regrettably observe that the patent system is technocentric and not ecocentric, any ecological or environmental value being placed almost outside it. This trend has been recently observed in the *Plant Genetic Systems Case* (*PGS)*[60] - a landmark case for patent applications in the field of plant genetic engineering whose findings have similar consequences for transgenic animal inventions[61] - where the Board concluded that all claims of the main request fulfill the requirements of *Article 53(a)* EPC and thus set the standard high in holding that the alleged damage to the environment was unproved, i.e. all the evidence pointed to the *"mere possibility"* of environmental damage and was therefore insufficient to deny patentability. As the opinion of Advocate General Jacobs states in the *Kingdom of the Netherlands v. European Parliament and Council of the European Union Case*, the concept of *ordre public* in Article 6.1 of the European Directive on Biotechnological Inventions includes "a sufficiently serious threat to the environment" which is a clear concept and which does not impair legal certainty and further endorsed the concepts as explained in *PGS* case[62]. From the difficulties, very briefly explored,

---

[58] *Merriele Dow Pharmaceuticals v. Norton and Co,* (1995) 33, IPR 1. See also SHERMAN and BENTLEY, *op. cit.,* pp. 124-125.

[59] See Lord Hoffman, in *Biogen and Medeva PLC,* 1997, R.P.C. 1, in Abbott F., Cottier Th. and Gurry F., *op. cit.*, Part I, Kluwer Law International, 1999, pp. 42-64. As stated above, a detailed examination of the requirements of patentability falls outside the scope of this study. For a thorough study on this issue see VAN den GRAAF E.S., *op. cit.* Decision T356/93. *Plant cells / Plant Genetic Systems* OJ EPO 1995545.

[61] Greenpeace, after having seen immediately rejected its first objection stating that granting a patent for a superior form of life was intrinsically immoral (see paragraphs 3.4 and 3.10), started the proceedings against PGS with the hope that the Opposition Division, through its cost-benefit analysis, would come to different conclusions from those of Onco-Mouse, by revoking the patent in favour of the preservation of the biological diversity given the potential ecological risks. The Opposition Division declared that an objective attempt can at least be made to consider the merits of this argument by trying to assess the potential risks associated with the present invention. Notwithstanding the positive expectations of Greenpeace, the balancing exercise made by the Board has revealed quite disappointing. Indeed the Opposition stated that Greenpeance failed to convince the Board by submitting scientific data about the eventual ecological harms caused by transgenic plants (see paragraphs 3.12 and 3.13). The lack of scientific certainty is the reason why the Opposition Division "does not see any possibility of determinant the morality of the invention on the basis of what amounts to risk/benefits assessment", paragraph 3.16. The arguments further developed by the Board of Appeal confirm that the environmental threat has not been "sufficiently substantiated" by the appealing party (PGS II, paragraph 5). The reasoning of the Opposition Division is supported by the Board of Appeal in that the scientific evidences on the possibility of harm caused by the exploitation of herbicide resistant plants is not sufficient to revoke a patent. It follows that it is not even necessary to make a cost-benefits analysis since the real existence of the alleged costs has not been proved, paragraph 18.8. The principle to learn from this decision is that where the scientific data are controversial and provoke uncertainties, the EPO decides that a biotech application can be patentable. Despite the researches along several years undertaken to prove the potential risks of genetically modified organisms, it is the scientific uncertainty that justifies the granting of patents to biotechnological inventions : "there is still no agreement concerning the extent of these risks and the Opponent has indeed conceded that the risks are impossible to determine with certainty. Scientific expertise thus does not provide a sufficient basis to conclude that the risks… preclude any application of this technology" PGS I, *cit.*, paragraph 3.13.

[62] *Opinion of Advocate General Jacobs, op. cit.* 37, paragraph 109.

inherent in the structure of the patent system itself, the problem of precise definition of the various categories of biological materials for purposes of exclusion[63] or otherwise and the wide concepts of *ordre public* and morality, it is evident that the national and regional law provides unclear definitions and loopholes. Thus one can question whether traditional patent law is the appropriate science to apply to various issues involved. Or at least we can wonder whether it is the right IPR. It is precisely because the patent system was originally not designed to protect living matter and still it has being used in this respect, that it has met with much criticism.

III. RELATIONS BETWEEN INTELLECTUAL PROPERTY RIGHTS ON BIOTECHNOLOGY AND PROTECTION OF BIODIVERSITY

The patentability of life forms and many delicate issues thereunder, remaining unresolved in fairly similar industrialized systems of IP protection such as US and EU, have recently irrupted in the fragile balance of international commercial relations between North and South. Before embarking on the examination of the question of benefit sharing arising from the exercise of IPRs, we need to give an overall explanation of the alleged major tensions existing between TRIPS Agreement and the CBD.

A. Globalization of Patentability of Life Forms through the TRIPS Agreement

In the last round of GATT negotiations, which gave rise to the establishment of the WTO, the absence of strong IPRs had emerged as a third generation of trade barriers, after the generations of tariff and non-tariff measures. TRIPS was thus directed to bring developing countries to the level of IP laws, particularly under the pressure of transnational trading groups in developing countries who suffered a considerable loss in royalties by the absence of this protection. Therefore TRIPS was an initiative of an international business coalition consisting of mainly European, Japanese and US multinationals[64] who saw the IP issue as exclusively an investment issue. These interest groups under the leadership of the US pursued three broad objectives. Firstly, the globalization of IP protection by the adoption mainly in developing countries of IP laws. Secondly, the start of a process of harmonizing IP laws to higher standards, thereby taking advantage of the principle of national treatment that had long been part of international IP law. Thirdly, the inclusion of TRIPS in WTO would ensure that States took their international obligations seriously through the advantage of the enforcement mechanism and dispute settlement procedure[65].

After being outvoted in fora such as WIPO and UNESCO by a coalition of developing countries, the US undertook a strategy of shifting the issue of IP into the GATT, consequently catching the train of the Uruguay Round to fit it into WTO Treaties. It goes without saying that abovementioned goals on IP are more likely to be achieved in WTO. This operation was largely successful since the US and other supporting countries could use the size of their markets: US used negotiating capabilities and the multi-bargaining dimensions of the WTO to secure outcomes for IP

[63] T 1054/96 *Transgenic Plant/Novartis* 1998/1999. For a discussion of the case see NOTT, « The Novartis Case in the EPO », *European Intellecual Property Journal*, 1, 1999, p.33.
[64] For the history see DRAHOS P., "Global Property Rights in Information: The Story of TRIPS at the GATT"' *Prometheus*, 13, 1995, pp. 6-19.
[65] For an outlook on the objectives and general principles of TRIPS see DUTFIELD G., *Intellectual Property Rights, op.cit*., pp. 14-17.

and finally dominate the agenda setting process, and thus accomplish all results which remained beyond US reach in fora like WIPO or UNESCO.

1. Article 27 and its Exceptions: Is there Any Way Out of Patenting Life?

TRIPS is the first international treaty which makes it legal – and compulsory – to patent life[66]. It requires member States to provide patent protection for all fields of technology. Paragraphs 2 and 3 of Article 27 outline which inventions member states may exclude from patent protection and under which conditions.

Article 27 of TRIPS states:

> ***Patentable Subject-matter***
>
> *1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, 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.*
>
> *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.*
>
> *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 micro-organisms, 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.*

The TRIPS Agreement offers patent protection for inventions in all areas of technology, whether products or processes, that are new, involve an inventive step, and are capable of industrial application (Article 27.1). This requirement provides the first important exception - particularly supported by the European States – namely the exclusion of inventions from patentability where it 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" (Article 27.2). According to the second exception, members are not required to grant patents on plants or animals (Article 27.3(b)). The prohibition of patents on plant and animal varieties contained in EPC has strongly influenced that

[66] The TRIPS Agreement came into force on 1 January 1995 and must be implemented by all WTO member States. It entails obligations for seven areas of IPRs available for all fields of technology. It must be implemented in developing countries by the year 2000 and in the least-developed countries by the year 2005. It is subject to the same dispute settlement procedures as other WTO agreements: failure to implement the terms of the agreement will result in trade retaliation against the offending country. A Procedure of revision of Article 27 as commenced in 1999 and 2000, see GRAIN, For a Full Review of TRIPS 27.3(b), March 2000, available at: http://www.grain.org/publications/TRIPSfeb00-en.cfm.

phrasing[67]. However, in the absence of international jurisprudence, the interpretation of this provision will be left to domestic patent law and interpretation of pertinent judicial bodies.

Article 30[68] provides the third type of limited exceptions to the exclusive rights conferred by patents, when subject to certain qualifications. Members may permit use of the patented invention by third parties without the authorization of the patent owner in certain circumstances (Article 31).

Finally, we find four possible options to implement this provision. The first would be that member countries can allow patents on any invention in biotechnology by not excluding plants, animals and biological processes; the second would consist in the option to exclude plants, animals and biological processes, but not exclude plant varieties, from patentability; the third, they have an option not to patent plant varieties, i.e. to exclude plant varieties from patentability and introduce a *sui generis* system, an IPR protection of its own kind for the protection of plant varieties. They also can choose not to exclude plant varieties from patentability and to provide in addition, *sui generis* rights, which is the double protection system. As a result, it seems to us that TRIPS obliges member States to provide some kind of IPR protection on almost all life forms.

Table 1. Patentability Subject-Matter of Article 27.3(b)[69]

WTO members must provide protection for:	**WTO Members may exclude from patent protection:**
Micro-organisms	Plants
Non-biological processes	Animals
Microbiological processes	Essentially biological processes for the production of plants or animals
Plant varieties (by an IPR system which may be patents, a *sui generis* alternative, or a combination thereof)	Plant varieties

2. Article 27.3(b): *Sui Generis* Systems for Plant Variety Protection

Article 27.3(b) currently requires all member States to protect plant varieties either by patents or by "an effective *sui generis* system", or by as combination of both. *Sui generis* identifies a law that is specially created for its purpose[70]. The WTO Secretariat has defined the difference between a patent system and a *sui generis* system saying that the latter "gives […] more flexibility to adapt to particular circumstances arising from the technical characteristics of inventions in the

[67] Provisions similar to those of the TRIPS Agreement appear in the Convention on the Grant of European Patens, Oct. 5, 1973, 1065 UNTS, 199. Interpretation of provisions relating to patent genetically engineered plants and animals have been complex with the European Patent Office. See MURPHY S., "Biotechnology and International Law", in *Harvard International Law Journal,* 42, 2001.

[68] 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".*

[69] This scheme is to be found DUTFIELD G., "Sharing the Benefits of Biodiversity: Is There a Role for the Patent System?", to be published in the *Journal of World Intellectual Property*, 2002.

[70] Another example of *sui generis* protection can be found in databases. The European Union has recently created a *sui generis* system of protection of intellectual property over electronic databases, since copyright in the area presented some weakness in the age of the Internet. See also NIJAR G. S., '*Sui generis* options: the way forward' in BIOTHAI/GRAIN (eds, 1998), Signposts to *Sui generis* Rights, p. 79. Available at http://www.iatp.org/TRIPS99.

field of plant varieties, such as novelty and disclosure"[71]. For instance, as we have seen above, the Europeans set up a system of plant breeders' rights in the 1960s. Breeders had been asking for some kind of ownership over their varieties for decades. Europeans found that the patent system was not appropriate for plants since plants reproduce themselves. Therefore they created the UPOV system – a *sui generis* system for plant varieties. UPOV stands for Union for the Protection of New Varieties of Plants[72] and it has 42 members today, mostly industrialized countries[73].

However, in Article 27, no definition of "effective *sui generis* system" is given; yet developing countries had to put such a system in place by the end of 1999 if they choose this as an alternative to patenting and if they wish to avoid punitive trade sanctions[74].

3. General Critique on the Scope and Utility of Article 27

Article 27 contains one of the most contentious provisions underpinning the new multilateral trade system. Although Article 27.3(b) allows countries to exclude plants and animals from patentability, TRIPS requires that all countries provide patent protection on micro-organisms[75] which are life forms. And depending on how it is defined, a plant cell can be considered a micro-organism yet it can grow into an entire tree. A patent on such a cell[76] could extend to trees even if

[71] See document WT/CTE/W/50, of 20 May 1997, prepared by the WTO Secretariat.

[72] The acronym UPOV, which is the common reference to the UPOV Convention, is derived from the French name of the organization established by that Convention, namely, "Union internationale pour la protection des obtentions végétales", 1991 Act of the International Convention for the Protection of New Varieties of Plants. Through this Convention, protection is afforded to new varieties of plants both as an incentive to the development of agriculture, horticulture and forestry and to safeguard the interests of plant breeders. Breeding new varieties of plants requires a substantial investment in terms of skill, labor, material resources, money and time. The opportunity to obtain certain exclusive rights in respect of his new variety provides the successful plant breeder with a better chance of recovering his costs and accumulating the funds necessary for further investment. In the absence of plant breeders' rights, those aims are more difficult to achieve since there is nothing to prevent others from multiplying the breeder's seed or other propagating material and selling the variety on a commercial scale, without recognizing in any way the work of the breeder.

[73] The fact is that TRIPS makes no mention of UPOV, so it argued that there is no reason, other than political pressure from countries like the US to use it as a model. GRAIN, *PVP in the South: The Flow Towards UPOV*, March 2001, available at: http://www.grain.org/docs/towardsupov.pdf .

[74] TRIPS Agreement lays down some rather complicated transition provisions which give countries periods of time to adapt their legislation and practices to their TRIPS obligations. These periods, however, differ according to the type of obligation and the stage of development of the country concerned. With regard to the protection of pharmaceutical inventions, there are two situations. The basic rule is that developing countries had until the 1st January 2000 and least developed countries until 1st January 2006 to meet their obligations. A small number of developing countries, which did not grant patent protection for pharmaceutical products, have until 1st January 2005 to introduce such protection.
It is worth noting that under the Doha Declaration on the TRIPS Agreement and Public Health it was agreed that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66(1) of the TRIPS Agreement. The Council for TRIPS was instructed to take the necessary action to give effect to this pursuant to Article 66(1) of the TRIPS Agreement.

[75] A micro-organism is an organism that can be seen only under a microscope, usually, an ordinary light microscope. They are usually of the order of microns (millionths of a meter) or tens of microns in linear dimensions, and include bacteria, mycroplasm, yeasts, single-celled algae and protozoa. Multicellular organisms are normally not included, nor fungi apart from yeasts. Viruses are also not automatically included; many scientists do not classify them as organisms as they depend on cells to multiply; see biotech-dictionary http://biotechterms.org/sourcebook/index.phtml.

[76] A cell line is a supposedly genetically uniform population of cells derived from one individual, or it could be a clone (theoretically genetically identical descendants) of one original cell. The genetic identity of all the cells is a fiction, as

one cannot patent a plant variety. Most constitutions affirm (like the one of the Republic of the Philippine, Article XII sec. 2) that the State is the owner of all "flora and fauna" and "with the exception of agricultural lands, all other natural resources shall not be alienated". In this case allowing IPRs over fauna or flora can be seen to be a form of alienation since IPRs are exclusive monopoly rights that prevent other people from using or producing something.

It is also true that the language of this provision is open to wide interpretation. For most developing countries, it is not clear how TRIPS distinguishes plants, animals and micro-organisms which must be patented; nor it is clear why essentially biological processes[77] do not have to be patented, but microbiological[78] and non biological processes do. After all, a microbiological process is an essentially biological process. In cases where the microbiological process whereby an engineered gene[79] is used to modify a product is new, involves an inventive step and is capable of industrial application, it apparently can be a patentable invention under TRIPS. The sole fact that it relates to a life form is not a ground for denial of IP protection since it excludes only "plants and animals to other than micro-organisms" and genes are not whole organisms (but micro-organisms)[80]. Still States may argue that genes are not micro-organisms, since they are unicellular organisms capable of propagation or can invoke *ordre public* or morality in order to deny such an IP right. Is this denial to be justified under the TRIPS Agreement with respect to a gene used to create a vitamin-enriched food product, where there is no scientific basis for regarding the gene or the rice as harmful to human health or the environment? It is evident that TRIPS, resulting from a painstaking negotiation on a wide number of issues of IP, cannot provide a precise guidance but can only have the power to influence the attitude of certain States towards transnational biotechnology companies.

B. General Observations on the Legal Tensions between TRIPS and CBD

While the TRIPS is being incorporated within the national laws of WTO member States, access to genetic resources - from which genetically engineered products are developed - is becoming one of the most critical areas of concerns for developing countries. The international

---

the genetic material is subject to many 'fluid genome' processes which constantly make cells genetically different from one another. A genome is the totality of all the genetic material (deoxyribonucleic acid or DNA) in an organism, which is organized in a precise, though by no means fixed or constant way. In the case of viruses, most of them will have ribonucleic acid or RNA as the genetic material; see biotech-dictionary http://biotechterms.org/sourcebook/index.phtml.

[77] An "essentially biological process" is scientifically suspect. Does it mean a process that occurs naturally or which is carried out by organisms? Similarly, a "non-biological process" is difficult to define, as all processes in biotechnology, by definition, are biological. A weak case may be made on the ground that it is one that does not occur naturally, or which is not normally carried out by organisms; see biotech-dictionary http://biotechterms.org/sourcebook/index.phtml..

[78] A "micro-biological process" is presumably one that is carried out by micro-organisms.

[79] A gene is a stretch of genetic material (DNA or RNA) with a defined function in the organism or cell. It usually codes for a protein. There are many genes within a genome. For example, the human genome is estimated to contain 100 000 genes. A DNA sequence refers to the sequence of bases in a stretch of DNA. DNA is a linear molecule consisting of units strung together. There are 4 different units, each identified by the specific base contained. There are 4 different bases, which are simply represented by the alphabets, A, T, C and G. An example of a DNA sequence is as follows: ATTTCCGCTACGCGTTA... A RNA sequence is similar, except that the alphabet T is replaced by U; ; see biotech-dictionary http://biotechterms.org/sourcebook/index.phtml.

[80] LESKIEN D. and FLITNER M. "Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System", *Issues in Plant Genetic Resources,* No. 6. International Plant Genetic Resources Institute, Rome, June 1997, pp. 18-22.

regulation of access to genetic resources is enshrined in CBD general principles on which the impact of IPRs, promoted by TRIPS, needs to be explored.

At this juncture, we will deal with the issue of access to genetic materials, without delving into the details of application in the bioprospecting practice but confining the discussion to the general principles arising from States' obligations under TRIPS and the relevant provisions of the CBD. It is indeed alleged that, as a consequence of the implementation of both international treaties, an acrimonious legal conflict may arise from inconsistent provisions contained therein. Accordingly, the study of the relations between TRIPS and CBD, which encompasses all types of genetic materials, will be preparatory to apprehending the peculiarities of an IP *sui generis* system for plant varieties to be built up by WTO Members. Indeed in chapter IV, we will examine the interaction between TRIPS and CBD in light of FAO Treaty and UPOV Convention which are more precisely concerned with plant genetic resources.

1. The International Regime of the Genetic Resources: from "Mankind's Heritage" to the Affirmation of State Sovereignty in the CBD

The CBD[81] is a result of prolonged international pressure to respond to the destruction of, and unequal profits from, the biodiversity of the Southern Hemisphere. After years of debate, the Convention was agreed upon in 1992, came into force in 1993 and today it is almost universally ratified (183 Parties as of 15 March 2002). The CBD represents an important watershed in international efforts to promote biodiversity conservation. In the first place, the Convention binds signatories to a number of basic principles regarding how, by whom and for whose benefit biodiversity should be conserved[82]. The CBD codifies the well-established principle in international law that States have a sovereign right over their territory, including their natural resources[83]. Before then many questioned that biological resources were under a regime of "heritage of mankind" in the sense that States therefore had no sovereignty over them or that genetic resources could not be subject to private property rights. This shift was due to an increasing commercial interest in these resources, making them subject of private property claim, namely IP, in the form of plant breeders´ rights and patents, which give their owner an exclusive right to control any commercial use of these resources[84].

CBD's overall objectives are: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies. The main obligations of the Convention are: recognition of the sovereign rights of States over their biological resources (Articles 3 and 15); access to biological resources can only occur with the 'prior and informed consent' of States (Article 15.5); protection and promotion by the signatories of the rights of communities, farmers and indigenous peoples *vis-à-vis*

[81] *Convention on Biological Diversity*, done at Rio de Janeiro, 5 June 1992, UNEP/Bio.Div/N7-INC5/4; 31, *International Legal Material* p. 818.

[82] For in depth study of the preparatory works of the CBD see McCONNEL F., *The Biodiversity Convention. A Negotiating History,* Kluwer Law International, The Hague, 1996.

[83] See CORREA C. M., *Sovereign and Property Rights over Plant Genetic Resources, FAO Background Study Paper No. 2. Commission on Plant Genetic Resources - First Extraordinary Session*, Rome, 1994.

[84] See e.g. KAGEDAN B. L.., *The Biodiversity Convention*, *Intellectual Property Rights, and Ownership of Genetic Resources: International Developments*, Ottawa, 1996, p. 10. REID W.V., LAIRD S.A, GAMEZ R., SITTENFELD A., JANZEN D.H., GOLLIN M.A., JUMA C., « A New Lease of Life » in REID W.V., LAIRD S.A, GAMEZ R., SITTENFELD A., JANZEN D.H., GOLLIN M.A., JUMA C., (eds.) *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*, 1993, p. 20.

their biological resources and TK systems (Article 8(j) and 10). It establishes access to the biological resources of developing countries on a *quid pro quo* basis with technology transfer from the industrialized countries (Article 16). It requires the equitable sharing of benefits arising from the commercial use of communities' biological resources and local knowledge (Article 15.7). It asserts that IPRs must not conflict with the conservation and sustainable use of biodiversity (Article 16.5).

2. General Impact of TRIPS on the Obligations under CBD

The position of many developing countries is that the relationship of CBD with TRIPS, at a non-legal level of abstraction, is best characterized in terms of an opposition of principles, an opposition between the principle of sustainable development served by CBD and the principle of economic growth purported by TRIPS. The justification adduced by industrialized countries for globalizing and harmonizing IPRs is that such rights will strengthen the supply of innovation to the market. Economic growth, it is said, will be the result of improving dynamic efficiency through stronger IPRs. Pushing markets in the direction of more technological innovation, the high technology fix stands in stark contrast to the kind of economy that some committed environmentalists want. For the latter, development is subject to environmental costs and implications.

The CBD is intended to strengthen developing countries' capacities to conserve and use biological diversity on a long-term basis, taking into account all rights over those resources, and including the right to enjoy the benefits of this resource base. Southern hemisphere countries feel consistently exploited because of the structural imbalances between countries rich in biological diversity and those strong in technological and legal instruments. On the opposite side, TRIPS is intended to provide private property rights over products and processes, be they biodiversity-based or not. We remind that the pressure of certain non-State actor interests, namely those of multinational companies, has been overwhelming in achieving these results.

Besides the first-glance fundamental contradiction between CBD (which recognizes sovereign rights on genetic resources) and TRIPS (which obliges States to grant private rights to same), moving on a more legal ground, inconsistencies between IPRs applied to life forms under TRIPS and the obligations of CBD are multifaceted. They can be seen in light of the influence of TRIPS Agreement on the provisions of the preexisting CBD particularly in the following fields: (i) the access to genetic resources, (ii) the fair and equitable sharing of benefits from the utilization of genetic resources, (iii) the respect for TK held by the indigenous communities and (iv) the transfer of technology[85].

While describing these apparent points of conflict, we will bear in mind that Contracting Parties to the CBD, recognizing that *"patents and other IPRs may have an influence on the implementation"* of the provisions of that convention, are under the obligation of cooperation to

[85] In case a conflict arises between two conventions having the same subject-matter, the well known rule *lex posterior derogat lex anterior* - enshrined in article 30 of Vienna Convention Law on Law of Treaties - will be applied. If it is accepted that CBD and TRIPS have the same subject-matter, the latter will control the issue having come into force after CBD. We believe however that the subject-matter of TRIPS and CBD is not exactly the same, nonetheless certain provisions contained in the two treaties TRIPS and CBD need to be harmonized for the sake of full application of both instruments universally ratified. Rather than an incompatibility some authors define the controversial relations between the two international instruments as an apparent conflict (namely an *"emboîtement"* or *"désarticulation"*) and that a relation of complementarity is yet to be built. See for instance MALJEAN-DUBOIS S., "Biodiversité, biotechnologies, biosécurité: Le droit international désarticulé", *Jounal du Droit International,* 127, 2000, p. 966-967.

ensure that IPRs are *"supportive of and do not run counter to its (CBD's) objectives"* (Article 16.5). Moreover, Article 22 states that the CBD's provisions will not affect rights and obligations of countries to other *"existing international agreements, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity".* This harmonization process is mainly *"subject to national legislation and international law"* and stands as a basis for countering the runaway march of the IPR regimes described above[86].

3. Impact of TRIPS on the Access to Genetic Resources Provided by CBD

Genetic resources under CBD may be affected by the IPR system construed by TRIPS Agreement. Indeed, its Preamble defines IPRs as being private rights. Because these rights are subject to the general WTO principle of national treatment, the implementation of Article 27.3(b) of TRIPS will give global jurisdiction to private individual property rights. Therefore, it is argued that the global scope of these rights will destabilize the regime of national sovereignty espoused by CBD, which itself aims to recognize the inherent rights of indigenous and local communities (see Article 3 of the CBD)[87]. Although Article 15(1) of the CBD recognizes *"the sovereign rights of States over their national resources"* and that national governments might determine access to genetic resources, the provision does not refer to the question of the ownership of genetic resources. The CBD simply submits access to genetic resources to the *"prior informed consent"* (PIC) of the party on mutually agreed terms aimed at sharing the benefits arising from the utilization of such resources (Article 14(4) and (5))[88].

Genetic resources are not only to be found within the boundaries of State Parties, but also in a number of germplasm and seed banks. The CBD, dealing with *"the conservation of components of biological diversity outside their natural habitat"* (Article 9), leaves unanswered the legal issues on the ownership of biological resources held in trust in gene banks of international agricultural research institutes. For instance, the phenomenon of biopiracy, that will be later addressed, has been advantaged by this loophole on the legal status of the material held by the Consultative Group on International Agricultural Research (CGIAR)[89]. According to Article 15.3[90], national authorities should provide for the acquisition, conservation, storage and management of these *ex situ* collections. We think nevertheless that, except when the State exercised its sovereign right over a

[86] See NOIVILLE Ch., "Biodiversité et propriété intellectuelle l'impossible conciliation ?", in Sandrine Maljean-Dubois (ed.), *L'outil économique en droit international et européen de l'environnement*, Documentation Française, 2002, pp. 281-303.

[87] Article 3 Principle, « States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction ».

[88] Article 15. Access to Genetic Resources *« Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article. 5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party ».*

[89] The CGIAR, established in 1971, is an informal association of 57 public and private sector members that supports a network of 16 international agricultural research centers. For a thorough discussion on the controversies raised by their interaction with IPRs see BLAKENEY M., "Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes – Some Recent Problems", *Bio-science Law Review,* n. 1, 1998, pp. 3-11.

[90] *« 3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention ».*

genetic resources collection prior to the entry into force of CBD, it cannot insist upon a share of any benefits derived from the use of that collection[91].

4. The Phenomenon of "Biopiracy" and the Problem of Equitable Benefit Sharing Arising from the Utilization of Biological Resources

The private property regime established by the TRIPS may undermine the implementation of the benefit sharing provisions of the CBD that require that genetic resources and TK be used following the granting of PIC by the holders of such material and knowledge[92]. It is generally understood that the PIC requirement would be embodied in some form of agreement for the sharing of benefits and for the transfer of biological material or TK[93]. Such agreements would be made between foreign firms and the governments of the developing countries. TRIPS Agreement, however, does not require PIC and it is therefore deemed to be inconsistent with the CBD. Without such an obligation, countries (generally industrialized) that use genetic resources in an innovation process will limit their efforts to seek benefit sharing with the origin countries (generally developing).

The aim of TRIPS to attempt to homogenize IP regimes may jeopardize a country's or community's freedom to choose the way in which it wants to deal with the use and protection of biodiversity and the related TK. This issue blatantly arises when the genes are not appropriated from the State that patents them but from another State that manipulates and sells the genetically modified product. Developing countries rise against this kind of "piracy" of indigenous and local community knowledge following the imposition of IPRs on life forms and related knowledge[94].

---

[91] See also YUSUF A.A. "International Law and Sustainable Development the Conventionon Biological Diversity", Yusuf A.A., (ed), *African Yearbook of International Law*, vol. 2, The Hague, Boston and London, Kluwer, 1995, 109.

[92] Article 1 of the CBD envisages *"appropriate access"* to genetic material and the *"fair and equitable sharing of benefits arising out of the utilization of genetic resources"*.

[93] Article 15(5) of the Convention on Biological Diversity provides that: *"Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party"*.

[94] For example, the patenting of traditional Indian herbal remedies derived from the use of turmeric or a patent related to the *ayahuasca* plant used for centuries by the indigenous people of the Amazon have been the object of legal challenges taken to the U.S. and European patent offices. In the turmeric case, the Indian Council for Scientific and Industrial Research (CSIR) launched proceedings against the Medicinal Center to reverse the patent grant on the grounds that the patent application failed to meet the requirement of novelty. In the *ayahuasca* case, after challenge by the Coordinating Body for Indigenous Organizations of the Amazon Basin, the Coalition for Amazonian Peoples and their Environment, and the Center for International Environmental Law, the patent was overturned in 1999 for lacking novelty. The decision of the USPTO, however, failed to consider whether patents should be prohibited on the public policy ground that the plant is sacred. The controversy worsened when RiceTec - a Texas based company – patented *Basmati* rice, derived from traditional a product long used in Pakistan and India (see The Times of India Online *India Business,* 24 July (2000) available at http://www.timesof india.com/240700/24busi2.htm). Another infamous case is the Sweet Berries patent that was granted to the University of Wisconsin over a super sweet substance derived from the berries of the plant *Pentadiplandra brazzeana*, from Gabon. Licensing arrangements have lead to the commercialization of the product. The compound has been genetically engineered into maize plants, from which it will be manufactured as a low calorie sweetener that is likely to earn a significant return. See also the Blight-Resistant case in Mali, *Oryza longistaminata* WIPO/UNEP, *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge,* Geneva, 2001, p. 13. Another recent example is the *Enola bean* case, which involved yellow beans from Mexico, which are patented in the United States (US Patent No 5,984,479). The patent was used by POD-NERS, Plc to bring legal suits against two companies that were selling the Mexican yellow beans in the US, claiming that the beans infringed his patent monopoly, see Rural Advancement Foundation International (2001) : Enola Bean Patent Challenged. Press Release January 5, 2001, available at: http://www.biotech-info.net/enola_bean.html and see RAFI, "Enola Bean Patent Challenged", News Release, 5 January

The well-known phenomenon of "**bioimperialism"[95] or "biopiracy"** has been invoked in order to define the way in which industrialized countries "conquer" illegitimately the biological resources. The term "biopiracy" was coined by Mooney as part of a counterattack strategy on behalf of developing countries that, as already said, are accused by developed countries of supporting "intellectual piracy", but who felt they were hardly as piratical as corporations which acquire resources and TK from their countries, use them in their research and development programs and acquire patents and other IPRs without compensating the provider countries and communities[96]. What has then become an anti-biopiracy rhetoric, adopted by some developing country trade negotiators, has not prevented, in a certain sense, the legalization of this "conquest" through TRIPS obligation on the part of the Southern Countries to grant patents, trademarks and trade secrets without any compensation to the local communities who have preserved and bred these resources. All this is done knowing that some 90% of genetic information and TK are found in developing countries[97].

For all these reasons it is argued that IPRs can prevent the CBD from realizing the full and practical meaning of Article 3 on national sovereignty over their natural resources and Article 8(j) [98] on the rights of local and indigenous communities - with the ultimate goal of the fair distribution of the benefits of the use of genetic resources situated in the territories of the Contracting Parties[99].

2001, www.rafi.org. Yacon case can be studied in HUAMAN, "Unethical distribution to Japan of Yacon held in trust by CIP" on the list-server run by BIONET www.bionet-us.org, 7 April 2001. Another important case is *Nuna* Beans: a patent granted to a US corporation in relation to a bean-nut popping bean apparently derived from crosses involving at least 33 Andean nuna bean varieties from indigenous communities in Peru, Bolivia, Ecuador and Colombia. For a thorough study on this issue see NIJAR, G.S., *Towards a Legal Framework for Protecting Biological Diversity and Community Intellectual Rights: A Third World Perspective*, ICCBD 2nd Sess., Nairobi, 20 June - 1 July 1994.

[95] AOKI K., "Neocolonialism, anticommons property, and biopiracy in the (not-so-brave) new world order of international intellectual property protection", *Indiana Journal of Global Legal Studies*, 6, 1, pp. 59-115. The author raises questions about the emerging globalized vision of IPR protection embedded in multilateral agreements such as TRIPS. In particular, there are serious distributive questions about the international political economy of intellectual property protection that should be addressed. Additionally, the question of constructing and maintaining an intellectual public domain or commons remains extremely important, if only because the unprecedented grab by IPR owners of the developed nations seems to be imminent. This grabbing obscures traditional understanding that IPR law is about striking a balance between the rights of authors and inventors and the public of consumers and users as well as the fact that all IPR owners are also users. Finally, is the massive and generally uncompensated flow of cultural and biological resources out of the developing nations into the laboratories, universities, and factories of the developed countries.

[96] MOONEY P. R., "Why We Call It Biopiracy", in *Responding to Bioprospecting: From Biodiversity in the South to Medicines in the North*, Hanne Svarstad & Shivcharn S. Dhillion eds., 2000, p. 37, and SHIVA V., Biopiracy: the Plunder of Nature and Knowledge, 1998, pp. 1-5. See also STORY A., "Biopiracy and the dangers of patent over-protection", *New Law Journal*, 149, 6874, 1999, p. 158.

[97] COTTIER Th., "The Protection of Genetic Resources", *op. cit.*, p. 1827.

[98] *Article* 8(j) of the CBD calls for national laws to *"respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices"*. Due to the importance of *article* 8(j), several workshops have been organized to advance its implementation and related provisions. WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Fact Finding Missions on Intellectual Property and Traditional Knowledge,* Geneva, 2001, p. 50.

[99] The CBD relevant provisions on benefit sharing are Articles 1, 15.7 and 19.2 for those relating to the conservation of TK and the conservation of biodiversity articles 8(j) and 10(c). For some socio-economic consideration see GOLDMAN K. A., "Compensation for Use of Biological Resources under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry", *Law and Policy*

5. Absence in TRIPS of Safeguard Provisions on Traditional Knowledge Held by Indigenous Communities

TK is a fundamental source for the sustainable management of biological diversity and for the development of new and socially beneficial products through, for instance, long-term selective breeding of food crops or knowledge of medicinal plants[100]. The categories of IPRs traditionally recognized in TRIPS Agreement are not completely adequate to guarantee the protection of practices and the knowledge held by local and indigenous communities which have informally crystallized along the centuries and which play an outstanding role in the conservation of biological diversity.

In this short-thesis we will refer to 'indigenous peoples' as those *"peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonization or the establishment of present State boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions"*[101].

It is argued that the potential benefits flowing from conservation and exploitation of biological diversity as called for by the CBD are jeopardized under a global regime of private monopoly rights. Conservation of biological resources implies enormous responsibilities that TRIPS does not allocate to those who will benefit from ownership rights to these resources. The private monopoly of IPRs holders can only begin where national or community sovereignty over their knowledge related to genetic resources has been effectively suspended. In this situation, governments and communities will have little means of regulating access or demanding a share of benefits because they will be subject to private ownership.

The literature is divided on the ultimate influence of IPRs on TK. As we will see, some authors adduce that IPRs will eventually encourage the investment in the preservation of these practices while many others denounce the lack of protection of same that leads to the misappropriation by IP holders. This discussion becomes more complicated when many leaders of indigenous communities affirm that the commodification of TK is inherently unjust on religious grounds. Consequently, even IP protection of TK is considered inappropriate.

While the TRIPS Agreement is apparently undermining the CBD objectives in this field, in the following chapters we will demonstrate how IP law can still undergo a development in the sense of benefit sharing, especially through existing IPRs and/or *sui generis* systems apt to protect TK and to compensate its holders when their preserved genetic resource is the basis of a patent.

6. Positive and Negative Impact of TRIPS on the International Transfer of Technology Promoted by the CBD

International Business, 1994, p. 695 and PRAKASH S., "Towards a Synergy between Biodiversity and Intellectual Property Rights", *Journal of World Intellectual Property*, 1999, p. 821.

[100] DUTFIELD G., "The Public and Private Domains, Intellectual Property Rights in Traditional Knowledge", *Science Communication*, 21, 3, March 2000, pp. 276-278.

[101] International Labor Organization Convention, Convention Concerning Indigenous and Tribal Peoples in Independent Countries, June 7, 1989, Article 1(b), available at: http://www.cwis.org.

It is important to elucidate the links between IPRs on biodiversity and technology transfer being aware of the fact that benefit sharing is also enhanced by this matter. However, technology transfer is a complex question that lies mostly outside our subject-area.

The impact of a regime granting IPRs over plants, animals and related biological resources (according to TRIPS) on the transfer of technology is not less contradictory than that in preceding fields related to the environment and the biodiversity. The TRIPS regime, on the one hand can utterly negatively challenge the rigorous implementation of the CBD provisions on transfer of technology in two fundamental manners and, on the other hand, may create extraordinary incentive for innovation[102].

In the negative perspective impact on CBD, an IPR regime without derogations, namely inflexible, can first of all seriously hinder the environmentally-sound technology transfer among States, and particularly from industrialized countries to developing ones. Indeed transfer of appropriate technology is a key tool to achieve the goals fixed in the CBD[103]. The CBD refers to technologies that are *"relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment"* (Article 7(c))[104]. It also requires Parties to transfer technology to developing countries on *"fair and most favorable terms"*, including on concessional and preferential terms where mutually agreed (Article 16.2). This provision means that, where a developing country has provided access to genetic resources, that country should have facilitated access to technology that makes use of those resources (Article 16.3). This objective certainly needs corresponding national and international IP Law to ensure that IPRs "*are supportive of and do not run counter to*" CBD's objectives (Article 16.5)[105].

Another possible negative impact of IPRs protection on living matters is constituted by the fundamental step of the development of environmentally harmful technologies. These preoccupations are mainly addressed with regard to the modern genetic technologies which are essentially based on the modification of plant animal and micro-organisms genome with the aim to embody a special characteristic – for instance the resistance of herbicide or the predisposition to avoid certain diseases – in order to attain a commercial advantage. As regards to transgenic plants

---

[102] ALEXANDER D., "Some Themes in Intellectual Property and the Environment", *Review of European Community and Int. Environmental Law,* 1993, p. 113. See also PAVONI R., "Brevettabilità genetica e protezione della biodiversità: la giurisprudenza dell'Ufficio Europeo dei Brevetti", in *Rivista di Diritto Internazionale*, 2000, pp. 430-433.

[103] On the question of transfer of technology it is to notice the compatibility between Article 16 of CBD and the fundamental principle of WTO agreements on the Most Favorite Nation in Article 3 and 4 of TRIPS, see TARASOFSKI R., "The Relationship between TRIPS Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approach", in *Review of European Community and International Environmental Law*, 1993, p. 150.

[104] Article 7(c) imposes on the Sates to identify *"processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity"*. Such activities have to be coherently managed (Article 8.l). See TARASOFSKI R., *op. cit.*, 148 ss. According to this author the two regimes of protection can be reconciled although the *chapeau* of Article 8 uses vague expressions like "as far as possible" and "as appropriate" that can be an element of uncertainty.

[105] On this point the CBD secretariat has also noted that: "Due to the rapid development of technologies, particularly biotechnology, further consideration of the impacts of IPRs on the achievement of the objectives of the Convention, including in facilitating access to and transfer of technology is urgently needed"; UNEP, *The Relationship between Intellectual Property Rights and the Relevant Provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention on Biological Diversity*. Note by the Executive Secretary, Doc UNEP/CBD/ISOC/5, para. 23.

and animals, specified environmental risks have been identified as particularly harmful for human health which can concretize in irreversible harms for the global ecosystem and for human welfare (after their entry into the environment and market). This is particularly true for technologies that produce "terminator seeds"[106], namely sterile seeds. They require a chemical "switch" to be applied before performing certain characteristics like flowering. In this context, national and international bodies should more clearly define the concepts of patentability exceptions under Article 27.2 of TRIPS which are the only defense for the IP inventions threatening the biodiversity.

Despite these concerns created by a strong IP regime, TRIPS itself seems to offer a solution through its Article 7 that states that IPRs should *"contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations"*. Technology transfer is one of the objectives of the TRIPS which in turn is instrumental to satisfy the incentive of innovation worldwide. More precisely, Article 66.2[107] encourages technology transfer to the least developed countries. The debate on the achievement of these objectives is open since empirical research on the matter is inconclusive given the complexity of the relations between developed and developing countries. In the field of pharmaceutical technology which is genetic resources dependent, it is uncontestable that about 10 corporations hold 36% of the pharmaceutical market, 40% of the seed one, and 82% of the agrochemical one[108]. It is clear therefore that if countries grant overly broad biotechnology patents that cover crop species etc., these IPR holders may raise prices, impose restrictive licensing conditions and limit further research, thus undermining their competitors. Ultimately, all this hinders the diffusion of technology.

Table 2. Synopsis of the Points of Conflicts between CBD and TRIPS according to the Developing Countries Standpoint[109]

CBD Says	TRIPS Says	The Conflict

[106] See DUTFIELD G., *Intellectual property Rights, Trade and Biodiversity, op. cit.* pp. 51-52.

[107] Article 63.2, Least-Developed Country Members: *"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base"*.

[108] RAFI, *The Life Industry,* 1999, available at www.rafi.org.

[109] This synopsis has been inspired by the one effectuated by GRAIN, we have modified it in accordance to our convenience to illustrate the relations between the two conventions.

Nation States have sovereign public rights over their biological resources *(Preamble, Article 15.1).*	Biological resources should be subject to private intellectual property rights. Compulsory licensing, in the national interest, should be restricted *(Article 27, Article 21).*	National sovereignty implies that countries have the right to prohibit IPRs on life forms (biological resources). TRIPS requires the provision of IPRs on micro-organisms, non-biological and microbiological process, as well as patents and/or *sui generis* protection on plant varieties.
The use or exploitation of biological resources must give rise to equitably shared benefits (*Articles 15.7, 19.2).*	Patents must be provided for all fields of technology, therefore the use or exploitation of biological resources must be protected by IPR. There is no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country from which the invention is derived *(Article 27.1).*	CBD gives developing countries a legal basis to demand a share of benefits. TRIPS does not mention that legal authority.
The use or exploitation of traditional knowledge, innovations and practices relevant to the use of biodiversity must give rise to equitably shared benefits *(Preamble, Article 18.4, Article 8.j).*	Patents must be provided for all fields of technology, therefore the use or exploitation of biological resources must be protected by IPR. There is no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country from which the invention is derived *(Article 27.1).*	CBD gives developing countries a legal basis to demand a share of benefits. TRIPS does not mention that legal authority.
Access to biological resources requires the prior informed consent of the country of origin. It also requires the 'approval and involvement' of local communities *(Article 15.5)*	There is no provision requiring prior informed consent for access to biological resources which may subsequently be protected by IPR.	CBD now gives States legal authority to diminish the incidence of biopiracy by requiring prior informed consent. TRIPS does not mention this authority with the risk to promote the phenomenon of "biopiracy".
States should promote the conservation and sustainable use of biodiversity as a common concern of humankind taking into account all rights over biological resources.	The safeguarding of public health and nutrition, and the public interest in general.	CBD places the public interest and common good over private property and vested interests. TRIPS grants private rights on the same subject matter.

C. Reviewing Article 27.3(b) of TRIPS

Various arguments of authors, NGOs representatives, corporate associations, etc. have been channeled into the positions held by WTO member States in the TRIPS Council during the revision process of Article 27.3(b).

In this section we will outline the three major options for the revision of Article 27.3(b) that are under discussion in WIPO and in WTO. The maximum position would be to revise Article 27.3(b) so as to exclude life forms altogether from the ambit of TRIPS Agreement (option I). A variant to this position is to leave full discretion to exclude any life form from patentability (option II). The minimum position would include, among the patentability subject-matters, animals and plants and impose UPOV as the effective *sui generis* system for plant varieties. This position summarizes the desire of the US and of many EU countries, but they do not dare pushing for it. Finally, an intermediate position (option III), that seems to be the outcome of the negotiation bargain under way, seeks to preserve the *status quo* of the existing text. In this way the statutory IP patentable subject-matter is neither strengthened nor extended any further at the multilateral level, so that the present textual ambiguities may be exploited in the implementation process and also through bilateral treaties on stronger IP standards than TRIPS ones[110].

1. No Patents on Life

The first option reflects the maximum position, one which seeks to exclude life forms from the ambit of TRIPS Agreement altogether. In particular, we note that the African Group of countries in the WTO has proposed that Article 27.3(b) should be amended to clarify that plants, animals, micro-organisms and all other living organisms and their parts cannot be patented. Thus, Article 27.3(b) should be revised so as to prohibit the patenting of plants and animals, including their parts, and the processes which make use of, or are related to, plants, animals and their parts. The prohibition against patenting parts of plants and animals must include genes, gene sequence, cells, seeds, etc. which are very much part of the particular plant or animal. A number of other developing countries in the WTO have supported this position[111].

2. Full Discretion to Exclude Life Forms from Patentability

The second option stops short of excluding life forms from the ambit of TRIPS Agreement. In this instance, the words "*may exclude*" are used to denote the discretion available to national governments to determine the issue of patenting of life. The effect of this formulation is that WTO members will retain the right to exclude patentability of plants and animals, without the condition of providing protection for micro-organisms, microbiological processes, non-biological processes and also plant varieties[112]. Moreover, Article 27 should incorporate requirements in the CBD concerning

---

[110] Some of thess proposals can be found in *"Relations entre les droits de propriété intellectuelle et les dispositions pertinentes de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce et la Convention sur la diversité biologique"*, Réunion intersessions sur le fonctionnement de la Convention, Montréal, Canada, 28-30 juin 1999, Union Mondiale pour la nature.

[111] Draft Communication by **Kenya** Review of the Provisions of Article 27.3(b) of the TRIPS Agreement, WT/GC/W/302, 6 August 1999. **India** proposes to exclude patents on all life forms. If this is not possible, then at least exclude patents based on traditional/indigenous knowledge and products and processes essentially derived from such knowledge. There must be disclosure of the country of origin of the biological resource and associated knowledge, and proof of the provider's consent, to ensure equitable sharing of benefits. It should be left to national policy to decide what are patentable micro-organisms, including in light of Article 27.2 (morality and *ordre public*). Developing countries like India cannot accept any further strengthening of the protection presently provided to life forms, WT/L/326 of 22 October 1999.

[112] *Article* 27.3(b) of the TRIPS Agreement: Review options for the South on this point, it has been suggested that since *Article* 27.3(b) refers to "plants and animals" and not to any particular class thereof (such as "varieties", "races" or

access authorization from the government of the country providing a genetic resource used in an invention, PIC, benefit sharing, protection of TK and technology transfer. Proponents[113] of this measure argued that this would ensure that source countries' laws on access and benefit sharing and on protection of TK would be respected by patent applicants and would prevent abusive patenting of existing TK by parties other than the holders of the TK (see section VI.B.1).

3. Maintenance of the *Status Quo*

The main legal ground relied on by European Countries[114], USA[115] and some others[116] for the *status quo*, is that the two treaties, TRIPS and CBD, do not deal with the same subject-matter. The objectives of the CBD are: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The main objectives of TRIPS Agreement are to set minimum standards of IP protection within WTO Members and to ensure that States make available to rights holders judicial and/or administrative procedures to enforce their IPRs. It is clear that implementation of patent legislation may impact on the implementation of the CBD.

"species"), this reference should be read to include both naturally occurring plants and animals and parts thereof, as well as those which have been genetically modified (i.e. transgenic).

[113] The **African group** proposes the that the review of 27.3 should clarify that plants, animals, micro-organisms, their parts and natural processes cannot be patented. TRIPS should contain provisions to promote, not undermine, the conservation and sustainable use of genetic material. Finally TRIPS should contain provisions to prevent "biopiracy", WT/GC/W/302 of 6 August 1999 and IP/C/W/206 of 20 September 2000. **Southern Africa Development Cooperation** (SADC) maintains that the exclusion for essentially biological processes should extend to microbiological processes, WT/L/317 of 1 October 1999. **Brazil** proposes that the flexibility for members to exclude plants and animals should be retained. Article 27.3(b) should be amended to allow members to require further conditions for patentability, *viz.* (i) identification of source of genetic material; (ii) TK used to obtain that material; (iii) evidence of fair and equitable benefit-sharing; and (iv) evidence of prior informed consent for the exploitation of the patent. Article 27.3(b) should bear an interpretative note clarifying that discoveries or naturally occurring materials are not patentable. IP/C/W/228 of 24 November 2000. This is also the position of **Venezuela** , WT/GC/W/282 of 6 August 1999 and **Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe**, JOB(99)/3169 and Add. 1. The Least Developed Countries Group affirm that there should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological processes, are not patentable. Incorporate provision that patents must not be granted without prior informed consent of country of origin. Patents inconsistent with Article 15 of CBD should not be granted, WT/GC/W/251 of 13 July 1999. **Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda** add that the review should also: clarify the artificial distinction between biological and microbiological organisms and processes; ensure the continuation of traditional farming practices including the right to save and exchange seeds and sell their harvests; and prevent anti-competitive practices that will threaten food sovereignty of people in developing countries, WT/GC/W/354 and WT/GC/W/355 of 11 October 1999. See also SEURET F., ALI BRAC DE LA PERREIERE R., *L'Afrique refuse le brevetage du vivant: Le Monde Diplomatique*, July 2000, p. 24.

[114] WT/GC/W/193 of 2 June 1999 and IP/C/W/254 of 13 June 2001.

[115] WT/GC/W/115 of 19 November 1998 and IP/C/W/209 of 20 September 2000.

[116] This is the position of **Singapore** TRIPS should not be used to enforce benefit-sharing arrangements or any common approach to benefit-sharing, JOB(00)/7853. **Japan** WT/GC/W/242 of 6 July 1999. Norway adds that - It should be considered whether a provision on the disclosure of the origin of genetic resources should be inserted in the TRIPS Agreement to ensure a more effective implementation of the CBDIP/C/W/293 of 29 June 2001. **Switzerland** fosters no lowering of standards of protection and the exclusion for plants and animals is a balanced provision that takes into accounts members' needs and interests. Switzerland also agrees with Singapore that the UPOV system is a useful reference for the basic level of protection of any *sui generis* system for the protection of plant varieties. Nonetheless, also agrees that there may be other *sui generis* systems that meet the requirements of Article 27.3(b) besides UPOV and considers the elements listed by the US to be helpful in drawing up such systems, IP/C/W/284 of 15 June 2001.

Nevertheless, it is argued that IP is only one of many complicated aspects concerning access to genetic resources and benefit sharing. IPRs do not aim either to regulate the access and use of genetic resources, or to regulate the terms and conditions for bioprospecting and commercialisation[117] of IPR-protected goods and services[118]. Patent authorities should not examine whether an invention meets criteria other than those applying to an invention[119]. The arguments of the majority of the Southern hemisphere countries should be developed in appropriate international instruments particularly to achieve the objectives of access to genetic resources, benefit sharing and protection of TK. However, WIPO should be the forum of negotiation of measures aiming at facilitating benefit sharing and protecting sovereign access right by for instance inserting a disclosure of origin obligation or by developing protection of TK.

D. Bilateral Treaties and the Creation of a "TRIPS Plus" Regime[120]

Notwithstanding the numerous concerns raised by TRIPS, industrialized countries and the transnational corporations consider this Agreement to be only a minimum standard of protection of IPRs on biological resources. In order to achieve much stronger standards of protection, developed countries are negotiating, one by one, a range of bilateral, regional and subregional agreements with governments of the Southern countries under the mantra of “national treatment” and “Most Favoured Nation” principles. This practice may soon make TRIPS obsolete[121] achieving what has been called a "TRIPS plus Agreement".

One of the biggest novelties introduced by these bilateral agreements is the requirement to provide patent protection on plants and animals (but through bilateral agreements with industrialized countries). This is true for Jordan, Mongolia[122], Nicaragua, Sri Lanka[123] and

---

[117] Note here that commercialisation does not refer only to when products developed from the patented invention are placed on the market. Patents themselves are products for many companies, since they can be sold and licensed.

[118] DE KONING M., "Biodiversity Prospecting and the Equitable Remuneration of Ethnobiological Knowledge, Reconciling Industry and Indigenous Interests", Blakeney M. (ed.), *Intellectual Property Aspects of Ethnobiology,* Sweet & Maxwell, London, 1999, pp. 23-42.

[119] "Therefore, the EC does not favor incorporating into the TRIPS Agreement overly complex requirements which would oblige patent applicants to provide, in their patent application, an official certificate of the source and origin of the genetic material and the related TK used, evidence of fair and equitable benefit sharing and evidence of prior informed consent from government or local communities for the exploitation of the subject-matter of the patent". However, the European Communities "are open to examine possible effects of the patent system and look into different ways of positively support States in achieving the objectives of the CBD, in particular benefit sharing, while maintaining existing standards and level of intellectual property protection and not unduly increasing the burden on patent applicants and taking into account the outcome of the above – outlined negotiation process which is taking place in the frame work of CBD. As already mentioned above, further discussions on access and benefit-sharing will take place under the CBD.

[120] For a more indepth study on this matter see DRAHOS P., *Bilateralism in Intellectual Property*, http://www.oxfam.org.uk/policy/papers/bilateral/biltateral.rtf.

[121] Using the TRIPS-plus criteria described above, and looking at only a portion of these agreements, GRAIN has, in 2001, identified 23 cases of bilateral or regional treaties between developed and developing countries that should be classed as TRIPS-plus as far as IPR on life forms is concerned. These agreements affect more than 150 developing countries. Which means that something serious is going on: the TRIPS-plus features of these treaties cannot be accidental. See also the updated list of bilateral treaties on this matter http://www.grain.org/docs/trips-plus-table-en.pdf.

[122] Agreement on Trade Relations between the Government of the United States of America and the Government of the Mongolian People's Republic. http://199.88.185.106/tcc/data/commerce_html/TCC_2/MongoliaTrade.html [Art 9(c)i].

[123] *Agreement on the Protection and Enforcement of Intellectual Property Rights between the United States of America and the Democratic Socialist Republic of Sri Lanka.*

Vietnam[124]. Under another approach, South Africa and the 78 African Caribbean Pacific (ACP) countries are supposed to grant patents on "biotechnological" inventions[125]. This presumably means plants and animals, in addition to the micro-organisms required by TRIPS.

In the field of micro-organisms, TRIPS does not advocate the Budapest treaty system for patent protection of micro-organisms. Indeed this treaty obliges Parties to recognize the physical deposit of samples of micro-organisms, *in lieu* of full written disclosure of the invention, through an international depository authority. Under the Budapest Treaty, deposit fulfils the requirement for disclosure. This treaty, whose Contracting Parties are mostly industrialized states, relies on a network of recognized international depository authorities which operate special rules on access to the biological samples, especially to avert potential patent infringement. Under bilateral agreements with industrial countries such as Korea[126], Mexico[127], Morocco and Tunisia[128] have been required to join the system, while Jordan must implement its substantive provisions[129].

The presence of the clause that calls for implementation of IPRs in developing countries "in accordance with the highest international standards"[130] is at the center of concerns of NGOs and peoples. These undefined standards open the door to new standards being generated through the investment treaties. This kind of agreements represents simply a tip of the iceberg of the unrelenting pressure to patent plants and animals. This phenomenon of TRIPS-plus regime that was quietly brewing away in a corner is now becoming rampant[131].

---

http://199.88.185.106/tcc/data/commerce_html/TCC_2/Sri_Lanka_Intellectual_Property/Sri_Lanka_IntellectualProperty.html (Sec 2c).

[124] Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations. http://usembassy.state.gov/vietnam/wwwhbta.html [Chpt II: Art 1.3 and Art 7.2(c)].

[125] Partnership Agreement between the African, Caribbean and Pacific States and the European Community and its member States, CE/TFN/GEN/23-OR, ACP/00/0371/00, 8.2.00. http://europa.eu.int/comm/trade/pdf/acp.pdf [Art 45]. Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, Official Journal L 311 of 4 December 1999 p. 0003-0297. http://europa.eu.int/eur-lex/en/lif/dat/1999/en_299A1204_02.html [Art 46].

[126] *Record of Understanding on Intellectual Property Rights.* http://199.88.185.106/tcc/data/commerce_html/TCC_2/KoreaIntellectual.html [Sec. B.6].

[127] Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, Official Journal L 276/45 of 28 October 2000. http://europa.eu.int/comm/trade/pdf/oj276_mex.pdf [Art 12.1]. Decision No 1/----- of the Joint Council. http://europa.eu.int/comm/trade/pdf/text_dec.pdf [Title IV, Art 36.2 and 36.4].

[128] *Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Tunisia, of the other part*, Official Journal L 097 of 30 March 1998 p. 0002-0183. http://europa.eu.int/eur-lex/en/lif/dat/1998/en_298A0330_01.html.

[129] *Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area*. http://192.239.92.165/regions/eu-med/middleeast/textagr.pdf [Art 4.1(b), Art 4.18, Art 4.21 and Art 4.29(b)].

[130] Euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organization (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part, Official Journal L 187 of 16 July 1997, p. 0003-0135. http://europa.eu.int/eur-lex/en/lif/dat/1997/en_297A0716_01.html [Title II, Art 33].

[131] See Bureau of National Affairs (BNA) (2001), "Cooperation, enforcement, TRIPS case will help protect IPRs, leader says", *BNA Daily Report for Executives* 1 October: A-20; Genetic Resources Action International (GRAIN) (2001), "'TRIPS-plus' through the back door: how bilateral treaties impose much stronger rules for IPRs on life than the WTO", Barcelona: GRAIN.

CONCLUSION OF PART I

The TRIPS Agreement has opened up new commercial opportunities through IP protection of biotechnology in all countries. In this conclusion of part I, we must admit that, in spite of its incomplete construction and already in its inherent vagueness, Article 27 of TRIPS can bring forth powerful implications in the context of international commerce. This however has resulted in a massive campaign mainly organized by NGOs and indigenous communities in developing countries to wrest market control over biodiversity through the patent system, as well as to change the rules of that system in the process[132]. These controversies are aggravated by the fact that many genetic 'inventions' claimed in the North derive from traditional knowledge misappropriations in the South. The developed countries' companies have sophisticated technologies – such as genetic engineering – to extract value from biodiversity. Through patent protection on life forms, major transnational corporations, say Monsanto/Car, can take genes from, for instance, a butterfly in the fields, forests and coastal waters of developing countries, manipulate them in their labs and obtain patent protection thereon. Public outcry rages against the fact that people in developing countries would have to pay royalties on their own resources and knowledge!

A patent under TRIPS is recognized on the basis of novelty whereas community rights under CBD are founded on the basis of pre-existing rights to biodiversity and associated knowledge. IPRs on biodiversity-related 'inventions' are therefore dependent upon the prior "rights" of communities. It is thus asserted that these latter rights are undermined by the very existence of the rights detailed in TRIPS and inspired by myopic industrial interests. It is finally argued that the implementation of TRIPS will systematically negate the wider historical contribution made by communities in developing countries to the planet's biodiversity.

A response in different international fora has been withstanding this trend that is dangerous for the indigenous communities. In light of the undergoing debate, we will now put forth a series of proposals to make the patent system envisaged by TRIPS more compatible with the CBD. This means that we shall need to take up for discussion various IP strategies aiming at positively protecting or valorizing TK. Since we must move within the strait and narrow path whose boundaries are defined by TRIPS obligations, much effort will be required in order to come up with reasonable and realistic ways to eventually strike a balance between the interests of biotechnological IPR holders and those of TK holders.

[132] According to WIPO, citizens and corporations of industrialised countries hold 95% of the patents in Africa, almost 85% of those in Latin America and 70% of those in Asia. WIPO, data set IP/STAT/1994/B, released November 1996.

PART II. IMPLEMENTING TRIPS AND BENEFIT SHARING OBLIGATIONS BETWEEN INTELLECTUAL PROPERTY RIGHT-HOLDERS AND INDIGENOUS COMMUNITIES THROUGH THE VALORIZATION OF TRADITIONAL KNOWLEDGE

Thinking beyond the ban on patenting of biological and genetic material, national/regional IP law and the practice of developing countries can integrate various proposals that, by complying with the existing international instruments, are also compatible with their interests. In this second part of our short-thesis, it is our aim to explore the proposals that have been put forward by governments at the relevant fora, by the international legal doctrine and by NGO sponsored studies making the IP system more supportive of the CBD's benefit sharing provisions.

The opening chapter will consider the various methods to integrate agricultural TK into a *sui generis* system of plant variety protection, as imposed by Article 27.3(b) on all WTO Members.

In the following paragraphs we will deal with TK protection in other fields. One group of proposals resides in the use of existing and new IPRs contained in TRIPS to protect TK. Another group of proposals tends to observe how a patent system can promote the sharing of benefits between the commercial users of genetic resources (and associated traditional knowledge) and the provider States (and indigenous communities).

Among such proposals we find the obligation, on the part of the biotech-patent applicant, to disclose the geographical origin of the genetic material and associated TK relating to biotehc-inventions. A variant of this proposal is that documentation should also be submitted with the application proving that the material and associated TK were acquired legally and subjected to whatever conditions which were imposed by the source country or indigenous community. This proposal can also be facilitated by the compilation of TK in a databases. If developing countries let patent examiners consult their TK databases, they can be of paramount importance to prevent the mistaken granting of patents whose claims overlap existing TK which can be eventually considered prior art able to destroy novelty.

In this respect, our underlying intention is to make a call for serious efforts to address the growing problem of poor patent quality by improving the examination system and maintaining high standards of novelty and inventive step (or non-obviousness as the case may be).

In the final section of this part II, we will also take up for discussion TRIPS compatible exceptions to patent rights that developing countries are allowed to implement domestically.

This part of our study is therefore devoted to examine these proposals though it would be preposterous for us to aver that we can do so exhaustively in a few pages. An outlook, general though it be, on the methods of synergy between the TRIPS and CBD is useful to better grasp interpretative ways of compatibility of existing international instruments on the subject-matter of genetic resources.

IV. RECOGNITION OF FARMERS' RIGHTS IN AN "EFFECTIVE *SUI GENERIS* SYSTEM" FOR PLANT VARIETIES (ARTICLE 27.3(b) OF TRIPS)

Given the obstacles in the revision of Article 27.3(b) of TRIPS in light of the provisions of the CBD, all WTO Members remain under the obligation to provide protection for plant varieties "either by patents or by an effective *sui generis* system".

In this chapter, we shall analyze the rather limited choice left open by Article 27.3(b) of TRIPS to developing countries to effectively protect plant varieties and at the same time to assure benefit sharing with their farmers. First of all, we will study the already existing UPOV *sui generis* system of protection of plant varieties whose distinctive mark is to have narrowed farmers' rights. It is clear that no understanding of the relations between CBD and TRIPS can be complete without an analysis of other multilateral treaties containing provisions which have the same object. Hence, we need to consider FAO's efforts deployed in view of the recent adoption of the International Treaty of Plant Genetic Resources and Agriculture. It forms with the CBD and TRIPS a triad of almost universal instruments dealing with genetic resources as to create a kind of complementary overlap that will eventually engender more careful attention on the utilization of biological resources as well as the sharing of benefits resulting from their commercialization.

While the UPOV regime seems to conform with the TRIPS Agreement, it is argued that the very fact that, for instance, farmers do not have the right to save the protected seed, is not consonant with the objective of conservation of biological diversity purported by the CBD. The debate, on this and other relevant points, will be examined in order to formulate suggestions for developing countries to create not only an effective but also an equitable *sui generis* protection of plant varieties in compliance with Article 27.3(b) of TRIPS.

A. Tightening the Monopolistic Restrictions in UPOV Convention

The International Union for the Protection of New Varieties of Plants, UPOV is being promoted by some industrialized countries as the benchmark of the "effective *sui generis* system" for plant variety protection required by Article 27.3(b) of TRIPS. UPOV was established by the International Convention for the protection of new varieties of plants which was signed in Paris in 1961 and entered into force in 1968. The Convention was revised in Geneva in 1972, 1978 and 1991. During these revisions, genetic engineering has contributed to bring substantive manipulations of plant genetic codes; consequently plant breeders have progressively sought to soften the distinction between UPOV and patent regimes.

Until recently most countries allowed farmers and other traditional breeders to be exempted from the provisions of such rights, as long as they did not indulge in branded commercial transactions of the varieties. Now, however, after an amendment in 1991 and the subsequent harmonization of the principles established in the Convention, UPOV itself has tightened the monopolistic nature of Plant variety breeder rights by substantially removing the exemptions to farmers.

Although UPOV offered member States the possibility of taking national circumstances into account in their legislation, the major amendments of the UPOV Convention of 1991 leave them little autonomy having set certain precise provisions which, in comparison to UPOV 1978, can be summarized as follows:

(i) **Scope of plant protection**: in 1978 countries may exclude certain plants whereas, in 1991, protection is required for all plant kingdom (Article 3(i) and (ii)).

(ii) **Nature of protection**: the 1978 Act recommends member countries of UPOV to recognize the right of the breeder by means of either a special title of protection or patent. In other words double protection of plant variety is not acceptable. But under the 1991 Act, a plant variety may qualify for both patent and *sui generis* protection.

(iii) **Novelty**: In UPOV 1978 the variety had to be "clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for", e.g., cultivation or marketing, entry in official register, inclusion in reference collection, precise description in a publication. UPOV 1991 narrows the concept of novelty providing that a plant variety is novel when the propagating or harvested material has not been sold or otherwise disposed of with the consent of the breeder (Article 6).

(iv) **Exceptions**: UPOV 1978 did not confine itself to private and non-commercial acts. It allowed the innovation based on protected varieties and provided for the doctrine of exhaustion of rights. UPOV 1991 introduces provisions that restrict exceptions under UPOV 1978 (see Article 15 UPOV 1991).

(v) **Farmers' rights**: in UPOV 1978 there were no limits put on farmers' rights. Whereas UPOV 1991 restricts farmers' rights.

(vi) **Duration of protection**: in UPOV 1978 the duration was 15 years (18 years for vines and trees) and the duration under Article 19 of UPOV 1991 is 20 years (25 for vines and trees)[133].

B. FAO International Treaty of Plant Genetic Resources and Agriculture and the Legal Nature of Farmers' Rights

This treaty upgrades the International Undertaking on Plant Genetic Resources which was the first comprehensive international agreement dealing with plant genetic resources for food and agriculture. It was adopted by the FAO Conference in 1983 as a non-legally binding instrument to promote international harmony in matters regarding access to plant genetic resources for food and agriculture. One hundred and thirteen countries (excluding the USA) have adhered to the Undertaking. It seeks to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes[134]. It is monitored by the Commission on Genetic Resources for Food and Agriculture (CGRFA).

The Undertaking's system was originally predicated on the principle that plant genetic resources should be freely exchanged as a "heritage of mankind" and should be preserved through international efforts. But this principle has not lasted long. The Undertaking was the subject of a

[133] For a thorough discussion on these points see CULLET Ph., "Plant Variety Protection in Africa: Towards Compliance with the TRIPS Agreement", *Journal of African Law*, 45, 1, 2001, pp. 97-122 and KONGOLO T., "New Options for African Countries regarding Protection for New Varieties of Plants", *The Journal of the World Intellectual Property*, Vol. 4, No. 3, May 2001, pp. 352 ff.

[134] This instrument provides for the exploration and collection of genetic resources (Article 3), for conservation *in situ* and *ex situ* (Article 4), for the availability of plant genetic resources (Article 5), for international cooperation in conservation, exchange and plant breeding (Article 6), for international coordination of genebank collections and information systems (Article 7), and for funding (Article 8).

series of agreed interpretations, in the form of three FAO Conference resolutions, which are now annexed to it. They were intended to achieve a balance between the interests of developed and developing countries, namely between the products of biotechnology (commercial varieties and breeders' lines) on the one hand, and farmers' varieties and wild material on the other; in other words between the rights of breeders (formal innovators) and farmers (informal innovators). Resolution 4/89 recognized that plant breeders' rights, as provided for by the UPOV, were not inconsistent with the Undertaking, and simultaneously recognized farmers' rights defined in Resolution 5/89[135]. The principle of free exchange was drastically reduced particularly when the sovereign rights of nations over their genetic resources were recognized in Resolution 3/91, and it was agreed that farmers' rights would be implemented through an international fund for plant genetic resources.

We are reminded that this evolution has been paralleled by other relevant international legislative events: while the preparatory works for the CBD were also affirming the States' sovereign rights over genetic resources, during the revision of UPOV 1991 the monopolistic restrictions created by plant breeders rights were strengthened among developed countries. Hence, most of developed countries neglected the contribution made by traditional farmers who conserved and improved the breeding materials from which new varieties are derived.

In this paradoxical context, the concept of farmers' rights was developed as a counterbalance to IPRs so that industrialized countries would commit to reward the past present and future contributions of farmers in conserving, improving and making available plant based on the germplasm that farmers had conserved over time. In 1991 an International Fund for Plant Genetic Resources was proposed to support plant genetic conservation and utilization programs[136].

In 1992, the Agenda 21 (chapter 14) called for the strengthening of the FAO Global System on Plant Genetic Resources, and its adjustment in line with the outcome of negotiations on the CBD. In adopting the agreed text of the CBD in May 1992, countries also adopted resolution 3 of the Nairobi Final Act, which recognized the need to seek solutions to outstanding matters concerning plant genetic resources, in particular: (i) access to *ex situ* collections not addressed by the Convention, and (ii) the question of farmers' rights.

Similarly to TK these rights have been progressively conceived as moral obligations, rather than an economic incentive. This system of "retrospective equity" will be further developed in the following section concerning the suggestions for developing countries for the protection of plant varieties.

Since it was requested that these matters be addressed within FAO's forum, in 1993, the FAO Conference accordingly adopted Resolution 7/93 for the revision of the International Undertaking and requested FAO to provide a forum in the CGRFA, for the negotiation among governments and for the adaptation of the International Undertaking on Plant Genetic Resources, in harmony with the CBD. This objective has been achieved through the 2001 International Treaty on

[135] Resolutions 4/89 and 5/89 adopted by FAO Conference, 25th Sess., Rome, 11-29 Nov. 1989. In the latter one Farmers' Rights are defined as "rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centers of origin/diversity. These rights are vested in the International Community, as trustee for preset and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions".

[136] See GLOWKA L., *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, Gland, IUCN, 1998, p. 4.

Plant Genetic Resources and Agriculture (FAO treaty). Article 9 defines farmers' rights as a TK holder, although, as we will further see, not all TK holders are farmers:

> *9.1. The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all region in the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis for food and agri-arts production throughout the world.*
>
> *9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments. In accordance with their needs and priorities, each Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:*
>
> *(a)* ***protection of Traditional Knowledge*** *relevant to plant genetic resources for food and agriculture;*
>
> *(b) the right to* ***equitably participate in sharing benefits*** *arising from the utilization of plant genetic resources for food and agriculture;*
>
> *(c) the right to* ***participate in making decisions,*** *at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.*
>
> *9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.*

Even after the upgrade of the International Undertaking the term farmers' rights remains somewhat indeterminate[137]. It is simply a starting point in a probable effective protection of indigenous agricultural knowledge. The potential subject-matter protected by farmers' rights are plants, plant varieties, crops, landraces, traditional plant genetic resources for food and agriculture with their wild and weedy relatives from *in situ* and *ex situ*, and the related know-how of informal plant breeders[138].

The FAO treaty leaves undecided the legal form of farmers' rights. In legal doctrine, authors dispute over the legal form and their opinions can be divided in supporters of farmers' rights as IPRs and supporters of implementation of alternative legal form.

---

[137] The terms farmers' right, used in this treaty, overlaps with other expressions used in literature such as "plant breeders' rights", "farmers' privilege", "traditional IPRs", "genetic resource rights", "traditional resource rights". A full explanation of the content of these rights developed in the doctrine falls outside the scope of this study, see GIRSBERGER M., *Biodiversity and the Concept of Farmers' Rights in International Law*, Peter Lang, Berne, 1999, pp. 172 ff.

[138] Plant resources that are covered by the FAO treaty may also be patentable thus becoming unavailable to Members of the FAO treaty. Two options can be envisaged at this stage: (i) forbidding recipients of material from the multilateral system from claiming IPRs that would limit facilitated access to the resources; (ii) forbidding recipients of material from claiming IPRs over material received via system of facilitated access Article 13.2 (d). With regard to the method to share benefits, if IPRs create a restriction on further access for research and plant breeding which was previously submitted to facilitated access system of the FAO treaty, the rights holder shall pay an equitable royalty to a mechanism set up under the Article 14(d)(iv) of the FAO treaty. Where there is no restriction on access for research and breeding, payment of a royalty is encouraged.

According to Cottier the concept of Traditional IPRs[139] may encompass *inter alia* the one of farmers' rights being TK or know-how relating to plant and animal genetic resources (grassroots innovations). They seem suitable to refer to IP since the knowledge and information concerned, while in the public domain, has been part of the traditional heritage of specific communities and individuals: "it has been intellectual and mental, and it should become a legal property in the future", by removing this intangible knowledge from the public domain[140]. It is evident however that TK does not rely on the concept of novelty[141]. States that wish to thoughtfully and carefully craft a national legislation should primarily seek an interface between traditional resources rights and IP law[142]. Then in this vein, Cottier proposes an international registration system which could be realized by WIPO or in collaboration with other international institutions[143].

A different opinion has been expressed by Girsberger who draws a distinction between farmers' rights and Plant Breeders' rights: the latter are IPRs protecting plant varieties while the first are exceptions to such IPRs. If farmers rights were to be realized as IPRs, they should include by definition a right to exclusiveness in using, selling or reproducing the protected subject-matter, and the exclusive right to compensation. This is not suitable for farmers rights that are group rights, assigned to the collective interests of all involved in conserving crop germplasm without being innovations assigned to specific farmers[144]. Moreover, the IPR option can cause substantial expenses (by administrative bodies and procedures, litigation and scientific investigations) that can consum the compensations achieved through farmers' rights, especially if the demand for their use is not so large.

In this view, farmers' rights are intended to be just incentives for the conservation of biodiversity so that they should include simply the right to compensation[145]. In this line of thought,

---

[139] In a very broad-brushed approach Traditional IPRs can implement a part of the wider of the concept of Traditional Resource Rights. These latter have emerged as a unifying concept having brought together principles of 'bundles of rights'. Traditional Resource Rights typically include laws and aspirations relating to human rights, land and territorial rights, religious rights, development rights, cultural property, collective rights, farmers rights, neighboring rights, and cultural heritage. These rights also typically include issues such as prior informed consent, contracts and covenants, customary law and practice, folklore and cultural landscapes, and rights of privacy. Clearly, such a wide range of issues goes far beyond other *sui generis* models in that Traditional Resource Rights seek to protect not only knowledge relating to biological resources but they also seek to reassert indigenous peoples right to self-determination and to safeguard their culture in the broadest sense, DUTFIELD G., "The Public and Private Domains: Intellectual Property Rights in Traditional Knowledge", *Science Communication*, 21, 3, 2000, p. 287.

[140] COTTIER Th, "The Protection of Genetic Resources", *op. cit.,* p. 1841.

[141] *Ibidem*, *op. cit.,* pp. 1836 ff.

[142] On this point see COTTIER Th., p. "The Protection of Intellectual Property Rights: A Requirement for Technology Cooperartion, Foreign Investment and Equitable Returns in Biotechnology Prospecting, *Biotechnologie für Entwicklungsländer? Chancen und Risiken der Biotechnologie bei Landwirtschaftlichen Nutzpflanzen,* Schweizerisches Zentrum für Internationale Landwirtschaft ed., 1995, p. 65.

[143] COTTIER, "The Protection of Genetic Resources", *op. cit.,* pp. 1845 ff.

[144] See also BRUSH B. *Farmers' Rights and Genetic Conservation in Traditional Farming Systems,* World Development, 1992, p. 1617 ff.

[145] This important aspect deserves some explanation since it falls squarely within our subject area. The creditor of the compensation should be an international fund whose benefits should be distributed among the holders of farmer' rights. The international fund should act as intermediary between the debtors interested in the traditional plant and genetic resources for food and agriculture, their wild and weedy relatives and the related TK and the holders of the farmers' right. Compensation owed by national governments can be assessed in the same mode of contribution to international organizations whereas private seed companies could be taxed a certain percentage on their profits or returns achieved with the sale of seed. Since the aim of the system should be the conservation and the sustainable use of traditional plant and genetic resources for food and agriculture and related know-how, the holders of farmers' rights are all those entities

Girsberger's doctoral thesis concludes that geographical indications, patents, undisclosed information and plant breeders rights are not suitable to protect the subject-matter of farmers' rights mainly because these IPRs are aimed at protecting modern innovations[146].

Girsberger discusses in depth the possible content of farmers' rights[147], detects the applicable criteria of protection[148] and identifies their holders with specific rights and obligations[149], for instance the right to compensation. Holders of these rights can be individual farmers, groups such as indigenous or other rural communities, all farmers involved in informal plant breeding, State entities and the international community.

Without delving in the merits of this discussion, broadly speaking, we wonder whether both proposal can be valid according to the circumstances at hand. For instance, a specific national legislation may consider farmers right to be simply exceptions to an eventual exclusive rights of a *sui generis* system of plant variety protection and at the same time, if a grassroots innovation matches the requirements (yet to be set) to become an IPR, it will inherently be qualified by the element of exclusiveness.

Other authors from industrialized countries regard indigenous agricultural knowledge systems as similar to general scientific information in that they are part of public knowledge[150]. And this mainly because even traditional knowledge innovations characterized by a high degree of inventiveness are seen as ignoring novelty and non-obviousness that generally qualify a subject-matter worth of IP protection.

Although many questions in this respect still need to be addressed, it goes without saying that the implementation of the FAO Treaty will play a crucial role in moving toward a harmonized

---

involved therein. In order to effectively protect them, these rights must have an international validity not subject, like IPRs, to the principle of territoriality. The definition of a term of protection seems inappropriate because traditional plant and genetic resources for food and agriculture are the result of intangibles achieved in the past present and future activities. The realization of farmers' rights should be set through private agreements, statutory provisions or the combination of both. “Statutory provisions” means that international or national law determines nature, content and effects of farmers rights. The author argues that the most effective way to protect farmers' rights either through an existing international agreement (that has recently happened with the FAO treaty) or new international agreements. We propose that in order to have their complete efficacy these rights should be enshrined in TRIPS Article 27.3(b) during its current revision. GIRSBERGER M., *op. cit.,* pp. 255-259.

[146] Anyway Girsberger explains also how the characteristic of exclusiveness can be included in the notion of Farmers’ Rights, see *ibidem,* p. 321.

[147] *Ibidem.,* pp. 206 ff.

[148] *Ibidem*, *op. cit.*, pp. 215 ff.

[149] *Ibidem, op. cit.,* pp. 227 ff.

[150] PHILIPS J., “The Diminishing Domain”, *European Intellectual Property Review,* 8, 1997, pp. 429-430. This author argues that the public domain is under threat under all IP regimes. They are currently enabling the intrusion of private claims on areas of the public domain. The public domain, the author asserts, is a special and valuable domain which should be cultivated for the good of both present and future generations, not parceled up among those most able to assert their territoriality over it. At the opposite side see SWAMINATHAN M. S., "Farmers’ and Breeders’ Rights for India – Farmers’ Rights and Plant Genetic Resources: Recognition and Reward; A Dialogue", Macmillan India Ltd, 1995, pp. 246-247. See also EWENS L.E., Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds, *Boston College International and Comparative Law Review,* 23, 2, 2000, pp. 285-310. According to this author the debate on TK belonging exclusively in the public domain raises serious distributive problems. Until international IPR law increases awareness of the importance of the public domain in preserving genetic diversity, protecting the global food supply, and safeguarding genetic resources, IPR law will under-value and under-compensate the contributions and agricultural concerns of the developing countries that safeguard the vast majority of the world’s plant genetic resources, available at: http://infoeagle.bc.edu/bc_org/avp/law/lwsch/journals/bciclr/23_2/23_2_TOC.htm

interpretation between CBD and TRIPS. Moreover, it will help developing countries identify and implement such traditional agricultural systems, heading toward a full implementation of Article 27.3(b).

C. Plant Variety Protection and Safeguard of Farmers' Rights in Developing Countries

Now that we have studied the principal content of farmers' rights according to FAO treaty, it will not be unwarranted to observe more attentively the impact that UPOV Convention could have on developing countries if they had to adopt it as the *sui generis* system under 27.3(b) of TRIPS.

The following lines attempt to bring forward the different opinions as regards to both positive and negative aspects of this regime of protection of new varieties of plants. Our attention will particularly focus on breeders' rights and the effects of UPOV on traditional grassroots innovators in developing and least developed countries. In light of the definition of farmers' rights in FAO treaty, we will finally attempt to elaborate some proposals to be incorporated in domestic or regional laws aimed at the creation of an "effective *sui generis*" protection for plant varieties in compliance with Article 27.3(b) of TRIPS.

1. Negative Impact of Plant Breeders' Exclusive Rights on Farmers' Rights under UPOV Regime

Indigenous and local communities state that their traditional systems have been largely disregarded when formulating the UPOV Convention. It does not recognize or support communities' inherent rights to biodiversity but it is even detrimental to it.

UPOV monopoly rights do not recognize the scientific or technical knowledge of farmers and of other local actors as scientific knowledge worthy of protection. This means that plant breeders' rights granted under UPOV 1991 neglect the contribution of the farmers of developing countries and undermine their traditional (or customary) rights[151].

Most of the population in developing and the least developed countries strongly depend on agriculture because it is the major means of income of the people. "The typical features of agricultural systems in these countries include: small land holdings, traditional practices, use of simple tools, seed saving from their harvest for further propagation, selling and exchange of seeds"[152].

Ricolfi stresses what is the rationale of seed management in traditional agriculture and its relevance in preserving genetic diversity: "traditional farmers do not confine themselves to replanting the same seeds from one crop to the next in their own farm. They also engage in what is known as seed exchange 'across the fence' from one neighbor to the other. If I understand correctly, this practice - which takes place within the same community and is cooperative rather profit-

[151] CULLET Ph., *op. cit.*
[152] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 477.

oriented - is essential to preserve the vitality of the crops across their different generations and contributes to genetic diversity"[153].

The restrictions provided by UPOV 1991 preventing traditional farmers to save, exchange and sell seeds may adversely affect their traditional livelihood systems as well as the cooperative practices that have been maintained for centuries[154].

We are reminded that these negative impacts for people in developing countries arise while they are much concerned with loss of their bioresources and indigenous knowledge due to biopiracy indirectly led by Transnational Companies under plant variety protection systems. Amongst the countries so affected include India, Thailand, Ethiopia and several other Asian and African countries. "The danger of community plant genetic resources to the detriment of developing countries is symbolized by 'Neem' (a well-known medicinal tree in India) whose bio-pesticidal properties are patented in the U.S. in the new form, ignoring the rights of the people who conserved the knowledge and the properties of 'Neem'[155].

Moving now to the delicate issue of sharing benefits in a fair manner, we have noticed how UPOV provides more benefits to breeders as against farmers whose rights have been severely restricted. That is why Cullet sets the objective saying that "the State is to ensure that at least fifty per cent of the benefits derived from the utilization of their resources or knowledge is channeled back to the communities"[156]. Meantime, UPOV does not provide for any sharing of benefits for exploiting the biodiversity of developing countries, particularly by the transnational companies. The inequity between the source seed providers and the end rights holder even further perpetuated by granting breeders' rights over "essentially derived" varieties.

"Lack of clear code of transferring technology in the UPOV regime is another shortcoming in respect of developing countries. Since UPOV provides stronger protection for the breeder, the risk of imitation will be lower and to the extent that the plant breeder can exploit its technology alone. As a result, it could become more difficult to obtain protected technology and if it is obtained, royalties and other prices are likely to be higher. Moreover, there is no particular requirement for the plant breeder to disclose his/her invention in terms of the UPOV convention"[157].

Therefore, the aversion for the UPOV 1991 regime by certain NGOs in developing countries is not only due to the deterioration of public sector research in the field of plant variety protection or to allegation based on the fact that UPOV overrules of CBD and the directives of FAO[158].

---

[153] RICOLFI M., "The Interface between Intellectual Property and International Trade: The TRIPS Agreement", A lecture delivered at the International Conference on Intellectual Property Education and Training held in New Delhi, July 11-13, 2001 organized by WIPO, the Indian Government and the Indian Institute of Technology.

[154] Gaia Foundation, *Genetic Resources Action International, Ten Reasons Not To Join UPOV*, London & Barcelona, Gaia Foundation & GRAIN, Global Trade and Biodiversity in Conflict, 2, 1998. This report provides ten reasons why joining UPOV is contrary to the interests of developing countries and traditional communities.

[155] VERMA S. K., "TRIPS and Plant Variety Protection in Developing Countries", *European Intellectual Property Review*, 17, 1, 1995, pp. 288 ff.

[156] CULLET Ph., *op. cit.,* p. 104.

[157] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 479.

[158] We however notice that some authors assert that UPOV Convention seems to be in contrast with TRIPS and WTO rules because it leads to results that counter the objective of free trade, by imposing non-tariff barriers and anti-competitive practices, see on this point BADIMBOLI ATIBASAY J. F., *op. cit.,* footnote 116.

In light of all these restrictions it is thus easy to endorse a rhetorical tone on the part of authors from developing countries by emphasizing how "UPOV system encourages genetic erosion of the biodiversity of developing countries. Granting monopoly rights to powerful commercial breeders in order to develop varieties, which are genetically uniform, may destroy the genetic diversity in agriculture. The effects of these exclusive rights in this field would replace the genetically diverse traditional varieties by genetically uniform modern seeds"[159].

Since certain developing countries have joined the UPOV relatively recently, there is still little experience on the impact of UPOV 1991 regime on their economic growth. However, "[l]imited lessons can be learnt from the experience of Kenya and Zimbabwe, which already have plant variety protection regimes in place. In both cases, the introduction of plant variety protection has not substantially fostered the development of new food crops. On the contrary, in Kenya, out of 136 applications filed and tested since 1997, only one was a food crop while most concerned cash crops such as ornamentals or sugarcane and more than half concerned rose varieties"[160].

From these considerations it seems that the positive aspects of UPOV have been highlighted predominantly by the industrialist countries in the North which have joined the UPOV many years back. However, some scholars in developing countries have predicted that certain aspects of a plant variety IP protection (other than UPOV) may benefit developing countries as well. Such arguments are mainly referred to the benefits of biotechnology in the field of plant variety protection if these countries deploy efforts to introduce it.

2. Importance of a *Sui Generis* Protection System for Plant Varieties

Agricultural productivity in developing countries can be improved through an adequate protection for breeding of new plants varieties. Such protection would enhance local investment in research & development and also participation in the global economy. This will help developing countries to set up a core of specialized scientists because the scientific knowledge in agriculture, and particularly in biotechnology, is quite location-specific and not readily transferable from one physical environment to another. Strengthening protection may lead to an increase in innovation in the field of biotechnology only in the case national research and development infrastructure is also stronger.

If on the one hand biotechnology is able to yield improved and faster results in the growth of new crops of a better quality that those obtained by traditional plant breeding methods, this science applied in industry implies additional costs and is in general very expensive. It can then be counter-argued that it is just through IP protection of breeders' rights that inventors to recoup these costs. "Therefore, there is a greater need for protecting plant varieties in developing countries in order to promote research in biotechnology, which has a greater potential for many of the problems faced by developing countries. However, it is important to stress that countries should protect plant varieties while conserving their biodiversity"[161].

---

[159] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 479.
[160] CULLET Ph., *op. cit.,* p.107.
[161] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 481. See on this point M. S. Swaminathan Research Foundation, *Methodologies for Recognizing the Role of Informal Innovation in the Conservation and Utilization of Plant Genetic Resources,* 1994, Madras.

As already said, IPRs help inventors to recoup their costs of development and classic economic theory states that without this legal monopoly innovative products would be likely to be developed. In the process of globalization, developing countries stand in a situation where they need to improve their standards of living in the developed world. Industrial innovation can be crucial for the achievement of this goal. Yet financial investment in research are increasingly flowing from private investors rather than from public funds or private charity.

It is well-known that plant variety protection has been conducive in the USA to achieving greater successes in the field of agriculture: "first generation biotechnology products used by USA have traits that result in reduced pesticide use or higher yields due to reduced pest losses"[162]. Cotton, for instance, is a widely grown biotech crop that kills several important cotton pests. These products provide indirect benefits for consumers and the environment through lower agricultural chemical usage. And this can be true also for developing countries: "The DNA techniques can create disease resistant crops which reduce the use of chemicals and pesticides dangerous to soil and river life. It produces varieties that can grow on agriculturally hostile grounds with high growth rate or size, greater crop uniformity […] The potential offered through biotechnology to produce new varieties for developing countries is very great, particularly in areas where agricultural growth performance has been poor" [163].

We agree with Arunasiri, Chodhury and Abdel-Latif when they conclude their study on this matter stating :

"Research in the field of biotechnology in Switzerland, which has been a long standing member of UPOV, since 1997 has developed (under a Rockefeller Foundation grant) a new rice variety containing Vitamin A. Each year nearly one million child deaths and 14 million children with blindness and other eye problems have been linked to Vitamin A deficiency.

Several European countries including Germany and Switzerland as well as Canada, China, Argentina, South Africa and Japan have already approved several biotech varieties such as corn, soy bean and other crops. European companies are very active in developing and offering transgenic varieties for commercial planting in the USA. For example, AgrEvo, a German company and Novartis, a Swiss company, both have offered commercial varieties of genetically modified corn and soy bean to US farmers. Moreover, about one half of the applications for approval of transgenic varieties currently pending in the EU regularity system are sponsored by EU companies.

It is evident that views of developing countries and industrialized countries on the protection of plant varieties are different because of the diversity in economies, cultures and other socio-political factors. Therefore, each of these factors needs to be carefully studied before a new and effective sui generis system is introduced in developing countries. There is no controversy in granting and safeguarding rights of the breeders as well as farmers in plant variety protection. However, each country needs to study his/her own situation and draft regulations to protect the rights and benefits of both parties concerned".

[162] P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, *op. cit.,* p. 481.
[163] VERMA S. K., *op. cit.,* p. 287.

3. Overview on the Proposals for an Effective *Sui Generis* System in Developing Countries

During the Uruguay Round negotiation of TRIPS, developing countries did not content to the mere fact that UPOV system was not included in Article 27.3(b) as the *sui generis* protection of plant varieties. The African group tried to insert a footnote stating that any *sui generis* law for plant variety protection could provide for the protection of innovations of indigenous communities, the continuation of the traditional farming practices, and prevent anti-competitive rights or practices which will threaten sovereignty of people in developing countries. Such precisions could effectively balance the monopoly rights granted by TRIPS, nevertheless the footnote was refused because of the countering pressures by industrialized countries.

The obligation thus remains for developing countries, not members of UPOV, to provide protection of plant varieties by an "effective *sui generis* system". If on the one hand the attempt to include certain suggestions in a revision of UPOV can be deemed highly hypothetical at present, on the other hand developing countries can consider a national or regional system which we can call "UPOV plus CBD plus FAO treaty". Therefore, considering the UPOV model, these countries can create an acceptable "effective *sui generis* protection" of plant varieties by amending it and keeping pace with the interest of the farmers and environment. The goal of the following suggestions is to grant rights and privileges to farmers so that they can produce, save and exchange seeds freely. In a wider sense, farmers' rights may be extended to farming communities:

(i) **Definition of variety**: the term variety defined in UPOV text should be amended in the way that a plant variety developed by the farmers shall be eligible for protection. Further, a provision should be incorporated that a variety shall be eligible for protection only if it differs from another variety not in one characteristic, but by a wider margin in order to prevent series of genetically homogenous or closely related lines in several characteristics and not just by one. The protection requirements of plant varieties should be more flexible and adapted to the "country varieties"[164].

(ii) **Lowering the required level of uniformity/stability:** The requirements of uniformity and stability as currently applied by UPOV Act 1991 member States do not allow for the heterogeneity required in such situations. An acceptance of such heterogeneity would facilitate and create incentives for the breeding of varieties that are better adapted to the needs of indigenous and small-scale farmers, it may therefore be recommendable to lower the required level of uniformity/stability. This is the background of the proposal to switch from "distinctness", "uniformity" and "stability" to "distinctness" and "identifiability"[165]. On the other hand, it is evident that broadening the limits of heterogeneity within a plant variety to be protected inevitably leads to broader property claims. This has to be taken into account when defining the acts requiring the right holders' authorization in relation to the protected variety. The scope of protection has to correspond to the requirements for protection and the breadth of the claims.

(iii) **Extension of farmers' right**: farmers right should not be confined necessarily to save seeds for reuse on the farms, they should be extended to wider scope. Farmers' rights should include the right to save and share seeds, to sell their product, as well as to have their contribution to the selection, breeding and conservation of existing varieties duly

[164] DUTFIELD G., *Intellectual property Rights, Trade and Biodiversity, op. cit.,* pp. 82 ff.
[165] LESKIEN D. and FLITNER M., *op. cit*., pp. 54-55.

recognized. In order to do that, a provision should be made available so as to protect the interest of the farmers. This right should extend to any variety 'essentially derived' from a variety that was developed by traditional breeders. The right should be recognized in accordance with the custom of traditional breeders. The right to plant variety is to be recognized regardless of whether or not it is registered.

(iv) **Exclusion of certain varieties**: The requirement of extending rights to all varieties of plants should be amended. To secure public interest, certain varieties may not be registered if it appears that the prevention within their territory of the commercial exploitation of such variety is necessary to protect *ordre public* (for instance, crops essential for the nation's food security needs such as rice, cereals etc.) or morality including to protect human, animal or plant life or health to avoid serious prejudice to the environment.

(v) **Twin recognition:** Twin recognition of commercial breeder's rights and farmers rights was proposed at the international level a decade ago but its concretisation is still being discussed. Concerning farmers, the aim should be, *inter alia* to protect farmers' current techniques or varieties and also allow them to derive benefits from any improvements they will carry out without being stopped by patents.

(vi) **Inclusion of public interest clause:** The grant of compulsory licensing should be incorporated. The provision may be laid down that compulsory licence to a party is to be granted if the reasonable requirements of the public for seeds have not been satisfied or that the seed of the variety is not available to the public at reasonable prices.

(vii) **Reference to CBD:** This model should mention its compliance with the CBD.

(viii) **Declaration of resource:** At the time of filing an application, the breeders must declare the name and source of all varieties used in the breeding of new varieties where a land race or farmer variety had been used. The application for protection should specify the parental lines and their country of origin to safeguard the rights of local farmers. If one or more lines have been derived from a particular country, a royalty should be paid to farmers, communities or research organizations who have developed them. In a case where it is not possible to find out the above or when they do not seek such royalty, it has to be credited to a fund to be established under the Convention. Along with this, the principle of "derived variety" has to be excluded in regional Agreements. This is made possible by having a wider margin of the distinctiveness requirement.

(ix) **Prior informed consent**: The traditional breeder's PIC must be obtained by any commercial breeder wishing to use the variety to develop other varieties. In this case sharing of benefits arising out of the use of TK and genetic resources should be ensured[166].

(x) **Inclusion of limitation provision**: Limitation provision to the breeders' right should be provided. Those limitations may be, for example, acts done privately and for a non commercial purpose, use of variety for research and experimentation not designed for commercial exploitation and use of variety for teaching purposes[167]. Moreover, privileges should be granted to research institutions or people to use protected varieties for the development of varieties for non-profitable, namely public interest uses.

(xi) **Promotion of transfer of technology**: All applications for protection should be made to demonstrate the ability to promote immediate, substantial and direct benefit to the people of

[166] See section VI.D.1 for a discussion about the introduction of PIC into the patent system.

[167] *The Interface between Intellectual Property and International Trade: The TRIPS Agreement,* lecture delivered by Prof. Marco Ricolfi of Torino Law School, at the International Conference on Intellectual Property Education and Training held in New Delhi, July 11-13, 2001 organized by WIPO, the Indian Government and the Indian Institute of Technology.

the respective countries by the cultivator of such a new variety. The mode of developing the variety entitled to protection should be disclosed in order to facilitate the transfer of technology.

Notwithstanding these suggestions that we have formulated on the basis of scholarly works[168] and personal contacts[169] on the issue, as Cullet puts it, "relatively little conceptual work" has been done on the definition of an alternative system to monopoly rights. This is mainly motivated by the pressure made on developing countries to join UPOV. By our suggestions we have tried to show that without rejecting genetically engineered seeds, it is possible to conceive an alternative system in which the allocation of IPRs is established in compliance with other commitments under international environmental law. A plant variety protection regime, accompanied by the aforementioned characteristics, can eventually foster positive environmental results in the interests of these countries. Finally this regime can aver to be an inherent part of the act of implementation of the CBD in domestic or regional legislation.

V. CBD AND THE DUTY OF NEGOTIATION: THE FRAGILITY OF THE CONTRACTUAL SOLUTION[170]

The CBD encouraged mutual agreements between bioprospecting companies and hosting States in view of attaining equitable benefit sharing. In this chapter we seek to verify the effectiveness of international contracts by answering two main questions: (i) are the benefits arising from IPRs equitably shared between the screening companies and the indigenous communities, sometimes represented by their governments? (ii) is the contractual practice able to satisfy not only the interests of the Parties but also the imperatives of the conservation of the biodiversity? Besides the fact that satisfying answers would necessitate a long and large inquiry on the disparate international contractual practice, we hasten to add that such contractual arrangements remain mostly confidential and their categories vary on a case-by-case basis. We are nevertheless committed to find some general common characters by examining some major contracts that have been available in the UNEP reports and whose reproduction has been found in secondary sources[171].

---

[168] DUTFIELD G., *Intellectual Property Rights, op. cit*., pp. 78-85. LESKIEN D. and FLITNER M., *op. cit.* For a deeper analysis on the development of *Sui Generis* Variety Protection in Africa see CULLET Ph., *op. cit*., pp. 117-122. See also VERMA S.K., *op. cit.,* pp. 281 ff. and ROBERTS T., "Patenting Plants around the World", *European Intellectual Property Review,* Vol. 18, 1996, pp. 281 ff. CORREA C. M., Biological Resources and Intellectual Property Rights, *European Intellectual Property Review*, 14, 5, 1992, pp. 154-157.

[169] These proposals are the results of a joint collaboration and discussions with P. H. J. ARUNASIRI, Sh. A. CHOWDHURY and R. O. ABDEL-LATIF, see also *op. cit.,* pp. 483-484. These suggestions are also inspired by conversations held with Professor Ricolfi and with Mr. Lavignol of UPOV in Geneva.

[170] We thank Ch. Noiville of the French CNRS for her important insights that have largely contributed to the drafting of this section see also NOIVILLE Ch., "Biodiversité et propriété intellectuelle l'impossible conciliation ?", in Sandrine Maljean-Dubois (ed.), *L'outil économique en droit international et européen de l'environnement*, Documentation Française, 2002

[171] DRAHOS P., "Indigenous knowledge, intellectual property and biopiracy: is a global bio-collecting society the answer?", *European Intellectual Property Review*, 6, 2000, pp. 245-250. Finding ways to encourage mutually satisfactory contractual arrangements between life science companies and indigenous groups over the use of traditional knowledge has become a major regulatory challenge. Part of the solution, it is argued in this article, lies in the creation of a global bio-collecting society. A global bio-collecting society will overcome some of the problems of uncertainty

I approach this matter with the underlying hope to see in reality a transition from an era of confrontation to an era of cooperation between developing and industrialized countries. This is one of the areas of IP global issues that urges synergy and strong interdependence between technologically advanced and biodiversity rich countries.

A. Are Contracts Adequate to Fairly Share Benefits Arising from Utilization of Genetic Material and Related Traditional Knowledge?

Contractual freedom is the solution that is proposed by most of the industrialized countries to the problem of benefit sharing on the TK related to biodiversity[172].

When TEK serves as a starting point for patented products, one very basic shortcoming is that in most of the cases, TEK is considered as know-how which cannot be qualified as *per se* an "inventive contribution" in the sense of patent law in order to claim "joint inventorship"[173]. However this know-how may represent a fundamental precondition to all subsequent research and development work carried on by recipient industries. In this connection I will observe that the entitlement of the provider countries to receive compensation should be made independent from the existence, from the validity and from the duration of biodiversity-based patents. The simple fact that a bioprospecting company develops and uses biodiversity-based industrial products is enough for claiming benefit sharing obligation.

When reading the provisions contained in the preamble of several of benefit sharing

---

and enforcement that confront Contracting parties in this area. See also TOBIN B., "Know-how Licenses: Recognising Indigenous Rights Over Collective Knowledge"*, Bulletin of the Working Group on Traditional Resource Rights*, 4, 1997, pp. 17-18. This author shows how legally-binding agreements such as contracts and licenses can be used to guarantee benefit sharing with local communities. In Peru, the Aguaruna people have negotiated a know-how license with an American drug company called Searle. The Aguaruna pass on medicinal plants and knowledge (i.e. 'know-how') to the company and in exchange receive an annual know-how license fee. Another important article on this issue is YANO L. I., "Protection of the Ethnobiological Knowledge of Indigenous Peoples", *UCLA Law Review,* 41, 2, 1993, pp. 443-486, though treaties and contracts are possible mechanisms to protect traditional knowledge, the authors demonstrates that these have not yet proved effective in ensuring equitable benefit sharing. The author reviews economic patent theories and concludes that patent protection should be extended to include traditional knowledge.

[172] For instance, the US representative to the WIPO IGC, in order to promote international contracts as the best solution to benefit sharing problems, has mentioned the relevant example of the National Institute of Health in its recent contracts concluded with the developing countries. One of these cases involves the National Institute of Health identifying a compound, known as protstratin, as effective in treating HIV. Prostratin, a protein kinase C activator, was isolated from the stems of the small Samoan tree *Homalanthusnutans*. Traditionally, *H.nutans* plays an important role in Samoan ethnopharmacology, with the leaves being used to treat back pain, the root used to treat diarrhea and stem wood used to treat yellow fever. Studies that led to the discovery of Prostratin as a treatment for HIV were developed through a collaboration between an American scientist and healers from the village of Falealupo under terms of a covenant negotiated with the village chiefs and orators, and with the concurrence of the Samoan Prime Minister and members of parliament. Under the covenant, over $480,000 have been supplied to the village for schools, medical clinics, water supplies, trails, an aerial rain forest canopy walkway, and an endowment for the rain forest. In addition, if prostratin is approved for marketing, the non-profit research organization that is working on the drug agrees to pay the following royalties as percentages of net revenues: 12.5% to the Samoan government, 6.7% to the Falealupo village, 0.4% each to the descendents of the two healers associated with the identification and formulation and use of the original genetic resource. Furthermore, the representative of US has assured that once the drug is approved and marketed, the drug will be distributed at minimal profit in developing countries; see Intervention of the Delegation of the United States of America to the *WIPO Intergovernmental Committee on Intellectual Property And Genetic Resources, Traditional Knowledge and Folklore*, Third Session, Geneva, June 13 to 21, 2002, Agenda 5: Traditional Knowledge; documents WIPO/GRTKF/IC/3/7, 8, 9.

[173] BLAKENEY M. "Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective", *European Intellectual Property Review*, 1997, pp. 299-300.

agreements between bioprospecting companies and providing countries one may receive the impression of a good-will to conform to the principles and the spirit of the CBD, especially in the perspective of equitable relations between the parties. Sudden disillusion is the feeling at the reading of the single substantive? provisions that in reality hardly match the balanced articulation among the paradigms of bioprospecting/IPRs/sustainable exploitation. One of these examples is the agreement concluded between the U.S. National Institutes of Health and the Government of the Philippines for the screening of specimens of important therapeutical relevance.

Three principal shortcomings are recurrent in many contracts of this type:

A. The contractual benefit sharing arising out of IPRs remains very uncertain or distant in the future. The main reason lies on statistical figures: generally, only one sample out of 10.000 or even 100.000 gathered specimens will yield the development of a marketable invention. Consequently, the benefit sharing at the contractual stage remains highly unpredictable. This is the reason why it is extremely unusual to find examples of contracts like the one between the Company Merck and the Biodiversity National Institute of Costa Rica In Bio, in which Merck is under the obligation to transfer a certain amount of money for the simple right to gather samples[174].

At the stage of sample gathering there is indeed a deep difference between the contracts for the genetic modification of biological resources and those for the direct valorization of biodiversity. In the latter types of contracts, the company or the bioprospector tends to acquire a great quantity of biological resources that will be used in a classical industrial process. This is the case of the sale of seeds by horticulturists that will sow and then sell under the forms of plants, or of the sale of tree-barks for the fabrication of a drug. In these contracts IP issues are very marginal. Mention can be made of those concluded by *Shaman Pharmaceuticals* with the *Consejo Aguarana/Huambisa* in Peru[175].

The parameters change (i.e. some benefits can flow to the provider State entities) when the bioprospecting company seeks to obtain genetic resources in order to develop a search process through biotechnology. But another hindrance appears very soon: in this case once a molecule is synthesized or once the gene is cloned, the biotechnological company will not need to come back to the indigenous community to ask for more samples. The reproduction of the successful sample can be comfortably pursued in a lab without undertaking further sample gathering activity. As a result, bioprospecting companies are hesitant to continue to remunerate the community or the provider State from which the sample used to be gathered. A solution to this more equitable economic relations pertaining to the screening activities can be achieved through statutory provisions adopted by the country of origin. National legislation can provide for a contractually defined framework regulating the matter from the genesis of the bioprospecting operations[176].

---

[174] In 1991, Merck, a multinational pharmaceutical company, entered into a bioprospecting agreement with the Costa Rican Association Instituto Nacional de Biodiversidad (INBio), a non-profit organization. Under this agreement, over a two-year period, Merck received 10.000 plant samples that were supplied with information about their traditional use. Currently, three of the drugs that Merck sells earn over US $100 billion each. If one of the 10,000 samples becomes a billion-dollar drug then Merck has agreed to pay 10-30 million dollars in royalties. This is clear evidence of the commercial value of TK on intellectual property at the basis of many pharmaceutical companies. POSEY D. and DUTFIELD G., *Beyond Intellectual Property Rights: Towards Traditional Resource Rights for Indigenous Peoples and Local Communities*, International Development Research Centre, Ottawa, 1996, p. 44.

[175] *Ibidem.*

[176] See, for instance, the Mission in Madagascar performed by the French CNRS led by HERMITTE M.-A. to help the Madagascarian Government in drafting new law in conformity with TRIPS and CBD, *Mission sur la valorisation de la diversité biologique à Madagascar*, April 2000, available at : http://panjuris.univ-paris1.fr

B. The fragility of the economic relationship inherent to such contracts is due to a second dilemma: indigenous communities will hardly be able to control the development of eventual inventions because the researches on the samples are rarely made *in situ*. In other words, local people should invest enormous research efforts to know when and if their biological resource, once genetically modified, has been patented.

C. The problem B has a much deeper implication which needs to be addressed specifically: the lack of participation of the local community or of its State into the development process of the biodiversity-based product. To illustrate this shortcoming, I can refer for instance to the *Agreement between the Peruvian Communities representing the Aguaruna and Huambisa peoples and G. D. Searle & Co. of Monsanto Group*, a U.S. Company, where the inherent potential of patenting the genetic resource has endowed the "industrial party" (the licensee) with a much higher contractual power. Indeed the long Article 6.03 provides the sole duty on the licensee of the biodiversity material and industrial developer and owner of the patent on the new drug or seed to "grant back" to the biodiversity providing licensor a non-exclusive license "for research use"[177] but "not for any commercial use". This means that it could not be conferred to and shared with a locally operating industry. Moreover according to Article 6.05, while the indigenous people are free to continue to make and sell their traditional products, it is clearly stated that *"all products covered by such patent rights shall be conclusively deemed not to constitute traditional Aguaruna and Huambisa Medicinal Products and any and all methods covered by such patent rights shall be deemed not to constitute Traditional Aguaruna and Huambisa Methods"*. Accordingly, I did not find in the contract any provision of any participation of the local communities in the industrial development of the new products. As a result, the biodiversity-related innovation based on the traditional germplasm, be it patented or not, will not be profitable to the community whose TEK has been crucial in the preservation of the successful compound (see *infra* para. D.2.xiv for a possible solution).

D. Another problem relates to the fairness of the economic relationship set by the international contract as regards to the subject entitled to the compensation. As earlier observed, in the great majority of cases the benefit sharing provisions remunerate the resources themselves and very seldom the related know-how transferred by the indigenous communities[178]. The situation changes when a "trust fund" is especially instituted. The optimal solution is that the local communities must be either directly involved or even party to such agreements, which is rarely the case. In some other contracts the remuneration is uncertain because there is generally no obligation on the government to pay a compensation of the benefits to the local populations[179]. The problem is that, in spite of the fact that there is an international mandate to seek the fair and equitable sharing of the benefits from the commercialization of their genetic resources and related knowledge, contracts currently in existence are far from being satisfactory. Moreover, even where a local community is a direct party to the agreement, it will be much less able to take legal action against a

[177] McMANIS Ch., "Recent Publications on Indigenous Knowledge Protection--New Directions in Indigenous Knowledge Protection", *ATRIP 1999 Collection of Papers*, p. 71.

[178] In the contractual perspective the industrial party attributes to the biodiversity-providing local communities just a financial return, be it a lump sum and/or a royalty, from commercial exploitation of the new biodiversity based drug or food produce such U.S. contractual models like the "Diversa-Yellowstone CRADA-Cooperative Research and Development Agreement", and "INBio-Merck", both involving mere profit-sharing: reference in "The need and possible means of implementing the Convention on biodiversity into patents law", *AIPPI Yearbook 2001/II,XXXVIIIth Congress, Report of the US Delegation on Question 159,* 388 f.

[179] COOMBE R.-J., « Intellectual Property, Human Rights and Sovereignty : New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity », *Indiana Journal of Global Legal Studies*, 1998, n° 6, pp. 59 ff.

company in another country in case of infringement. Therefore, legal advice at the early stages of the negotiation and the establishment of a "trust fund" can constitute preliminary warranties to such unpleasant situations. For instance, local communities can be assisted by IP knowledgeable NGOs to mediate and evaluate the terms and the implementation of such agreement.

In sum, entire freedom of negotiation of contracts cannot be overestimated as a tool to enhance the biodiversity valorization and preservation policies. International standards should be elaborated to protect the weaker party and at the same time to avoid the forum shopping of bioprospecting companies that, when attracted by important compounds, may go where there is no national legislation protecting the weaker contractual party.

B. Are National Laws Able to Create a Legal Framework to Enhance Benefit Flows to Local Communities?

That the contractual practice frequently fails to match the basic requirements set forth by the CBD, does not exclusively depend on the "ferocity" of the bioprospectors. The specialized legal doctrine has shown that the quality of national laws in the field of access to biodiversity bears its part of responsibility in the manners in which CBD provisions have been applied[180].

Among the recently adopted legislation I can mention the one of the Andean Pact[181], the Organization of the African Unity[182] and Costa Rica[183]. Besides the fact that such full-fledged model laws on these issues appear to be exceptions, the existing ones meagerly put into place the subtle mechanism envisaged by the CBD[184]. Actually, most of them fail to institutionalize revenues to the indigenous communities whose TK is crucial in orienting the bioprospecting (or gathering of information). A number of other countries seem to be so "obsessed" with the outflow of genetic resources from their territories, that they scarcely manage any possibility of bioprospecting by foreign companies and even oppose the objective of commercial valorization of their biodiversity in the terms of the CBD[185].

---

[180] For an updated overview of the situation of implementation of these laws see DUTFIELD G., "Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries", UNCTAD, 2002. See also GOPALAKRISHNAN N. S., "An "Effective" *Sui Generis* Law", *Journal of World Intellectual Property*, 2001, pp. 165 ff. and pp. 168 ff.; KONGOLO T., "New Options for African Countries regarding Protection for New Varieties of Plants", *Journal of World Intellectual Property*, 2001, pp. 349 ff.; CULLETT P., "Property Rights over Biological Resources"*, Journal of World Intellectual Property,* 2001, pp. 211 ff., p. 215, pp. 222 ff. and "Plant Variety Protection in Africa: Towards Compliance with the TRIPS Agreement", *Journal of African Law*, 2001, pp. 97 ff., pp. 105 ff.; BLAKENEY M., "The Protection of Traditional Knowledge under Intellectual Property Law", *European Intellectual Property Review*, 2000, pp. 251 ff., especially p. 252. See also J. ROBERTSON-D. CALHOUN, "Treaty on Biological Diversity: Ownership issues and Access to Genetic Materials in New Zealand", *European Intellectual Property Review,* 1995, pp. 219 ff., pp. 222 ff.

[181] CORREA C., *The Access Regime and the Implementation of the FAO Treaty on Plant Genetic Resources for Food and Agriculture in the Andean Group Countries. An Exploratory Report*, University of Buenos Aires, February 14, 2003.

[182] DUTFIELD G., *Intellectual Property Rights, Trade and Biodiversity*, IUCN, Earthscan Publications, London, 2000, p. 114.

[183] In April 1998, the Legislative Assembly of Costa Rica passed the "Ley de Biodiversidad", or "Biodiversity Law". To date this is perhaps the most ambitious and elaborate national law to implement the CBD.

[184] See also Mission in Madagascar performed by the French CNRS led by HERMITTE M.-A., *op. cit.*

[185] See for example the « Organization of African Unity Draft Legislation on the Community Rights and Access to Biological Resources », besides lacking essential definitions of the relevant key terms and concepts, emphasizes the

For instance, the Decision 391 of the Andean Pact, generally considered as the model law, has been effectively implemented (with the limitations that I will indicate here below) only in Colombia and Venezuela. The other three Contracting Parties either procrastinate to transcribe it into domestic legislation (Bolivia) or question its very *raison d'être* (Peru and Ecuador)[186]. Very paradoxically, while it is clear to all that a total control over genetic resources of a country is a mere wishful thinking, many States focus more on strengthening their laws and judiciary machinery to fight biopiracy than on creating a flexible system apt to promote forms of benefit sharing with the some big bioprospecting institutions[187]!

This aversion to IPRs, especially on the part of the peoples of certain developing countries, is becoming so acute that sometimes no conciliation seems likely to be found with their manner of interpreting the CBD. In other words, these peoples are becoming more and more persuaded that IPRs are utterly useless and will always be unfavorable to their interests[188]. They do not confine to expose such or such patent based on an alleged biopiracy case, they rather work on a real coalition striving to obtain a moratorium on the bioprospecting activities and ban any form of IPR on genetic resources[189], e.g. to revise Article 27.3(b) by abrogating the obligation to protect biotechnological innovations[190].

Even in the rather advanced situation in the Andean Group Countries, I observe that no information is systematically made available about access applications submitted to and the contracts approved by the National Competent Authority, instituted under the aforementioned Decision 391.

At the national level, in Venezuela only five of the twenty applications have been transformed into contracts signed exclusively with research institutions and only one with a foreign entity. No application has been filed by a private company. A few applications seem to be involved in activities related to the conservation and use of plant genetic resources for food and agriculture. Three applications were submitted to the national authority in Bolivia and, despite the

---

controlling access rather than establishing favorable conditions for benefit sharing and equitable partnership with the private sector, cf. DUTFIELD G., *Intellectual Property Rights. Trade and Biodiversity, op. cit.,* p. 116.

[186] CORREA C., *op. cit.*

[187] RUIZ-MULLER M., "Regulating Bioprospecting and Protecting Indigenous Peoples Knowledge in the Andean Community", in SAHAI S., *Commercialization of Indigenous Knowledge and Benefit Sharing, UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices*, Geneva, 30 October – 1 November 2000. See also, DUTFIELD G., *«* Bioprospection ou Biopiratage ? *», Biofutur*, n° 204, October 2000, p. 45.

[188] For the opinions expressed by these States see the Conference on *Biodiversity Conservation and Intellectual Property Rights*, New-Dehli, 29-31 January 1999. On the contrary recommendations that bring into effect international IP treaties in their national regimes have been suggested by DUTFIELD G., *Intellectual property Rights, Trade and Biodiversity, op. cit.,* p. 139.

[189] See for instance the Coordinating Body for the Indigenous Peoples' Organization of the Amazon Basin (COICA), *Consultation of Indigenous People's Knowledge and Intellectual Property Rights*, Final Statement, Suva, April 1985, UNCTAD Expert Meeting.

[190] See on this matter MULVANY P., "TRIPS, Biodiversity and Commonwealth Countries : Capacity Building Priorities for the 1999 Review of TRIPS Article 27.3 (b)", in *Commonwealth Secretariat and Quaker Peace and Service*, Rugby and London, quoted by DUTFIELD G., *Intellectual property Rights, Trade and Biodiversity, op. cit*., p. 93. The position of these countries can be also studied in *Queen Mary Intellectual Property Research Institute, Study on the Relationship Between the Agreement on TRIPS and Biodiversity Related Issues*, a study commissioned by the general direction of trade of the European Commission, September 2000, pp. 6-7. See also some extreme positions by STENSON A. J. and GRAY T. S., *The Politics of Genetic Resource Control*, Macmillan Press Ltd, Basingstoke, 2000.

implementation problems noted above, one contract has been signed. In Colombia and Ecuador three applications have been submitted but no contract has been concluded yet[191].

Generally speaking, access regimes have not spurred on the interest of local or foreign companies in access to genetic resources, as shown by the small number of applications filed and on the predominance of applications for academic research rather than for commercial purposes. No case can be identified where benefit sharing has actually taken place. If on the one hand it seems that there is no conclusive evidence indicating that the Andean access regime has actually impeded bio-prospecting, on the other hand it can be said that it has not promoted the collection of, research on, and commercial exploitation of genetic resources[192]. It would nevertheless be unjustified to attribute this failure to the characteristics of the Andean legal regime that *prima facie* does not pose particular hurdles to the bioprospecting company. One of the fundamental reason seems to be found in the declining interest by pharmaceutical companies in bio-prospecting for new drugs, because of the higher probability to generate successful pharmaceutical products from the research in combinatorial chemistry, also bioinformatics, genomics and proteomics. There is much disillusion among the specialists of this sector since the adoption of Decision 391 was based on the presumption that important economic benefits could be generated by bio-prospecting.

In this context, a very important aspect of achieving benefit-sharing goals is to promote the exchanges between potential contractual partners. For instance the Andean Community is currently setting the example by signing an agreement with the Corporación Andina de Fomento (CAF) to study ways to promote "bio-trade".

Finally, as professor Reichman puts it, "governments in developing countries should […] regulate the manner in which foreign firms obtain access to local germ-plasm, with a view to sharing in both the technical knowledge that may result and the proceeds of commercial exploitation"[193]. Instead of cultivating the antinomy between IPRs and their own development, biodiversity rich developing countries should know that the preservation of biodiversity itself necessitates expensive programs, whose financial resources need to be found in the licensing of traditional know-how.

C. Bioprospecting Cartels among Developing Countries to Access to their Biological Resources

The preoccupation that indigenous and local communities poor financial means to enforce their rights in other jurisdictions and that they are not self-sufficient to eventually start judicial proceedings against foreign companies has led Vogel to formulate an urgent and dramatic proposal on the use of "cartels among States" on biological resources.

Of course this strategy is totally CBD compatible and would not run counter any IP international obligation. Developing countries that supply biological resources might exercise their exclusive sovereignty through oligopoly rights over their genetic resources. The cartel among them fixes a royalty rate and distributes economic rents according to their ability to have provided the patented biochemical. Vogel suggests a royalty of 15% on net sales of biotechnologies with 2%

[191] The information on Bolivia and Ecuador is based on *Informe Final. Primera Reunión del Comité Andino sobre Recursos Genéticos*, November 3 2000, SG/RC.RG/I/Informe Final, February 16, 2001.

[192] Professor Carlos Correa has indicated that the Fundación Humboldt is carrying out in Colombia a project (with an interdisciplinary team of about 12 researchers) on the application and implications of Decision 391.

[193] REICHMAN J., "From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement", in *N.Y.U. Journal of International Law and Politics*, 11, 1997, p. 39.

going to the country of contact for the value added to the genetic information in taxonomy and preparation of extracts and the other 13% to be divided among all countries that could have supplied the same biological sample in proportion to the existence of that genetic information in the country[194].

If on the one hand the submission to the rigor of a regional cartel with this high royalty rate system would encourage real incentives to conserve biological diversity and may also succeed in persuading the CBD Parties to give up some of their hard won, albeit illusory, sovereignty obsessions over biological diversity; on the other hand, we have already observed that bioprospecting companies are not yet strongly interested in coming into contracts with State entities for accessing germplasm or other genetic samples. Hence, they may substantially be discouraged by such costly and complicated cartels. During the years to come biodiversity rich countries should rather focus on the worldwide promotion of their genetic resources by several marketing measures (see for instance the clearinghouse mechanisms). On the contrary, strategies based on high prices on genetic resources can carry their hoped results in a future in which there will be a strong demand on accessing biodiversity for research and development of successful genetic resources based and patented products.

VI. PROTECTION AND VALORIZATION OF BIODIVERSITY RELATED TRADITIONAL KNOWLEDGE IN INTELLECTUAL PROPERTY SYSTEMS

The rise of modern information technologies has led to an increasing awareness of the value of TK. At a time when the wealth of nations lies increasingly in the knowledge which their peoples hold, the use of IPRs related to TK has become an important issue. Unfortunately this importance is neither recognized in the Paris Convention for the Protection of Industrial Property of 1883 as amended nor in the TRIPS Agreement. Indeed both the Paris Convention and TRIPS grant monopoly rights by way of patents to inventions, whether products or processes, in all fields of technology only provided that they are new, involve an inventive step and are capable of industrial application (Article 27). Despite the apparent insurmountable legal difficulties to patent TK and although to date no international system has been designed to provide for an effective legal protection of TK[195], all is not bleak for TK.

Universality of IPRs, promoted by TRIPS, urgently calls for the exploration of new ways in which the IP system can serve as an engine for social, cultural, economic and technological progress of the world's diverse population, and one of the areas identified for exploration is the needs and expectations of groups, such as indigenous peoples, which until now have had little or incomplete exposure to the IP system. As indigenous peoples everywhere acquire a deeper understanding of IPR regimes and ways of challenging them when they impinge on their human or resource rights, they start to invoke the implementation of the relevant provisions of the CBD, especially those dealing with TK and overall access to genetic resources.

In response, developing countries are seeking IP registration systems that would identify and document the sources of genetic material and indigenous knowledge used in product

[194] VOGEL J. (ed.), *El Cartel de Biodiversidad* (The Biodiversity Cartel) Quito, CARE, available at: www.thebiodiversitycartel.com, 2000.
[195] WIPO Report, *Intellectual Property News and Expectation of Traditional Knowledge Holders* (1998-1999), Geneva, April 2001, p. 16.

development[196]. Such a system would allow the equitable sharing of benefits arising from the use of such genetic material and knowledge in accordance with the CBD[197].

While the development of new IP standards or rights for the protection of biodiversity related TK has been taking place, effective protection can be already sought through existing "formal" IPRs (low-cost patents, trademarks, trade-secrets and geographical indications)[198]. These attempts to protect TK by IP and the needed infrastructures will be taken up for discussion, trying, at least superficially, to consider proper distinctions among IPRs apt to protect various TK subject-matters (traditional agriculture, traditional medicinal knowledge, informal breeding, etc.). Indeed, a deeper analysis in this sense would very probably demonstrate that the suitability for protection by existing IPRs or by a new *sui generis* IPR depends very much upon the category or subject-matter of TK concerned.

In light of the intense scrutiny and heavy criticism addressed to the patent system, in the final part of this chapter we discuss the feasibility of some of the proposed measures in order to valorize biodiversity related TK within patent law. These methods include disclosure requirements and certification of origin, the usefulness of TK databases for the international prior art search and finally the national and regional implementation of different types of exceptions envisaged by TRIPS in patent law.

A. A Working Definition of Traditional Knowledge

TK, by gaining importance, has become the new buzzword for IP Protection. For the definition of TK, WIPO uses the term to refer to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and, all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. The notion "tradition-based" refers to knowledge systems, creations, innovations and cultural expressions "which have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; have generally been developed in a non-systematic way; and, are constantly evolving in response to a changing environment"[199].

Categories of TK include subject-matters such as: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related

[196] See JACOBY A. and WEISS Ch., "Recognizing Property Rights in Traditional Biocultural Contribution", *Stanford Environmental Law Journal*, 16, 1997, p. 74.

[197] On this issue see GLOWKA L., *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources,* World Conservation Union, Gland, Switzerland 1998. Similar debates have been going under the auspices of the FAO Commission on Plant Genetic Resources for Food and Agriculture. The work of the commission focuses on revising the International Undertaking on Plant Genetic Resources to bring it in line with the Convention on Biological Diversity.

[198] *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (2001): First Session, Geneva April 30 to May 3 : Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Doc No. WIPO/GRTKF/IC/1/3.

[199] *Intellectual Property Needs and Expectations of Traditional Knowledge Holders — WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge,* WIPO, April 2001, p. 25. See also *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore Elements of a* Sui Generis *System for the Protection of Traditional Knowledge,*WIPO/GRTKF/IC/3/8, p. 5.

medicines and remedies; biodiversity-related knowledge; "expressions of folklore"[200] in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of TK would be items not resulting from intellectual activity in the industrial, scientific, literary or artistic fields, such as human remains, languages in general, and "heritage" in the broad sense[201].

The working definition of TK within the CBD is : "The knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles" as well as "indigenous and local technologies"[202]. But this formal and concise statements mention what TK contains more than what TK is. It seems that a precise and accepted legal definition of TK has not been conceived yet. Meanwhile, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC) has not deemed it necessary for identifying the legal elements of a mechanism for its protection: "Most patent laws, for example, do not precisely define the concept of an 'invention'; equally, international harmonization and standard-setting in patent law have proceeded without specific or authoritative international definitions of this fundamental concept – although what constitutes an 'invention' has strong elements of harmony in practice, significant differences continue to apply at the national level after some 120 years of progressive international harmonization"[203].

The WIPO IGC Secretariat has however been deciding to break the holistic working concept of TK into two separate categories with correspondent legal tracks : (i) TK related to the biodiversity, i.e. genetic (or, more generally, biological) resources such as traditional medicinal know-how, traditional agricultural practices and local/indigenous planting materials, can be also called "technical TK"[204] and be suitable for sui generis system. (ii) TK related to the arts such as handicrafts and expressions of folklore would be destined to the development of a system duly adapted to the characteristics of expressions of folklore. As we will further examine in section

---

[200] Folklore is defined as the literary, artistic, religious, scientific, technological and other traditions and products as a whole, of communities and that have been handed down from generation to generation. It includes (a) literary works of any kind in oral or written form, stories, legends, provides, epics, chronicles, myths; (b) artistic styles and productions; (c) religious traditions and celebration; (d) educational traditions, initiations, sports, games, codes of manner and social conventions; (e) scientific knowledge and works; (f) technological knowledge and works.

[201] *Intellectual Property Needs and Expectations, op. cit.,* p. 23.

[202] CBD. Articles 8(j) and 18.4. Moreover, the UN has made significant contribution in this domain. This is conspicuous in the various agencies it has created preoccupied with this question. A United Nations international year for the World's Indigenous Peoples was declared and this led to the promulgation of a draft Declaration on the Rights of Indigenous Peoples. Article 12 of that draft has recognized the rights of indigenous people to *"practice and revitalize their cultural traditions and customs, including the right to maintain, protect and develop the past, present and future manifestation of their culture ... as well as the right to restitution of cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs"*. Furthermore, this right has been recognized by the UN in Article 29 of the draft Declaration on the Rights of Indigenous Peoples when it provides that indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and IP, including the right *to special measures to control, develop and protect their sciences, technology and cultural manifestations, including human genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions*" UN Commission on Human Rights, Sub Commission on Prevention of Discrimination and Protection of Minorities: *Draft UN Declaration on the Rights of Indigenous Peoples*, 39 *Intellectual Legal Material,* 5th (1995), see also ABBOTT F., *op. cit.,* p. 506.

[203] WIPO/GRTKF/IC/3/8, p. 5.

[204] For more specific definition and usage of terminology in the field of TK see *Traditional Knowledge –Operational Terms and Definitions* intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore, WIPO/GRTKF/IC/3/9 Third Session, Geneva, June 13 to 21, 2002.

VI.B.C, this distinction appears to have various conceptual advantages in the attempt to make TK subject-matters more suitable for protection IP systems.

B. Using Existing Intellectual Property Rights to Protect Traditional Knowledge

1. Suitability of Low Cost Patents for Traditional Knowledge

As the patent is the first IPR to be sought for a biotech-invention, it is by this form of IPR that we will commence our survey on the integration of TK in IP law.

A low-cost patent system has been proposed particularly by Gupta[205] and Cottier[206]. Gupta believes it is possible to establish a global "register of innovation" entailing a one-shop, one-stop filing procedure with national offices or international organizations. He also stresses that this system would be more suitable for individual applications rather than community ones. Petty-patents are already available in several countries to complement the traditional patent system designed for industrial purposes. All national patent offices would have facilitated access to this register to ensure that patent claims duplicating innovations contained in the register are rejected. Cottier notices that - moving towards a post-modern generation of “Traditional IPRs” in the electronic era – the gaps between a national system and real international one can be easily bridged. Gupta suggests various reward mechanisms for grassroots innovators. National institutions can be supported by specialized NGOs and international institutions such as Clearing House Mechanism and the CGIAR.

Cottier further suggests that the registrations should be *pro futuro* since TK was submitted to a previous regime of free access. An opposition mechanism should be envisaged for the concurring claims so that a successful opposition would result in annulment of registration or in a joint ownership[207]. The TK already existing in the public domain or under contractual bioprospecting after PIC, can be registered but not against current industrial applications. Moreover, after the entry into force of such a regime, a period of time should be granted in which unregistered TK can be claimed by the holders concerned. The aim is not to prevent registration of TK already absorbed by the biotech-industry.

Should the system be too expensive for the farming communities, Cottier proposes a financial support through cross-subsidization from profitable parts of the international IPRs system within WIPO. In this case an international understanding on this endeavor is necessary.

2. Does Traditional Knowledge Lack the Patent Requirement of Novelty?

Here above we have suggested that indigenous communities could benefit from patenting improvements or new elements of traditional products and practices, where these improvements

[205] GUPTA A., *Rewarding creativity for conserving biodiversity in the Third World*, AIPPI, Interlaken, 1996. The author evaluates the arguments of those who condemn the TRIPS Agreement for the inability of IPRs to protect traditional knowledge or on the grounds of morality and international equity. The author dispels many of these arguments, while proposing an alternative based on the development of local innovations databases linked to a low-cost and more accessible patent system. The author is the founder of Honey Bee Network and the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), which together work to be an institutional window available to recognize, respect and reward their creativity and innovation of poor people in developing countries.
[206] COTTIER Th., “The Protection of Genetic Resources”, *op. cit.* p. 1834.
[207] *Ibidem*, pp. 1844-1845.

would satisfy the criteria of the legal requirements for patents[208]. It is however obvious that the ordinary patent rules contained in the Paris Convention and TRIPS would hardly apply since some of the requirements would be difficult to be met, such as the proof of novelty and inventive step. Should then they be left without protection or should their knowledge be introduced in the databases to help establish prior art and no more? Certainly, according to many militants for an IP protection of TK this would be unfair.

An Indian example of collective patent application in the field of traditional medicine may be cited as justification for the protection of TK by way of the existing patent system. Under the canopy of an association of grassroots innovators, fifteen traditional healers from India did intend to collectively file a patent for a veterinary medicinal kit consisting entirely of natural plant medicines and compiled from their traditional practices and formulations. The fifteen healers, it is said, were named in the patent application as inventors and in association with the applicant. The collective filing allows the healers who individually could not afford the patent filing fee, to share the cost of the application, the research on commercialization possibilities and the risk of disclosure in case of rejection of the application. Even here too, it needs to be ascertained whether they are processes and products being typically considered to be part of an existing body of knowledge or practice that may be considered "new" in terms of the novelty criteria and inventive step. In light of the Swiss experience in the field of petty-patents, Cottier indicates that, instead of examining the requirement of novelty at the stage of the patent office registration, this can be left to courts in the case the patent is challenged[209].

Since, generally speaking, TK seems to fail to comply with the very basic patentability requirements, it should be given some other forms of protection, very probably not by patents, by which the requirements novelty and inventive step would not have to be proved.

3. Common Characteristics to Geographical Indications and Trademarks Protection of Traditional Knowledge

Continuing our analysis on the aptness of existing IPRs at protecting TK we will now turn to two IP instruments, namely geographical indications and trademarks. Instead of patents, geographical indications or trademarks do not reward innovation, but rather are aimed at rewarding the reputation built up by a group of producers over many years or even centuries without conferring monopoly rights over the use of certain information. The social benefit is to provide consumers with reliable information and assurances of authenticity. Local and indigenous communities, who maintain in perpetuity trademarks and geographical indications on products based upon sustainable traditional production practices, may be enabled to limit the class of people who can use a certain symbol.

These kinds of IPRs may be based upon collective traditions and a collective decision-making process. We consider these IPRs as instruments in the hands of local and indigenous communities particularly suitable to protect their know-how because: (i) they protect and reward traditions while allowing their evolution, (ii) they emphasize the relationships between local

[208] For example, although the IPRs of indigenous peoples are not dealt with in the ILO Convention (169) on Indigenous Peoples, other documents within the international arena do deal with this issue. For example, the UN Draft Declaration on the Rights of Indigenous Peoples proclaimed that "indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property." 34 *International Legal Materiasl,* 541 Article 29 (1995).

[209] COTTIER Th., "The Protection of Genetic Resources", *op. cit*., p. 1834.

cultures and their local land and environment, (iii) they cannot be freely transferred from one owner to another, (iv) they can be maintained as long as a certain tradition knowledge is maintained.

For a sustainable use of geographical indications or trademarks on TK subject-matter the construction of a national legal registration pattern and system is essential. Although such a system is expensive to set up, many developing countries are already bound under TRIPS to provide for the registration and enforcement of trademarks, and several among them are considering registers for geographical indications at least for wines and spirits.

Furthermore, indigenous communities might find it useful to use several different forms of IP protection in an overlapping way to ensure that various elements are protected, i.e. the use of geographical indications does not exclude the simultaneous protection of trademarks and *vice versa*. As software designers use patent and copyright protection to cover different technical aspects of their product, trademark and perhaps trade-dress and trade-secret protection as well, so too might a practitioner of traditional medicine rely on overlapping forms of protection to protect his plant variety, medicinal formula, designs and ritual chants[210].

We find another very important advantage in fragmenting TK in various IPRs: in order to protect the integrity of a certain TK subject-matter, its holder would just need to prove the violation of one of these IPRs that cover a single element of the whole TK subject-matter. On the contrary, had its holistic nature be adopted within an IP protection framework, its holder should seek to prove the total infringement of all parts of TK element. This advantage can be illustrated by the following brief example. Imagine a shaman that holds the knowledge of a traditional healing method. He has protected various element of this traditional medicinal knowledge by various IPRs: the traditional medicinal formula is protected by a petty patent or by a *sui generis* right; the traditional chant protected by a copyright etc... If someone were to repeat the traditional medicinal in a chemical process without reproducing the traditional chant, the TK holder, in order to protect the whole traditional healing method, the shaman (or the TK holder) would just need to prove of infringement of the petty-patent.

i. Geographical Indications

After these preliminary remarks on the common characteristics to these two IPRs, we can now address the distinctive attributes of geographical indications in relation with TK. Geographical indications, especially appellations of origin, may be used to enhance the commercial value of natural, traditional and craft products of all kinds in so far as their particular characteristics may be attributed to their geographical origin.

Geographical indications are contemplated internationally in the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1979) and the Protection under the Madrid Agreement for the Repression of False and Deceptive Indications of Source (1891).

Few of the developing countries are party to the Lisbon Agreement, whereas most of them are members of TRIPS where geographical indications are defined as *"indications which identify a good as originating in the territory of a [WTO] member, or a region or locality in that territory,*

[210] WIPO/GRTKF/IC/3, see US intervention.

where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin" (Article 22.1).

WTO Members must prohibit registration of trademarks that are misleading regarding geographical origin, and must provide legal procedures for interested parties to prevent competitors from placing designations on their products that mislead the public about their geographical origin (Article 22). The TRIPS Agreement also provides for additional protection of geographical indications for wine and spirits (Article 23). Obligations regarding geographical indications are subject to a number of exceptions (Article 24). For instance, if the name of a geographical region has become "generic" – that is, associated with a broader category of products – then it can be used outside the region, even if it originally denominated a products from that region.

The sheer importance of registration system in developing countries is stressed by paragraph 9 of Article 24, which provides that WTO Members are obligated to provide legal protection of geographical indications only if they are protected in their country of origin.

Based on the distinctiveness of local and regional products that provides the consumer with reliable information with regard to authenticity, geographical indications enhance the power of local producers to sell their distinctive products in a global marketplace. Additionally, geographical indications can increase the price of the product that they differentiate, thereby increasing rents captured by local and indigenous communities of these geographical indications regions by differentiating products by their area of origin, restricting supply and creating barriers to entry into production. Registration of TK related to certain geographical area may be used as protection, as was the case of "Basmati rice" for instance. Without association to "Basmati", aromatic rice produced by Rice-Tec will be less appealing to the public and will not be a competitive product for the real "Basmati"[211]. This illustration will further be developed once we will have introduced the usefulness of trademarks in this matter.

Finally, it can be said that a better exploitation and promotion of traditional geographical indications would make it possible to afford better protection of community economic interests and of traditional product from certain regions of origin.

ii. Trademarks

Article 15 of TRIPS defines trademarks as being *"[a]ny sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark"*. Through registration and protection of trademarks, WTO members shall grant *"the exclusive right to prevent third parties, without the owner's consent, from using similar signs"*. Indigenous and local communities can thus apply for a certification mark for their products based on their biodiversity and related TK, that will create distinctiveness and enhance economic returns[212].

A national or regional trademark system involves complex but streamlined procedures and legal expertise to assist the communities in application proceedings, and repeated communication

[211] For the specific use of geographical indication for protecting Basmati rice See DOWNES D. and LAIRD S., "Case Study in Innovative Mechanisms for Sharing Benefits of Biodiversity and Related Knowledge Geographical Indications and Trademarks", available at: http://www.ciel.org/Publications/InnovativeMechanisms.pdf, pp. 37-38.

[212] Intervention of the Delegation of the United States of America, To the WIPO *Intergovernmental Committee on Intellectual Property And Genetic Resources, Traditional Knowledge and Folklore Third Session*, Geneva, June 13 to 21, 2002, Agenda 5: Traditional Knowledge (documents WIPO/GRTKF/IC/3/7, 8, 9).

with national or international government offices[213]. Developing countries are required anyway by TRIPS to set up such national registration and enforcement mechanisms.

An assessment of the suitability of geographical indications or trademarks will depend on the consumer interest in the distinctive feature of traditional production, cultivation or processing methods. This preliminary question implies an evaluation of the export market for the product. Secondly the real impact of current national and international production norms on the eventual benefits flow back to local communities should be studied. Finally, the potential linkages to conservation, sustainable use and benefit sharing require further study.

We may now come back to the previous illustration on the usefulness of geographical indication and trademarks for a traditional product like Basmati rice produced in its region of origin.

As we have said, Basmati would qualify for protection as a geographical indication under TRIPS Agreement if its quality, reputation or other characteristics were *"essentially attributable to its geographical origin"*. Basmati rice is a long-grained aromatic variety of rice that is cultivated in areas of Northern India and Pakistan, mainly in the Punjab. Basmati is widely recognized as having specific desirable qualities. It has also a distinctive, rich flavor that is highly prized in the cuisine of the Indian subcontinent and around the world[214].

Achieving protection of the term "Basmati" as a geographical indication in the national legal system requires us to assemble the evidence that basmati rice - from the Indian subcontinent - has unique characteristics and a reputation based on its geographic origin. Moreover, it should enable the IP holder to counter the arguments from competing producers in other countries of the world.

Basmati can simultaneously qualify for trademark protection, which may offer useful measures for Indian or Pakistani producers or their buyers in importing countries, if they have registered trademarks using the Basmati name. Article 16.1 of TRIPS[215] provides that WTO Members must protect a trademark owner's right to prevent competitors from using similar trademarks on similar goods in a way that is likely to cause confusion among buyers. Whilst names like the "Texmati" term used by RiceTec Company connote Texas more than they evoke the Indian subcontinent, in the current case of the use of Basmati name among French trademarks can be more successfully challenged - being utterly misleading for the consumers.

Since TRIPS allows an exception to a trademark owner's right for the fair use of descriptive terms, competing producers can however demonstrate that Basmati term indicates merely rice having a certain flavor regardless of where it is produced. Yet, Basmati rice indigenous producers can also appeal unfair competition.

---

[213] DOWNES D., *Using Intellectual Property as a Tool to Protect Traditional Knowledge: CIEL Discussion Paper,* Washington D.C.: Center for International Environmental Law. November 1997, p. 8, discussion draft.

[214] DOWNES D. and LAIRD S., *op. cit.*, p. 34.

[215] *"The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use".*

Generally speaking, since in the market economy, each trader strives to gain an edge over his competitors by way of innovation, research or reputation, unfair competition is generally appealed to refer to the act of one trader misappropriating the intangible fruits of another trader's skill, time and labor. This concept can be widely used to protect TK. The legal basis can be Article 10*bis* of the Paris Convention[216], which obliges Members to ensure that people are protected from unfair competition resulting from (for example) acts that cause *"confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities of a competitor"*, could also be relevant to indigenous groups seeking to control the imitation or unauthorized commercial sale of indigenous products. A failure to provide such protection for indigenous peoples could arguably be a breach of this Convention's Article which obliges Members to provide nationals with "appropriate legal remedies to repress effectively all the acts referred to in Article 10*bis*"[217].

Of course, the argument of unfair competition can give ground to undertake legal actions in United States or French courts, i.e. to prevent companies from marketing their competing rice in a way that misleadingly implies that it has its geographic origin in the Indian subcontinent[218]. But in order to be successful, such an action should only follow the creation of a logo and trademark duly registered in a strong trademark national system. Only then Basmati rice indigenous producers will be much better situated to take action to protect even against unfair competition in their export markets[219].

C. Proposals for a *Sui Generis* System of Protection for Biodiversity Related Traditional Knowledge in Developing Countries

So far we have postulated recommendations suggesting protection of TK only in the perspective of the existing IPRs. We deem these instruments to be good but not enough to satisfy the exigencies of equitable benefit sharing according to both Article 7 of TRIPS and Article 8(j) of the CBD[220].

---

[216] Article 10(bis): *(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.*
(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
(3) The following in particular shall be prohibited:
1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

[217] YAMIN F. and POSEY D. A., "Indigenous Peoples, Biotechnology and Intellectual Property Rights", *Indigenous peoples*, 2, 2, 1993, pp. 141-148.

[218] DOWNES D. and LAIRD S., *op. cit.*, p. 36.

[219] On this issue see also DOWNES D., "Global Trade, Local Economies and the Biodiversity Convention" in William J. Snape ed., *Biodiversity and the Law,* Washington: Island Press, 1996. DOWNES D., *Integrating Implementation of the Convention on Biological Diversity and the Rules of the World Trade Organization: Law and Policy Discussion Paper: April 1998 Discussion Draft.* Gland, Switzerland: The World Conservation Union - IUCN, Center for International Environmental Law (CIEL), 1998.

[220] Article 8 (j) of the CBD interpreted in light of Article 7 of TRIPS which provide for equitable sharing and protection through a certain enforcement which should *"contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations"*.

Developing countries and their local communities feel that current IPR regimes are inadequate to protect all types of TK in view of such a holistic approach. They have therefore concluded that, "apart from using suitable modern IPR instruments for appropriate cases, a national *sui generis* system for the protection of TK may be useful"[221]. This sort of system of IP protection would encompass only TK that has been handed down from generation to generation or even that had become public domain but whose innovation could be traced to a particular community[222].

This suggestion follows the anthropological approach to TK that considers it not as the mere sum of its separated components, but rather as a coherent combination of them into an indivisible piece of knowledge. Indeed petty patents, trademarks, designs, copyrights, cannot attend this holistic nature of TK. A concrete example may better illustrate this peculiar nature of TK subject-matter. Imagine a member of an Amazon rain forest tribe has become sick and visits the aforementioned shaman for medical services. The shaman, after examining the patient, goes to his garden to collect some leaves, seeds and fruits from different plants that he breeds[223]. He prepares a potion according to a recipe of which he is the sole holder by mixing those materials. While he wears his ceremonial garments for the healing, he inhales the smoke of the leaves in a propitiatory vase decorated with symbolic designs to the patient with a specific dosage that he will likewise prescribe. He then prays to the gods of the forest and performs a religious dance.

The "holistic" approach to TK aspires to an IP protection of the whole procedure of exercising this TK. On the contrary, the "reductionist" approach will consider the separate elements that compose the same (i.e. the prayer, the plant as such, the design of the vase, the know-how of the plant breeding, the formula), as suitable to be protected by various existing IPRs (namely, by copyright, by utility model certificates or industrial design system, by a trademark and by a petty-patent).

However, the WIPO IGC Secretariat has persuaded the delegation representatives that this complex holistic approach of TK stands at odds with existing IP legal concepts generally recognized. After all, this holistic nature of TK is not a legal concept itself. Hence, a third middle way has been accepted by most of the governments that are slowly but surely shaping an IP *sui generis* right according to the specific policy needs that it will serve. This trend should ultimately elaborate a more flexible *sui generis* protection system where TK can be registered inasmuch as it corresponds to certain requirements that still need to be specified corresponding to a system whose elements need to be defined.

These ideas developed within the WIPO IGC are encouraging national governments in setting up commissions at various municipalities with the task of collecting information pertaining to traditional medicinal and agricultural knowledge of antiquity. Meanwhile, the Secretariat is currently trying to answer the following inquiries: (i) what is the policy objective of the protection? (ii) what is the subject-matter? (iii) what criteria should this subject-matter meet to be protected?

---

[221] UNCTAD (2001): The Sustainable Use of Biological Resources, Systems and National Experiences for the Protection of TK, Innovations and Practices. UNCTAD Doc. TDB/COM.1/38 WIPO has also developed a model for *sui generis* protection of certain TK-related subject-matter in cooperation with UNESCO, namely the UNESCO-WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1982).

[222] See note 99.

[223] See PLOTKIN M. J., *Tales of a Shaman's Apprentice — An Ethno botanist Searches for New Medicines in the Amazon Rain Forest*, ed. Penguin Books, 1993 quoted in WIPO/GRTKF/IC/3/8.

(iv) who owns the rights? (v) what are the rights? (vi) how are the rights acquired? (vi) how to administer and enforce the rights?; and (vii) how are the rights lost or how do they expire?

Seeking to answer exhaustively all these complex questions would demand an in-depth study entirely dedicated to this matter. Since our purpose is to capture the nature and the place occupied by TK inside the IP related international treaties, we will limit ourselves to portray the "big picture" of the debate concerning the scope of this new right to be grafted in the existing IP system.

As to its defensive purpose from the phenomenon of biopiracy in the field of traditional agriculture or traditional medicine, this *sui generis* right should be such that the community is identified as owner. If subsequently anyone were to take that knowledge into the laboratory, he should first either negotiate with the community in question, or acknowledge its source of information and compensate that community on equitable terms: The bioprospector should consider that through biotechnology he can only merely improve upon that original value contained in the preserved biological resource[224].

If the protection were collective[225] then negotiations could be undertaken with the representatives of the community in question – the village head or council or the municipal council which is usually headed by a mayor. It should be such that whatever compensation or royalties they receive, a certain percentage should be injected into their budget and the remainder deposited in the national treasury. It may be contended that some communities would be minorities and that sharing the proceeds of collective protection may lead to inequities. The question does not arise as that could be dealt with an agreement reached, at the meeting of the representatives. The representatives, it must be stressed, need not to be political representatives. It may only be so where there is non existing traditional structure capable of playing that role. But what is obvious is that there would always be a village head or council to designate their representatives for that purpose. The share of the community would be used to improve upon its infrastructure, create employment, award scholarships to deserving students, etc. In this way, the objectives of TRIPS and related conventions would have been satisfied – the equitable sharing of the fruits of their knowledge.

The manner in which all this has to be done should of course be regulated by national legislations and it will be for the respective national authorities to do so. For example, it would be for the national authorities to determine what percentage should go to the communities and what percentage deposited in the national treasury. The international agreement must set a minimum

[224] A good starting point can be found in the models of *sui generis* systems from Organizations of African Unity, Peru and Panama in UNCTAD (2001): *op. cit.* There is also a binding international instrument currently in force, which establishes obligations for Contracting parties to provide legal protection for TK-related subject-matter. Additionally, several non-governmental organizations have developed national models for *sui generis* protection of TK. These include, *inter alia*, "A Conceptual Framework and Essential Elements of a Rights Regime for the Protection of Indigenous Rights and Biodiversity" (1996) by the Third World Network; the "Model Biodiversity Related Community Intellectual Rights Act" (1997) by the Research Foundation for Science, Technology and Ecology; and the "Intellectual Integrity Framework" (1994) by the Rural Advancement Foundation International. The United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (1994) establishes obligations for Contracting parties to provide legal protection for TK-related subject-matter : Parties shall*: "protect, promote and use in particular relevant traditional and local technology, knowledge, know-how and practices and, to that end, they undertake […]" "(b) ensure that such technology, knowledge, know-how and practices are adequately protected and that local populations benefit directly, on an equitable basis and as mutually agreed, from any commercial utilization of them or from any technological development derived there from"* (Article 18.2(b)).

[225] On this point see WIPO/GRTKF/IC/3/8 p. 19 and also WIPO/GRTKF/IC3/17.

standard to be respected by all the member countries to avoid discrepancies on treatment in different geographical areas.

Alternatively, since there may be TK similar or identical in different communities within the same country and maybe regional grouping, the authorities that be, depending on the case, may set up collecting societies responsible for licensing, assigning and collecting compensation or royalties, which they may then distribute equitably to the various parties as the case may be. The details on how they should function should be determined by national legislation where one country is involved or by an agreement of the regional authorities, where more than one country is involved.

Where, for instance, the traditional medicine is such that entails a combination of herbs for curing an ailment, it would be expected that there would be disclosure in return for protection. It may be argued that such disclosure is not disclosure because it already existed in the community in question and maybe, even to others outside that community. However, it is also correct to say that the breadth of such disclosure was limited in space. Once collective protection is granted, full disclosure would be made in the database and it would be there for the whole world to consult and exploit at the terms of protection. So there would be equitable sharing of the proceeds of the traditional medicinal knowledge and there would be enabling disclosure which falls squarely within the objectives of TRIPS (see Article 7).

The above proposals certainly hold true for TK that had been handed down time immemorial in a particular community or where an individual holds that knowledge not for himself but on behalf of his community. It is certainly not true for knowledge known to or owned by individuals in that community only.

1. Adapting the Traditional Knowledge Subject-Matter to the Proper Intellectual Property Protection: the Example of Traditional Medicine

In the attempt to grasp the vast complexity of the elements forming this *sui generis* right, one has to pay attention to the nature and use of each TK subject-matter. Benefit sharing is not the sole or most important objective of indigenous peoples or local communities. Therefore this issue needs to be considered within the wide spectrum of their exigencies in respect of their culture and sensitivity. It can happen that even within the same protectable subject-matter there may be categories that fit the *sui generis* protection and other that do not. In order to elucidate this concept, we will briefly introduce a distinction between two sides of the traditional medicinal knowledge: spiritual healing or ritual regimes on the one hand, and protection of non-spiritual healing on the other.

i. Trade Secrets for Spiritual Healing or Ritual Regimes

When we speak about “spiritual healing” we refer to complex rituals, magic or spiritual beliefs that surround indigenous medicine. When added to non-spiritual healing methods, it promotes and diffuses traditional medicinal innovations in local and indigenous communities. We examine here the reasons for which such innovations are not suitable to be protected by a *sui generis* system. In this regards Dashaco John Tambutoh, Agus Sardjono and Memunat Dabiri have stated :

“It is our proposal that since most of these regimes are secret and the knowledge attached thereto can only be acquired through initiation, the best form of protection would be by customary law or alternatively in limited cases**,** trade secrets, if the existing IP system is insisted upon. As

concerns the former, in Cameroon, for example, the *obasinjom* of the Manyu people is a secret society with unimaginable healing powers. It has been impossible so far, for an outsider to acquire the knowledge of the healing potentials or secrets of that secret society, unless he has been initiated. And even then, a member of the secret society only possesses the healing powers when he enters into the robe of the *obasinjom*. It is a secret, well guarded and has been so for generations.

This regime has so far been given adequate protection by the customs and tradition of the Manyu people and it would be an aberration and even an effort against these people to envisage some other form of protection for their knowledge no matter the reasons advanced. In fact, even the people themselves who have not been initiated into the secret society, look upon the *obasinjom* in awe and that tells very much what it is – a secret society that would dare even the devil. The only reasonable conclusion here is that such regimes can only be adequately protected by the customs of the people concerned, and how they should distribute the proceeds from the practice, is their affair"[226].

Alternatively, as already mentioned, some other forms of spiritual or ritualized healing which are not adequately protected by the customary laws of the people could be given protection under the trade secret paradigm with all that it entails, according Article 10*bis* of the Paris Convention (1967) and Article 39 of TRIPS[227].

ii. *Sui Generis* Rights for Non-spiritual Healing [228]

The major difference of this regime from the previous one is that it does not generally require the practice of divination, magic, etc. in treating ailments. This practice relies more on the use of herbs or combination of herbs (concoctions) for that purpose. So this is knowledge which is vulnerable and may be "infringed" easily (i.e. subjected to the so-called biopiratical actions). This type of existing TK can also yeald future innovations. These characteristics make it more suitable to be registered in a database and be available for further research and exploitation after PIC and proper negotiation on the sharing of the benefits arising from IPRs obtained thereupon.

It is our presumption that future innovations with respect to non-spiritual traditional medicine would concern more individuals than groups. It should be therefore recommended that where there is innovation by an individual, the individual should be given protection for it. However, the requirement of inventive step should be discarded. This is so for the simple reason that it is quite a herculean task to prove inventive step with traditional medicine which does not follow the very strict rules related to pharmaceuticals.

---

[226] D. TAMBUTOH, A. SARDJORNO, M. DABIRI, « Traditional Medicine And Intellectual Property Rights - A Move Towards Protection In Developing Countries », in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001, pp. 444.

[227] In several cases the transformation of TK into trade secrets would enable indigenous peoples to benefit from foreign bio-prospecting activities. Knowledge from communities wishing to participate in the project will be catalogued and deposited in the aforementioned restricted access database. A mechanism of control should solve the rather intricate problem of the presence of TK in the public domain. In the case other communities bear the same trade-secret, i.e. the same TK, a cartel between the two may be envisaged. Negotiations between the bioprospecting company and the community can lead to a so called "Material Transfer Agreement" including benefits sharing clauses between the host government and the cartel members, DUTFIELD G., *Intellectual property Rights, Trade and Biodiversity, op. cit.,* p. 130.

[228] See in general on this matter D. TAMBUTOH, A. SARDJORNO, M. DABIRI, *op. cit.,* pp. 444-449.

2. General Constraints to Protect Traditional Knowledge by Intellectual Property Rights

All the above suggestions in the attempt of protecting TK by existining and new *sui generis* rights face also several constraints that may be regarded as being five-fold:

Firstly, a very basic difficulty is that most of the TK holders are illiterates or ignorant of their rights. So, the various national authorities would again, have the responsibility to set up agencies with the task of assisting these people either by way of advice or representation. How that should be done should be defined by the national authorities who in turn, must respect the minimum standards set up by an international agreement to be negotiated and concluded under the auspices of WIPO.

Secondly, many indigenous tribes consider some of the current areas that are protected under IP regimes as being unethical due to their impact upon cultural values. This difficulty arises most especially with regard to the tinkering with, and then patenting of life. Although 'moral exceptions' already exist under the current IPR regime, the extent to which these exceptions may be utilized is questionable[229].

The third concern is one which is largely political in nature. In other words, much of the current discussion may be usurped by the current debate on the ownership of indigenous flora and fauna within a certain State. Who is the owner, the State or the indigenous community? This question has arisen in New Zealand where the Ngati Porou claimants before the Waitangi Tribunal 262 have asserted their pre-emptive right: "to develop or limit the development of processes such as genetic technology, genetic manipulation, bio-prospecting and bio-technology as those practices impact on indigenous flora and fauna and their ecosystems"[230].

The fourth problem is that patent laws generally require individual or joint inventorship to be clearly established before protection can be given. However, it can be difficult to determine who originally created a specific tribal TK element as it may have developed over generations and may be collectively owned.

The consideration of the length of time that IP is to apply forms the focus of the fifth concern. As it stands, patents only last for a limited period of time. This is because it is believed that it is in the public's interest to limit monopolies since if they endure beyond a certain period of time they may restrict innovation instead of promoting it. Therefore, if the Maori, for instance made some of their secrets subject to IPRs, the result would probably be that they would be agreeing to

---

[229] This problem has been extensively examined by BENTLY L., *Intellectual Property and Ethics,* 1998. Broadly speaking, according to many tribal beliefs, all life forms - animate and inanimate - have divine origins as they all have a genealogy which may be traced back to the Gods, the source of their life and being. Each life form, including each person makes a substantial contribution to the Cosmos and all things that live within. Not only the biodiversity, but also elements of the environment, such as cold, heat, wind, rain and soil types, as well as plants and animals are all believed to be related to each other as if they were species. Since these kinship ties connect all living things, acts that change or degrade the essence of one life form have an impact on all other life forms. The alteration of genetic material would mean to alter the blood of the ancestors, namely to introduce "new blood" that may impact on the other rights that are passed down, rights of authority, status and control.

[230] This paragraph is from the Ngati Porou/ Ngati Kahungunu Submission on the Draft New Zealand Biodiversity Strategy (1999) 3.1.3. (c). See also paragraphs 8.8.0-8.8.4.

make that information known to the general public when their IPRs expire. The utilization of this information would then be freely available to anyone[231].

Sixthly, developing countries, where most of the TK exists, have limited resources, funds and expertise. They are already challenged by the expensive task of establishing the existing IP laws-infrastructures, and as a consequence efforts to also establish protection of TK will necessarily enjoy low priority. Moreover, the concept of registration is anathema to and may be expensive for TK holders. It has to be considered that TK does not always exist in written form, therefore there would be difficulties in using it as prior art for patent or industrial designs. Efforts to build a customary database for the purpose will be constrained by lack of funds and expertise. Yet, databases should be used as a tool for accreditation, rather than as a center around which to build a *sui generis* system. While databases in most cases would be a prerequisite for the protection, it will also make TK more open and more vulnerable to misappropriation. Finally it will be the enforcement, a more difficult task, that will make the system worth its costly creation.

Finally, the negotiation process for the acquisition of IP protected genetic resources and related TK can trigger complex issues. The companies of industrialized countries, with the exclusive background of traditional IPRs, have to face indigenous peoples that possess their own collective or communally-based systems of jurisprudence with respect to classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, the rights and responsibilities attached thereto. All of which are embedded uniquely in each culture and its language. This problem can be overcome through the parties' mutual adaptation of the communication and negotiations skills between different legal cultures.

At this stage, without having benefited from the experiences of various domestic contexts, we understand the concerns pronounced by the delegations of Australia, Brazil, the United States and the European Union, according to which it seems indeed premature to begin conceiving an international *sui generis* system of protection for TK[232]. Once developing countries will have started to deal with methods to overcome these basic challenges, the WIPO IGC work will also be enabled to discern more scientifically which kind of TK subject-matter can be covered by existing IPRs and which subject-matter necessitates a *sui generis* IPR mechanism. This can eventually be achieved in a future multilateral treaty under the auspices of WIPO.

D. Valorization of Biodiversity Related Traditional Knowledge through a Flexible Patent Law System

The patent system has recently been subject to much criticism because of the grant of over-broad monopoly rights to biodiversity related inventions without having addressed very basic questions regarding morality and particularly the benefit sharing specific provisions under public international law. We maintain that the patent system can still undergo a modification to achieve a more equitable benefit sharing in the context of biotechnological patent rights. This can be done through a constructive harmonization of TRIPS and CBD. Indeed, certain universally accepted

[231] After the expiration of the IPR, it should be studied whether it is perhaps possible that some Maori inventions could be commercially exploited while keeping the details of those inventions secret (as for example, the formula of Coca Cola was kept secret for many years). Details of such inventions could be protected by the law as "confidential information." (e.g. trade secrets). Moreover, Maori who do not wish their traditional knowledge to be commercially exploited could possibly take steps to keep that knowledge secret. The law relating to "confidential information" may provide some protection for this concern.

[232] WIPO/GRTKF/IC3/17.

obligations enshrined in the CBD will corroborate precise modifications and improvements to patent systems such as the introduction of certificate of origin at the patent application and real international prior art search on relevant TK. Moreover, where TRIPS envisages exceptions to patent rights, developing countries may be free to adapt the patent system to their needs and interests (in the forms of compulsory licences, international exhaustion and exception to exclusive rights on the ground of public health).

No doubt, this *ensemble* of insights about patent law is much easier to be said than done. It should be remembered that, in order to verify the feasibility of such proposals, much efforts is still to be needed to take into consideration the varieties of regional or national expectations. Yet, it is important to try to gain a reasonably general but clear idea of how reconciling TRIPS and CBD - in this rather technical field of patent law - is feasible. We hasten to add that political and diplomatic aspects of a precise and practical realization of these proposed measures are somewhat overlooked in the following paragraphs. Indeed, it would be preposterous for us to aver that, in a few pages, we can exhaustively cover the development of the activities of various international for a on the relationships between IPRs and biodiversity-related TK. This is so because these matters are becoming omnipresent in each forum discussing self-determination of indigenous peoples and related human rights issues, biodiversity protection, etc…[233]

1. Implementing the Concept of Prior Informed Consent in Patent Law System

i. Is the Obligation to Submit a Certificate of Origin: a Procedural or Substantive Patent Rule?

In such a volatile matter as the benefit sharing arising out of the IP exploitation of genetic resource, biodiversity-provider countries alone can set up only some measures to ensure such sharing of benefits. A real international control on the respect of the provider country national legislation becomes crucial.

One important instrument in this perspective could have been the introduction of an obligation of disclosure of the origin of the genetic material by the patent applicant. The so-called “certificate of origin” has to be obtained by the provider State authorities - once the industrial

[233] Efforts to identify issues pertaining to TK have been relentless in a wide range of international fora : WTO, WIPO, the CBD, and the FAO and ILO. See POSEY D. and DUTFIELD G., *op. cit*. These two authors explain in their comprehensive work on TK how various conventions and "soft-law" instruments acknowledge and promote these rights: *U.N. Conference on Environment and Development*, June 3-14, 1992, Agenda 21, U.N. Doc A/CONF.151/5/Rev.1 (1992) (hereafter Agenda 21); In the Rio Declaration in Principle 22 it is stated that "Indigenous peoples and their communities, have a vital role in environmental management and development because of their knowledge and traditional practices". Chapter 26 of Agenda 21 detailed the relationship which conference participants recognized between indigenous peoples and their lands. Agenda para. 26.3(a) required states to recognize the values of TK, enhance the capacity-building for indigenous communities establish arrangements to strengthen the active participation of indigenous peoples in national formulation of policies and laws, *Conference on Environment and Development, Rio Declaration on Environment and Development*, UN Doc A/CONF.151/5/Rev.1, 1992 (hereafter Rio Declaration); See also *International Labour Organization Convention Concerning Indigenous and Tribal Peoples in Independent Countries*, No. 169, June 27, 1989, 28 *International Legal Materials* 1382, 1989, *International Labor Organization Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi Tribal Populations in Independent Countries,* No. 107, 328, UNTS 247. In addition, various instruments affirm the right to development and the entitlement of peoples to full sovereignty over all their natural health and resources, *U.N. General Assembly Declaration on the Right to Development,* G.A. Res.41/128*,* Annex, UN GAOR, 41th Sess., Supp. No. 53, p. 186, UN DOC A/31/128 (1986).

party/biorprospecting company has shown that it has complied with the national access legislation. The international debate on this matter is far from being settled, mainly because sharp disagreement currently exists on the question to know whether this "certificate of origin" is a substantial or procedural patentability requirement.

During the Sixth Meeting of the Conference of the Parties, which took place in The Hague in May 2002, the Parties to the CBD officially adopted the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*. Parties with genetic resource users under their jurisdiction are suggested to consider adopting "measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights"[234].

Some authors have been maintaining that the submission of a certificate of origin is a formal *demarche* that would create more transparency in the patent application procedure[235]. Patent offices should require applicants to undergo an administrative procedure requiring inclusion of a sworn declaration as to the genetic resources and related knowledge, innovations and practices of indigenous peoples and local communities utilized, directly or indirectly, in the research and development of the relevant samples for the subject-matter of the IPR application (including samples helpful for the research but that did not form the basis of the final product); and evidence of PIC of the country of origin and/or indigenous or local community.

Moreover an international certification system would standardize these conditions. This would lead to a national system in the provider State that issues certificates only after having indicated that all obligations of access to genetic resources have been fulfilled such as PIC, equitable benefit sharing, and perhaps other conditions imposing limitations on the use of the genetic material or knowledge. Patent will then be granted upon inclusion of such certificates without which they would automatically be rejected.

This proposal has been partially discussed within the WIPO Meeting of Intellectual Property and Genetic Resources on April 17 and 18, 2000, in which Colombia jumpstarted discussions by the proposing introduction into the Patent Law Treaty of an article providing for protection of the country's biological and genetic heritage. The condition for the grant of a patent was that the acquisition was made legally and that every document shall specify the registration number of the contract affording access to genetic resources and a copy whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources from the specified country of origin. This issue was also discussed in the Autumn of 2000 at the WIPO

[234] See Secretariat of the Convention on Biological Diversity (2002), *"Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity",* UNEP/CBD/COP/6/20, paragraph 16(d)(ii). As means to implement the CBD provision that benefit sharing be upon mutually agreed terms, two elements to be considered as guiding parameters in contracts and as basic requirements for mutually agreed terms are that "provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent", and "the possibility of joint ownership of intellectual property rights according to the degree of contribution" Paragraph 42(c) and (d).

[235] It seems that this idea has been firstly suggested by Frédéric Hendrickx, Veit Koester and Christian Prip in some articles, the first of which was published in 1993, see HENDRICKX F., KOESTER V. and PROP C., "Access to genetic resources: a legal analysis", *Environmental Policy and Law,* 23, 6, 1993, pp. 250-258. See also GADGIL M., and DEVASIA P., "Intellectual property rights and biological resources: specifying geographical origins and prior knowledge of uses", *Current Science* 69, 8, 1995, pp. 637-639.

General Assembly[236], where the major proposal to include in the filing of patent application an indication of origin of the genetic material, was objected to by the US on the ground that this requirement was a modification to substantive law and not only to procedural law. In compensation the WIPO General Assembly established the WIPO IGC which held its first meeting from 30 April to 5 May 2001.

Besides the fact that it is hard to see how such a simple filing requirement in the procedure of the patent application would constitute substantive law[237], it is well-known that in some patent systems the presence of additional patentability requirements has never been deemed to be inconsistent with patent law and even less with TRIPS. A sounding example of an additional requirement is the "enabling disclosure", that operates in UK and Germany and other countries especially in relation to biotechnological patents. It implies that the invention has to be disclosed in a way that "any information that is obtained as a result of an analysis undertaken by a person skilled in the art must be obtained without undue burden or without the need to exercise any additional inventive effort"[238].

If adding a "certificate of origin" patentability requirement is considered too burdensome for the classical patent system, it is possible to make the submission of this document a simple and integrating part of the examination, just like renewal fees paid regularly by applicants.

The confrontation on this matter is animated by a more profound difference as regards to the two main approaches to patent law. The "classic" or "orthodox" approach to this matter - that inspires most of industrialized countries' patent systems – views the patent system as neutral and technical, e.g. it has the exclusive mandate to reward the technological innovation without being concerned with what happens before or after the achievement of the invention. Since this proposed patentability requirement is inspired by a CBD obligation, no wonder why industrialized countries maintain that this problem lies outside international patent law. It is consequently argued that the solution to the problem of benefit sharing/biopiracy should be found in the international fora dealing with the whole problem of access to genetic resources and not in those dealing with intellectual property *stricto sensu*.

The "radical" approach views the patent system as unequivocally embedded in the realm of *droit commun.* When any international/regional/national authority grants a patent, society is in reality not only rewarding the efforts of the technical innovator, but it is also justifying this legal

---

[236] *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc. WO/GA/26/9. The Group of Countries of Latin America and the Caribbean (GRULAC) submitted two documents to the WIPO General Assembly on *Matters Concerning Intellectual property and Genetic Resources, Traditional Knowledge and Folklore* WIPO Doc. WO/GA/26/9 and WO/GA/26/6. The thrust of the document was to recognize practical methods of securing adequate protection for IPRs in TK. The GRULAC documents envisaged an adjustment of existing IP regimes or the creation of new ones. This can be done by the Standing Committee by clarifying: (i) the notions of public domain; (ii) the recognition of collective and individual rights in traditional works and knowledge currently in the public domain; (iii) model provisions and model contracts with which to control the use and exploitation of genetic and biological resources for the equitable distribution of profits in the event of a patentable product or process being developed from a given resource; (iv) embodiment of the principle of PIC; (v) the protection of undisclosed TK.

[237] For instance declaring the sources of single compounds and tracing of new drugs should not normally be a particularly onerous task for pharmaceutical companies.

[238] BENTLY L. and SHERMAN B., *Intellectual Property Law*, Oxford University Press, 2001, pp. 420-422. For a landmark case law on the enabling disclosure in the biotechnological patent application see *Biogen and Medeva PLC,* 1997, R.P.C. 1, in Abbott F., Cottier Th. and Gurry F., *op. cit.*, Part I, Kluwer Law International, 1999, pp. 42-64.

monopoly, i.e. an exception to free competition, in order to create an incentive to innovation. At the same time patent law tries to strike the balance among the monopoly of the right holder, the competitors and the users of the invention. Since the patent system is viewed as a fundamental tool for increasing the level of technological innovation in a given society, it cannot be seen as socially neutral.

The problem of "misappropriation" simply stirs up additional anger and rejection of this imposed system. Interestingly enough the major benefits from the utilization of a genetic resource flow from its patented products. In this context, to continue to maintain that the international patent system is socially neutral and does not need any adjustment can become detrimental to the functioning of the international patent system itself, that indeed needs support of developing countries to affirm its legitimacy.

For all these reasons, these latter insist that the best manner in which the international community can verify whether the genetic resources has been lawfully appropriated and the CBD duty of negotiating truly implemented is through an evidence to be brought at the moment of the patentability of the biodiversity based biotech-invention.

ii. Is the European Biotechnology Directive of 1998 in Breach of the CBD "Prior Informed Consent" Obligation?

In the EU context, government and non government forces have tried in vain to curb the biopiracy impact of the European Directive No 98/44[239], by attempting to introduce a clause that would require full disclosure of a country of origin's consent to transfer genetic material in any application for a patent related to biological resources from developing countries[240].

Nothing was achieved but a weak allusion to PIC requirement in the recital 27[241] of the preamble, whereas the substantial provisions do not positively fulfil it. This "conditional obligation"[242] to disclose the country of origin, it is argued, runs counter to Article 16.5 of the CBD that states that "*recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights"* – including patents – *"are supportive of and do not run counter to its objectives"*. The well-known objectives of the CBD are contained in Article 1: *"The conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and*

[239] See section II.C.

[240] For a clear account of the legislative history see STERCKX S., "Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions", *European Intellectual Property Review*, 1998, pp. 123 ff.

[241] *"Whereas if an invention is based on biological material of plant or animal origin or if it uses such a material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents"*.

[242] The International Chamber of Commerce supports this weak conditional obligation of the Directive, see ICC (2002), "Policy statement: should patent applicants disclose the origin of biological materials on which they file patents? Should they demonstrate Prior Informed Consent (PIC) for their use?", prepared by the Commission on Intellectual Property, available at: http://www.iccwbo.org/home/statements_rules/statements/2002/should_patent_applicants.asp.

by appropriate funding"[243]. Since all EU members are also Contracting Parties of the CBD, the alleged incompatibility of the Directive with the CBD was one of the grounds on which Directive has been challenged before the European Court of Justice[244]. However, the European Court absolved the Directive from charges of non compliance with obligations under the CBD[245]. Also Advocate General Jacobs, in his lengthy Opinion of June 14, 2001, concluded that the reach of the European patent legislation has inherent limits. In other words, it cannot cover matters like access to genetic resources in provider States[246].

While this is in line with the mainstream developed countries' position expressed in WTO premises, we maintain that it is still not consistent with the recent development of international law binding treaties (CBD and with FAO Treaty which in his Part IV, provides for a Multilateral System of Access and Benefit Sharing at Articles 10-13), with the soft-law that emanates from many other international organizations and with the overwhelming majority of the doctrine dealing with the intersection between IP, biodiversity and food and agriculture.

The opinion of the Advocate General explains how the whole regulation of access to genetic resources is a matter which lies in the sole responsibility of provider states and not in the patent laws of recipient countries. This reasoning does not imply the non existence of an international obligation in this sense, but rather the conviction that the measures to establish controls over their genetic resources and to prevent the unregulated plundering of such resources, still are insufficient in provider countries. Hence, the EU IP legislation cannot assure the achievement of these goals[247].

---

[243] See also the obligations contained in Articles 5, 6(b), 7, 8, 9, 10, 11 and 14 of the CBD.

[244] Court of Justice 9 October 2001, case C-377/98, *Kingdom of the Netherlands v. European Parliament and Council of the EU*, case "Biotech Directive", nyr. For an excellent treatment of the issues subsequently decided by the Court see SCOTT A., "The Dutch Challenge to the Bio-Patenting Directive", *European Intellectual Property Review*, 1999, pp. 212 ff.

[245] The core of the reasoning of the Court that leads to this conclusion is to be found in the following paragraphs: *"65. It cannot be assumed, in the absence of evidence, which is lacking in this case, that the mere protection of biotechnological inventions by patent would result, as is argued, in depriving developing countries of the ability to monitor their biological resources and to make use of their traditional knowledge, any more than it would result in promoting single-crop farming or in discouraging national and international efforts to preserve biodiversity.*
66. Moreover, while Article 1 of the CBD states that its objective is the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, it specifies that this must be done taking into account all rights over those resources and technologies. There is no provision of the CBD which requires that the conditions for the grant of a patent for biotechnological inventions should include the consideration of the interests of the country from which the genetic resource originates or the existence of measures for transferring technology.
67. Finally, as regards the possibility that the Directive might represent an obstacle in the context of the international cooperation necessary to achieve the objectives of the CBD, it should be borne in mind that, under Article 1(2) of the Directive, the Member States are required to apply it in accordance with the obligations they have undertaken as regards inter alia *biological diversity"*, Court of Justice 9 October 2001, case C-377/98, *Kingdom of the Netherlands v. European Parliament and Council of the EU*, case "Biotech Directive", nyr.

[246] See paragraph 181 of the Opinion of the Advocate General Jacobs of June 14, 2001, case C-377/98, "Biotech Directive", above at note 13: "The Directive, being concerned with patents, does not seek to regulate matters outside the realm of industrial property. Again as discussed both above and below, it is not for patent legislation to provide for broader matters such as monitoring the source of biological material in respect of which patent is sought. The Directive does not – *nor can it* – affect the ability of developing countries to establish controls over their genetic resources in order to prevent the unregulated plundering of such resources. At least a dozen countries have already taken such steps, in accordance with the Convention on Biological Diversity, and a similar number are currently developing controls".

[247] See the Opinion of the Advocate General Jacobs of June 14, 2001, case C-377/98:
177. In my view, the arguments that the Directive is incompatible with the Convention on Biological Diversity betray a failure to appreciate the respective objectives and spheres of application of the two instruments.

It is certainly true that a PIC requirement within the recipient State patent law would not have any effect if the provider State does create the adequate legislative framework of negotiated access with mutual agreement on benefits. Indeed we have already observed in chapter V that this legislative task - to be performed by developing countries - is fraught with several difficulties. Nevertheless, the contrary is true as well: whatever effort a provider State may make in putting in force all the indispensable legislative measures and making them workable in actual practice, it is likewise essential that there is an appropriate and simultaneous cooperation by recipient States.

This is so because of the ubiquitous nature of IPRs and particularly when applied to genetic resources. Being information in nature, they can be hidden and stored away and made finally untraceable until the borders of the provider country are crossed and an act of "biopiracy" is committed. What can the provider State do in this case? Of course it can declare the transfer invalid or stipulate for sanctions ranging from tort liability to administrative or criminal sanctions, with all the problems of cross-border effectiveness. While these cases of biopiracy are rarely discovered at airports or at the borders, such discovery of biopiracy acts could more frequently occur in the course of patent grant proceedings in recipient States[248].

For all these reasons, we disagree with the Advocate General that the recipient countries cannot contribute in avoiding unauthorized appropriation of genetic information and consequently this negligence in the European Directive amounts to be, at least in principle, a breach of the CBD's rules on access to genetic resources and on the sharing of the benefits[249].

In spite of the timid allusion to the PIC principle in the EU Directive, member States are still empowered to make use of their legislative discretion in shaping implementing legislation in accordance with international obligations. Of course, they are not in a position to contradict specific

---

178. The Directive, as is clear from the analysis in the context of the earlier grounds for annulment, requires the Member States of the European Union to ensure that their national law provides patent protection for biotechnological inventions as there defined. To that effect it imposes a few highly specific obligations on the Member States in that narrow context. Patents conferred in accordance with the Directive will of course, as with all patents, be territorial in effect.

179. The Convention, in contrast, is more in the nature of a framework agreement. Having set out its objectives in Article 1,the Convention proposes a series of approaches which Contracting Parties (which as at 5 June 2001 numbered 180 States worldwide) are to adopt, in many cases only 'as far as possible and as appropriate. The scope of the Convention is rather wide; the suggested measures are rather varied and in most cases couched in general terms".

[…]

181. The Directive, being concerned with patents, does not seek to regulate matters outside the realm of industrial property. Again as discussed both above and below, it is not for patent legislation to provide for broader matters such as monitoring the source of biological material in respect of which patent is sought. The Directive does not – nor can it – affect the ability of developing countries to establish controls over their genetic resources in order to prevent the unregulated plundering of such resources. At least a dozen countries have already taken such steps, in accordance with the Convention on Biological Diversity, and a similar number are currently developing controls.

182. I do not understand how, as the Netherlands submits, traditional products and processes originating in developing countries may be patented in accordance with the Directive even though they are discoveries not inventions".

[248] This argument is vociferously expressed in the *Documents submitted by the Group of Countries of Latin America and the Caribbean (GRULAC)*, in *WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, First Session*, Geneva, April 30 to May 3, 2001, available at: http://www.wipo.int/eng/meetings/2001/igc/document.htm. *Traditional Knowledge and the Need to Give It Adequate Intellectual Property Protection, Wipo Committee on the Relationship between IP, Genetic Resources and Traditional Knowledge,* WIPO/GRTKF/IC/I/5 of March 16, 2001.

[249] For a similar conclusion see WELLS A. J., "Patenting Life Forms: An Ecological Perspective", *European Intellectual Property Review*, 1994, p. 117. RICOLFI M., Biotechnology, Patents and Epistemic Approaches, *Biolaw and Business*, 2, 2002.

provisions of the Directive, as the one concerning validity of patent grant, because the European Court of Justice decision (as to the validity of the Directive) – however flawed in the perspective of public international law – still is binding on them.

European States that are sensitive to the aforementioned legal reasoning supporting the arguments challenging the Directive and are willing to implement this PIC international obligation, will also have to face many legal questions that still remain unanswered: Who are the partners to negotiate with a central public body or a local authority or still a private association of citizens? Who is to represent a local community? What is the extent of his powers? If no authority exists and there is no mechanism of grant of the certification of origin in the provider, should the requirement for a certification be waived? What can restrain a company from claiming that a resource was obtained from such a country when it was actually collected illegally from another country with access and benefit sharing regulations? In the case of patenting a plant variety, what should be done when genetic material may come from numerous sources some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programs?[250]

Given all these uncertainties, I may understand that recipient States may not be willing to engage in setting up another patentability requirement as long as these issues are not properly addressed. Broadly speaking, it is then likely that the acceptance of the proposal of deposit of a certificate of origin at the patent application may eventually be subjected to (i) the establishment of access to genetic resources and benefit sharing regulations in provider countries, (ii) to the increase in the understanding on the part of industrialized recipient countries on the definition of the key terms, such as biopiracy, traditional knowledge and its registration systems in databases and (iii) to the establishment of efficient authorities that have to grant the "certificate of origin" that should also act according to internationally agreed standards. I am confident that the work within the *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* and the Conference of the Parties of the CBD will trigger crucial achievements in that sense.

2. How Traditional Knowledge Databases Can Improve the International Prior Art Search to be Performed by the Examiners

TK can be also considered a form of novelty-destroying prior art. The previous proposal on the disclosure requirements is instrumental for international prior art search which offers another defensive method against misappropriation of TK. In this respect, the setting up of TK databases in developing countries can consistently improve international prior art search. In this section we explore the interaction of these proposals and the relevant opened questions pertaining to their application.

i. Importance of Publishing TK in Databases for an Effective International Prior Art Search

[250] See on this point also RICOLFI M., "Biotechnology, Patents and Epistemic Approaches", *The Journal of Biolaw and Business, Special Supplement*, 2002, 77-90
Biolaw and Business, 2, 2002.

Prior art search is embedded in various national patent laws. For the purposes of Article 15.2 of PCT, relevant prior art is everything that has been made available to the public anywhere in the world by means of written disclosure, and which can be of assistance in determining that a claimed invention is novel or non-obvious[251].

Unfortunately, the application of this provision is not always the same in all national patent systems. Indeed at the patent application stage, most patent offices may not survey foreign literature in which descriptions of TK appeared if an invention is already part of the prior art and therefore not novel[252].

Under US Patent Law it is fairly easy to patent a TK-based invention because it does not consider that the "novelty" requirement has been lost if divulgation outside the USA occurs by means of public use and sale. The essential requirement of "novelty" can be destroyed only through publications[253]. Unlike US Patent Law, in Europe and most countries in the world, novelty is lost by any type divulgation, whether it is oral or written made in a foreign country.

Therefore, in the US indigenous and local communities in developing countries have little opportunity to bring attention to unwritten knowledge, practices, and innovations that demonstrate lack of novelty or non-obviousness. This has been the case of the *hoodia*[254] and the *turmeric*[255] patents which were allegedly based upon misappropriated TK unrecorded in any published document. These cases demonstrate that patent examiners were not apprised of nor did not seek out the available prior art contained in the TK held within the knowledge systems of indigenous and local communities. During the re-examination process the burden was placed on the knowledge holders to protect their TK. Yet thousands upon thousands of poor and isolated villages that have

---

[251] PCT Regulations rule 33.1(a) (WOPCR 1/40, Jan. 1, 1999), available at www.wipo.org/eng/main.htm.

[252] See *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Second Session*, Geneva, December 10 to 14, 2001, Progress Report on the Status of Ttraditional Knowledge as Prior Art, WIPO/GRTKF/IC/2/6.

[253] Section 102 of the Patent Act, 35 U.S.C. § 102: *"A person shall be entitled to a patent unless -*
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States…". In the Turmeric case PTO cancelled all six of the patents claims after such an examination requested by Indian Council of Scientific and Industrial Research. See Use of Turmeric in Wound Healing, U.S. Patent No. 5,401,504, issued March 28, 1995.

[254] The South African Council for Scientific Research (CSIR) has in several countries patented certain compounds found in a plant called *hoodia*, traditionally used by certain groups of Bushmen people known as Xhomani as an appetite suppressant. This patent aspires to the basis of a successful anti-obesity blockbuster drug treatment and will become Africa's first (WIPO/PCT International Publication No. WO 98/46243 (Pharmaceutical compositions having appetite suppressant activity). Bushmen groups, not mentioned in the patent application, are challenging the novelty of this invention. After being heavily criticised for initially failing to share benefits with the Bushmen, the CSIR has agreed to make such commitment. The *hoodia* patent case exemplifies this point, as do the patents relating to *maca*, and another one based upon *Phyllanthus amarus*, a medicinal plant used in India for treating various ailments including jaundice, which was discovered in tests to show effectiveness against viral hepatitis-B and E.
It seems that while a plant or animal extract or mixture of extracts known by an indigenous group to have a useful characteristic cannot be patented due to its lack of novelty, the achievement of being first to explain the extract's effectiveness by way of some tests, by describing its mode of action in the language of chemistry, or even by just modifying the mixture in some modest way seems to be sufficient in some jurisdictions to merit the award of a patent. Often such patents make no reference to the relevant traditional knowledge (e.g. the *hoodia* patent) or merely mention it in a cursory manner as if it is of little importance (e.g. the turmeric patent).

[255] See note 91.

rich TK have limited legal expertise and financial means for discovering that their resources are being improperly claimed by, for instance, United States corporations. Until the patent is awarded, they have little chance of learning about this misappropriation.

ii. Are Traditional Knowledge Databases Enough to Improve the Novelty-Destroying International Prior Art Search?

If we are not completely sure that an international prior art search on the TK related to these genetic resources registered in a database would have resulted in the rejection of patents like the aforementioned ones, it is at least certain that it would have narrowed the scope of the exclusive rights claimed.

This is why we stress the importance of undertaking a serious international prior art search. Two tracks can be followed by national or regional examiners in order to gain access to TK that may be relevant as prior art: (i) examiners should more fully integrate the existing rules and guidelines governing international and international-type searches into the normal examination process for national applications; (ii) examiners should review all databases, that have been created, and other known registries of TK to ensure that each aspect of an applicant's claims represent a truly inventive step.

With respect to the first proposal, it can be noted that the guidelines for international-type searches into the examination process for patent applications treat TK prior art more flexibly than do PTO examiners under their current practices. Indeed PTO examiners perform the statutory duty of an "international-type" searches only for applications that enter the national stage from international applications. A closer look at 37 C.F.R. § 1.9 will indicate that the examiners have the statutory duty to search according to the definition of a "national application" which includes any U.S. application for patent filed under 35 U.S.C. § 111, and not only applications entering the national stage from international applications. Consequently, the international-type search must be performed on all U.S. patents filed on and after June 1, 1978[256].

We hereby stress that an "international-type" search should be undertaken as international search as defined under the Patent Cooperation Treaty (PCT)[257]. Indeed, according to the aforementioned Article 15.2 of the PCT, the objective of the international search is to discover relevant prior art internationally.

Although written disclosure is the condition *sine qua non* for the material information to become relevant prior art for the purposes of an international search[258], "[t]he date on which the written disclosure was made available to the public may have been *after* the filing date of the international application"[259]. This means that while orally transmitted TK would not qualify as prior art, it would once it is collected in a database, even if these data were not registered in that form until after the patent application had been filed. Here resides all the importance of a database collection or printed publication to be undertaken at the national level in developing country.

---

[256] 37 C.F.R. § 1.9(a)(1).

[257] Patent Cooperation Treaty (PCT) of June 19, 1970, as amended and modified, to which the United States became a Party on January 24, 1978. Available at World Intellectual Property Organization web site, <www.wipo.org/eng/main.htm>.

[258] *Ibidem* rule. 31.1(b); PCT International Search Guidelines, PCT Gazette, chptr. VI § 1.2 (Special Issue No. 06/1998, Oct. 8, 1998), available at www.wipo.org/eng/main.htm>.

[259] PCT International Search Guidelines, chptr. VI § 1.2 (emphasis added).

Moving to the second proposal we adopt a more problematic tone on a process that has been occurring. In light of differences in national patent laws, we pose a very basic question: if TK information concerning the aforementioned *hoodia* and *turmeric* were published in a database would it suffice to constitute novelty-destroying prior art? We think that there would still be the problem of knowing how it should have been described. In some countries, even if published, TK could not be able to challenge some biopiracy based patents because it was not disclosed in a way that would teach someone to come up with an invention similar or exactly as described in the specification of the actual patent[260]. Without delving in the complex problem of the description of relevant TK in the database, it is important to note that national laws vary with respect to how information or material in the public domain should be presented or described in order to constitute novelty-defeating prior art[261]. On this point, we draw attention to the important statement of the European Patent Office Technical Board of Appeal (in accordance with Lord Hoffman) "the concept of novelty must not be given such a narrow interpretation that only what has already been described in the same terms is prejudicial to it … *There are many ways of describing a substance*"(italics added)[262].

There are still questions unresolved about the creation of TK databases: in the field of plant variety patents, it is hard to see how a database can destroy it if the information in the database does not describe all existing landraces. Should their access be private or public, with the risk that in the latter case it may even be counter-productive since they could also provide opportunities for further biopiracy cases[263]? This is particularly true since there is still no international understanding on the way to interpret novelty-destroying prior art. Industry can see these TK databases as valuable sources of knowledge that can avoid painstaking and timely research. Furthermore, should only published TK be entered in databases available only to patent examiners? If, on the one hand, the databases need to be accessible to examiners so that they do not grant patents in error, on the other hand, their access should be restricted to prevent further abuses.

The problems hereby posed are not to deny TK databases' usefulness, but to caution that without other reforms to the patent system databases would be useful only for the most egregious cases of TK misappropriation, and not even all of these.

iii. Interaction between the Elaboration of Disclosure Requirements and the International Prior Art Search

For the purpose of connecting sections VI.D.1 and VI.D.2, we recapitulate the main proposals in the case that patent offices were to establish specific requirements to help ensure that examiners have access to material information pertaining to the patent application:

---

[260] Merrell Dow v. HN Norton, *Intellectual Property Reports,* 33, 1996, p. 11.

[261] This is shown by the different answers given by the governments and regional patent offices to the questionnaire carried out by WIPO's Standing Committee on the Law of Patents, World Intellectual Property Organization - Standing Committee on the Law of Patents (2001), "Information provided by members of the Standing Committee on the Law of Patents (SCP) concerning the definition of prior art. Brief summary. Prepared by the International Bureau", SCP/6/INF/2. In Japan, for example, "novelty-defeating disclosure… has to be enabling, i.e. it teaches those skilled in the art how to make and use the claimed invention. If novelty-defeating disclosure fails to provide such information, the disclosure will not be a novelty-defeating bar", MORNEAULT M. A. and RADEMAKER B. F., "A maze of laws and exceptions: examples of novelty around the world", *Journal of World Intellectual Property,* 4, 1, 2001, p. 28.

[262] BENTLY L. and SHERMAN B., *Intellectual Property Law*, Oxford: Oxford University Press, 2001, p. 421.

[263] World Intellectual Property Organization (2002), "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Third Session, Geneva, June 13 to 21, 2002. Draft report prepared by the Secretariat", WIPO/GRTKF/IC/3/17 Prov.

(i) Applicants must disclose TK that they used in the process of inventing the patentable subject-matter and this should not be limited to printed publications or patents, instead it should disclose also other sources of material information.

(ii) Applicants must conduct prior art searches of TK including publications, databases herbarium specimens, etc., in relation with the used TK.

(iii) It should be required that the applicant disclose country and exact geographical location from which the knowledge or related resources (for instance, plants identified as medicinal on the basis of TK) were obtained.

(iv) A more difficult requirement is that applicants have to demonstrate that they have used TK in compliance with applicable local laws of official source jurisdiction.

3. Implementing the Existing Exceptions to Patent Law and Limiting the Rights Conferred

In this final section, we intend to demonstrate how certain TRIPS provisions leave room for manoeuvre in adopting different solutions in the national patent legislations according to needs of developing countries. In light of fundamental principles of social and economic welfare provisions enshrined in TRIPS, we will study to which extent these countries can be also justified to limit those that they can consider "abuses" of biotech-patents.

Though Article 28 of TRIPS grants monopoly rights to the patent owner for 20 years, they are not absolute but subject to certain limitations and exceptions. In accordance with the Preamble, the main goal of TRIPS Agreement is *"to reduce distortions and impediments to international trade"*. Although it is recognized that IPRs are "private rights", "*the underlying public policy objectives of national systems for the protection of IP, including developmental and technological objectives"*, are recognized as well. More specifically, we remind that Articles 7 and 8 provide a framework for interpretation and implementation of IPRs.

The concepts of Article 7 on "transfer and dissemination" of technology, mean that the recognition and enforcement of IPRs are not ends in themselves, but are meant to enable each country – within the limits defined by TRIPS - to define a balanced regime of protection, to *"mutual advantage"* of producers and users of technological knowledge and in a manner conducive to social and economic welfare.

Article 8 of TRIPS, stipulates that "*Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provision of this Agreement"*. Though a "consistency test" is to be applied, this principle stresses that no Member country can be prevented from taking into account its own public interests in its IPRs legislation in the post-TRIPS Agreement environment.

Article 8.2 of TRIPS states that*"appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of IPRs by rights-holders or the resort to practices which unreasonably restrain trade or adversely affect the international*

transfer of technology". The implementation the TRIPS provisions can be freely determined within their "own legal system and practices" of each country (Article 1.1 of TRIPS). This implies that provider States of biological resources have leeway to implement TRIPs provisions in their own national legal systems.

Under those provisions, developing countries' national legislations can provide for a variety of measures that promote competition and balance, to some extent, the rights of the title biotechnological and particularly pharmaceutical patent holders with those of the users of the technology. Such measures may include the following:

(i) Compulsory licensing (Article 30)
(ii) Admissibility of parallel imports (Article 6)
(iii) Exceptions to exclusive rights (Article 30) such as: use of public policy measures outside the field of IP on issues of access to and prices of drugs[264].
(iv) Fair use from infringement.

i. Compulsory Licenses

A compulsory license is the license issued by a government to a third party, whether a private company or government agency, for the right to use or exploit a patent without the patent holders consent. Compulsory licensees generally compensate the patent holder through payment of remuneration. Many developed countries make available some forms of compulsory licences, either under their patent law or, as in the U.S., through anti-trust legislation.

ii. International Exhaustion of IPRs and Parallel Imports

In order to appreciate how the admissibility of parallel imports can be useful for the IP-related benefit redistribution, it is important to remind the *raison d'être* of the doctrine of international exhaustion.

It is first of all a response to the ubiquitous nature of IPRs. Generally in a national context an IPR is exhausted as soon as – or the first time - the patented product is put on the market by the holder or with its consent.

In this latter case, whilst this is a perfect rule for the national market, internationally it is more difficult to be applied. After having freely chosen the price of the IP protected product and sold it for the first time in country A, the right holder exhausts his exclusive rights to resell the product in all other countries. As a consequence the same product can be purchased by anybody and circulated at the price set by the resellers who will gain from the differences of price between the two markets and by importing the product from countries where the product is cheaper. In other words, since in some countries the same product is cheaper, one tends to buy abroad and resell inside the country where the product is more expensive. This is the case where you have a parallel import. At the international level, parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the

[264] South Africa's Medicines Amendment Act 90 of 1997 (the 1997 Amendment Act).

exporting country by the patent holder[265]. Three levels of exhaustion are identified: national, regional[266] and international.

"Parallel trade was one of the most contentious issues in the TRIPS negotiations, with developing countries, led by Hong Kong and others, arguing in favor of and the United States arguing against permitting parallel imports, at least under certain circumstances. In the end, it was decided to remove the subject of exhaustion of IPRs from the TRIPS Agreement because there was no understanding about the kinds of exhaustion to apply whether international, regional or national - a solution that was acceptable to the United States as it does not explicitly endorse national discretion on this matter, nor rule out the use of unilateral trade measures on this issue"[267]. The US fights the international exhaustion, arguing that parallel imports are indeed a counterfeit of the rights of the holder.

However, it is suggested that the underlying concept for parallel imports – in which the patent holder has been rewarded through the first sale or distribution of the product so that he no longer has the right to control the use or resale of the product- is indeed in line with WTO's trade liberalization objective that from the moment a product is marketed, the patent holder can no longer control its subsequent circulation[268].

We are now in a position to address the question of how parallel imports are a chance to be seized by developing countries for benefiting of biotechnological inventions related to biodiversity. As observed in the recent and famous South African pharmaceutical case, parallel imports are of particular importance for public health interests, since the pharmaceutical industry generally prices the same medicines differently throughout the world[269]. Parallel imports would prevent market segmentation and price discrimination by patent holders on regional or international scale. In other words, parallel imports allow consumers to effectively shop on the world market for the lowest price for a patented good. Exactly the same can be said for those that possess biotechnological patents based on biodiversity.

This theory would allow importing at a cheaper price products, like non-chemical insecticides, that can be favourable for the conservation of biodiversity. The ban on parallel imports has already been detrimental to free trade when, for instance in 1994, the strawberry plant growers in Argentina were forbidden to export their plants to Europe, because the US breeders and the

---

[265] CORREA C. M., *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, Geneva, available at www.twnside.org.

[266] The EU, as stated in the S*ilhouette* case, applies the regional exhaustion: from the moment in which there has been the first selling by the holder or with his consent within EU it is not possible to avoid that another purchaser resells the same products everywhere in EU. International exhaustion is however not accepted and as a consequence most countries do not accept parallel imports which would allow to access the IP protected product to a lower price.

[267] MWAKYEMBE H., MPUNDU KANJA G. and MUNKHONDIA M., "Implications of the TRIPs Agreement on the Access to Cheaper Pharmaceutical Drugs by Developing Countries, Case Study of South Africa vs. The Pharmaceutical Companies", *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001, pp. 305-306.

[268] *Intellectual Property Rights, the WTO and Developing Countries – The TRIPS Agreement and Policy Options*, Third World Network, Malaysia.

[269] For instance, parallel importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the medicines. Such measures would also not prevent patent owner from receiving remuneration for the patented invention in the country where the product is first sold

European licensees "did not want the plants produced in Europe to compete with those coming from outside Europe"[270].

Parallel importation is implemented in some countries, both developed and developing. Parallel importing is a useful policy tool by which developing countries will be able to provide quick access to life-saving drugs, and to respond speedily to a health crisis or need[271]. In this regard, parallel importation must be regarded as a legitimate measure, which the WTO Members are permitted to adopt to protect public health and nutrition as is provided for in Article 8(1) of TRIPS Agreement[272].

We agree with Mwakembe, Mpundu and Munkhondia when they state that "Article 6 allows each Member country the freedom to incorporate the principle of international exhaustion of rights – the underlying justification for parallel imports – in its national legislation. Indeed this is in line with the WTO Doha declaration on TRIPS Agreement and Public Health which stated that the effects of the provisions in TRIPS Agreement that are relevant to the exhaustion of IPRs are to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the most-favored-national treatment and national treatment provisions of Article 3 and 4"[273].

The main hindrance is still the fact that the many developing countries might lack the necessary technology to develop the patented product.

iii. Local Working Requirement as an International Patent Law Obligation

The problem of benefit sharing seems to be entrapped between two extreme solutions: on the one hand the adoption of the extreme measure of compulsory licenses and, on the other hand, the imposition by the patentee stronger party of a mere financial compensation for the germplasm or for any other genetic resource of the developing country. Legal thinking needs to be stretched in order to suggest some solutions to the bio-colonialist pattern whereby the developing country exports its raw materials and the industrialized country returns its finished goods in the provider country to be sold at unaffordable high prices.

A compromise solution between the safeguards of the companies from industrialized countries and the interests of the biodiversity provider States can be found in the obligation upon the licensee to locally work the patent after the provider country has granted him the biodiversity-based patent. Of course, this solution is better than the straightforward imposition of a compulsory license under Article 31 and 8.1 of TRIPs because it is less intrusive in the exclusive rights of the patentee.

I maintain that the local working requirement in the provider country represents a very effective way to implement both the *« benefit sharing »* obligation under Article 19 of the CBD and the *« mutual advantage »* objectives of TRIPs Agreement.

---

[270] DUTFIELD G., *Intellectual Property Rights, Trade and Biodiversity*, *op. cit.,* p. 54.

[271] It is worth noting that though Article 6 gives WTO Members very broad leeway to implement parallel importation policies, the doctrine of international exhaustion as applied to patents, if not properly used can be of serious consequence to pharmaceutical patent holder as they might threaten the pharmaceutical protection system more especially in cases where pharmaceutical drugs which are cheaper and intended to be sold in poor countries find their way in the developed countries or world markets.

[272] DUTFIELD G., *Intellectual Property Rights, Trade and Biodiversity*, *op. cit.,* p. 54.

[273] MWAKYEMBE H., MPUNDU KANJA G. and MUNKHONDIA M., *op. cit.,* p. 307.

First of all, this solution guarantees patentee's competitive advantage since it avoids that the industrialized country company suffers from the « free riding » approach by the provider country through the issuance of a compulsory license to an unrelated third party that can even be a competitor. On the contrary, in this case the patentee can directly choose the local licensees/co-venturers, whereas, of course, this would not be possible when a compulsory license is issued. Indeed the patentee can secure a slow spill-over of industrial and commercial know-how with the consequent reduction of the patentee's time-lead natural to the patent. Substantial benefits of image returns[274].

Through the ensured local working of the patent the provider State gains the transfer of technical know-how and the flow of financial resources that in many cases may exceed those resulting from a blunt compulsory licence to a third unrelated party. This means growth in the own capacity for research and development even after the time when patent right has elapsed. A domestic know-how can be then developed through its own biodiversity-based products.

The legal ground supporting this proposal is Article 5.A.2 of Paris Convention which has been incorporated into the TRIPs Agreement (see Article 2.1). On this matter, Paris Convention states that: *"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work"*. The default of local working can thus be seen as an abuse *per se*.

The local working of the patent has been a long-established requirement for patent protection at the national level. However, it can be argued that Article 27.1 of TRIPs has somehow repealed this principle when it affirms that patents rights shall be enjoyable *"without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced"*. According to this interpretation the patentee would incur into patent "abuse" in the sense of Article 5.A.2. of Paris Convention only if it should not provide, even by mere export, "enough" products to the country that has granted the patent.

According to a systematic interpretation Article 27 expresses the *lex generalis* on the patentable subject-matter and in no way can be deemed as addressing directly or especially the matter of local working of the patent. On the contrary Article 5.A.2 of Paris Convention contains the *lex specialis* on this matter by specifically addressing the possibility of issuing a compulsory license in case of default in the local working of the patent on the part of the patentee.

In order to understand the teleological meaning of these provisions reference should be made to Article 7 of TRIPs where, among the objectives of the treaty, it is stated that the *"protection and enforcement of intellectual property rights should contribute to the promotion […] to the mutual advantage of produces and users of technological knowledge"*. It is also reminded that if flexibility has to be used, it should then be done so in favour of developing countries' compliance options[275]. The subsequent practice of TRIPs parties shows well that the

[274] VAN OVERWALLE G., "Belgium Goes Its Own Way on Biodiversity and Patents", *European Intellectual Property Review*, 2002, pp.235-236.

[275] REICHMAN H., "The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?", *Case Western Reserve Journal International Law*, 32, 2000, see note 72 and *From Free Riders to Fair Followers:*

CBD obligations lead unequivocally towards this interpretation. It suffices here to mention Articles 1, 8j, 16 and 19 of the CBD.

Even in the hypothesis that Article 27.1 repealed the local working of the patent, it can be stated that Article 8.1 gives the possibility to exceptionally derogate to a general principle, even in the absence of a formal States' reservation. This is the case when, according to Article 8, the requirement of local working can be viewed as a measure necessary to protect a sector of vital importance to the socio-economic and technological development. I agree with Ghidini when he stresses that this outlined interpretation/proposal does not violate Article 27.1 of TRIPs, which expresses a general principle, especially because the local working requirements would cover only and exceptionally the biodiversity providing country. Meanwhile the repeal of this principle can be applied to all other countries in which the patent holder wishes to apply[276].

iv. The Doctrine of Fair Use From Infringement

Moving back to the a little more confrontational ground, another proposal put forward by Ricolfi is the exercise of the concept of "fair use from infringement"[277].

In case the material transferred from the provider country is genetically modified and then patented, exceptions to patent exclusive rights may be formulated; for instance the fair use from infringement claims, borrowing this notion from copyright law doctrine. An example can illustrate the thrust of this proposal: let us imagine a specie of aloe preserved for millennia by a certain community a certain country. Where a western company patented the method to modify the gene of the said aloe to create a pharmaceutical product, the very fact that the invention is based on that specific genetic resource would immunize the community if it repeats that invention within the boundaries of the members of that group of people, i.e. not entailing manufacture or sale of propagating material so entering in competition to the right holder.

It can be contested that this idea hardly fits a traditional patent system since fair use doctrine is inherently linked to copyright exercise of rights. But this is not entirely correct since there are a lot of exceptions both in patent law and in trademark law. It is just that especially in continental law it is seldom spoken about faire use outside copyright law. Stiull it can be said that repetition is not considered an infringement *per se* whereas the repetition of a patented invention without proper right holder's authorization constitutes an infringement, as a general principle of patent law. Moreover, I see with a certain difficulty how can a local community have the financial and technological means to manufacture the invention within its boundaries without the transfer of

---

Global Competition Under the Trips Agreement, New York University Journal of International Law & Politics, 29, 1996, pp. 36-39.

[276] GHIDINI G, *op. cit.*

[277] See RICOLFI M., "The Interface between Intellectual Property and International Trade: the TRIPs Agreement", *Italian Intellectual Property*, 2002, 29 ff. This proposal is also contained in "WIPO Worldwide Academy, International Conference on Intellectual Property Education and Training", New Delhi, July 11 to 13, 2001, Geneva. This proposal has been expressed in the context of the problem of implementation of Article 27.3(b) on plant variety protection in developing countries.

technology by the patent holder. This skepticism leads to the confirmation that the "local working requirement" in the form of a statutory contractual provision remains, in my view, the most realistic solution to manufacture the invention in the biodiversity provider country.

VII. FINAL OBSERVATIONS

The phenomenon of "globalization" of IPRs on biotechnology, promoted by Article 27 of TRIPS, has spawned various controversies in public international law. The issues involved range from ownership of genetic resources and the protection of derivatives to the phenomenon of biopiracy, from the problem of preservation and sustainable use of biodiversity to the equitable benefit sharing thereof, without mentioning the ethical and moral issues that have largely fallen outside the scope of our study.

It is clear that TRIPS, promoted by highly technologically endowed countries, keeps the pace with the advancement of the biotechnological industry without bothering with recognizing the rights of local communities (TK innovations or farmers rights etc.). Nor does TRIPS deal with methods to curb biopiratical actions which, on the contrary, form preoccupations at the basis of the CBD.

During and after the negotiation of multilateral treaties establishing legal regimes of utilization of genetic resources (TRIPS, CBD and FAO Treaty), this acrimonious conflict has particularly opposed, on one side, gene-hunting countries (technologically rich but poor in biodiversity), and, on the other side, gene-endowed countries (technologically poor but rich in biodiversity). And of course their approaches to IPRs on life forms vary according to their structural characteristics.

In the debate described in section III.B, the interpretation of the concept of State sovereignty over genetic resources has been one of the most difficult areas of conflict between TRIPS and CBD. In the following sections we have widely demonstrated that no argument based on the concept of sovereignty according to the CBD or FAO Treaty can warrant any suspension of IPRs, i.e. non-compliance with TRIPS provisions. This means that a WTO Member country cannot reject a patent application for a genetic invention on micro-organisms (found on their territory) simply because it argues that this kind of patenting is contrary to the object and purpose of the CBD. In this Convention national sovereignty over biological resources is a simple re-affirmation of the right of States to control exports and imports, or to set conditions for access to biological resources within its borders. Hence, the fact that States, by ratifying the CBD, have committed themselves to preserve biodiversity under their sovereignty and that later they came under the obligation of TRIPS to grant some forms of IPRs over biological resources, does not amount *per se* to a legal contradiction. We thus conclude that, in accordance with the principles *pacta sunt servanda* and *ut magis valeat quam pereat*, there is a presumption that both conventions are enforceable without contradiction.

Moreover, the wording of key provisions in the CBD - whether on the benefit sharing or on PIC for the access to genetic resources - is so vague and ambiguous that we hardly see how it can be maintained that they are legally incompatible with Article 27 of TRIPS. From a *stricto sensu* legal point of view, the object and purpose of the two treaties are basically different so that they ought to be fully implemented, i.e. one treaty cannot be appealed not to comply with the other. Undoubtedly, both Article 27 of TRIPS and some of the provisions of the CBD deal with the utilization of biological resources, yet they do so to achieve two different objectives that are not mutually exclusive.

Most of the argued conflict between TRIPS and CBD is in reality spurred on by moral and rhetorical assumptions, legitimate they might be: (i) patent regime is a western form of IPRs totally unsuitable to the majority of the societies in the south, and (ii) private rights are completely alien to indigenous communities because the vast majority of their farmers, who manage biodiversity at the local level, are used to collective rights[278]! Moreover, no biotechnological patent based on unauthorized appropriation of biological materials and related TK can nowadays escape unanimous condemnation from developing countries.

Throughout our study we have striven to persuade that TRIPS and CBD are complementary and can eventually build up a synergy. This burning controversy may indeed be quenched, or at least defused, if national IP law makers and officers (in developing as well as in developed countries) undertake interpretative efforts to seriously comply with TRIPS, CBD, other relevant international legal instruments. Broadly speaking, this means that, on their side, developed countries should not deliberately interpret in a restrictive manner the safeguards and flexibilities offered by TRIPS to developing countries to strike a balance of interests[279]. On the other side, developing countries should create national IP protection of TK through existing or new forms of IPRs able to recognize and compensate the creators and possessors of such knowledge (as discussed in sections VI.B and VI.C).

As TK issues are perceived at the moment within international fora, it seems unlikely to us that a multilateral treaty on TK will be rapidly negotiated. Considerable conceptual divergences still exist among regions of the world on the objectives, scope and content of possible rights to be recognized. This will be a difficult task at the national level itself, as evidenced by the small number of countries that have materialized the establishment of some forms of protection in this area (as discussed in sections VI.B and VI.C).

However, a small step forward in this sense has been made during the last Ministerial Conference of WTO in Doha, Quatar, in which unexpected language has entered the Declaration of November 14th 2001:

> *"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*** **TK** ***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".*

Although this declaration seems to accommodate some of the claims of developing countries, it should not be forgotten that a reviewing process of Article 27.3(b) might open wide a full review of the TRIPS Agreement as a whole pursuant to Article 71.1. This can become the pretext for industrialized countries to bring new IP standards into the negotiations, for which most

[278] See for instance the African approach on human rights who encompass collective rights enshrined *The African Charter on Human and Peoples' Rights* adopted 17 June 1981, entered into force 21 October 1986, OAU Doc. CAB/LEG/67/3 Rev.5, 21, *International Legal Materials*, p. 59.

[279] We have argued that exceptions like compulsory licensing and parallel imports are in compliance with TRIPS Agreement, As such WTO Members should be at liberty to include them in their domestic legislation. This is also in line with the spirit of the Doha Ministerial Declaration stating that the TRIPS Agreement « can and should be interpreted and implemented in a manner supportive of WTO Members rights to protect public health and in particular to ensure access to medicine for all ».

of developing countries are not ready. These issues include patents on business procedures, patents on life, extended plant variety protection, *sui generis* protection of databases, renewed standards on enforcement, etc. This may considerably weaken developing countries' opportunities in rebalancing the TRIPS Agreement, especially in areas of interest for developing countries such as: non patentability of life, flexible *sui generis* systems for protecting plant varieties, recognition of farmers rights, inclusion of the requirement for identification of the genetic resources' origin and the protection of TK.

In any event, we stress that paragraph 19 of the Doha Ministerial Declaration calls for an *examination* of issues, not for *negotiations*. Changes in the Agreement can be introduced only through negotiations, whereas examination of issues does not imply any change in the current status of the work already undertaken by WTO Members. Finally we can wonder: is there any revision negotiation of Article 27.3(b) on the horizon? The fact that the "Implementation text on TRIPS Agreement" fails to include biodiversity issues in those ready for immediate action, shows that the procedure to transfer the principles of the CBD into the WTO system is an extremely long political road.

But the full reconciliation between TRIPS and CBD does not pass only through the revision of Article 27.3(b). The improvement of the quality of patents granted by Patent Offices in developed countries, as discussed in section VI.D, can also offer constructive solutions. It is presently argued that accommodating the wishes of certain biotechnology sectors has seriously blurred the distinction between discovery and invention in patent law. Biotechnological patent holders are merely tinkered with the natural substance or traditional practice, making only minor changes[280]. Therefore, it seems to be unjust that the biotech-patent holder gains exclusive rights for making changes that are either minor or obvious. And when such doubtful patents are based on a flagrant misappropriation of genetic resources, even the most persuasive justifications - that patents reward the additional time and resources necessary to maintain high standards of biotechnological innovation – would hardly support the validity of such a patent. We believe that determining whether such types of patents are non-obvious certainly warrants further investigation.

Even more problematic is it to know to which extent the invention is novel considering TK on which it is based. The starting point for such assessment can be the integration of prior art search on TK databases and some form of PIC requirements in the US and European patent systems (as proposed in section VI.D.1 and VI.D.2). Then these patent systems will be more credible and will better counter the sharp criticisms that argue that novelty and invention step/non-obviousness requirements for biotechnological patent applications have been unduly loosened.

These matters do not only concern the patent offices in developed but also those of developing countries (that have been creating). The latter have to be aware of the importance of setting commissions of well-trained examiners who will have to deal with these issues for the sake of the benefit sharing with their communities. All patent examiners should bear in mind that a patent is an exclusive right that covers only the invention described and nothing more. If the invention based on a certain type TK is indeed minor with regard to the TK on which it is based, then its exclusive rights cannot prevent the reproduction of this TK. On the contrary, if the invention is a major advance, the patent rights should be more extensive.

[280] NIJAR G. S., *In defence of indigenous knowledge and biodiversity: a conceptual framework and essential elements of a rights regime*, Malaysia, Third World Network, Penang, 1996, p. 4.

It is wrong to think that this kind of superficiality in granting biotech-patents might constitute a problem affecting solely developing countries. If the biotechnological patent quality remains so poor, this phenomenon will eventually stifle innovation, even in the industrialized world. The life science corporations are already complaining about the patenting practices of small biotechnology firms that amass sizeable patent portfolios on basic research tools. Even though many of these patents would struggle to survive a legal challenge, they are asserted aggressively because they are the only assets many of these companies have. Here lie important issues that should increasingly concern IP legal doctrine in industrialized countries.

Coming to the conclusion of our study, we observe that the history of IP protection of the life science industries suggests that regulatory reforms were undertaken only if powerful businesses pushed for them given the underlying commercial interests at stake. Therefore we wonder, who is the commercial representative who will lobby for the inclusion TK protection in TRIPS Agreement? What is the business entity that will support the introduction in the patent system of the requirement of submission of a certificate of origin or improvement mechanisms of international prior art search? Even governments of biodiversity-rich developing countries, that should normally defend the interests of their indigenous peoples, are now bending their knee to negotiate TRIPS-plus standards through bilateral treaties. Meanwhile, we can be sure that, until patent and IP systems will undergo proper modifications in accordance with the CBD principles, indigenous peoples will continue to vociferously respond by calling for a ban on patents on life forms.

<u>This short-thesis has presented the following proposals to reconcile TRIPS and CBD:</u>

A. Proposals to be implemented by provider countries (generally developing countries) :

1. National legislation on the access to genetic resources and for the contracts with bioprospecting companies
2. Bioprospecting cartel among developing countries for the access to their genetic resources
3. *Sui Generis* System for Plant Variety Protection incorporating the principles of the CBD
4. Protection of TK by
    i. Petty Patents
    ii. Geographical Indications
    iii. Trademarks
    iv. *Sui Generis* Right with TK databases
    v. Trade Secrets

B. Proposals to be implemented by recipient countries (generally industrialized countries):

1. Consideration of environmental issues in the examination procedure of biotechnological patents

2. Prior informed consent through certification of origin
3. International prior art search in TK databases
2. Accept exceptions to patent rights:
    i. Compulsory licensing
    ii. Admissibility of parallel imports
    iii. Exceptions to exclusive rights such as: use of public policy measures outside the field of IP on issues of access to and prices of drugs

iv. Fair use from infringement

BIBLIOGRAPHY

I. PRIMARY SOURCES

A. Treaties and Official Documents

1. United Nations

i. Treaties

United Nations Convention on the Law of the Sea, December 10, 1982, U.N. Doc. A/Conf.62/122, U.N. Sales No. E.83.V.5 (1983), reprinted in 21 International Legal Materials, p. 1261.

Convention on the Fishery and the Conservation of Biological Resources in the High Seas, 29th April 1958, in Nations Unies – Recueil des Traités, 1966, pp.280-296.

Convention on Biological Diversity, Done at Rio de Janeiro, 5 June 1992, UNEP/Bio.Div/N7-INC5/4; 31 International Legal Material, 818.

International Covenant on Economic, Social and Cultural Rights, (1966), 993 UNTS, 3.

The Vienna Convention on the Law of Treaties, 1969, 1155 *U.N.T.S*, 331.

International Labour Organization Convention Concerning Indigenous and Tribal Peoples in Independent Countries, No. 169, June 27, 1989, 28 International Legal Materials 1382, 1989.

International Labour Organization Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi Tribal Populations in Independent Countries, No. 107, 328 UNTS 247.

ii. Official Documents

UN Doc. E/CN.4/Sub.2001/13, *Intellectual property rights and human rights*, Report of the Secretary-General submitted to the Sub-Commission on the Promotion and protection of Human Rights at its 53rd session.

UN Doc. A/CONF.157/24, *Vienna Declaration and Programme of Action*, World Conference on Human Rights, Vienna, 14 – 35 June 1993.

General Assembly Resolution 217 A (III), *Universal Declaration of Human Rights*, 217 A/III, 10 December 1948.

UN Doc. E/C.12/2000/15, *Drafting History of Article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights*, background paper submitted by Green, Maria to the Committee on Economic, Social and Cultural Rights, at its 24th session, Agenda Item 3, Implementation of the International Covenant on Economic, Social and Cultural Rights.

UN Doc. E/C.12/2000/18, *Protection of intellectual property under the TRIPS Agreement*, background paper submitted by the Secretariat of the World Trade Organization to the Committee on Economic, Social and Cultural at its 24th Session .

UN Doc. A/RES/48/141, General Assembly Resolution 48/141 of 20 December 1993, *High Commissioner for the promotion and protection of all human rights*.

UN Doc A/CONF.151/5/Rev.1 (1992), *U.N. Conference on Environment and Development*, June 3-14, 1992, Agenda 21, (hereafter Agenda 21).

Conference on Environment and Development, *Rio Declaration on Environment and Development*, UN Doc A/CONF.151/5/Rev.1, 1992.

UN DOC A/31/128 (1986), *U.N. General Assembly Declaration on the Right to Development*, G.A. Res.41/128, annex, UN GAOR, 41th Sess., Supp. No. 53.

2. World Intellectual Property Organization

i. Treaties

Berne Convention for the Protection of Literary and Artistic Works (9 September 1886), Act of Stockholm (1967), Publication of the World Intellectual Property Organization No. 282(E), Paris Act (1971) as modified in 1979, Publication of the World Intellectual Property Organization No. 287(E).

Paris Convention for the Protection of Industrial Property, (20 March 1883), Stockholm Act (1967), modified in 1979, Publication of the World Intellectual Property Organization No. 201(E).

Treaty on Intellectual Property in respect of Integrated Circuits, Washington Conference, 1989. Publication of the World Intellectual Property Organization No.202 (E).

Agreement Between the World Intellectual Property Organization and the World Trade Organization, concluded 22 December 1995, entered into force on 1 January 1996, World Intellectual Property Organization, Geneva 1997. Publication No. 223.

ii. Official Documents

Réunion sur la propriété intellectuelle et les ressources génétiques, Genève, 17 et 18 avril 2000, OMPI/PI/RG/00/2.
WIPO Intergovernmental Committee on Intellectual Property And Genetic Resources, Traditional Knowledge and Folklore, Third Session, Geneva, June 13 to 21, 2002, Agenda 5: Traditional Knowledge; documents WIPO/GRTKF/IC/3/7, 8, 9.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (2001): First Session, Geneva, April 30 to May 3 : Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Doc No. WIPO/GRTKF/IC/1/3.

Intellectual Property Needs and Expectations of Traditional Knowledge Holders — WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge, WIPO, April 2001, p. 25. See also *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore Elements of a* Sui Generis *System for the Protection of Traditional Knowledge*,WIPO/GRTKF/IC/3/8.

Documents submitted by the Group of Countries of Latin America and the Caribbean (GRULAC), in *WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, First Session,* Geneva, April 30 to May 3, 2001, available at: http://www.wipo.int/eng/meetings/2001/igc/document.htm, *Traditional Knowledge and the Need to Give It Adequate Intellectual Property Protection, Wipo Committee on the Relationship between IP, Genetic Resources and Traditional Knowledge,* WIPO/GRTKF/IC/I/5 of March 16, 2001.

3. World Trade Organization

i. Treaties

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, art. 27, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 1994, 22 International Legal Materials 81, 94, 1994.

ii. Official Documents

The Results of the Uruguay Round of Multilateral Negotiations, The Legal Texts, The World Trade Organization, 1995.

Draft Communication by Kenya Review of the Provisions of article 27.3(b) of the TRIPs Agreement, WT/GC/W/302, 6 August 1999.

Proposal of the African group for the Revision of art 27 of TRIPs Agreement WT/GC/W/302 of 6 August 1999 and IP/C/W/206 of 20 September 2000.

Proposal of Southern Africa Development Cooperation (SADC) *for the Revision of art 27 of TRIPs Agreement,* WT/L/317 of 1 October 1999.

Proposal of Brazil for the Revision of art 27 of TRIPs Agreement, IP/C/W/228 of 24 November 2000.

Proposal of Venezuela for the Revision of art 27 of TRIPs Agreement, WT/GC/W/282 of 6 August 1999.

Proposal of Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe, for the Revision of art 27 of TRIPs Agreement, JOB(99)/3169 and Add. 1.

Proposal of The Least Developed Countries (LDC) Group for the Revision of art 27 of TRIPs Agreement, WT/GC/W/251 of 13 July 1999.

Proposal of Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda for the Revision of art 27 of TRIPs Agreement, WT/GC/W/354 and WT/GC/W/355 of 11 October 1999.

Proposal of Singapore for the Revision of art 27 of TRIPs Agreement, JOB(00)/7853.

Proposal of Japan for the Revision of art 27 of TRIPs Agreement, WT/GC/W/242 of 6 July 1999.

Proposal of Norway for the Revision of art 27 of TRIPs Agreement, CBDIP/C/W/293 of 29 June 2001.

Proposal of Switzerland for the Revision of art 27 of TRIPs Agreement IP/C/W/284 of 15 June 2001.

WTO Ministerial Conference Declaration on the TRIPS Agreement and Public Health, Fourth Session, Doha, WT/MIN(01)/DEC/W/2, 14 November 2001.

4. European Communities

Directive 98/44/EC of the European Parliament on the Council of 6 July 1998, in O.J.L. 213, 1998.

5. Treaties of Other Intergovernmental Organizations

The African Charter on Human and Peoples' Rights adopted 17 June 1981, entered into force 21 October 1986, OAU Doc. CAB/LEG/67/3 Rev.5, 21, International Legal Materials.

The American Convention on Human Rights, entered into force, January 22 1969, *U.N.T.S* 17955, vol. 1144.

The African Charter on Human and Peoples' Rights adopted 17 June 1981, entered into force 21 October 1986, OAU Doc. CAB/LEG/67/3 Rev.5, 21 International Legal Materials p. 59.

6. Bilateral Treaties

Agreement on Trade Relations between the Government of the United States of America and the Government of the Mongolian People's Republic. http://199.88.185.106/tcc/data/commerce_html/TCC_2/MongoliaTrade.html.

Agreement on the Protection and Enforcement of Intellectual Property Rights between the United States of America and the Democratic Socialist Republic of Sri Lanka. http://199.88.185.106/tcc/data/commerce_html/TCC_2/Sri_Lanka_Intellectual_Property/Sri_Lanka_Intellectual_Property.html.

Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations. http://usembassy.state.gov/vietnam/wwwhbta.html.

Partnership Agreement between the African, Caribbean and Pacific States and the European Community and its Member States, CE/TFN/GEN/23-OR, ACP/00/0371/00, 8.2.00. http://europa.eu.int/comm/trade/pdf/acp.pdf.

Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the one part, and the Republic of South Africa, of the other part, Official Journal L 311 of 4 December 1999 p. 0003-0297. http://europa.eu.int/eur-lex/en/lif/dat/1999/en_299A1204_02.html [Art 46].

Record of Understanding on Intellectual Property Rights. http://199.88.185.106/tcc/data/commerce_html/TCC_2/KoreaIntellectual.html [Sec. B.6].

Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, Official Journal L 276/45 of 28 October 2000. http://europa.eu.int/comm/trade/pdf/oj276_mex.pdf [Art 12.1]. Decision No 1 of the Joint Council. http://europa.eu.int/comm/trade/pdf/text_dec.pdf.

Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Tunisia, of the other part, Official Journal L 097 of 30 March 1998 p. 0002-0183. http://europa.eu.int/eur-lex/en/lif/dat/1998/en_298A0330_01.html.

Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area. http://192.239.92.165/regions/eu-med/middleeast/textagr.pdf.

Euro-Mediterranean Interim Association Agreement on trade and cooperation between the European Community, of the one part, and the Palestine Liberation Organization (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the other part, Official Journal L 187 of 16 July 1997, pp. 3-35. http://europa.eu.int/eur-lex/en/lif/dat/1997/en_297A0716_01.html.

B. Cases

1. International Cases

Fisheries, United Kindgdom v. Norway, Merits Judgement 18, December 1951.

Panel Report on *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (Complaint by the United States), WT/DS50/R, 5 September 1997.

Appellate Body Report on *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 19 December 1997.

Panel Report on *Canada-Patent Protection for Pharmaceutical Products*, WT/DS/114/R, 7 April 2000.

2. European Patent Office case law

Onco Mouse/Harvard III, Examining Division, 3rd April 1992, O.J.E.P.O, 1992.

Onco-Mouse/Harvard II, Technical Board of Appeal 3.3.2., 2 October, n. T 19/90, O.J.E.P.O., 1990.

Relaxin, EP- BI 112 114 OJ EPO 1995 388.

Plant cells / Plant Genetic Systems, OJ EPO 1995545.

3. European Count of Justice

Court of Justice, *Kingdom of the Netherlands v. European Parliament and Council of the EU*, case C-377/98, 9 October 2001.

4. Domestic Case Law

Diamond, Commissioner of Patents and Trademarks v. Chakrabarty, Supreme Court of the United States, 447 U.S. 303; 1980 U.S. LEXIS 112 (1980), in ABBOTT, *op. cit.*, p. 29.

Brenner v. Manson 148 U.S.P.Q. 698, 1966.

State Street bank and Trust Co v. Signature Financial Cup Inc. 47 USPQ.2d.1596, 1000 Fed/Circ. 1998.

Amgen Inc v. Chunghai Pharmaceutical 18 U.S.P.Q. 2d 1016, (Fed. Cir. 1991).

Harvard Oncomouse, 447 US at 307.

Ex parte Hibberd 227 U.S.P.Q.443, 444 – 448.

Ex parte Allen 2 U.S.P.Q. 2d 1425, 1427.

Moore v. Regents of the University of Californi[1] 793 P. 2d. 479, 1991.

Riddlesbarger's Application (1936), 53 R.P.C. 57.

Merriele Dow Pharmaceuticals v. Norton and Co, (1995) 33, IPR 1.

II. SECONDARY SOURCES

A. Books

ABBOTT F., COOTIER Th. and GURRY F., *The Intellectual property system; Commentary and Materials*, Part II, Kluwer Law International, 1999, Part I and II.

BENTLY L. and SHERMAN B., *Intellectual Property Law*, Oxford University Press, 2001.

BLAKENEY M. L., *Trade related aspects of intellectual property rights: a concise guide to the TRIPS Agreement*, Sweet and Maxwell, London, 1996.

BOSTYN S.J.R., *Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*, European Patent Office, München, 2001.

COASE R. H., *The Firm, the Market and the Law*, University of Chicago Press, 1990.

DUCOR P., *Patenting the Recombinant Products of Biotechnology*, Kluwer, The Hague, 1997.

DUTFIELD G., *Intellectual Property Rights, Trade and Biodiversity*, IUCN, Earthscam Pulications, London, 2000.

DUTFIELD G. (in press), *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Aldershot, Ashgate.

GLOWKA L., *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources,* World Conservation Union, Gland, Switzerland, 1998.

GIRSBERGER M., *Biodiversity and the Concept of Farmers' Rights in International Law*, Peter Lang, Berne, 1999.

HERMITTE M.-A., (ed.), Actes du Colloque "Les ressources phytogénétiques et le droit", Université Senghor, Paris, 20-21 December 2001, under publication 2002.

JUMA C. and OJWANG J., eds., *In Land We Trust: Environment, Private Property and Constitutional Change,* Initiatives Publishers, Nairobi and Zed Books, London, 1996.

KAGEDAN B. L., *The Biodiversity Convention, Intellectual Property Rights, and Ownership of Genetic Resources: International Developments*, Ottawa, 1996.

LADIDOTH R., *Autonomy: Flexible Solutions to Ethnic Conflicts*, United States Institute of Peace Press, Washington, DC, 1997.

McCONNEL, *The Biodiversity Convention. A Negotiating History*, Kluwer Law International, The Hague, 1996.

NIJAR G. S., *Towards a Legal Framework for Protecting Biological Diversity and Community Intellectual Rights: A Third World Perspective*, ICCBD 2nd Sess., Nairobi, 20 June-1 July 1994.

NOIVILLE Ch., *Ressources génétiques et droit*, Pédone, Paris, 1997.

PLOTKIN M. J., *Tales of a Shaman's Apprentice — An Ethnobotanist Searches for New Medicines in the Amazon Rain Forest*, ed. Penguin Books, 1993.

POSEY D. and DUTFIELD G., *Beyond Intellectual Property Rights: Towards Traditional Resource Rights for Indigenous Peoples and Local Communities*, International Development Research Centre, Ottawa, 1996.

SERAGELDIN I. and PURSLEY G. J., *Promethean Science. Agricultural Biotechnology, the Environment and the Poor,* CGIAR, Washington, 2000.

SHAW M. N., *International Law*, 4th edition, Cambridge University Press, Cambridge, 1997.

TORREMANS P., *Intellectual Property Law*, Butterworths, London, 2001.

B. Articles and Contributions to collective works

ACHIMUGU O., CURCI STAFFLER J. and KHAN A., "Patentability of Animal Life: Regional Current Practices and Legal Challenges on the International Level" published in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001.

H. J. ALEXANDER D., "Some Themes in Intellectual Property and the Environment", *Review of European Community and International Environmental Law,* 1993.

ARUNASIRI P., CHOWDHURY Sh. A. and ABDEL-LATIF R. O., "International Convention On The New Varieties Of Plants UPOV Convention And Its Implementation For Developing And The Least Developed Countries", in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001.

BADIMBOLI ATIBASAY J. F., "The International Legal Regime for Biotechnology Patenting: an Appraisal from the Standpoint of Developing Countries", *Revue générale de droit*, 31, 2001.

BEIER F.-K., “The Patent System and its information Function – Yesterday and Today”, in *Industrial Property Copyright Journal*, 8, 1977

BLAKENEY M., *Protecting the Cultural Expressions of Indigenous Peoples under Intellectual Property Law – the Australian Experience*, CIER Conference on the Protection of Cultural Identity and Indigenous Knowledge, Utrecht 16 November 2001.

BLAKENEY M., *Intellectual Property Aspects of Traditional Agricultural Knowledge*, paper presented November 22nd 2001 at the WIPO-Torino Law School Specialization Course in Intellectual Property.

BLAKENEY M., *Protection of Plant Varieties and Farmers' Rights*, International Seminar on the Role of Intellectual Property in the Field of Biodiversity and Traditional Knowledge, Jointly Organized by the Brazilian National Institute of Industrial Property and the European Commission, Manaus/Amazonas/Brazil, 9-11 September 2001.

BLAKENEY M., “Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes – Some Recent Problems”, *Bio-science Law Review,* n. 1, 1998.

BOSTYN S. J. R., “One Patent a Day Keeps the Doctor Away? Patenting Human Genetic Information and Health Care”, *European Journal of Health Law*, 7, 2000.

BOVENBERG J. A., “Should Genomics Companies set up Database in Europe? The EU Database Protection Directive Revisited”, *European Intellectual Property Review*, 23, 2001.

BOZICEVIC K., “Distinguishing ‘products of nature’ from products derived from nature”, *Journal of the Patent and Trademark Office Society,* 69, 8, 1987.

CARVALHO N. P., “From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?”, *Revista da ABPI*, 40, 1999.

CORNISH, *Intellectual Property -Patents, Trademarks, Copyrights and Allied Rights*, London Sweet and Maxwell, 1999.

CORREA C. M., *Sovereign and Property Rights over Plant Genetic Resources, FAO Background Study Paper No. 2. Commission on Plant Genetic Resources - First Extraordinary Session*, Rome, 1994.

COTTIER Th., "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law" in Abbott F., Cottier Th. and Gurry F., *The Intellectual property system; Commentary and Materials*, Part II, Kluwer Law International, 1999.

COTTIER Th., p. "The Protection of Intellectual Property Rights: A Requirement for Technology Cooperartion, Foreign Investment and Equitable Returns in Biotechnology Prospecting, *Biotechnologie für Entwicklungsländer? Chancen und Risiken der Biotechnologie bei Landwirtschaftlichen Nutzpflanzen,* Schweizerisches Zentrum für Internationale Landwirtschaft ed., 1995

CRESPI R., “Debate in Biotechnology Patents and Morality”, in Streckx S., ed., *Biotechnology, Patents, and Morality*, 1997.

CULLETT P., “Property Rights over Biological Resources”, *Journal of World Intellectual Property*, 2001.

DE KONING M., "Biodiversity Prospecting and the Equitable Remuneration of Ethnobiological Knowledge, Reconciling Industry and Indigenous Interests", Blakeney M. (ed.), *Intellectual Property Aspects of Ethnobiology,* Sweet & Maxwell, London, 1999.

DOWNES D. and LAIRD S., “Case Study in Innovative Mechanisms for Sharing Benefits of Biodiversity and Related Knowledge Geographical Indications and Trademarks”, available at: http://www.ciel.org/Publications/InnovativeMechanisms.pdf

DRAHOS P., "Global Property Rights in Information: The Story of TRIPS at the GATT"', *Prometheus*, 13, 1995.

EWENS L. E., Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds, *Boston College International and Comparative Law Review*, 23, 2, 2000.

GOLDMAN K. A., "Compensation for Use of Biological Resources under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry", *Law and Policy International Business*, 1994.

GREENFIELD M. S., "Recombinant DNA Technology: a Science Struggling with the Patent Law", *Stanford Law Review*, 44, 1992.

JACOBY A. and WEISS Ch., "Recognizing Property Rights in Traditional Biocultural Contribution", *Stanford Environmental Law Journal*, 16, 1997.

KO Y., "An Economic Analysis of Biotechnology Patent Protection", *Yale Law Journal*, 102, 1992.

KONGOLO T., "New Options for African Countries regarding Protection for New Varieties of Plants", *Journal of World Intellectual Property*, 2001.

IWASAKA R. M. T., "From Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law", *Yale Law Journal*, 109, 2000.

LESKIEN D. and FLITNER M., "Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System", *Issues in Plant Genetic Resources*, No. 6. International Plant Genetic Resources Institute, Rome, June 1997.

LLEWELYN M., "The legal Protection of Biotechnology Inventions : an Alternative Approach", *European Intellectual Property Review*, 1997.

MALJEAN-DUBOIS S., "Biodiversité, biotechnologies, biosécurité: Le droit international désarticulé", *Jounal du Droit International*, 127, 2000.

MANGANI Th. A., "Chimeras : The Patentability of Human-Animal Chimeras", in 14 *Berkeley Technology Law Journal*, 445, 1999.

MAZZOLENI R. and NELSON R., "Economic Theories about the Benefits and Costs of Patents", in XXXII *Journal of Economic Issues*, 1998.

MOKYRB., *The Level of Riches: Technological Creativity and Economic Progress*, Oxford University Press, 1990.

MOONEY P. R., "Why We Call It Biopiracy", in *Responding to Bioprospecting: From Biodiversity in the South to Medicines in the North*, Hanne Svarstad & Shivcharn S. Dhillion eds., 2000.

MULVANY P., TRIPS, "Biodiversity and Commonwealth Countries : Capacity Building Priorities for the 1999 Review of TRIPS Article 27.3 (b)", in *Commonwealth Secretariat and Quaker Peace and Service*, Rugby and London, available at: http://www.ukabc.org/TRIPs/trips99.pdf.

MURPHY S., "Biotechnology and International Law", *Harvard International Law Journal*, 42, 2001.

MWAKYEMBE H., MPUNDU KANJA G. and MUNKHONDIA M., "Implications of the TRIPs Agreement on the Access to Cheaper Pharmaceutical Drugs by Developing Countries, Case Study of South Africa vs. The Pharmaceutical Companies", *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001.

NOIVILLE Ch., "Biodiversité et propriété intellectuelle l'impossible conciliation ?", in Sandrine Maljean-Dubois (ed.), *L'outil économique en droit international et européen de l'environnement*, Documentation Française, 2002.

PAVONI R., "Brevettabilità genetica e protezione della biodiversità: la giurisprudenza dell'Ufficio Europeo dei Brevetti", *Rivista di Diritto Internazionale*, 2000.

PHILIPS J., "The Diminishing Domain", *European Intellectual Property Review*, 8, 1997.

PRAKASH, "Towards a Synergy between Biodiversity and Intellectual Property Rights", in *Journal of World Intellectual Property*, 1999.

RAY BARELL and NIGLE PAN, "Foreign Direct Investment, Technological Change and Economic Growth within Europe", *The Economic Journal*, 107, 1997.

REID W. V., LAIRD S. A., GAMEZ R., SITTENFELD A., JANZEN D. H., GOLLIN M. A., JUMA C., "A New Lease of Life" in REID W. V., LAIRD S. A., GAMEZ R., SITTENFELD A., JANZEN D. H., GOLLIN M. A., JUMA C., (eds.) *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*, 1993.

RUIZ-MULLER M., "Regulating Bioprospecting and Protecting Indigenous Peoples Knowledge in the Andean Community", in SAHAI S., *Commercialization of Indigenous Knowledge and Benefit Sharing, UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices*, Geneva, 30 October – 1 November 2000.

SPRANGER, "Ethical aspects of Patenting Human Genotypes According to EC Biotechnology Directive, 2001, 31, *International Review of Industrial Property and Copyright Law.*

SCOTT A., "Biotech Challenge to Biotechnology Patent Directive", *European Journal of Intellectual Property*, 212, 1999.

SCOTT A., *The Dutch Challenge to the Bio-Patenting Directive*, in *European Intellectual Property Review*, 1999.

SCHATZ U., "Patentability of Genetic Engineering Inventions in European Patent Office Practice", 29, *International Review of Industrial Property and Copyright*, 1999.

SHERMAN and BENTLEY, "The question of Patenting Life", in *Intellectual Property and Ethics*", Vol. 4, 1998, London Sweet and Maxwell, p. 120.

STORY A., "Biopiracy and the dangers of patent over-protection", *New Law Journal*, 149, 6874, 1999.

STRAUS J., "Patenting Human Genes in Europe - Past Developments and Prospects for the Future, 26, *IIC*, 1995.

SUBRAMANIAM A., "The International Economics of Intellectual Property Rights Protection: A welfare-theoretic Trade Policy Analysis", in *World Development Journal*, 1991, pp. 1945-1956.

TARASOFSKI R., "The Relationship between TRIPs Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approach", in *Review of European Community and International Environmental Law*, 1993.

TAMBUTOH D., SARDJORNO A., DABIRI M., « Traditional Medicine And Intellectual Property Rights - A Move Towards Protection In Developing Countries », in *Collection of Papers of the Post-Graduate Specialization Course on Intellectual Property, Turin, Italy,* WIPO Worldwide Academy, 2001

TOBIN B., "Know-how License: Recognizing Indigenous Rights Over Collective Knowledge", *Bulletin of the Working Group on Traditional Resource Rights*, 4, 1997.

VAN den GRAAF E. S., *Patent Law and Biotechnology , A Comparative Study about the Requirements and Scope of Protection*, Gouda Quinta, p. 427.

VERMA S. K., "TRIPS and Plant Variety Protection in Developing Countries", *European Intellectual Property Review*, 17, 1, 1995.

VOGEL J. (ed.), *El Cartel de Biodiversidad* (The Biodiversity Cartel) Quito, CARE, available at: www.thebiodiversitycartel.com, 2000.

WELLS, "Patenting New Life Forms: An Ecological Perspective", in *European Intellectual Property Review*, 1994.

YANO L. I., "Protection of the Ethnobiological Knowledge of Indigenous Peoples", *UCLA Law Review,* 41, 2, 1993.

YUSUF A. A., "International Law and Sustainable Development the Convention on Biological Diversity", Yusuf A. A., (ed.), *African Yearbook of International Law*, vol. 2, The Hague, Boston and London, Kluwer, 1995.

iii. Contributions and Studies available on the Internet.

C. Reports and Studies available on the WEB

GRAIN, *For a Full Review of TRIPS 27.3(b)*, March 2000, http://www.grain.org/publications/tripsfeb00-en.cfm.

GRAIN, *PVP in the South: The Flow Towards UPOV*, March 2001, http://www.grain.org/docs/towardsupov.pdf.

NIJAR G. S., '*SUI GENERIS* OPTIONS: THE WAY FORWARD' IN BIOTHAI/GRAIN (EDS., 1998), SIGNPOSTS TO *SUI GENERIS* RIGHTS, P. 79, AVAILABLE AT HTTP://WWW.IATP.ORG/TRIPS99.

RICOLFI M., Presentation of the Geneva Papers on the occasion of the National Meeting on *Farmers' Rights, Intellectual Property Rights and Biodiversity Conservation: the Duty to Cooperate,* available at www.ulpiano.com/IP/J_Pat_1a.htm.

HERMITTE M.-A., *Mission sur la valorisation de la diversité biologique à Madagascar*, avril 2000, consultable sur : http://panjuris.univ-paris1.fr.

RAFI, "Enola Bean Patent Challenged", News Release, 5 January 2001, www.rafi.org.

HUAMAN, "Unethical distribution to Japan of Yacon held in trust by CIP" on the list-server run by BIONET www.bionet-us.org, 7 April 2001.

CORREA C. M., *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre, Geneva, available at www.twnside.org.

FAO, *Global meeting to assess progress on World Food Summit goals*, available at www.fao.org/news.

Socio-political Impact of Biotechnology in Developing Countries, NOVARTIS Foundation for Sustainable Development, 2001, p. 1, available at www.foundation.novartis.com.

Variety of Life, Biodiversity Web, p. 2; available at: www.biodiversity.nl.biodiversity.htm.

D. Institutional Sites with Useful Documents

Convention on Biological Diversity (CBD), Fourth Conference of the Parties - Documents and Draft decisions
< http://www.biodiv.org/cop4/cop4docs.html>
< http://www.biodiv.org/cop4/FinalRep-/finrep.html>

Food and Agriculture Organization of the United Nations (FAO)
Plant Genetic Resources pages including the papers for the 5th extraordinary session of
the CGRFA and Leipzig Global Plan of Action
<http://web.icppgr.fao.org/>
<http://web.icppgr.fao.org/ITCPGR/Leipzig.html>
<http://web.icppgr.fao.org/CGRFA/Ex5/docs.html>

Rural Advancement Foundation International (2001) : Enola Bean Patent Challenged. Press Release January 5, 2001, available at: http://www.biotech-info.net/enola_bean.html

Institute for Agriculture and Trade Policy (IATP), USA.
TRIPS99 website. Resources for upcoming negotiations on the review of TRIPs Article 27.3(b).
<http://www.iatp.org/trips99>

Sterile Fields: The Impacts Of IPRs And Trade On Biodiversity And Food Security, by Kristin Dawkins (IATP) November 1996
<http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=Sterile_Fields_The_Impacts_Of_Intellectual_Pro.htm>

Signposts to Sui Generis Rights (GRAIN, BioThai) *Resource material from an international seminar on sui generis rights* (1-6 Dec 1997).
<http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=SIGNPOSTS_TO_SUI_GENERIS_RIGHTS,_Chapter_1,_Fe.htm> [Chapters _1 to _8]
Of especial note is Chapter 3 - Signposts to Sui Generis Rights: Strategy Ideas for the 1999 TRIPS Review & Beyond. Also available at:
<http://dspace.dial.pipex.com/ukfg/UKabc/suigen1.htm>

For selected extracts from this document see
<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_GRAIN.htm>

The outcome of the Seminar was the Thammasat Declaration.
<http://www.twnside.org.sg/souths/twn/title/tham-cn.htm>
IUCN Environment and Law programme
Including:

The Trade & Environment Agenda: Survey of Major Issues and Proposals - From Marrakesh to Singapore, Tarasofsky, R.G., K. Ewing 1996
< http://www.iucn.org/themes/law/elp_publications_trade.html>

A Guide to the Convention on Biological Diversity, Glowka, L., et al., 1994
<http://www.iucn.org/themes/law/elp_publications_guide-e.htm>

PCT International Search Guidelines, PCT Gazette, chptr. VI § 1.2 (Special Issue No. 06/1998, Oct. 8, 1998), *available in* www.wipo.org/eng/main.htm>

UPOV - the Union for the Protection of Plant Varieties. Main resource page including 'What is UPOV?', Brief Outline of the Role and Functions of the Union, 'Texts of the UPOV Convention (Acts of 1961, 1978, 1991)'
<http://www.upov.int/eng/index.htm>

UPOV 91 comes into force - 24 April 1998 UPOV Press Release
<http://www.upov.int/eng/prssrlss/30.htm>

World Seed Industry Associations including ASSINSEL
< http://www.worldseed.org/~assinsel/>

Organisation for Economic Cooperation and Development (OECD)
Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies (1996) <http://www.oecd.org//dsti/sti/s t/biotech/>

World Intellectual Property Organisation (WIPO)
Global Intellectual Property Issues programme

<http://www.wipo.org/eng/newindex/intellct.htm>

For selected extracts from this document see
<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro WIPO.htm>

World Trade Organisation
WTO: Intellectual Property including 'What is Intellectual Property?', 'An overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)', 'The text of the TRIPS Agreement', 'Other intellectual property conventions incorporated by reference into the TRIPS Agreement'
<http://www.wto.org/wto/intellec/intellec.htm>
For selected extracts from this document see
<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_WTO.htm>

WTO: Trade and Environment including 'Background to WTO work on trade and environment' 'The Marrakesh Ministerial Decision on Trade and Environment', 'The relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environnemental agreements'.
<http://www.wto.org/wto/environ/environm.htm>

WTO: Trade in Agriculture including Implementation of the Uruguay Round Reform: the Programme for Trade in Agriculture
< http://www.wto.org/wto/goods/agrintro.htm>