Part I

The main problems

1 Introduction to legal issues related to genetic resources and traditional knowledge in the international intellectual property system

In the new millennium, biotechnology is enabling genetic engineering to yield very important breakthroughs, with immense possibilities for novel organisms to be developed. The myriad biotechnological applications released into the environment for pharmaceutical, agricultural, and medicinal purposes generate transnational concerns that pose an enormous challenge to national and international communities. The means of protection sought for these types of inventions is the patent. Although opinions about how much patent systems contribute to long-term economic growth vary, there can be no dispute that patents are vital to the business models of many companies and are playing an increasing role in society. As human technological prowess has expanded throughout the natural and human worlds, the patent has followed, not far behind. Questions about the proper place of patents in society, some old and some new, have found increasing urgency and importance, especially as patent law extends to societies not accustomed to its peculiarities.

Peoples in developing countries (DCs) denounce the patentability of genes, which reduces the world's genetic resources (GRs) down to mere property rights, resulting in corporate control over access to food, medicinal technology, and other resources essential to mankind's health and welfare. Additionally, potential transnational harm caused by genetic engineering may also arise through the destabilization of regional ecologies via genetic pollution and through an accelerated decline of biological diversity on a global scale. Thus, legal control over biodiversity is an issue of serious international consequence.

The present book focuses particularly on the international legal regime of commercial exploitation and ownership of GRs, on which biotechnological innovation is based. At the core of this study lies the problems of sharing benefits arising from the exercise of intellectual property rights (IPRs) over plant genetic resources (PGRs) and traditional knowledge (TK) under existing treaties and conventions with special attention to the contractual relations between companies from industrialized countries and indigenous communities and genetic resource providing countries.

Although this analysis is conducted through an international law approach, it does not neglect some anthropological and sociological aspects of private ownership of living forms and its interaction with different value systems.

1.1 Defining the problems

This chapter starts with general considerations on the problem of ownership and patents on PGRs; in a second stage, it observes the interaction among the international public domain, the States' sovereign rights over PGRs and private IPRs over the same, and ultimately introduces the new problem of traditional knowledge (TK).

It lays out the methodological aspects of the analysis and presents a brief overview of the theories of creation of the sources of international law that are relevant to this subject-matter and that will be used through the development of analysis. Accordingly, the impact of international law, with particular attention to World Trade Organization (WTO) law, shall be taken into account in a comparative approach. Because the European Union (EU) and United States (US) jurisdictions have developed various laws, policies and judicial decisions on the relationship between protection of biodiversity and intellectual property they offer broad examples of implementation of international law that are worthy to be described and discussed when appropriate.

1.1.1 Patents and ownership of genetic resources

The patentability of biotechnology took off after the US Supreme Court's landmark decision in *Diamond v. Chakrabarty*.[1] By acknowledging that statutorily patentable subject-matter included "anything under the sun that is made by man," the Court encompassed both foreseeable and unforeseeable subject-matter. This *Diamond* standard encompassed the inventive work of biotechnology and gene sequences. Consequently, an "imitation effect" rippled from the US to Europe and other jurisdictions, generating a series of legislative measures to patent living forms. In addition, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights[2]

[1] *Diamond v. Chakrabarty*, 447 United States, 303–09 (1980), reported also in F. Abbott, T. Cottier and F. Gurry (eds.), *The Intellectual Property System: Commentary and Materials* (Kluwer, The Hague, 1999) 25.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights (April 15, 1994) Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round 31–33 *International Legal Materials* (*ILM*) 1197 (1994).

(TRIPS) internationalized the patent protection of biotechnological practices.

In industrialized societies, investment and innovative output in the biotechnology industry has been so conspicuous that the benefits of innovation in this field have generally been viewed as outweighing the costs of the monopolistic restrictions created by patents. Now, not only plant varieties but also micro-organisms and genetically modified animals are patentable. Genetically altered animals, such as the infamous *Onco-Mouse* of Harvard University (bred for cancer research), have also been given patents. Thousands of patent claims have been made and granted on human genetic material, including material that has arguably been altered from its natural state.

The patent is the primary IPR that is sought in the field of biotechnology because it is meant to be a right concerning innovations used in new or improved products 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 or process. After a patent is granted, the owner has a monopoly over commercial exploitation of the invention 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.[3]

There are two problems that patent protection generates. The first concerns the monopolistic feature of the cost analysis of patent protection in this field. 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 patent grant.[4] And the "mainstream legal literature" has applied this standard principle from IP economics to the patenting of biotechnology as well.[5]

The second problem is generated when formal, industrial, patentable knowledge builds upon prior art of informal TK which is in a quasi-commons

[3] Abbott *et al.*, *The Intellectual Property System*, 25.

[4] P. Torremans and J. Holyoak, *Intellectual Property Law* (Oxford University Press, 2006) 16, 20. N. Carvalho, "From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?" (1999) 40 *Revista da ABPI* 3–28. R. H. Coase, *The Firm, the Market and the Law* (University of Chicago Press, revised edition, 1990), see chapters 1 and 2 "The Firm, The Market, and The Law" and "The Nature of the Firm."

[5] Which includes, in the European literature in the bibliography quoted in M. Ricolfi, "Biotechnology, Patents and Epistemic Approaches" (2002) *Journal of Biolaw & Business, Special Supplement* 77–90.

regime. When it comes to the benefit sharing of the profits arising from the exploitation of this knowledge at the international level these problems are amplified.

A vivid example of benefit sharing illustrates the controversy of private property rights in GRs based on TK held by indigenous groups. Imagine a plant that produces a natural sweetener and has been preserved for several millennia in a local farming micro-culture. This sweetener performs its sweetening function without negative dietary or health side effects. A foreign corporation comes along bioprospecting and secures samples of the local sweetening plant, maps its genome, and then proceeds to genetically engineer a plant that yields sweetener with a potency tenfold that of the original. The corporation then patents the modified plant, and the world quickly forgets the original plant as the patented plant is markedly more productive. Consequently, through commercialization, all of the profits flow to the company patent holder without a farthing going to the indigenous farmers who preserved the plant for millennia. Some 6.5 percent of all genetic research undertaken in agriculture focuses on germ plasma derived from wild species and land races (farmer-developed varieties of crop plants that are adapted to local environmental conditions). Thus, the question is posed: is it fair to give the entire pastry to the one who adds the final cherry to the pie?[6]

This tendency has been popularly called *biopiracy* or *biocolonialism*. The origin of the two terms reveals that the context in which they were formed is the one of political science or sociology. These are not legal terms, let alone technical intellectual property terms. The term *biopiracy* was coined by Mooney as part of a counter-attack strategy on behalf of DCs that, as already said, are accused by industrialized countries of supporting *intellectual piracy*, i.e., counterfeiting all types of goods protected in the industrialized countries by IPRs. In turn, DCs feel that they are no more pirates than corporations that 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.[7] This anti-*biopiracy* rhetoric adopted by some DC trade

[6] Ricolfi, "Biotechnology, Patents and Epistemic Approaches", 77; T. Cottier, "The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law", in Abbott *et al.*, *The Intellectual Property System* 1820–27; M. Blakeney, Presentation at the World Intellectual Property Organization (WIPO) – Torino Law School Specialization Course in Intellectual Property, International Property Aspects of Traditional Agricultural Knowledge (TAK) 2 (Nov. 22, 2001), unpublished, on file with the author.

[7] R. Mooney, "Why I Call It Biopiracy", in H. Svarstad and Sh. S. Dhillion (eds.), *Responding to Bioprospecting: From Biodiversity in the South to Medicines in the North*

negotiators has not prevented the legalization of this so-called "conquest" through the TRIPS Agreement. This treaty extends to all the developing and least developed members of the WTO the obligation to grant IPRs (patents, trademarks, and trade secrets, etc.), and, to some extent, also to innovations based on GRs, without mandating any compensation to the local communities who have bred and preserved these resources. At the same time, some 90 percent of genetic information and related TK are found in DCs.[8]

Biocolonialism is another term related to *biopiracy* and it often refers to the pattern whereby the industrialized country corporation extracts raw genetic materials from the DC, patents the genetically modified products based on the raw materials without prior informed consent (PIC) and benefit sharing, and then sells the finished product to the provider country at unaffordably high prices. In addition to these perceptions of injustice and misappropriation, the wide scope of the exclusive patent rights granted in industrialized countries stirs animosity on the part of the consumers in DCs, especially when the patent itself is based on a GR or TK preserved by the consumers of the patented product in DCs.

Even part of the legal doctrine has been vociferously arguing that IP regimes may jeopardize the freedom of countries or communities to choose the way in which they want to deal with the use and protection of biodiversity and the related TK. This issue blatantly arises when the genes are not appropriated by the sovereign State that patents them but by a foreign entity that manipulates and sells the genetically modified product. As a consequence of the double expansion of patent law both from inanimate to animate subject-matter (biotechnological inventions) and from a small group of industrialized countries to most of developing and Least Developed Countries (LDCs), several peoples in DCs are reacting against this kind of "piracy" of indigenous and local community knowledge.

These are some of the reasons for which peoples in DCs allege that IPRs in the field of biotechnology could prevent the Convention on Biological Diversity (CBD) from realizing the full and practical meaning of Article 3[9] on national sovereignty over their natural resources and Article 8(j)[10] on

(Spartacus Press, AS., Oslo, 2000) 37; V. Shiva, *Biopiracy: the Plunder of Nature and Knowledge* (South End Press, 1998) 1–5; A. Story, "Biopiracy and the Dangers of Patent Over-protection", (1999) 149 *New Law Journal* 158.

[8] Cottier, "The Protection of Genetic Resources", in Abbott *et al.*, *The Intellectual Property System*, 1827.

[9] Article 3 of the CBD, Convention on Biological Diversity (June 5, 1992) UNEP/Bio.Div/N7-INC5/4, 31 *ILM* 818 (1992).

[10] WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Fact Finding Missions on Intellectual Property and Traditional Knowledge* (WIPO, Geneva,

the rights of local and indigenous communities. These provisions aim at fairly distributing the benefits resulting from the use of GRs situated in the territories of the Contracting Parties.

Industrialized countries respond by affirming their effort to develop technology enabling the modification, the innovation, and the marketability of raw genetic materials that otherwise would remain unexploited within developing country indigenous communities that do not have such capacities. The debate is acrimonious and solutions are not easily at hand.

1.1.2 International public domain, sovereign rights, and intellectual property rights over genetic resources

This section moves from the general concept of ownership of GRs to the conflict between a State's public law regime of exercise of sovereignty rights upon GRs and then to the private exercise of IPRs upon the same.

The international exercise of patent rights has an impact both on the ownership regime over the GR *per se* and on the knowledge of the uses for and the characteristics of plant and animal GRs. Biotechnology depends on biological diversity as the basis of innovation. The access to biological diversity in a given country has traditionally been free and open. This led to the basic inequity (already sketched in section 1.1 above) consisting of the freedom of appropriation of GR and of TK on the part of the inventor on one side, while on the other the users in the country in question had to purchase the secondary products subjected to proprietary protection. Profits flow into the hands of right-holders in industrialized countries for the exploitation of biodiversity and related knowledge in DCs.

For example, suppose a researcher were to incorporate into his studies TK that had been generated by a particular community over hundreds of years and not attributable to any particular person. As far as the researcher is concerned, the TK used in his research is, for all intents and purposes, public domain knowledge. Suppose further that the researcher subsequently reports this knowledge with or without acknowledging the intellectual contributions of the initial TK holding community. Should that information ever prove useful in the creation of a patentable good, i.e. the creation of a drug through use of TK on a particular medicinal plant, the community would be without recourse to claim ownership or rights in the TK at the heart of the innovation, merely because that TK was

2001) 50. T. Taubman, "Genetic Resources" in S. Von Lewinski, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (Kluwer, The Hague, 2nd edn, 2008) 192–216.

within the public domain at the time it was recorded. Meanwhile, the company owning the patent exclusively reaps all the commercial benefits.

In the systems of protection of IP in industrialized countries, TK related to GRs has until recently been considered as international public domain because of the confusion of the public domain with the international legal concept of *res communis humanitatis* (common heritage of mankind).[11] The assimilation of TK into *res communis humanitatis* was necessary to justify the free accessibility of TK to all private users.[12] While the concept of *res communis humanitatis* covers the ocean floor,[13] Antarctica,[14] the moon,[15] and outer space,[16] it is doubtful, in my view, whether biodiversity in general should be placed under the concept of common heritage of mankind, *stricto sensu*.[17] There is no treaty or customary principle[18] that places TK and GRs under the concept of *res communis humanitatis*. On the contrary, starting from the colonial era, colonial states used to transfer GRs to their masters as contributions to their research centers.[19]

The international community finally discussed the position of GRs in international law during negotiation of the CBD adopted in 1992. At the start of the negotiations, the legal status of GRs *in situ* and *ex situ* was very

[11] C. Joyner, "Legal Implications of the Concept of the Common Heritage of Mankind", (1986) 35 *International and Comparative Law Quarterly* 190; R. Wolfrum, "The Principle of the Common Heritage of Mankind" (1983) 43 *Zeitschrift für ausländisches öffentliches Recht und Völkerrecht, Heidelberg Journal of International Law* 312.

[12] *Matter Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – an Overview*, WIPO/kritf/IC1/3, 8–9 (March 16, 2001).

[13] J. Van Dyke and C. Yuen, "Common Heritage v. Freedom of the Seas: Which Governs the Seabed?" (1982) 19 *San Diego Law Review* 493.

[14] F. Francioni and T. Scovazzi (eds.), *International Law for Antarctica* (Kluwer, The Hague 1996); F. Francioni, *International Environmental Law for Antarctica* (Giuffrè, Milano, 1992); C. Joyner, "Antarctica and the Law of the Sea: Rethinking the Current Legal Dilemmas" (1981) 18 *San Diego Law Review* 415.

[15] K. Baslar, *The Concept of the Common Heritage of Mankind in International Law* (Martinus Nijhoff, The Hague, 1998) 307–13. C. Christol, "The Common Heritage of Mankind Provision in the 1979 Agreement Governing the Activities of States on the Moon and Other Celestial Bodies", (1980) 14 *International Lawyer* 429.

[16] P. P. C. Hannapel, *The Law and Policy of Air Space and Outer Space: a Comparative Approach* (Kluwer, The Hague, 2003); L. Tennen, "Outer Space: A Preserve for All Humankind", (1979) 1 *Houston Journal of International Law* 145.

[17] I. Mgbeoji, "Rethinking the Role of International Law in Relation to the Appropriation of Traditional Knowledge of the Uses of Plants" 132, 139, 148, 150, 159, 161, 163–70, 179, 252, 253 (a dissertation submitted for the Degree of Doctor in the Science of Law, Dalhousie University Halifax, November 2001. Copy on file with author).

[18] A. D'Amato, "Trashing Customary International Law in Appraisals of the ICJ's Decision: Nicaragua v. United States", (1987) 81 *American Journal of International Law* 74–75; M. S. McDougal, H. D. Lasswell, and M. Reisman, "The World Constitutive Process of Authoritative Decision", (1967) 19 *Journal of Legal Education* 403.

[19] I. Mgbeoji, "Rethinking the Role", 163–70.

unclear: few national laws had been enacted for the commercial exploitation of the GRs *in situ* and no real international status had been created for the gene banks conserving germplasm[20] *ex situ* (see in more detail section 4.2.3 below). *Ex situ* collections of GRs could be acquired freely; no international obligations existed to share the economic benefits to the communities that provided and conserved the resources, and only very few international breeding programs were set up to develop and distribute crop varieties for use in the DCs.[21]

The status of GRs in international law started to be clarified with the adoption of a United Nations (UN) General Assembly Resolution 1830 (XVII) on 4 December 1962. At that time, the international community focused its efforts on the preservation of biological diversity and on its related knowledge under threat of extinction. Meanwhile, the slow process of globalization of IPRs was considered a successful tool in protecting and encouraging the further development of so-called "modern," "formal," or "technological" knowledge applied to GRs (see the relevant distinctions of TK in section 4.2 below). TK holders, especially in DCs, had felt that this knowledge, passed on from generation to generation, had progressively become an "economic resource." The increasing pace of exploitation of this knowledge through modern technological instruments led the international community to shift the focus of its attention from the "preservation" of GRs to their "utilization." Rapidly, various international fora became involved in the regulation of this matter: United Nations Environmental Program (UNEP), World Intellectual Property Organization (WIPO), United Nations Educational, Scientific and Cultural Organization (UNESCO), International Labour Organization (ILO), United Nations Conference on Trade and Development (UNCTAD), etc.[22]

One of the most important highlights in the chronological development of international public policy on this matter occurred in 1989, when the United Nations Food and Agriculture Organization (FAO) enacted the International Undertaking on Plant Genetics Resources (IUPGRs), which originally defined PGRs as the "heritage of mankind which should be available without restriction." In other words it considered the germplasm collected *ex situ* in gene banks as "common heritage of mankind."

[20] Germplasm is genetic material extracted from a plant.
[21] M. Hassemer, "Genetic Resources" in S. Von Lewinski (ed.), *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (Kluwer, The Hague, 2004) 159–60.
[22] See Table 1 "The Overview of the Regulatory Framework", in T. Taubman and M. Leistner, "Analysis of Different Areas of Indigenous Resources" in Von Lewinski, *Indigenous Heritage and Intellectual Property* (2nd edn, 2008) 200–1.

This concept was maintained in the IUPGRs of the FAO until 2001 (see section 3.3 below) when the international community adopted the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) that facilitated access to a database of PGRs held in trust by a Multilateral System for specific purposes of utilization.[23] This treaty thus establishes PGRs in a combination of a regime of State sovereignty and a regime of multilateral cooperation, although nowhere in the ITPGRFA is this concept explicitly stated.

The legal status of the rest of the biodiversity was defined by the CBD adopted by the UNEP in 1992. In its preamble, it is stated that the preservation of biodiversity is a "common concern of humankind," whereas, in its Articles 3 and 15.1, it acknowledges the principle of permanent sovereignty of the States over their natural resources on their territories. This means that access to GRs has to be regulated by a private law contract, a so-called "material transfer agreement" (MTA) involving the provider State and bioprospecting entity (see chapter 5). The international community has moved from this bilateral-contractual solution envisaged by the CBD to a clarification of the concept of "common concern of humankind" as it relates to the conservation and sustainable exploitation of PGRs.

Finally, the WIPO General Assembly, in creating in 2000 the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC on IPGRTKF) has started a new era of diplomatic discussions on the interaction among IP, GRs and TK. This IGC, supported by a Secretariat of technical experts in the field, is paving the way for the negotiation and adoption of a treaty which should clarify the relationship between private rights of intellectual property and TK.

1.1.3 Introduction to the tensions between the exercise of intellectual property rights and preservation of genetic resources

Six months after the CBD entered into force, WTO Members adopted the TRIPS Agreement in 1994[24] that marked the commencement of a new era of globalization of IPRs.[25] This treaty mandates minimum standards of private property protection of all types of "formal" or "modern knowledge," including knowledge developed from GRs. Since then IP scholars have intensely studied the ability of TRIPS-mandated IPRs to protect TK related to GRs, taking into account the parallel evolution of non-IP treaties (e.g. CBD and ITPGRFA). Indeed States' obligations under

[23] www.fao.org/Legal/treaties/033t-e.htm, last viewed November 2007. [24] TRIPS.
[25] As of January 2007 there are 150 Member States in WTO.