International Environmental
Law Research Centre

INTELLECTUAL PROPERTY RIGHTS, PLANT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

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Published in: S. Biber-Klemm & T. Cottier eds, *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives* (Wallingford: CABI, 2006) p. 112-154.

3 Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge[1]

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3.1 Introduction[2]

3.1.1 Overview

This chapter addresses in its first part the economic rationale of forms of protection that are granted under intellectual property laws and policies. In its second part, this chapter will discuss patent protection, plant breeders' rights (PBR) and *sui generis* forms of protection. It shall in particular explore the impact of these forms of protection on traditional knowledge related to plant genetic resources and, more broadly, on biodiversity and equity (benefit sharing). This assessment under existing laws (*de lege lata*) shall be completed by brief case studies to illustrate the legal issues at stake and shall propose solutions. The last part of this chapter outlines the impact of intellectual property rights on competition laws and policies. It describes certain contractual practices (licensing, patent pools, mergers and acquisitions) that can reduce competition. It also includes a case study pertaining to the seed sector to illustrate consequences of concentrations among economic players that are detrimental to public policies such as the promotion of biodiversity and equity. This analysis is relevant for our purposes as favourable impacts of intellectual property rights on biodiversity may be jeopardized by anti-competitive behaviours without appropriate safeguards.

The question of intellectual property rights is relevant both to promote TK related to plant genetic resources (their function as 'positive rights'), and to prevent misappropriation of these intangible values by third parties to the disadvantage of local communities and individuals (their function as 'defensive rights'). As positive rights, IPR may be used as complementary or alternative instruments with respect to subsidies in order to promote the sustain-

[1] The authors would like to thank Martin Girsberger and Marie Wollheim for their comments on this chapter.

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able maintenance and further development of TK. As defensive rights, IPRs, as adapted to the needs of TK holders and in line with applicable public policy goals, may serve to prevent abusive use of classical IPR in the context of TK related to plant genetic resources. Both approaches require an understanding of the rationale underlying the grant of IPR and a stocktaking of the scope of existing forms of protection. The purpose of this chapter shall therefore consist of the provision of a basis in order to elaborate ideas and concepts that would allow the use of IPR for the benefit of the sustainable promotion of TK related to plant genetic resources.

3.1.2 Forms of intellectual property protection

The term 'intellectual property' refers to a set of intangible products of human activity that are legally defined. Sources of law addressing intellectual property can be located on the national, regional and global levels of jurisdiction.[3] The legal competence among national, regional and international jurisdictions to define, grant and enforce intellectual property rights constitutes the international component of intellectual property law. One of the main characteristic features of this system lies in the principle of territoriality: the geographical scope of application of intellectual property laws is the territory of the state or community of states that has generated the corresponding rights and obligations. However, because the protection granted under intellectual property laws intrinsically requires a cross-border extension, the international law component of intellectual property has been essential since the beginning. This international law component was originally based upon reciprocity considerations, and more recently has obeyed the rationale underlying international trade rules. It is materialized by way of bilateral as well as multilateral agreements such as the Berne, Paris and Madrid conventions and, since 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that forms Annex 1c of the Agreement Establishing the World Trade Organization (WTO).[4]

Intellectual property laws provide so-called exclusive or *erga omnes* rights, i.e. a bundle of legally enforceable interests vested with their owner, who can oppose them against any third party. Based on law, the holder of intellectual property rights has the capacity to authorize or prevent others from acting in certain ways with respect to these specific rights. As regards the economic aspects, the holder has the right to perform activities enabling him or her to commercially exploit the results of their research and development efforts on an exclusive ('*erga omnes*') basis that provides for a competitive advantage. In addition, the holder may be granted non-economic rights in certain jurisdictions, such as inalienable moral rights to oppose mutilations of the work under author's rights laws (e.g. Article 6bis of the Berne Convention) or, more generally, the right to be named as author or inventor under the copyright or patent laws of most European countries (see for example Article 62 of the European Patent Convention 'EPC').

Intellectual property laws usually contain provisions concerning their scope of protection, the exclusive rights granted, the

[3] Plant variety protection for example is addressed nationally by plant variety legislation such as the Swiss Act on Plant Variety Protection of 20 March 1975, regionally by supra-national rules such as the Council Regulation EC No 2100/94 of 27 July 1994 on Community Plant Variety Rights, and globally by the UPOV Convention and Article 27.3(b) TRIPS. See also infra-sections II. C. and D. on Plant Breeders' Rights and *sui generis* protection systems.

[4] See the TRIPS Agreement under http://www.wto.org/english/docs_e/legal_e/legal_e.htm. For a detailed commentary on the TRIPS Agreement, see Cottier (2004). For the texts of international treaties administered by the World Intellectual Property Organization (WIPO), see http://www.wipo.int/treaties/index.html; national legislations on intellectual property in English may be downloaded from the Collection of Laws for Electronic Access (CLEA) under http://clea.wipo.int/clea/lpext.dll?f=templates&fn=main-h.htm&2.0

limitations to such rights, the duration of protection, the enforcement mechanisms and the sanctions for infringement. Once the period of protection has expired, intellectual property falls into the so-called public domain. Intellectual property is ubiquitous as opposed to property on tangible property (real estate, movables). This means that this form of property cannot be limited to a particular physical body incorporating the right: it is attached to all material or virtual occurrences of the protected work. Major forms of intellectual property protection include:

- Patent and related industrial design.
- Copyright and related neighbouring rights.
- Integrated circuit layout.
- Geographical indications of origin.
- Trademarks.
- Plant variety.
- Trade secrets (confidential information).

Within these main forms there are various sub-forms.[5] The relationship between these forms and sub-forms may vary over time, and different forms of protection may be available for the same intangible value. In this sense, protection can be assured by sequentially using different forms. For example, a pharmaceutical product may first be protected by patent and, after the expiration of the statutory protection term,[6] enjoy trademark protection for an indefinite duration of time, since the terms of trademark protection can be renewed indefinitely.

3.1.3 The functions of intellectual property rights

The various forms of protection are generally tailored to fulfil various legal, economic and social functions. While creativity or innovation requiring qualified individual efforts is to be encouraged for the benefit of society in a market economy, private actors typically need incentives to invest material resources in such efforts. These incentives may take the form of subsidies, or other advantages such as private property titles. In the latter case, the state grants intellectual property rights (IPR) to creators or innovators upon the fulfilment of certain conditions. These competitive privileges are usually limited in time, i.e. they last for the duration of the statutory terms of protection. They may take the form of patents for technical innovation or copyright for creative achievements related to content (such as text, music, films and, more recently, software, etc). The owner of a patent or a copyright has, subject to certain exceptions (e.g. compulsory licensing or fair use), the exclusive right to use, reproduce, disseminate, market, etc., the protected invention and content, respectively, for a given period of time. These terms of protection can vary from one jurisdiction to another, so long as they comply with the minimum duration set forth in international agreements such as the TRIPS agreement at the global or the EU directive at the regional level.

The World Intellectual Property Organization (WIPO) summarizes the rationale underlying the grant of IPR as follows:

> The primary purpose of most branches of the IP system (excluding trademarks and geographical indications) is to promote and protect human intellectual creativity and innovation. IP law and policy does so by striking a careful balance between the rights and interests of innovators and creators, on the one hand, and of the public at large, on the other. Thus, by granting exclusive rights in an invention, for example, the IP system encourages further innovation, rewards creative effort, and protects the (often substantial) investment necessary to make and commercialise the invention. The patent system also encourages people

[5] For an introduction to these various forms of protection, see WIPO, Intellectual Property Reading Material (status: August 2003), on http://www.wipo.org/news/en/index.html?wipo_content_frame=/news/en/documents.html

[6] The minimum duration of patent protection for Members of the WTO is 20 years according to Article 33 TRIPS.

> to disclose inventions, rather than retain them as trade secrets, thus enriching the store of publicly available knowledge and promoting further innovation by other inventors. Thus, public dissemination is an important IP objective. Copyright and other IP brands work in a similar way. The progress and well-being of humanity rests on its capacity for new creations in areas of technology and culture. The promotion and protection of IP can also spur economic growth, create new jobs and industries, and enhance the quality and enjoyment of life. However, the IP system also responds to the needs of the public at large. Most IP rights are of limited duration, after which the protected creations falls into the public domain (only trademarks may be renewed indefinitely, and geographical indications can subsist indefinitely).[7]

Intellectual property is a form of knowledge that societies have decided can be assigned specific property rights. They have some resemblance to ownership rights over physical property and land. Intellectual property creates a legal mean to appropriate knowledge. A characteristic of knowledge is that one person's use does not diminish another's use of it (e.g. reading a text). Moreover, the extra cost of extending use to another person is often very low or nil (e.g. copying an electronic file). From the point of view of society, the more people who use knowledge the better, because each user gains something from it at low or no cost, and society is in some sense better off. Economists therefore say that knowledge has the character of a non-rival public good. The other relevant feature of knowledge, or product embodying knowledge, is the difficulty of preventing others from using or copying it. Most products can be copied at a fraction of the cost it took to invent and market them. Economists refer to this characteristic as contributing to market failure. If a product takes considerable effort, ingenuity and research, but can be copied easily, there is unlikely to be a sufficient financial incentive from society's point of view to devote resources to invention (CIPR, 2002, pp. 11–14).

In short, IPR are thus entitlements granted under law to reward creative or innovative intellectual efforts. IPR protect intangible wealth, which can often be easily appropriated and reproduced. One of the characteristics of intellectual creativity is that it can be used and reproduced without depriving the creator of possession, as opposed to tangible wealth, which is usually subject to finite limitations of ownership and/or use. Furthermore, the products of intellectual creativity can often be reproduced at very limited marginal costs. Innovators and investors in innovation have therefore called for the development of a mechanism to protect the intangible wealth associated with intellectual creativity.

3.2 The Protection of TK Related to Plant Genetic Resources[8]

3.2.1 Definitions[9]

During the second half of the 19th century, the first modern patent laws were adopted in several European countries – in Britain in 1874, Germany in 1877 and Switzerland in 1887, whereas The Netherlands only reintroduced a patent system in 1910, which became effective in 1912; as well as in the USA (the initial Act of 1793 was revised in 1836, 1870 and 1874) and in Japan (1885).[10] At that time patent legislation was essentially designed to protect mechanical and conventional chemical inventions within industrialized countries. With the passage of time a number of new technologies emerged for which patentability was affirmed, most recently for biotechnology and, at least in certain jurisdictions,

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[7] WIPO, Intellectual Property Reading Material, see note 5. http://www.wipo.org/news/en/index.html?wipo_content_frame=/news/en/documents.html

[8] Author: Christophe Germann.

[9] See also Chapter 1.

[10] For an historical survey, see Machlup (1999, p. 224 ff.).

for computer programs. Genetic engineering is part of biotechnology, which generally addresses the technical use of biological processes. Modern genetic technology is considered to have started in 1973, when scientists were first able to bind genetic material *in vitro* and to plant it into bacteria as well as to reproduce it for the first time. Biotechnology includes *in vitro* culture, rhizobium technology, fermentation and more advanced techniques that involve genetic engineering.[11]

We shall confine our analysis to the protection of plant genetic resources (PGR) and their related know-how. Article 2 CBD defines 'genetic resources' as 'genetic material of actual or potential value'. The Convention does not further clarify the meaning of value. According to this same article, 'genetic material' includes 'any material of plant, animal, microbial or other origin containing functional units of heredity'. Genetic resources therefore comprise genetic material of actual or potential value of plant, animal, microbial or another origin. One can distinguish between genetic resources of wild species, cultivated or domesticated species and their relatives, and man-made genetic resources.[12]

Girsberger proposes the making of an additional distinction between PGR and PGR used in the production of food and agricultural products (PGRFA), and offers a definition for a 'traditional' PGRFA, i.e. the result of informal plant breeding activities. He further defines 'formal' and 'informal' plant breeding, the former type meaning plant breeding performed by private seed companies and public research institutions, and the latter type meaning plant breeding performed by individual farmers and indigenous and other rural communities, involving their traditional knowledge and know-how. A distinctive characteristic of informal plant breeding is that the breeding process usually proceeds over a long time period, sometimes over several human generations. Furthermore, the results of informal plan breeding are generally freely accessible to others, for example other informal plant breeders, collectors of PGRFA, or the remainder of the community (Girsberger, 1998, p. 1022).

Accordingly, the analysis will encompass traditional knowledge related to PGR in general and to traditional PGRFA, and to traditional PGRFA themselves, subsumed under the term 'traditional knowledge related to PGR'.

3.2.2 Patent protection

Introduction

In this section we shall outline the scope of patent protection in general, and specifically explore the extent to which patent protection is suitable for traditional knowledge related to plant genetic resources. There is little doubt that patents are appropriate for formal plant breeders' innovations. However, the advancement of biotechnology has focused attention on the intellectual property situation of holders of traditional knowledge and traditional PGRFA. As a matter of fact, certain biotechnological innovations draw substantial value from these sources. It is therefore useful to assess the scope of patent protection for innovations related to traditional knowledge and traditional PGRFA in order to better understand the various issues at stake and discuss the corresponding solutions in later chapters. Relevant questions include: What are the problems at the interface between IPR and TK related to plant genetic resources (see Chapter 7)? What solution can patent protection provide to traditional knowledge holders and holders of traditional PGRFA? What are alternative forms of protection that could contribute to reaching the relevant policy goals? How must patent protection be better adapted to

[11] For detailed definitions of 'genetic engineering' and 'biotechnology' and further relevant terms, see Girsberger (1998, p. 1023); and Girsberger (1999, p. 329 ff.) quoting 'Legal Environment'.

[12] Man-made genetic elements are the genetic resources of cultivated species that are characterized by a high degree of human intervention; see Heitz, Buenos Aires, November 1991, pp. 114 and 118.

fit with the interests of traditional knowledge holders?

With the advancement of biotechnology, the question of patenting life forms became a central topic in the intellectual property law and policy agenda of industrialized countries. In turn, this agenda had, and still has, a significant impact on developing countries, where arguably most valuable sources of traditional knowledge related to plant genetic resources reside. This discussion can be characterized by three main issues. First, there is the dichotomy of discovery *versus* invention; secondly, the question of novelty and the assessment of prior art and of the inventive step related thereto; and last, but not least, the debate on ethics and morality of patenting life forms. The track chosen in this area by the USA was quite straightforward. It was driven by strong business interests, and comparably weak opposition from other concerned parties. In contrast, the legislative process in the EU tended to consider non-business concerns, such as morality and equity, with more emphasis, most recently in the context of the elaboration and adoption of the Biotech Directive.[13]

With respect to the qualification of patentable 'invention' as opposed to non-patentable 'discovery', the landmark US Supreme Court case *Diamond vs Chakrabarty* in 1980 stated that the relevant criterion is human involvement in nature and not the distinction between inanimate and living material. In a nutshell, if an achievement can be shown to be human rather than natural, it should be open to patent protection, since human ingenuity should receive encouragement. A comparable approach also eventually prevailed in Europe and other industrialized regions and countries.[14]

The assessment of novelty remains a highly sensitive ongoing issue, both in the North and in the South. In industrialized countries the trial and error process, driven by patent registration-related administrative practices and case law, mainly focused on the balance pertaining to the appropriate level required for the criterion of inventiveness to be fulfilled. If the required inventive step is insufficient, there is concern for efficiency induced by competition. In contrast, if the required inventive step is prohibitive, patent protection no longer works as an incentive for research and development. In new technological fields, patent offices commonly tend to adopt a lax registration practice during the first stage, by requiring a relatively low inventive step. At a second stage, this practice is usually challenged by competitors through judicial review. Eventually, the resulting case law typically leads patent offices to be stricter and, thus, request a higher degree of inventiveness. This trial and error approach means that the initial broad scope of protection is subsequently fine-tuned in order to reduce it to a level where ideally the incentive function that is underlying the grant of the exclusive rights preserves sound competition among market actors.

The main concern of developing countries resides in opposing their prior art achievements against foreign corporations that take undue advantage of them. This is generally the case when companies want to register patents for inventions that draw from traditional knowledge related to plant genetic resources.[15] Concurrent to this concern is the legitimate aspiration of certain traditional knowledge holders to take advantage of the intellectual property system for equity as well as other policy considerations. In this context, the criterion of novelty can preclude protection for such knowledge that is by definition traditional or incremental. The insufficiencies of the current system, which is based upon national and regional legislations, may lead to a situation where certain parties can obtain patent protection for elements of traditional knowledge as inventions in their

[13] See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30 July 1998, pp. 13–21.

[14] For more detailed references, see text accompanying note 30.

[15] See the case studies below, in particular the turmeric case study, p. 135.

jurisdiction because of an insufficient prior art search, although these parties did not generate the knowledge, whereas the traditional holders of such knowledge may not be granted exclusive rights in other jurisdictions because of the lack of novelty that is inherent in this type of intellectual value achieved over generations. Although this is primarily an issue with respect to the US patent law and its definition of prior art, it may inspire legislators in other jurisdictions, and therefore cause a run to the bottom. Additionally, the difficulty to accede to existing TK when carrying out prior art search may be prohibitive if this TK is not documented in writing or in languages the patent authorities are familiar with. Therefore, even though such searches are carried out correctly, access to TK may not be possible in practice along the classical route. As of today, existing laws do not sufficiently address this issue, either on the national level, or on the international level. Some major industrialized countries are reluctant to introduce anti-biopiracy mechanisms to oblige patent applicants to provide relevant information pertaining to the use and sources of traditional knowledge or genetic material for their invention. These mechanisms could take the form of more efficient novelty-destroying international prior art searches and procedures to assess prior informed consent ('defensive rights'). Switzerland, for example, proposed several measures to combat 'biopiracy', e.g. to establish an international gateway (or internet portal) for traditional knowledge that would link local and national databases, improving access to existing traditional knowledge by patent authorities and thus facilitating prior art searches. Switzerland furthermore recommended amending the PCT abbreviation to explicitly enable the national legislator to require patent applicants to disclose the source of genetic resources/traditional knowledge in patent applications.

Finally, the ethical and moral questions respectively divide proponents and opponents of patent protection for living forms, both in the North and in the South. According to Dunleavy and Vinnola (1999, p. C11), the morality-based provisions in Article 6 of the EU Biotech Directive could arguably be considered to represent the most significant difference between future European practice and established US practice. However, these authors perceive that the USA appears to be moving towards an approach that is similar to that of the EU regarding the patentability of these types of inventions. In addition to the 'morality' or ethical questions that specifically refer to intellectual property rights in connection with living things, the very concept of private ownership, as opposed to public domain or collective ownership with respect to intellectual achievements, lacks legitimacy in certain Southern cultures. The intellectual property system itself is largely accepted in industrialized countries, and divergences of opinion mainly focus upon the appropriate standards of protection. In contrast, the ability to grant private rights to individuals or collectives for works of mind remains contested, or even rejected, by many local communities in developing countries for moral or ethical reasons.

To summarize, the debate concerning the patentability of TK related to PGR addresses not merely technical issues, but presents a remarkable conceptual complexity: it is about the legal meaning of 'invention', 'novelty' and 'property', and beyond that, about the legitimacy and acceptance of the entire system.

The following section aims to provide a brief stock take of the patentability of life forms in general, and specifically focus on legal aspects that are relevant to traditional knowledge related to plant genetic resources. It will furthermore outline the issues at stake in order to prepare the ground for reflection throughout later sections of this book concerning the approaches that can be utilized to adapt the current intellectual property system, and in particular patent protection, for the purposes of maintaining and further developing traditional knowledge related to plant genetic resources.

The rationale of patent protection

Patents offer protection for inventions, i.e. for solutions to specific problems in the field of technology. Patents define their owners' exclusive rights pertaining to inventions. They are statutory privileges that take the form of competitive advantages that are granted by governments to inventors for a specified period of time. Patents provide, at least in certain respects, the most extensive exclusive rights amongst the major forms of intellectual property protection. Patents have gained increased prominence with the development of genetic engineering, which is reliant on PGR to some extent. As a result of the increased activity by individuals and the private sector in this field, the scope of patentability has steadily increased over the past couple of decades. Calls for further expansion of the scope of patentability have been countered in recent years by counterclaims that patenting elements which are commonly used by researchers for further innovations, such as those used in gene technology, may end up hindering rather than promoting innovation.

The rationale underlying the grant of patents is based on equity as well as on pragmatic considerations. Equity considerations materialize the concepts of 'justice' or 'natural rights', whereas the pragmatic justifications refer to the promotion of the public interest. The so-called 'natural-law' thesis assumes that humans have a natural property right to their own ideas. Under the 'exchange-for-secrets' or the 'monopoly-profit-incentive' concepts, an inventor discloses the results of his or her efforts to the public. In exchange, the inventor is granted a monopoly-like privilege for a limited period of time, with respect to the commercial use of the invention. In this way, the state provides the inventor with a competitive advantage in consideration of the disclosure of the inventor's intellectual achievement. This disclosure allows third parties to perform further research and development based on the invention. It further enables them to work freely and use the invention after the expiration of its terms of protection. Thus, technological progress is promoted through a legal incentive, the patent, to diffuse the knowledge relevant to the invention that the inventor could otherwise keep secret. By this line of reasoning, the competitive privileges granted to the inventor may also be considered as an award for the investment in qualified inventive efforts that were already performed, and as an incentive to proceed to future inventive efforts. As a matter of fact, it allows the patent owner to derive a material benefit that compensates him or her for the research and development cost the invention has entailed (Machlup, 1999, p. 231 ff.). In the case of violation of this exclusive rights by another person, who exploits the protected invention without authorization, the patent owner can require the courts to order that the infringement ceases as well as awarding civil, administrative and criminal remedies.

The balance that patent laws try to achieve is, on the one hand, to encourage inventive and innovating efforts on an individual basis and, on the other hand, to disseminate knowledge and the resulting technological achievements for the general economic and social welfare of society as a whole. When investing in research and development, companies usually face what economists have labelled the 'incomplete appropriability of knowledge' (Arrow, 1962, p. 609). According to this concept, the investment in the production of knowledge will be difficult, if not impossible, to protect completely, since part of the newly generated knowledge will diffuse to competitors and into the public domain. For firms investing in the production of knowledge, patent protection provides only a partial solution. It allows the investing firm to appropriate a return on its investment in research and development by protecting its invention against unauthorized duplication. However, since the patentee must disclose her/his new knowledge, this enables competing firms to build upon such knowledge to create other inventions that can be similar, but not identical, to the protected one. It may require costly litigation to determine

infringement in such circumstances. The cost of substantially imitating an existing product, with or without improvement, is usually lower and less risky than the originator's cost of creating, developing and marketing the new product. Such a competitor can act in a shorter time than was needed by the patentee, and undercut the return to the patentee. Because of the diminished risk-weighted incentive to the originator, some authors have concluded that 'total welfare, but not the welfare of consumers, would be increased by making it more difficult to produce close substitutes for existing products'.[16]

It may be argued that the grant of a patent encourages investment in the production and distribution of an invention, since the patent monopoly assists the investor in penetration and defence of the market. On the other hand, the neutralization of competition during the terms of protection may trigger a rent in form of a high rate of return in favour of the inventor, inhibiting him from further innovation.

In the seed sector, for example, research and development initially were mainly performed by state-owned entities such as government agencies and universities. These efforts were thus funded by public money. For this reason, there was no demand for IPR protection until the private sector started to gain an interest in this business. As described later under Section 3.2.3, this development began with legislative action in the field of plant variety protection in the USA. In contrast to the legal solutions eventually adopted in Europe, innovators in the USA may claim protection both under plant variety and patent law. Subsequently, with the further growth of biotechnology, the private industry required intellectual protection for life forms and microorganisms. Once this sector began to attract private industry, the protection of intellectual property rights in these fields was put onto the legislative agenda of industrialized countries and regions. Private actors argued that effective protection was required in order to secure a return on large private investments performed for research and development into biotechnological innovations. Patents and other forms of protection grant an advantage over competitors who did not make the same investments into innovation. Furthermore, the industry required that this competitive advantage was to be extended *vis-à-vis* the users, because the relevant inventions were typically life forms that could reproduce naturally, and consequently, they did not need repeated purchases by farmers. In the case of genetically modified rape, for example, the results of this law-making process in the USA eventually raised a polemic, when farmers became aware of their increased dependency upon major producers and distributors. Since biotechnology allows the transformation of genes across species boundaries, the genetic modification of organisms raises not only merely economic questions, but also substantial ethical, environmental and social issues that the relevant laws also have to address as part of an ongoing process.

Whereas certain cultures oppose the concept of granting exclusive rights over living forms, other cultures accept this approach under clearly defined conditions in order to fulfil certain policy goals that are in the public interest. The latter cultures argue that intellectual property rights are a cost-efficient alternative to publicly funded innovation because they function as incentives for privately performed research and development.

Even if one accepts that the intellectual property system should be extended to apply to life forms, one can question the appropriate levels of protection. The incentive rationale primarily covers investments into research and development by granting legally secured competitive advantages during the marketing phase. However, too

[16] See *Hilton Davis Chemicals Co. vs Warner-Jenkinson Company, Inc.,* United States Court of Appeals for the Federal Circuit, 62 F.3d 1512; 1995 U.S. App. LEXIS 21069, 8 August 1995, quoting Besen and Raskind (1991).

much protection can cause a situation where major producers and distributors are able to control the market. In this case, undertakings having a dominant position can drive their smaller and, as the case may be, more innovative competitors out of business. Eventually, in the worst-case scenario, the consumers' choice becomes restricted to the products and services that are most powerfully marketed to the exclusion of the most innovative ones. This development undermines the incentive effect of intellectual property rights in contributing to the technological progress for general welfare.[17]

The allocation of IPR is premised on the notion that innovation is driven by profit. From a societal point of view, IPR strive to balance the private interests of creators, by ensuring that they still have an incentive to create, against those of society at large to have the information available for its use. Even though information does not diminish once it is shared, the role of IPR is to ensure that information providers do not lose rights to the information by disclosing it, since such information can be used by an infinite number of persons simultaneously (Landes and Posner, 1989; Baer, 1995). Indeed, one of the perceived philosophic underpinnings of IPR is to ensure disclosure of the information while maintaining exclusive rights for the creator. It is significant, however, that there is still no consensus, even in developed countries, concerning the social or economic utility of granting intellectual property rights. In fact, there have not been any significant empirical studies demonstrating the beneficial impact of the grant of patents on economic or social development (Abbott, 1989).

The concepts of invention and the protection of plant varieties

On the global level, the TRIPS agreement is currently the most detailed international instrument addressing substantive patent protection. This agreement, that is part of the WTO body of rules resulting from the Uruguay round, entered into force in January 1996 for industrialized countries, and, subject to the transitional arrangements in Articles 65 and 66 TRIPS, 4 years afterwards for developing countries and, if certain additional conditions are fulfilled, to previously centrally planned economies. In the area of patent protection, section 5 of the second part of the TRIPS agreement refers to, and further completes, the Paris Convention in the Stockholm version of 14 July 1967. From the perspective of industrialized countries, the Paris Convention needed updating and the addition of extra, as well as more detailed, rules concerning many aspects of patent protection. In particular, the scope of patent protection was highly controversial during the TRIPS negotiations (Cottier, 2004). Article 27 TRIPS provides that patents shall, subject to certain conditions, be available for any invention, whether a product or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The TRIPS Agreement does not define the term 'invention'.

Article 53(b) of the European Patent Convention of 5 October 1973 (EPC)[18] excludes plant and animal varieties or processes that are essentially biological for the production of plants or animals from patent protection, while not extending this exclusion to microbiological processes or the products thereof. In contrast, Article 27(3)(b) TRIPS provides that Members may exclude plants and animals other than microorganisms from patentability, as well as essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. This latter exception serves as criterion that enables a more concrete

[17] Compare Germann (2003), on the detrimental effect of excessive copyright and trade mark protection on cultural diversity in the audiovisual sector.

[18] Version as amended by the Act revising Article 63 EPC of 17 December 1991 and by the decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998.

distinction between discoveries and inventions. Members must provide legal tools for the protection of plant varieties, either by patents or by an effective *sui generis* system, or by any combination thereof. In other words, the TRIPS agreement distinguishes between the protection of plants and animals on the one hand, and the protection of plant varieties on the other. Whereas plant varieties must be protected by way of patents or through equivalent means, plants may be excluded from patent protection. At the European level, the EPC excludes plant varieties from patent protection. The TRIPS agreement contains neither a definition of a 'plant variety' nor of a 'plant'. This term is defined in Article 1(vi) of the UPOV Convention 1991:

> 'variety' means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be
> - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes;
> - distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
> - considered as a unit with regard to its suitability for being propagated unchanged.

The EPO Board of Appeal discussed the definition of 'plant variety' as set forth under Article 53(b) EPC in the decisions T 49/83,[19] T 320/87,[20] and, with reference to the above-quoted definition contained in the UPOV Convention 1991, in T 356/93,[21] as well as in T 1054/96.[22] According to the approach adopted under the EPC, plant varieties shall be protected under plant breeders' rights, which are specifically designed for this purpose. This form of protection can therefore be considered as a *lex specialis vis-à-vis* patent protection. The purpose and objective of these rights, as defined by the UPOV Convention, are to promote plant-breeding activities, i.e. the creation of new and improved plant varieties. Another rationale behind plant variety protection is the promotion of the seed trade (Girsberger, 1998, p. 1024, with indication of further sources). As Girsberger stresses, the general perception was decisive for concluding the UPOV Convention that protecting plant varieties by patents did not provide effective incentives for investment in plant breeding activities (Girsberger, 1998, p. 1027). This explains the reason why the form of protection of plant varieties is left open in Article 27(3)(b) TRIPS, and why a *sui generis* form of protection for plant varieties was considered to be more appropriate under the EPC.

In the USA, patent protection for asexually reproduced plant varieties was provided as early as 1930 under the Plant Patent Act. In 1970, the US Congress enacted the Plant Variety Protection Act (PVPA), which provided protection to new varieties of 'sexually' reproduced plants in addition to the Act of 1930. Under this legislation, the developer of a novel variety of plant can apply for protection, based on which he or she can exclude others from selling, reproducing, exporting and importing the protected variety for a period of 18 years.

The case law pertaining to the EPC that addresses the concepts of 'invention', 'novelty' and 'morality' in relation to plant genetic resources provides an insight into the current state of patent practice regarding patentability and scope of protection into the area of biotechnology in Europe. According to decision T 49/83 (OJ 1984, 112) that referred to Article 52(1), Article 53(b), R. 28 and R. 28a, no general exclusion of inventions in the sphere of animate nature can be inferred from the EPC. The landmark T 356/93 defined the concepts of '*ordre public*', 'morality', 'plant varieties',

[19] OJ 1984, 112.
[20] OJ 1990, 71.
[21] OJ 1995, 545.
[22] See summary of these cases at http://www.european-patent-office.org/legal/case_law/e/I_B_3.htm (status: August 2003).

'essentially biological processes for the production of plants', 'microorganisms', 'microbiological processes' and 'the products thereof'.[23] The meaning of the term 'plant varieties' was discussed in T 49/83 (OJ 1984, 112) and held to mean a multiplicity of plants, which were largely the same in their characteristics and remained the same within specific tolerances after every propagation cycle. The board added that plant varieties in this sense were all cultivated varieties, clones, lines, strains and hybrids, which could be grown in such a way as to be clearly distinguishable from other varieties, sufficiently homogeneous, and stable in their essential characteristics. The legislator did not wish to afford patent protection under the EPC to plant varieties of this kind, whether in the form of propagating material or of the plant itself. The board further observed that Article 53(b) only prohibited the patenting of plants or their propagating material in the genetically fixed form of the plant variety. Following T 320/87, the board addressed the meaning of a process that, as a whole, was not 'essentially biological' within the meaning of Article 53(b). It highlighted that the transformation step at stake in this case, regardless of whether or not its performance depended on chance, was an 'essential technical step' (i.e. as opposed to an 'essentially biological' one), which had a decisive impact on the desired final result and could not occur without human intervention.[24]

Article 28 TRIPS determines the exclusive rights conferred by a patent. This provision distinguishes between patents for products and patents for processes. Where the subject matter of a patent is a product, the owner is entitled to prevent third parties who do not have their consent from performing the acts of making, using, offering for sale, selling or importing for these purposes, the protected product. The same rights are granted for process patents that cover the process itself and the product obtained directly by such process.[25] This obviously extends the breadth of patent protection, since one may obtain a title for a new process that leads to a product that is itself already protected or in the public domain. Furthermore, patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Pursuant to Article 64 EPC, the European patent confers the same rights as would be conferred by a national patent granted in that state on its proprietor in each Contracting State in respect of which it is granted. This provision therefore refers to the exclusive rights as defined in the substantial patent laws of the Contracting Parties, except that it specifies within its second paragraph that the protection conferred by a patent on a process shall extend to the products directly obtained by such process. In comparison, under breeders' rights such as those provided by Article 14 of the UPOV Convention 1991, the production or reproduction (multiplication), conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, and stocking for the purposes of the previously listed acts, of the propagating material of the protected variety can only be performed with the right holder's authorization.[26]

Whereas breeders' rights address plant varieties, rights conferred by patent protection cover inventions. Article 52(2) EPC gives a negative definition of the latter term,

[23] This decision analysed Article 53 by taking into account the historical documentation ('*travaux préparatoires*') relating to the EPC, and substantially confirmed the findings of T 49/83, T 320/87 and T 19/90.

[24] See note 22. Case law summaries by the EPO may be found under http://www.european-patent-office.org/legal/case_law/e/I_B.htm

[25] Article 28.1(b) TRIPS sets forth: 'A patent shall confer on its owner the following exclusive rights where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process'. Article 34 TRIPS contains a special rule addressing the burden of proof of process patent containing presumptions that are in favour of the process patent owner.

[26] For a more detailed analysis of the UPOV Convention, see Chapter 2, Section 2.3.4.

according to which discoveries, scientific theories and mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers, as well as presentations of information, shall not be considered as inventions. The items on this list, which is not exhaustive, are commented upon in the EPO Guidelines[27] and are further clarified through case law.[28] The exclusions on this list are either abstract (e.g. discoveries, scientific theories, etc.) or non-technical (e.g. aesthetic creations or presentations of information). Article 52(4) provides that methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body, shall not be regarded as inventions which are susceptible to industrial application. In contrast to the EPC, the TRIPS agreement does not contain a definition of invention. Although Article 27(3)(a) TRIPS allows Members to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from patentability, this provision does not state that these methods are not inventions. Pursuant to *Black's Law Dictionary*, the term 'invention' can be defined as:

> … the act or operation of finding out something new; the process of contriving and producing something not previously known or existing, by the exercise or independent investigation and experiment. Also the article or contrivance or composition so invented … Invention is … not a revelation of something which exists and was unknown, but is creation of something which did not exist before, possessing elements of novelty and utility in kind and measure different from and greater than what the art might expect from skilled workers … The finding out – the contriving, the creating of something which did not exist, and was not known before, and which can be made useful and advantageous in the pursuits of life, or which can add to the enjoyment of mankind. Not every improvement is invention; but to entitle a thing to protection it must be the product of some exercise of the inventive faculties and it must involve something more than what is obvious to persons skilled in the art to which it relates.[29]

In the light of this definition of an invention and for the purposes of assessing the patentability of PGR, it is interesting to note that under US patent law the relevant distinction is not made between living and inanimate things, but rather it is between natural products, whether living or not, and human-made inventions. As mentioned above, the US Supreme Court decision *Diamond vs Chakrabarty* of 1980 addressed the question of whether an artificially created life form – a new form of bacterium obtained by genetic alteration – is a patentable subject matter. The Court quoted excerpts from the Congress report issued in the course of the enactment of the Plant Patent Act of 1930 as follows:

> There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful mineral. The mineral is created wholly by nature unassisted by man … On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man.[30]

According to this approach, the relevant criterion centres around the human involvement in nature: if an achievement is not nature's but human handiwork, it

[27] See Guidelines for Examination in the European Patent Office, Part C, Chapter IV on Patentability, version of October 2001, p. 50 ff.

[28] For an overview of the relevant case law, see http://www.european-patent-office.org/legal/case_law/e/I_A_1.htm.

[29] *Black's Law Dictionary* (1990), p. 824.

[30] S. Rep. No. 315, 71st Cong., 2d Sess., at 6 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., at 7 (1930); quoted in: *Diamond, Commissioner of Patents and Trademark vs Chakrabarty,* Supreme Court of the United States 447 U.S. 303; 1980 U.S. LEXIS 112 (1980) relevant excerpts in: Abbott *et al.* (1999, p. 36).

should be open to patent protection since human ingenuity should receive encouragement. In the case at stake, the Supreme Court considered that the patentee had produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.

The distinction between 'discovery' and 'invention' led, in particular, to detailed case law under the EPC with respect to the interpretation of 'essentially biological' within the meaning of Article 53(b). According to decision T 320/87 (OJ 1990, 71), whether or not a (non-microbiological) process was to be considered as 'essentially biological' within the meaning of Article 53(b) had to be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved. The necessity for human intervention alone was not a sufficient criterion for its not being 'essentially biological'. Human interference might only mean that the process was not a 'purely biological' process, without contributing anything beyond a trivial level. Furthermore, it was not simply a matter of whether such intervention was of a quantitative or qualitative character. In this particular case, it was concluded that the claimed processes for the preparation of hybrid plants did not constitute an exception to patentability, because they represented an essential modification of known biological and classical breeders' processes, and the efficiency and high yield associated with the product showed important technological character.

Protective criteria

As mentioned, in order to enjoy legal protection, an invention must fulfil certain conditions as set forth by national, regional or international rules. Based on the patent, both the inventor and subsequent assignee or licensee are entitled to produce and market the invention on an exclusive basis for a determined period of time.[31] The owner of the patent thus has the right to prevent third parties from manufacturing and commercially exploiting the invention without his authorization. The invention may relate either to a product or to a process. Patent laws generally rely upon four essential criteria for the grant of exclusive rights.

NOVELTY

According to the first criterion, the invention must be new or novel. This means that the invention has not been disclosed or described before the date of filling in the patent application. For the purpose of assessing the novelty condition, the patent examiner will perform a so-called 'prior art search'. A patent application will generally be defeated by an anticipating disclosure. There may be a controversy between an inventor and a patent examiner over whether a particular prior art disclosure does in fact anticipate an invention, for instance if a prior inventor described a device that is similar, but not identical, to the subsequent inventor's device.

UTILITY

Pursuant to the second criterion, the invention must be useful or capable of industrial application. This condition is particularly relevant within the fields of biotechnology and chemistry, where it is possible for researchers to develop new compounds with relative ease, yet without, at least initially, any immediate practical application in mind. The criterion of utility again became critical in the evaluation of claims for inventions in the area of biotechnology, in order to prevent 'speculative booking' of exclusive rights.

INVENTIVE STEP

As a third condition, the invention must involve an inventive step or, in other words, it should not be obvious. This

[31] See note 6.

means that the invention must not simply be novel, but must result from a qualified intellectual effort that makes it non-obvious. This criterion thus requires a higher standard of novelty through an inventive step. Strong protection leading to a competitive advantage shall only be granted to inventions that would be an apparent improvement to prior art to a person who is reasonably skilled in the art practised by the invention. This requirement is justified by the 'monopoly-profit-incentive' rationale, according to which strong protection shall only be granted to substantial contributions to the technological progress.

ENABLING DISCLOSURE

Finally, the fourth criterion obliges the inventor to disclose in the patent application either a means for enabling the practice of the invention (generally for Europe), or the best known means for practising the invention (for the USA). One of the reasons for this condition is based on the exchange theory of the award of the patent: the patent applicant is awarded exclusive rights in return for the disclosure to society of a new, useful and non-obvious invention. Without a disclosure that enables other persons to benefit from the invention for their own research and development work, this exchange between the inventor and the society would not make sense. This condition also performs the function of filtering out speculative applications, since it constitutes a reliable assessment of the usefulness of the invention for the purpose of its industrial application. The applicant will typically try to disclose to his competitors as little as possible about the secrets of his invention, and obtain as much protection as possible in return. This behaviour, which often leads to tensions between patent examiners and inventors, is obviously not in the public interest since healthy competition promotes innovation to the benefit of society.

PROTECTIVE CRITERIA ACCORDING TO TRIPS AND EPC

As mentioned, pursuant to Article 27(1) of TRIPS, 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. A footnote to this paragraph states that the WTO Members may interpret the terms 'inventive step' and 'capable of industrial application' as being synonymous with the terms 'non-obvious' and 'useful', respectively. However, the TRIPS agreement does not further define any of these protective criteria. For the time being, there is no WTO case law about the meaning of these criteria either. The Members thus have considerable discretion when implementing Article 27(1) TRIPS in their national laws.

In comparison, Article 52(1) EPC addresses patentable inventions, and provides that European patents shall be granted for any inventions which are susceptible to industrial application, which are new and which involve an inventive step. As regards the criteria of novelty, Article 54(1) EPC states that an invention shall be considered to be new if it does not form part of the state of the Article. Thus, the reference to the state of the art is pivotal in the determination of whether the criterion of novelty is fulfilled or not. Paragraph 2 of this provision clarifies that the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing date of the European patent application. In comparison, for the purposes of Article 15.1 of PCT, relevant prior art includes 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. Under US patent law it is fairly easy to obtain patent protection for inventions that are based on traditional knowledge, because it does not consider that the 'novelty' requirement has been lost if the knowledge is divulged outside the USA by means of public use and sale. The essential requirement of 'novelty' can be destroyed only

through publication.[32] Unlike US patent law, in Europe and most countries in the world, novelty is lost by any type of divulgation in a foreign country, whether it is oral or written. In the USA, indigenous communities in developing countries have little opportunity to bring attention to unwritten knowledge, practices and innovations that demonstrate lack of novelty or non-obviousness. To illustrate this issue, one can quote the neem case as an example of a patent that was allegedly based upon misappropriation of non-published traditional knowledge (see p. 136).

PROTECTION OF TRADITIONAL KNOWLEDGE UNDER THE EPC

In the specific context pertaining to the protection of plant genetic resources and traditional knowledge referring thereto, it is interesting to analyse the meaning of paragraph 5 of Article 54 EPC, which states that its previous paragraphs shall not exclude the patentability of any substance or composition comprised in the state of the art, for use in a method referred to in Article 52(4) EPC, provided that its use for any method referred to in that paragraph is not comprised in the state of the Article. Article 52(4) EPC requires that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body, shall *not* be considered as inventions that are susceptible to industrial application within the meaning of paragraph 1, i.e. they are not patentable. However, this latter restriction shall not apply to products, and specifically to substances or compositions, for use in any of these methods. For example, if a traditional healing method uses a substance or composition that contains plant genetic resources the composition of which is part of the state of the art, while the healing method is not, patent protection arguably should be granted to such a combination of method and substance or composition. This interpretation is relevant for patent protection of plant genetic resources in connection with traditional knowledge in the absence of the ability to protect such resources. This may be because of the absence of genetic engineering, or because it is already part of the state of the art, since traditional knowledge alone may not be patentable pursuant to Article 52 paragraph 2, letters c and d, which excludes schemes, rules and methods for performing mental acts, as well as presentations of information, respectively, from patent protection. Thus, the novel aspect would essentially be vested with the combination of traditional knowledge and plant-related genetic resources.

Scope and limitations of patent protection

The scope of protection for patents is determined by the terms of so-called 'claims' in the patent application that are eventually accepted by the patent office. The technical description of the process or product in the patent application usually serves to construe the claims. The scope of protection is limited by statutory provisions such as compulsory licensing and exhaustion rules.[33]

Rules limiting protection aim to ensure that the public interest remains preserved when granting exclusive rights over a given period of time. Public health (e.g. to provide access to essential medicine to poorer parts of the population) or education (fair use limitations) are typical grounds on which to restrain protection.[34]

[32] 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'.

[33] See, for example, Articles 6, 7, 8 and 40 of TRIPS for general limitations and Articles 30 and 31of TRIPS specifically for patents.

[34] For the discussion on patents for pharmaceuticals and non-trade concerns, see http://www.wto.org/english/tratop_e/TRIPS_e/pharmpatent_e.htm and http://www.cptech.org/

More fundamentally, the scope of protection is conditioned upon the quest of the intellectual to find a balance that addresses both Garrett Hardin's influential 'tragedy of the commons' and also the 'tragedy of the anti-commons'. According to the theory of the tragedy of the commons (or 'the tragedy of open access'), the absence of property rights or access regulations over resources will lead to their depletion. While individuals accrue benefits as they exploit resources, the costs of everybody's exploitation of the resources at unsustainable levels will have to be met by the community as a whole. In economic terms, resource depletion is a negative externality that results from the absence of individual property rights. As an example, Dutfield (2001) quotes the overexploitation of high seas fishing stocks. On the other hand, the tragedy of the anti-commons is the result of excessive intellectual property protection that hinders further innovation and creativity.

As mentioned above, patents are granted in order to provide an incentive for innovations and for the diffusion (disclosure) of these innovations. Without the protection provided by the patent system, inventors would have no incentive to disclose their inventions, and to keep them secret in order to preserve their economic benefits. With disclosure, patents help avoid the wasteful duplication of innovation efforts, and instead channel resources towards unexplored areas of technology. Furthermore, patents are instrumental for the commercialization of innovative products and processes.

However, patents impose a short-run efficiency cost, because of the deadweight loss corresponding to the grant of quasi-monopoly rights. In standard economic parlance, anything that is not perfect competition pays an inefficiency trade-off, in that the use of the innovation is less than optimal. Moreover, just as patents can help to promote innovations, they can also adversely affect the flow of future inventions, by stunting incentives for related innovation or further improvements, especially where the patents have broad scope and the licensing arrangements for the innovation are prohibitive.

Thus, patent policy is not an optimal solution, but rather a second-best solution to a market failure problem in innovation production. The market failure stems from the fact that knowledge is a public good, which, once available, has zero marginal cost if used by others. From the economic perspective, innovations are *non-rival* in consumption, which means that the use of the knowledge by others does not affect the amount that is available to the inventor. Conversely, if knowledge were a public good, then its producer who bore the cost of innovation would lose out from 'free riders', thus providing no incentive to produce the knowledge in the first place. The result would be an underproduction of knowledge or dearth in innovation.

To summarize, patents that provide the legal means of affecting the excludability attributes of an otherwise public good, solve the market failure problem of the non-appropriability of knowledge. Society pays for this by the economic inefficiency associated with monopolies. That is, the 'static inefficiency' (from a monopoly) is the trade-off for the 'dynamic efficiency' resulting from greater innovation.

Preliminary conclusions on patent protection for holders of traditional knowledge

The progress in the biotechnology field caused the meaning of fundamental notions of patent protection to be questioned. The concepts of 'invention', 'novelty', 'inventive step/non-obviousness' and, last but not least, 'morality', are at the heart of the discussion about patenting life forms. Critical observers argue that accommodating the wishes of certain biotechnology sectors has seriously blurred the distinction between 'discovery' and 'invention' in patent law. They focus on many instances where the actual substance resides mainly in nature or traditional practice, to which biotechnology adds only minor changes (Nijar, 1996, p. 4). The question of an inventive step or non-obviousness is closely connected to this issue. Granting property titles for little added intellectual value lacks legitimacy and runs counter to the public policy goals

underlying the whole system. Once one accepts that there is an invention, the questions concerning novelty, and more particularly the inventive step, are dealt with in the course of the examination procedure, as well as through subsequent judicial review mechanisms. Current systemic insufficiencies of law and practice pertaining to international prior art searches are causing a shift from prior *ex officio* patent examination to subsequent party-initiated judicial review procedures. From the perspective of holders of traditional knowledge related to plant genetic resources, challenging a patent because it does not fulfil the novelty or non-obviousness requirements may turn out to be a very costly undertaking, which is beyond the means of most individuals or local communities. Traditional knowledge holders are usually at a disadvantage in cases where patent offices are lax during the international prior art check and when, in practice, the effective test only takes place after examination through judicial review on the initiative of a concerned party. As a matter of fact, for the time being, the patent system is mainly tailored towards those corporations that enjoy substantial human and financial resources that enable them to register their own inventions, to administer the rights and, as the case may be, to challenge the registration of their competitors' inventions. Without appropriate institutional infrastructures, such as adapted rights management systems including databases, or collecting societies as flanking measures (see Chapter 7), today's patent system will remain a game for bigger corporations, and one that hardly provides any genuine level playing field for individuals and local communities holding traditional knowledge related to plant genetic resources. These flanking measures cannot be of a merely technical nature, but also need to address complex interactions between different legal cultures.

If traditional knowledge holders are not able to participate in the intellectual property system on a fair basis, this could contribute to the depletion of this knowledge within this system. In this case, holders of traditional knowledge will miss incentives to maintain and develop the intellectual achievements of their communities that may be misappropriated by other parties in stronger positions. When local communities cannot enjoy returns from, or are even precluded from free access to, inventions based on their traditional knowledge because third parties have become right holders, the rationale of equity underlying the grant of intellectual property rights does no longer work. Moreover, it leads to a perverse result of the system when excessive standards of protection start to hinder innovation because they mainly serve to attract capital for marketing efforts that eventually drive competitors out of business, even if they are more innovative.[35] This negative occurrence typically strikes marginal players such as traditional knowledge holders first, and at the end often leads to heavy concentrations among major producers and distributors that are detrimental to welfare. The term 'morality' can be used to express the third main issue to be addressed in this context. In the public debate within industrialized countries it covers the question of patenting life forms.[36] We extend the meaning of 'morality' in order to encompass the complex interface between various legal orders, where one order rejects a body of rules that another tries to bring to application across the formal limits of its own jurisdiction. There are several legal cultures that reject the very idea of private ownership for intellectual works that are based upon philosophical or religious traditions. How are clashes of legal cultures to be settled? On the one hand, the intellectual property system needs to overcome national barriers in order to be effective. On the other hand, there is no legitimacy behind the imposition of this system upon people who do not accept it because it runs contrary to their basic principles. Both 'morality' issues

[35] See Germann (2003).

[36] See text accompanying note 52.

exhibit at least one common feature: they challenge the intellectual property system for philosophical or religious reasons rather than for practical ones. The qualities and disadvantages of the system can no longer be discussed in a purely rational way. As is the case concerning questions about the death penalty or abortion, one could even contest the democratic decision-making process that leads to the adoption of an intellectual property system in which the opponents to the system are defeated simply because they are in the minority. The task to find a consensus concerning 'morality' considerations on the international level is more difficult by far than the reaching of a cross-border understanding over the more technical concepts of 'invention' and 'inventive step'. Nevertheless, these two latter concepts also pose substantial difficulties in their adaptation for the purposes of holders of traditional knowledge. These tasks include the determination of appropriate forms of protection, specific protective criteria, ownership, transfer of rights modalities, prior informed consent safeguards and efficient international implementation mechanisms. We will explore the corresponding solutions in the chapters below.

3.2.3 Plant breeders' rights[37]

Patents are not the only form of protection to encourage innovation. Several additional forms of IPR are available, such as trade secrets,[38] plant breeders' rights and *sui generis* protection for plant varieties.

Background

Traditionally, patents did not cover natural products. Over time, the scope of the exception relating to nature has been significantly reduced, but international intellectual property rights treaties have never yet gone so far as imposing patent protection for plant varieties. An alternative form of intellectual right protection for plant varieties has developed progressively.

Various factors have contributed to the difficulties of providing IP protection for plant varieties. One of these is that the notion of inventiveness, which characterized patents, would be diluted if plant varieties were brought on board, because a new plant variety was seen more as an improvement of an existing natural product rather than as a 'scientific' invention (Rangnekar, 2000). Furthermore, seeds had always been deemed to be part of the common heritage of humankind and were freely exchanged among farmers and farming communities (Shiva, 1994).[39] However, it was increasingly recognised that a form of intellectual property rights was necessary in the seed sector in order to encourage private investment.

Partly as a result of the progressive commercialization of the agricultural sector, and partly because of the push for the introduction of some form of IPR protection, plant breeders' rights (PBRs) evolved. These gave breeders specific legal rights to the varieties they developed, in a bid to foster the development of varieties that could, otherwise, easily be reproduced by other farmers or competing breeders. Because the impetus behind this measure came from large commercialized farming systems, PBRs, as they exist today, have been developed for the specific contexts and needs of

[37] Author: Philippe Cullet.

[38] The rationale behind trade secrets, in contrast to patents, is based upon property theory or the doctrines of tort, contract and trust, rather than being motivated by providing an incentive for innovation or creativity (Besen and Raskind, 1991). Its subject matter can be any formula, pattern, etc., which provides a business advantage over others who do not possess the information. Trade secret protection is not limited in time.

[39] The different positions expressed with regard to the introduction of plant breeders' rights have taken on added significance in the wake of the adoption of the TRIPS Agreement. Indeed, while a number of OECD countries had progressively adopted a form of PBR before 1994 to foster the development of their private seed industries, most developing countries had not introduced any form of intellectual property right protection in the agricultural sector.

developed countries. The legal regime for PBRs is quite uniform; thanks to the fact that most countries that have introduced PBRs have either joined the International Union for the Protection of New Varieties of Plants (UPOV) regime, or have modelled their legislation on the UPOV regime (on UPOV, see Section 2.3.4). The following paragraphs consequently analyse PBRs as they have developed in the UPOV context.

What are PBRs?

PBRs can generally be described as patent rights with some missing attributes. PBRs share a number of characteristics with patent rights: they provide exclusive commercial rights to the holder, reward an inventive process and are granted for a limited period of time.

To be more specific, PBRs protect plant varieties. Plant varieties can only be protected by PBRs if they fulfil the four basic criteria of: novelty, distinctness, stability and uniformity or homogeneity. Each of these characteristics is given further content by the UPOV Convention. The concept of novelty requires further elaboration because it differs from its acceptance under patent law. Under UPOV, a variety is novel if it has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for the purposes of exploitation of the variety.[40] Novelty is thus entirely defined by the issue of commercialization and not by the fact that the variety did not exist previously. UPOV gives a specific time frame for the application of novelty. In order to fulfil the requirement for novelty, a variety must not have been commercialized in the country where the application is filed for more than a year before the application, or for more than 4 years in other member countries (6 years in the case of trees and vines). The criterion of distinctness requires that the protected variety should be clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application.[41] The requirement of stability is satisfied if the variety remains true to its description after repeated reproduction or propagation.[42] Finally, uniformity implies that the variety remains true to the original in its relevant characteristics when propagated.[43]

Over time, the definition of protected variety has evolved, insofar as so-called 'essentially derived varieties' were not protected during the early days of plant variety protection. The latest revision of UPOV has introduced protection for such varieties.[44] Protection as an 'essentially derived variety' is obtained if the variety is predominantly derived from the initial variety and retains its essential characteristics.

Content and limitation of PBRs

The rights conferred upon plant breeders differ from patent rights insofar as they provide much more extensive exceptions to the rights they confer than patents. Breeders have exclusive rights to produce or reproduce protected varieties, to condition them for the purposes of propagation, to offer them for sale, to commercialize them, including exporting and importing them, and to stock them in view of production or commercialization.[45] These rights are restricted by a number of exceptions that are compulsory in the UPOV context. The rights of breeders do not extend to acts done privately and for non-commercial purposes; to acts done for experimental purposes; to the use of the protected variety for the purpose of breeding other varieties; or to the right to commercialize such other varieties

[40] Article 6 of the International Convention for the Protection of New Varieties of Plants, Paris, 2 December 1961, as revised in Geneva on 10 November 1972, 23 October 1978 and 19 March 1991 (Geneva, UPOV, Doc. 221(E), 1996) [hereafter UPOV-1991].
[41] Article 7 UPOV-1991, see note 40.
[42] Article 9 UPOV-1991, see note 40.
[43] Article 8 UPOV-1991, see note 40.
[44] Article 14.5 UPOV-1991, see note 40.
[45] Article 14 UPOV-1991, see note 40.

as long as they are not essentially derived from the protected variety. While the previous exceptions are compulsory, a set of further exceptions exists that has been progressively reduced over time. The so-called 'farmer's privilege' falls into this category. Under UPOV-1978 the rights of breeders were circumscribed in such a way that PBR did not interfere with farmers' use of the legally obtained protected variety for propagating purposes on their own holdings. Under UPOV-1991, the rights of breeders have been extended to the harvested material of the protected variety and the farmer's privilege has been made optional.

With regard to the duration of PBR, their first characteristic is that they are limited in time. The period of protection has evolved over time, but always with the idea in mind that the rights conferred expire at the end of a specific period of protection. Under UPOV-1978, the period of protection is for a minimum of 15 years. For vines, forest trees, fruit trees and ornamental trees, the minimum is 18 years.[46] UPOV-1991 extends the minimum period from 15 to 20 years. For trees and vines, the minimum is of 25 years.[47]

At first, PBRs were conceived as an alternative to patent rights, and it was accepted that the two kinds of intellectual property rights should be kept separate. Thus, under UPOV-1978, member states can only offer protection through one form of intellectual property rights.[48] The grant of a PBR pertaining to a given variety implies that no other intellectual property right can be granted to the same variety. Under UPOV-1991 this restriction has been eliminated and *double protection* is now allowed.

3.2.4 *Sui generis* protection systems[49]

Rationale of sui generis *protection*

The question of *sui generis* intellectual property right protection for plant varieties has become a matter of great importance following the adoption of the TRIPS Agreement. As a result of a negotiating compromise, TRIPS requires the introduction of plant variety protection in all member states, but it does not impose the introduction of patents. Article 27.3.b specifically requires all member states to 'provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'.[50] The introduction of the *sui generis* concept reflects two broad elements. First, a number of countries in the North and the South have rejected the compulsory introduction of plant patents. Second, negotiators did not manage to agree on one specific alternative to patents. As a result, TRIPS gives member states a wide margin of appreciation in determining how to implement their obligation to introduce plant variety protection.

The question of the introduction of plant variety protection is one that mostly concerns developing countries. Indeed, most developed countries had already introduced either plant patents or PBRs before the adoption of TRIPS. Developing countries that are members of the WTO were left with the choice of either adopting the existing regime proposed in UPOV or of devising their own plant variety protection system adapted to their specific situation. A few countries have joined UPOV since 1994, but the majority have decided to adopt their own plant variety protection laws. In a number of cases, these laws draw directly and significantly from the UPOV regime and generally most existing proposals introduce PBRs. In cases where PBRs are

[46] Article 8 of the International Convention for the Protection of New Varieties of Plants, Paris, 23 October 1978 [hereafter UPOV-1978].
[47] Article 19 UPOV-1991, see note 40.
[48] Article 2 UPOV-1978, see note 46.
[49] Author: Philippe Cullet.
[50] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh, 15 April 1994, reprinted in 33 I.L.M. 1125 (1994) [hereafter TRIPS Agreement].

adopted only as one part of the regime, the regime is completed by the introduction of a form of farmers' rights. In fact, existing *sui generis* options can be generally defined as regimes introducing PBRs and farmers' rights.

Country examples of sui generis *protection*

The prominence of the UPOV Convention in the debates concerning *sui generis* plant variety protection is partly linked to the fact that the interpretation of the concept of an 'effective' *sui generis* system in Article 27.3.b TRIPS remains problematic. The only generally agreed-upon interpretation is that UPOV is an effective *sui generis* protection regime under TRIPS. This has led to some countries, such as the member states of the African Intellectual Property Organization, simply adopting a regime modelled after UPOV-1991 and at the same time committing themselves to joining the UPOV Convention.[51]

Some countries, such as, India have decided to implement plant variety protection regimes that seek to provide protection to commercial plant breeders and to farmers. Thus, the Indian plant variety protection regime introduces both PBRs and farmers' rights. While a number of countries have attempted to draw up their own *sui generis* plant variety protection regimes, African states have taken a unique initiative in adopting a Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources at the level of the Organization of African Unity (OAU).[52]

The African Model Legislation is premised on the rejection of patents on life or the exclusive appropriation of any life form, including derivatives. Its provisions relating to access to biological resources make it clear that the recipients of biological resources or related knowledge cannot apply for any intellectual property right of exclusionary nature. The model legislation mainly focuses on the definition of the rights of communities, farmers and breeders. The community rights that were recognized include rights over their biological resources, and rights to their innovations, practices, knowledge and technology, and the right to benefit collectively from their utilization. In practice, these allow communities the right to prohibit access to their resources and knowledge, but only in cases where access would be detrimental to the integrity of their natural or cultural heritage.[53] Furthermore, the state must ensure that at least 50% of the benefits derived from the utilization of their resources or knowledge are channelled back into the communities.

In this legislation, the rights of farmers are slightly more precisely defined. They include the protection of their traditional knowledge that is relevant to plant and animal genetic resources, the right to an equitable share in the benefits arising from the use of plant and animal genetic resources, the right to participate in making decisions on matters related to the conservation and sustainable use of plant and animal genetic resources, the right to save, use, exchange and sell farm-saved seed or propagating materials, and the right to use a commercial breeder's variety to develop other varieties. The breeders' rights defined under the model legislation generally follow the definition given in the UPOV convention and the duration of the rights is, for instance, modelled after UPOV-1991.

One specific feature of the plant breeders' rights regime under the model legislation is the rather broad scope of the exemptions granted. Exemptions to the rights of breeders include the right to use a protected variety for purposes other than commerce, the right to sell plant or propa-

[51] See Agreement to Revise the Bangui Agreement on the Creation of an African Intellectual Property Organization of 2 March 1977, Bangui, 24 February 1999.

[52] African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000).

[53] Article 20 of the African Model Legislation, see note 52.

gating material as food, the right to sell within the place where the variety is grown and the use of the variety as an initial source of variation for developing another variety.[54]

In summary, the development of *sui generis* plant variety protection is still in its infancy. Until now, efforts have been made by developing countries to balance their obligations under Article 27.3.b of TRIPS with their specific needs and conditions. Since UPOV is the only model that is generally recognized as fulfilling the criteria of an 'effective' *sui generis* plant variety protection regime, a number of states that have not had the time or resources to devise a completely separate *sui generis* protection regime have decided to take this as a basis for a plant variety protection regime. On top of the PBR system, there seems to be a growing trend towards recognizing farmers' rights and providing for different compensation mechanisms (benefit-sharing). Other *sui generis* protection regimes will probably be developed in future years, particularly by least developed countries, who have had until 2005 to implement their plant variety protection regimes. Furthermore, even countries that are classified as developing countries may amend their legislation over time, as further *sui generis* models evolve. *Sui generis* protection is evolving and significant innovations can be expected in years to come.

3.3 Impacts on Existing PGR, Landraces and TK[55]

The progressive strengthening of intellectual property rights has already had significant repercussions in a number of countries on the management of existing PGR and TK. A number of 'problems' have surfaced between developed and developing countries, mostly linked to the different levels of intellectual property protection in these countries. These different levels of protection have led to a number of instances of appropriation of PGRFA and/or knowledge without compensation. These unidirectional flows of plant resources and knowledge are today often referred to as 'biopiracy', a concept that does not have recognition in international law, but conveys the sense of frustration of a number of developing countries with reference to existing legal arrangements (Odek, 1994).

The cases of appropriation without compensation must be understood within the context of the evolving international legal framework in the field of PGR. First, the appropriation of biological resources is governed by the principle of state sovereignty. The case of PGR is slightly more complicated: for several decades, PGR were considered as a common heritage of humankind and were therefore freely shared and distributed to all actors seeking access. At the international level, the CGIAR and its Centres constituted the vehicles for the implementation of this principle, and in particular with a view to fostering food security at all levels within developing countries. Over time, there has been increasing recognition of countries' rights over their PGR, and the ITPGRFA now sanctions states' sovereign rights over the PGRFA (ITPGRFA, preamble, 2001; see Section 2.3.2).

Secondly, the TRIPS Agreement now provides the minimum standards of intellectual property right protection that all WTO member states must introduce. However, TRIPS is implemented in each WTO member country through domestic intellectual property laws, which may differ significantly between countries. Divergences may stem from the different use of flexibility clauses provided in TRIPS. They may also be linked to the fact that countries can decide to provide standards of protection that go beyond the minimum levels required in TRIPS. There is therefore ample scope for divergences in levels of protection between different WTO member countries.

[54] Article 43 of the African Model Legislation, see note 52.
[55] Author: Philippe Cullet.

Further, there remain a number of countries that are not members of the WTO and are therefore not bound by the TRIPS Agreement. The differences in levels of intellectual property rights protection and other differences between domestic intellectual property laws provide the background to some of the problem cases highlighted in this section.

Thirdly, as noted above, the international legal system has already reacted to the problem of uncompensated appropriation by progressively developing the concept of benefit-sharing. Benefit-sharing is clearly a response to the existence of different levels of intellectual property protection in different countries and the fact that PGR-rich countries lost control over the germplasm they contributed to the CGIAR system.

3.3.1 Case studies

The turmeric patent

In this case, Suman K. Das and Hari Har P. Cohly, two researchers based at the University of Mississippi Medical Center in Jackson, Mississippi, USA, applied for a US patent on the use of turmeric in wound healing (US Patent No. 5,401,504). More specifically, the application related to the use of turmeric to augment the healing process of chronic and acute wounds. The inventors claimed to 'have found that the use of turmeric at the site of an injury by topical application and/or oral intake of turmeric will promote healing of wounds'. This was based on experimental evidence that showed that turmeric causes endothelial cells to proliferate, indicating that this molecule can be used to augment wound healing. The patent application acknowledged that 'turmeric has long been used in India as a traditional medicine for the treatment of various sprains and inflammatory conditions'.

The specific claims of the inventors were:

1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient.
2. The method according to claim 1, wherein said turmeric is orally administered to said patient.
3. The method according to claim 1, wherein said turmeric is topically administered to said patient.
4. The method according to claim 1, wherein said turmeric is both orally and topically administered to said patient.
5. The method according to claim 1, wherein said wound is a surgical wound.
6. The method according to claim 1, wherein said wound is a body ulcer.

Turmeric is one of the most basic ingredients found in Indian households and, besides its use in cooking, its antiseptic properties are widely known. The Indian Council of Scientific and Industrial Research (CSIR) therefore challenged the patent on the ground that the alleged invention was actually part of public domain knowledge in India. The patent was re-examined and all the claims cancelled.

The turmeric patent is noteworthy for two reasons. First, the turmeric patent highlighted one specific limitation of US patent law, in an era where inventions patented in the US can originate in any of the five continents. This relates to the interpretation of prior art in US law. 35 USC § 102 makes a distinction between anticipation in the US and in other countries. Thus, traditionally, prior art in foreign countries has only been recognized if it is described in a printed publication (*Hurlbut vs Schillinger*). In this case, printed materials were available but may not have been presented to the patents officer. Secondly, the turmeric patent provides important lessons in the context of the development of access regulations and TK documentation. This case provided a clear example of how difficult it can be to contest a patent abroad even for a large institution like the CSIR. As a result, there has been increased awareness of the need to document knowledge that is in the public domain and make it sufficiently available

so that patent offices around the world check claimed inventions against existing sources of information.

The neem patents

The neem tree, which is a widely planted tree in India, has various uses in Indian households and in agriculture. In particular, farmers have long used leaves from the neem tree to make effective pesticides. In recent decades, the properties of the neem tree have been the object of substantial attention and large-scale research has been carried out to turn some of the neem's properties into commercially viable products (National Research Council, 1992).

Attention has focused specifically on the uses of neem as a biopesticide, because of the commercial potential in this area. The challenge has generally been for manufacturers to extract the active properties of the neem and to find a way to increase the shelf life of the product. Indeed, one of the characteristics of the natural formulation is that the preparation lasts only a few days, thus making commercialization of the leaf extract an impossibility.

A number of neem-related patents have been filed in the US and in Europe by Indian and foreign companies and inventors. Their common characteristic is that the patents generally claim novel processes for making a neem-based or neem-derived pesticide and the resulting product (e.g. US Patents 5,827,521 and 5,885,600). Even though a number of patents have been filed, one patent claiming a method for long-term storage of the active pesticidal ingredient (azadirachtin) became the centre of vigorous debates. In the early 1990s, the United States Patent and Trademark Office issued a patent to W.R. Grace, which covers a method of creating a stabilized azadirachtin in solution and the stabilized azadirachtin solution itself (US Patent 5,124,349). Subsequently, the US Environmental Protection Agency registered Grace's stabilized azadirachtin solution for use on food crops under the name of Neemix (Wolfgang, 1995). W.R. Grace also filed a patent for neem for its use as an antifungal product with the EPO (European Patent 0436 257). This patent claimed the invention of a novel insecticide and foliar fungicide derived from a neem seed extract and the processes used to obtain the neem oil. This pesticide was alleged to have the ability to repel insects from plant surfaces, prevent fungal growth, and kill insect and fungal pests at various life stages. This patent was challenged by Indian NGOs and the Indian Government. Eventually, in 2000, the Opposition Division of the EPO revoked the patents after it was shown conclusively that the claims did not fulfil the requirement for novelty in view of their prior public use in India.

A number of interesting lessons can be learnt from the neem patent cases. First, while one specific patent was revoked in Europe, this has not affected the standing of other similar patents, since each and every patent must be opposed separately. Secondly, the neem patents constitute much less direct cases of appropriation of knowledge than do the turmeric patent. This is due to the fact that it is impossible to commercialize the solution that has traditionally been used as a pesticide in India. Drawing a line between appropriation of TK and novelty in the context of existing patent laws becomes a very difficult exercise. Thirdly, some of the neem patents may have practical implications in India, since the patented solutions require neem tree seeds as their primary material. The need for vast quantities of neem seeds may constitute a positive commercial opportunity for some people. Fourthly, it is striking that a number of neem-related patents have been filed by Indian citizens or companies. This clearly shows that the question of the appropriation of TK through patents is not exclusively a North–South issue nor one determined by political boundaries. From the point of view of TK, it is in fact immaterial whether the application is filed by an Indian or a foreign company.

The kava case[56]

Kava (*Piper methysticum*) is an indigenous plant from islands in the South Pacific, where it is commonly used to prepare a traditional drink for both ceremonial and medicinal purposes.

The kava plant is a large shrub that can reach heights of up to 15 feet. It has green, heart-shaped leaves with stems that can be green, red-and-black striped or spotted. Kava is cultivated in the South Pacific, including the Federal States of Micronesia (Lebot and Lévesque, 1989).

People started to use a wild form (*P. wichmanii*) of the kava plant about 3000 years ago, which was later domesticated in the Pacific Islands of Vanuatu. Later on, the plant spread to other islands in the Pacific.

Traditionally kava has been used in two different ways, one of which is related to a ritual that uses kava as a relaxant. Several nations in the Pacific islands follow a ritual in which kava is used as a ceremonial and social drink (WIPO, 1998–99). Kava has also been used traditionally as a medicinal plant in the region (Lebot *et al.*, 1992). It has been used to treat stress, anxiety, insomnia, muscle and back pain, tension headaches, menstrual pain, asthma, the common cold, urinary infections, stomach problems and other maladies. Once planted, the cultivation of kava requires little labour or capital investment. The kava roots continue to grow perennially, and gardens and plantations are usually passed down through the generations.

The protection of kava has not been achieved through patents. Kava does not have the inventive character required by patents. Furthermore, it cannot be considered patentable if it is already well known to the public. Presently, no Pacific island country has plant patent laws, but even if such laws were to become available, no variety of kava could be patented (Clark, 1999).

Despite patents not being sufficient for the protection of the kava plant and related traditional knowledge, patents have been granted to some companies in order to explore kava. An example in the USA is the patent granted to Natrol, Inc., a US-based company that obtained a US patent for 'Kavatrol', a dietary supplement that serves as a general relaxant, composed of kava, chamomile, hops and schizandra. (Downes and Laird, 1999). In Europe, two German companies, William Schwabe and Krewel-Werke, have patented kava as a prescription drug for treating strokes, insomnia, Alzheimer's disease, and so on. In France, L'Oreal has patented the use of kava for hair loss and to stimulate hair growth.

The existence of patents based on kava raises concerns about the conservation and protection of traditional knowledge related to kava. First, the commercialization of kava-based products has had a negative impact on its conservation. In particular, the increasing exploitation of the plant has led to the harvesting of immature kava, thus jeopardizing the quality of the medicinal product and reducing its resource base (Puri, 2002). Secondly, patents granted which exploit medicine that has already been developed and used for generations by local communities constitute a case of appropriation of traditional knowledge.

In the kava case, patents cannot provide protection for traditional knowledge. In this regard, the need remains to examine other potential instruments of intellectual property rights as tools to protect traditional knowledge, such as geographical indications and trademarks.

3.3.2 Proposed solutions[57]

Biodiversity registers

The progressive appropriation of TK through patents has fostered concerns in source countries over their possible loss of control over plant genetic resources and related knowledge. One of the reactions to cases like the turmeric, neem and kava cases has been the development

[56] Author: Andrea Nascimento Müller.
[57] Author: Philippe Cullet.

of biodiversity registers. Such registers generally seek to document existing knowledge in order to prevent unwarranted patent claims from being accepted by patent offices around the world because they do not have access to TK databases. The registers also provide a tool for asserting benefit-sharing claims in situations where a patented invention is directly derived from TK (Rangachari and Subbarav, 1998).

Most biodiversity registers have been conceived as open documents that are meant to foster better access to existing TK. This may encourage the sharing of knowledge amongst different unrelated communities, which may be beneficial from the point of view of the sustainable management of local resources. In cases where knowledge is directly attributable to an individual or community, the registers provide a tool to establish claims of original ownership. The registers also indirectly constitute an attractive source of information for researchers seeking to build on TK. They therefore provide an incentive for commercial research into TK and at the same time a means to ascertain public domain knowledge and a tool for holders of TK wanting to claim benefit-sharing (Gadgil, 1997).

The approach that seeks to make biodiversity registers open to all and to foster outsiders' use of the registered knowledge is not always accepted. In some situations, individuals or communities may either decide not to register their knowledge in a written form, or may register it but not give access to outsiders. The village of Pattuvam in the south-west state of Kerala in India took the latter approach when it decided to document all its biological resources and TK but decided not to make the results available to outsiders. In this case, the promoters of the register wanted to provide documentation of public domain knowledge but did not consider that this knowledge should be freely offered to the outside world for further use. Interestingly, the register is closed so as to avoid appropriation by outsiders, but the possibility of sharing knowledge with other local communities is recognized.

Benefit-sharing

The notion of benefit-sharing has largely been developed as a consequence of the development of genetic engineering and its increasingly frequent use of TK for the development of other products. In fact, there is increasing recognition that the commercial use of TK in a direct or derived form should be compensated in one form or another. In practice, benefit-sharing can give rise to a number of important questions, as illustrated in the case of Jeevani medicine.

Jeevani was developed after the Kani people of southern Kerala were persuaded by biologists from the Tropical Botanic Garden and Research Institute (TBGRI) to share some of their knowledge concerning a plant called *Aarogyappacha* (Anuradha, 1998). The biologists were intrigued by the strong anti-fatigue properties of the plant's leaves. Though widely used by local people, the plant itself seems to have been unknown to outsiders until 1987. The TBGRI carried out research on the plant and, after identifying the active ingredients of the plant, developed a drug with anti-fatigue properties. The rights to manufacture Jeevani were transferred to a private manufacturer for a licence fee of about US$21,000 (at today's exchange rate) for 7 years and a 2% royalty on sales for 10 years (TBGRI – Arya Vaidya, 1995). TBGRI decided to give 50% of the fee and royalty to the Kanis (Ministry of Environment and Forests, 1998). It is significant that while patent applications were made by TBGRI, no patent was granted in India, because the Indian Patents Act did not allow such patents at the time.

This benefit-sharing arrangement is very progressive from a financial point of view. However, it has not been immune to criticism. First, while the section of the Kani tribe that had had significant interactions with the outsiders – including the specific individuals who passed on the information to the scientists and were rewarded with special financial rewards – were generally happy with the benefit-sharing arrangement, other segments opposed

it. This is partly due to the fact that some factions of the tribe felt that they were not involved in the negotiating process and were handed down a decision without proper consultation. This raises an issue concerning the prior informed consent of the providers of knowledge. Secondly, benefit-sharing in the form of money may not be the most desirable form of contribution to the local economy. This aspect is highlighted in this case, because the Jeevani medicine can only be produced from leaves of the tree if it is grown in the area where the Kanis live, and not elsewhere. The Kanis could therefore have been given a stake in the production of the raw material for the medicine, a much more stable and substantial form of benefit-sharing (Gupta, 2001a).

The Jeevani case study highlights issues of broader relevance for benefit-sharing. First, benefit-sharing is not limited to transfers of knowledge between different countries. Secondly, the trigger for benefit-sharing is not necessarily the appropriation of knowledge through intellectual property rights, but is generally the commercialization of TK products or products derived from TK. Thirdly, monetary compensation, however attractive it may be as a form of compensation, may neither be the most effective nor the most appropriate way to reward the contribution of specific knowledge to the commercialization of a new product.

Local innovation

The increasing appropriation of knowledge – whether based on TK or not – through intellectual property rights has often led to attempts to preserve existing rights and to avoid or regulate transfers. In some cases, however, there have been initiatives aimed at using the existing intellectual property right system for the benefit of TK holders. The basic idea behind this is to provide a form of recognition for inventions and creativity that may not qualify for patent protection, but which constitute advances in the specific field of activity.

One such experiment is that of the Honey Bee Network in the state of Gujarat, India (Gupta, 2001b). Honey Bee seeks to foster knowledge dissemination among local communities and in the wider world. The specific approach behind this experiment is that rather than putting shared knowledge into the public domain, the information is clearly titled to the individual holder or inventor. In other words, Honey Bee seeks to provide incentives and benefits to innovators to foster information dissemination. Institutionally, this has been achieved through the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI; for general information on SRISTI, see http://www.sristi.org).

Honey Bee's work comprises a variety of different components. An important part of its work is the documentation of innovations, either of contemporary origin or based on traditional knowledge. The databases now include about 10,000 innovations. Since 1997, Honey Bee databases have also formed the basis for the commercial use of documented innovations. The Gujarat Grassroots Innovation Augmentation Network (GIAN) has been set up specifically to provide an interface between innovations, investment and entrepreneurship. The GIAN has helped to file patents on behalf of grassroots innovators and helped with the transformation of innovations into products that can be commercialized.

More recently, the Honey Bee model has been expanded and a National Innovation Foundation (NIF) has been set up by the Department of Science and Technology of the Government of India (for general information on NIF, see http://www.nifindia.org). The main goal of the NIF is to provide institutional support in the scouting, spawning, sustaining and scaling up of grassroots innovations and to assist in their transition to self-supporting activities. Furthermore, the NIF seeks to strengthen R&D linkages between excellence in formal and informal knowledge systems in a bid to help India become a global leader in sustainable technologies.

3.3.3 Problem analysis

The progressive interest in the exploitation of PGR and related changes in intellectual property laws have important practical and policy implications in a number of developing countries. The development of commercial products based on TK can have beneficial impacts for different actors in different countries depending on the specific situation and the legal framework in place. The Jeevani case illustrates a situation where TK is appropriated by a governmental body and then sold on to a private company of the same country. In this case, the commercialization of the medicine has the potential to benefit the national economy without any international implications. Concerns related to the control of TK and benefit-sharing are, however, similar, whether the situation is one where all the transactions happen within a given country or involves an international element. In both cases, there is a need for a legal and policy framework to regulate the appropriation and use of TK outside its area of origin.

The use of TK in commercial applications by outsiders raises even more complicated issues when intellectual property protection is sought for products derived from TK. In this situation, a number of specific problems arise. Even in the TRIPS era, different countries have different levels of intellectual property protection and, for the foreseeable future, it is likely that the level of patent protection in recipient countries such as the USA and Western European countries will remain much higher than in most developing countries. This implies that it will remain 'easier' to apply for some types of patents in the USA than in India, even when the latter introduces product patents on biotechnological inventions in all fields of technology. One of the consequences of this asymmetry is that an opposition to such a patent can be filed only from outside the country of origin, as in the case of the turmeric patent outlined above. Further, in the case of the US patent system, there is the added difficulty concerning the proof of prior Article. This difficulty will slowly reduce over time as the number of registers of TK increases around the world and as an increasing number of registers are uploaded onto the Internet.

The patentability of products derived from TK raises complicated policy issues at the international level. One of the problems is that appropriation does not follow a single path. In fact, as is illustrated in the case of the neem patents, while a majority of patents in Europe and the USA on TK-derived products may be owned by companies from the North, applications from the countries of origin are also prominent. In other words, the problem of 'biopiracy' is not limited to a North–South issue, but is also replicated at the national level or in relations between different developing countries. The international community has started to address two specific problems linked to the appropriation of TK through intellectual property rights. The question of prior informed consent (PIC) comes first in line. Article 15.5 CBD and the guidelines adopted at COP 6 clearly recognize the need for PIC, but this has not yet been implemented, either at the international level or within the national legislation of donor countries. The second issue is that of benefit-sharing, which is addressed in the CBD guidelines and in the ITPGRFA; however, both at the international and national levels, the scope and impact of these provisions is yet to be established in practice.

One of the most common reactions to TK appropriation in developing countries has been the fostering of the development of biodiversity registers comprising records of PGR, PGRFA and knowledge related to these resources. This remains on the whole a reaction to international trends, which seeks to prove the existence of knowledge already in existence, but does not provide an avenue for asserting claims of ownership over the resources or knowledge. Some initiatives, such as the one taken by the Honey Bee Nework, indicate that there can be other ways for developing countries to react to the expanding scope of intellectual property rights at the international level.

3.3.4 Impacts on PGR diversity

The direct impacts of intellectual property rights on PGR diversity are difficult to estimate since in most cases there is no direct impact. At the outset, the distinction between the impacts on PGR diversity and the impacts on TK must be clearly delineated. The latter relates to the impacts of intellectual property rights on the use of PGR and ownership of TK, while the former focuses on PGR conservation and management.

Intellectual property rights do not have direct impacts on PGR conservation and management because they do not directly deal with the issue of biodiversity conservation and do not address the question of the ownership of biological resources themselves. However, they are relevant in PGR management because the introduction of patents in agricultural biotechnology has, for instance, important impacts for agricultural management, and hence agro-biodiversity conservation.

The experience of developed countries that introduced plant breeders' rights and/or plant patents earlier does not provide many useful analogies, insofar as their socio-economic conditions were vastly different from the conditions under which a vast majority of developing countries operate today. However, it is possible to get a general idea of some of the possible impacts of the introduction of intellectual property rights in agricultural biotechnology by looking at the experience of the Green Revolution in Asian countries.

In effect, the practical impacts of hybrid varieties of the past and the genetically modified seeds of the present are largely similar if one excludes the specific biosafety concerns linked to the latter. Both seek to provide yield increases and both often require agricultural management techniques that largely differ from traditional practices by necessitating a number of external inputs, such as irrigation or chemical fertilizers.

A general assessment of the Green Revolution indicates that areas where high-yielding varieties were introduced witnessed significant yield increases (in the case of India see, for example, Sharma and Poleman, 1994). However, despite these gains, the Green Revolution package has come under increasing criticism since the beginning of the 1990s. First, over the long term, the Green Revolution has come to be associated with significant environmental costs. These include falling water tables due to the overuse of tubewells (Bavadam, 2000), waterlogged and saline soils from many large irrigation schemes, declining soil fertility with excessive chemical fertilizer use and water pollution with pesticides (Dhaliwal and Dilawari, 1991; Agarwal, 1995). The Green Revolution has also been associated with the spread of monoculture, which leads to a homogenization of species, greater vulnerability to insect pests and diseases, and to a loss of agro-biodiversity (Thrupp, 2000). Secondly, the sustainability of yield increases has been questioned in view of evidence of diminishing returns in intensive production with new varieties (Conway and Barbier, 1990). Thirdly, the application of the new technique necessitates important investments in seeds, fertilizers, pesticides and irrigation, which are beyond the reach of all but the largest farmers (Joshi, 1992). Indeed, new varieties perform well only when all the necessary inputs are available in sufficient quantities (Conway and Barbier, 1990). Thus, irrigation is often necessary, given that crops may fail if water is not provided in sufficient quantity at the opportune time. Uniformly produced seeds may also not be as well adapted to local conditions as farm-produced seeds. Furthermore, new seeds tend to be much more expensive than farm-saved seeds (Kahama, 1995).

The long-term implications of the Green Revolution for PGR diversity have only been moderately positive, since uniformity or monoculture generally leads to a loss of agricultural biodiversity. It is likely that this situation will be repeated with genetically modified varieties, with the added concerns about unwanted dissemination and contamination of biodiversity by the latter varieties. In both cases, a broader assessment of the impacts of the

introduction of new varieties must take into account not only the increased yields, but also the sustainability of the increases and the negative impacts on diversity. The main distinction is that in the case of the GMOs, the legal incentive for their development is provided in large part by IPRs.

3.3.5 Impacts on TK

Intellectual property rights undeniably have important impacts on TK. First, they foster a more commercial approach to the question of TK use. In other words, they foster a new outlook on TK that mainly focuses on the uses of TK that have commercial potential. Secondly, intellectual property rights provide an incentive for registering TK. This is becoming increasingly necessary in view of broader economic changes at the national and international levels which lead to the progressive erosion of TK. Thirdly, the direct and indirect appropriation of TK has increasingly led to the realization that procedures for access are imperative, given the important commercial stakes. As a result, there has been increasing pressure at the international and national levels for the development of a legal regime to regulate access to TK and to allocate the benefits accruing from products derived from TK.

The progressive appropriation of TK through intellectual property rights also has an impact on the ownership of TK. In fact, this is probably the most crucial aspect from a legal point of view. The main impact of the introduction of IPR over TK-related inventions is that TK itself cannot be protected through IPR and is therefore in the public domain. Further, TK generally does not qualify for patent protection because TK itself is not deemed to be 'state-of-the-art'. In general, intellectual property rights over TK-related inventions foster a shift in control from TK holders towards intellectual property rights holders. In fact, it is this shift in property rights in favour of new holders that has led individuals, organizations and governments to challenge patents, such as the turmeric patent (Anuradha, 2001). It is noteworthy that the practical consequences of the turmeric or neem patents for original TK holders are likely to be insignificant, at least in some cases. Thus, in the case of the turmeric patent, the existence of a patent in the USA would not have had any practical consequences for everyday users of turmeric as a healing agent throughout India, where it was not recognized.

3.3.6 Tension between IPR and competition

This section shall introduce the interrelationship between IPR and competition laws and policies. This interaction is relevant when it comes to assessing the scope of protection of IPR in the light of public policies aimed at promoting economic efficiency and the diversity of supply of protected goods and services. Intellectual property forms of protection grant exclusive rights that come close to monopoly rights. This can trigger tensions with competition laws and policies. The interactions between competition and IPR become even more complex on the international level. As illustrated in the case studies above, legal issues concerning TK related to PGR present in general strong cross-border characteristics. It is therefore necessary to deal with these issues not only at the national but also at the regional and global levels. There are a variety of different legal approaches towards competition, ranging from an absence of specific legislation via lax law to very strict and incisive rules with effective sanction mechanisms. In comparison to competition laws and policies, the international intellectual property system appears to be much more harmonized, in particular through the set of TRIPS rules that ensures minimum standards of protection. This higher degree of harmonization of intellectual property rights does not only concern procedural and substantive rules, but also the institutional design that serves to implement them such as public registries, specialized courts and collecting societies. In contrast, procedural and substantive competition rules are mainly national or, as in the case of the European Community,

regional.[58] The same applies for the institutional framework.[59] There are initiatives to promote multilateral cooperation in the field of competition in the OECD, the UNCTAD (United Nations Commission for Trade and Development), and more recently in the World Trade Organization (WTO).[60] A strong link between international competition and international trade laws and policies is obvious when anti-competitive private business practices have the effect of replacing traditional tariff and other non-tariff barriers to foreign markets after they have been removed by international trade rules (Kennedy, 2001). Possible approaches in the WTO consist of elaborating harmonized minimum competition policy standards (e.g. the TRIPS approach) or an agreement on core competition principles.[61] However, for the time being, there is no consensus on the question of whether the WTO should deal with this matter, and, if so, in what manner.

As described above, in the long term the Green Revolution has been detrimental to PGR diversity, as it has, in many instances, caused uniformity and monoculture and, thus, a loss of agricultural biodiversity. This development was partly caused by the absence of appropriate competition laws and policies. To address this risk, the impact on the competitive environment must be carefully taken into consideration when new forms of IPR are introduced. Lawmakers are therefore well advised to adapt also the competition laws when using intellectual property to achieve policy goals. Patent laws, for example, trigger contractual practices among the concerned economic players. These contractual arrangements may be reasonable and legitimate for private business purposes, but can be problematic for the achievement of policy goals in the public interest. Concretely, there are contractual practices that are necessary to cope with constraints induced by IPR that can qualify as anti-competitive behaviours. In the case of sequential inventions, for example, patent licence agreements help to overcome certain deadlock situations by structuring the relationship between primary and secondary innovators. The following section will discuss the questions of contractual arrangements that are based on IPR and their impacts on competition.[62] The last section will illustrate in further detail the issues at stake in the light of the example of the seed industry, where the introduction of IPR to promote private investments eventually contributed to building up a highly concentrated industrial sector dominated by a few big players. This example outlines how the instrument of intellectual property forms of protection may fail to reach public policy goals in the absence of appropriate competition laws and policies.

Contract arrangement among sequential innovators[63]

Overly broad patent protection can stunt or slow the pace of future innovation. The scope of patent protection refers to both breadth and height. The *breadth* of a patent defines the range of products that are encompassed by the patent claims, which protect the patent holder against potential imitators or closely similar inventions. The *height* of the patent confers protection against improvements or applications that are easy or trivial. The broader the scope of

[58] For a summary on different national and regional approaches in the area of competition law and policy, see Kennedy (2001, p. 22 ff.).

[59] With respect to the institutional design of US competition institutions and the complexities of their interactions, see Peters (1999, pp. 40–67).

[60] See Kennedy (2001) at p. 97 (overview of OECD guidelines); p. 110 (Draft International Antitrust Code); p. 118 (UNCTAD principles on restrictive business practices). This author outlines the arguments in favour of and against the integration of competition rules into WTO law, and comes to the conclusion that the WTO is not the appropriate forum to deal with this matter, in view of the very different legal approaches that exist between the countries in this field, for the time being.

[61] For further references, see the WTO website: http://www.wto.org/english/tratop_e/comp_e/comp_e.htm

[62] For an overview on policies that may be pursued by antitrust legislation, see First (2002, pp. 175–194).

[63] Author: Gloria Pasadilla.

the patent protection, the higher the degree of monopoly power; but conversely, the narrower the patent, the lower the incentive for the innovator. The question is, what is the optimal level of scope for society? The issue is how to balance the incentives, particularly in the case of *sequential innovations*, between the primary innovator and secondary inventor (those who introduce improvements that may have better industrial applications). The same issue applies to related inventions that somehow infringe upon an initial discovery. Clearly, both deserve some rewards because, for instance, without the initial invention, without its disclosure and knowledge spillover, the secondary innovation would not come about. Conversely, there are primary innovations that initially do not have significant applications, and whose value actually derives from the values of the secondary innovations built upon them. The problem concerns how to design an optimal contract that provides incentives for both.

This is an important issue because all technological advancement is the result of a combination of both primary and subsequent improvements of initial discoveries: hence all innovations require some form of encouragement and incentive at different stages. Having too broad or too narrow a protection can therefore stunt the growth of knowledge, either at subsequent stages or at the very font of discoveries itself. Consider a very broad protection of primary inventions. Barton (1997a) takes the example of a biological receptor, a research tool that is important for the study of schizophrenia, but may not be marketable in itself. If given a broad patent, the inventor of the receptor will have a monopoly over the entire research area, even without necessarily defining any marketable product that is of benefit to the public. From an economic efficiency standpoint, society does not lose out if the initial innovator also has a comparative advantage in the development of all related applications. However, if other innovators exist who have a better capacity to bring about the perfection of its application, then the broad patent that excludes better research companies implies an efficiency loss to society.

Obtaining a licence from the original innovator is one option for secondary innovators. The question arises as to when is the best time to negotiate. If *ex-post*, that is, after the secondary innovator has already invested in research, then his bargaining position is weak, because all his investments are already sunk (i.e. non-recoverable), while the original innovator has the option of refusing to grant any licence. This 'hold-up' problem, where all of the bargaining is on the side of the original innovator, can be solved through the imposition of compulsory licensing, perhaps invoking the 'essential facility doctrine'.[64]

If negotiations instead occur *ex-ante*, that is, before the secondary innovator has incurred sunk investment costs, then there is greater scope for a more balanced outcome. The secondary innovator's bargaining power is improved, making him less susceptible to a hold-up problem. But the nature of these contracts remains subject to possible competition challenges, as will be discussed below.

The joint venture agreement helps in the pooling and sharing of risks. Through joint ventures, researchers are allowed to proceed, and (if successful), rents are shared and divided up accordingly amongst the inventors. However, there is also the danger that joint ventures can function much like a cartel, deterring the entry of third-party innovators.

A 'dependency licence' for follow-on inventors is another possible arrangement (Barton, 1997b). This is akin to the situation pertaining to cross-licensing and grant-backs, whereby the follow-on inventor patent requires the authorization of the holder of the prior patent, and the original holder may not apply the same improvement without authorization by the holder of the follow-on inventor patent. This dependency licence essentially gives the follow-on innovator the right to obtain licences from the holder of the initial patent. It might require that a royalty is

[64] For an overview on the 'essential facility' doctrine under US and EC law, see Meinhardt (1996, pp. 137–160).

paid, but at least it significantly improves the secondary inventor's bargaining power and incentive. The royalties can either be determined in court or through negotiation.

Some basic principles for IPR and competition policy

Considering the number of possible contractual arrangements related to IPRs, not only between primary and secondary innovators, it is worthwhile gaining an overview of competition or antitrust aspects of these arrangements.[65] IPR can be viewed as conferring monopoly rights, whereas competition policy is concerned with the promotion of competition in the market; or it can be seen that competition policy is about short-run allocative efficiency and IPR about long-run dynamic efficiency. This fact appears to create an inherent conflict between governments' IPR and competition policies. It is true that competition policies may at times impose limits on market power of IPRs, but this conflict seems to be more apparent than real. In fact, the two instruments reinforce each other, because innovation is a spur to competition, and competition also acts as a spur to innovation.

Several market arrangements, including a variety of licensing techniques, help defray the short-run misallocations, e.g. from less than optimal use of the innovation, derived from exclusive IPR rights. They play an important role in further dissemination and utilization of the innovation. However, these arrangements can also be made into a front for anti-market activities, i.e. cartel activities. Such activities are examined briefly in the following section.

LICENSING

The granting of a licence allows the utilization of IPR by a non-patentee and promotes further innovation. A patentee may refuse to license, but if the IPR satisfies the 'essential facility doctrine', or if competition is severely threatened (for instance as is the case with mergers or abuse of dominant position), the patentee can be forced to grant a compulsory licence. In most cases the terms of the licence agreement depend upon the relative bargaining positions of the licensor and licensee. In general, licensing poses a greater competition risk if licensors and licensees are actual or potential competitors, or are in a horizontal relationship. Vertical relationships, on the other hand, or when a patent is an input to the production of another product, normally receive a more tolerant treatment by the competition authorities. However, some related agreements tied to licensing agreements have often fallen under competition scrutiny. Examples include licensee price restrictions, exclusive territories, exclusive dealing, grant-backs, reach-through royalties and tying arrangements.[66]

In most jurisdictions, the treatment of many licensing agreements has changed from being *per se* unlawful to one that merits a *rule of reason* approach. For instance, *exclusive territories* – where the licensor grants the licensee a monopoly over a particular territory by agreeing not to sell in the same territory, nor license anyone else who would operate in the same geographical market – may at times be anti-competitive, because this carves out markets among competitors. Yet often it may not be necessary for there to be any production of the licensed product at all. For example, in the *Maize Seed* case, the European court ruled that such an agreement between the INRA research institute in France and the Nungesser company in Germany was indispensable in order for the investment by the German firm to introduce the seed variety in Germany to be economically viable.[67]

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[65] See OECD (1998) and Anderson and Gallini (1998).

[66] See OECD (1989) for more detailed discussion on the different IPR and competition policy interaction.

[67] The contract was between Kurt Eisele, a German citizen, and INRA, but he transferred his rights under the agreement to his firm, Nungesser. Eisele agreed to register the varieties and arrange for their marketing in Germany. To encourage his investment, INRA promised Eisele that it would endeavour to prevent exports to West Germany from France (Korah, 1983).

Otherwise, their investment into the introduction and development of the seed variety would not have been worthwhile, if others could free ride on those initial costs by competing in the same market.

Exclusive dealing provides another example. This licensing agreement either prevents the innovator from transferring the innovation to the licensee's competitors, or prevents the licensee from purchasing its supplies from the licensor's competitors. The first can create a problem if the licence is transferred exclusively to a horizontal competitor in a concentrated market, particularly if this eliminates competition. Exclusive transfer to a firm that is vertically related to the innovator,[68] however, may create less of a competition problem. The second scenario has the effect of denying rivals sufficient outlets for exploiting their technologies, and thus has an adverse effect on competition. However, at the same time, this type of exclusive dealing may be the only way for the licensor to have control over the licensees, especially where it is difficult to determine how much a licensee uses up the technology *vis-à-vis* rival technologies. Noting that competition problems can arise on a case-by-case basis, exclusive dealing, like exclusive territories, is analysed under a rule of reason approach, rather than being considered to be a violation *per se*.

In an ordinary competition policy sense, *price restriction* tends to be viewed *per se* as being unlawful. Yet, in the context of IPR, licensee price restrictions may provide the incentive necessary for the innovator to license and thus permit the diffusion of the technology. The idea is that if the profit made through licensing would be less than the innovator's profit if he were to produce the product alone, then he would have no incentive to license. Hence, price restrictions may be considered to be one of the allowable restrictions that reasonably give the patentee the reward he is entitled to secure. But this again is scrutinized on a case-by-case basis, because not all licensing with price restriction is better than no licensing at all. In some cases, the negative allocative effects of price restriction may impose a greater economic cost than the positive benefits of diffusion.[69]

Grant-backs provide a method by which licensors seek to protect themselves against the possibility that licensing will foster the emergence and growth of future competitors. They allow the patentee some rights over improvements made by others upon his innovation. The economic justification behind allowing *bounded grant backs*, i.e. where the original licensor is not given an *exclusive* licence for any improvements to his innovation, is to give the original innovator an incentive to license. Bounded grant backs strike a middle course that ensures that the original licensor is not displaced from the market, while still leaving licensees with a significant motivation to innovate (OECD, 1998).

Reach-through royalties are royalties based on total sales. This is administratively simple, but is effectively similar to exclusive dealing arrangements in that it acts as a disincentive for using competing technology. Just like exclusive dealing, it is approached on a rule of reason basis. *Tying*, or linking the sale of patented products to the purchase of other goods (including goods whose patent protection may have lapsed), also has both pro- and anti-competitive effects. Tying has pro-competitive effects if it is necessary to secure the overall quality of the product, in the same way that car maintenance services tied to car sales can ensure a certain level of quality promised by the manufacturer. Hence, normal competition law applies a rule of reason standard in analysing such cases, but this may be prohibited if tying unnecessarily raises barriers to entry (similar to exclusive dealing agreements).

[68] A relationship is vertical when the IPR are complementary inputs (even if the licensor and licensee are otherwise competitors in manufacturing products covered by the IPR).

[69] See Gallini and Trebilcock (1998, p. 43).

MERGERS, ACQUISITIONS, PATENT POOL

Analysis of *mergers* of firms with significant IPR is carried out using standard merger analysis, i.e. the competition authorities consider dominant market positions and the potential impact on competition in the product market. But, in addition, they use the *innovation market approach*, which means that if mergers threaten to significantly reduce competition in the R&D market itself, then the mergers are in danger of being disapproved. This is the case, for instance, if the merged entities have less incentive to proceed quickly with innovation and R&D than is the case if they were separate entities. Some solutions can include compulsory licensing of one or the other of the IPRs, or the forcible spin-off of one R&D group in order to maintain competition in innovation.

Patent *acquisitions* are sometimes used to avoid costly licensing transactions. But if used to accumulate a '*killer patent portfolio*' to preclude any innovation around the main product, then there is scope for competition authorities to intervene. This is particularly true when firms monopolize a technology by not only obtaining patents on products and process which they intend to use and sell, but also patents which they intend to leave idle, thereby amassing a portfolio that it is difficult for competitors to innovate around. The usual solution for this type of acquisition is compulsory licensing.

Patent *pooling* is another useful arrangement, particularly if it puts into the same pool blocking patents. It helps in the efficient utilization of IPR and avoids costly infringement litigations. However, it can also function as a cartel-like arrangement for existing IPR holders, making it difficult for new entrants to innovate around any one existing patent in the pool. Per-use royalty of an IPR package from a patent pool can also increase the marginal cost of production. Patent pools can also act as a disincentive to future research, especially if any improvements to the existing IPR package are automatically shared between all of the patent pool members, thus giving rise to a free-riding problem. The useful rule of thumb to check whether patent pooling is efficiency enhancing is whether cross-licensing implicit in patent-pooling is necessary to compete at maximum efficiency (i.e. one firm cannot use its own technology unless it has a licence to use another IPR in combination with his own). Otherwise, the negative effects of patent pool may outweigh its positive effects.

IPR AND COMPETITION: THE CASE OF THE SEED INDUSTRY

This case study shall illustrate how intellectual property protection plays a role in affecting the market structure of an industry and derives competition implications from the changed competitive structure.

The seed industry market structure. There are about 1500 seed companies (Rabobank International, 2001); however, power is concentrated in only a few, with the top ten seed firms accounting for more than 30% of the roughly US$30 billion dollar commercial seed market. These seed companies specialize in the breeding and production of hybrid and improved crop seeds. Traditionally they have mostly been 'stand-alone' or independent firms, but with the advent of biotechnology, seed sales have become a crucial direct link for biotech firms, as they embody the input of genetic material into the agricultural production process. This is a fundamental reason behind biotech firms' vertical integration with the seed industry, as discussed below.

Prior to the merger frenzy in the mid-1990s, there was a wave of acquisitions approximately a decade earlier. The 1978–1980 period of mergers coincided with the strengthening of amendments to the US Plant Variety Protection Act. At that time, a number of observers identified a direct causal relationship between the strengthening of intellectual property rights and merger activity, as the IPR triggered expectations of increased earnings in the seed sector. However, whereas many of the acquiring firms in the 1980s' merger round were new entrants to the sector, the 1990s' round involved existing participants and high-profile multinational firms (Lesser, 1998).

Table 3.1. Key global players and their positioning in the seed market (Rabobank International, 2001).

Big league	Minor league	Niche players
DuPont (Pioneer)	Limagrain	Cebeco, Pau Euralis
Pharmacia (Monsanto)	Grupo Pulsar	Ball, Pennington
Novartis (Syngenta)	Sakata	DLF, Svalof Weibul
	Advanta (AstraZeneca)	Saaten Union, Sigma
	KWS	Ragt, DSV, Maisadour
	Delta & Pine Land	Barenbrug
	Dow Agro	
	Aventis	

This wave of consolidation has been thoroughly discussed elsewhere,[70] but what we shall provide here is a summary of the results of this series of acquisitions. It should be noted, however, that some of those acquisitions have been spun off a few years afterwards for a variety of reasons: (i) anticipated synergies might have failed to materialize; (ii) concerns over consumer acceptance of genetically modified organisms and thus, the underperformance of the biotech firms relative to pharmaceuticals, may have led to an increase in pressure from shareholders; and (iii) antitrust scrutiny of mergers might have had a deterrent effect.

Some of the basic features of the 1990s' merger round can, however, be highlighted. First, several large chemical and pharmaceutical firms moved into plant biotechnology, making huge investments in life sciences, and acquiring all of the large national seed firms (e.g. Pioneer, DeKalb, Agracetus, Mycogen, etc.). Some chemical and pharmaceutical firms merged horizontally (e.g. Rhône-Poulenc and Hoechst to form Aventis), then integrated vertically to seed breeding and marketing. The impact of this upon the seed industry is that the large set of small start-up firms which appeared in the 1980s had, by the end of the 1990s, either folded or been acquired by the new agronomic system's giants (Graff *et al.*, 2001).

Thus, in contrast to the diffuse structure in existence during the 1980s, the emergent industry structure now consists of a relatively small number of tightly woven alliances among pharmaceutical firms, biotech research firms and the seed industry. The life sciences industry has solidified to five–seven major firms that are highly vertically integrated and organized around a major life science firm (Table 3.1). These five major gene giants that dominate the life science industry are: Du Pont, Pharmacia (Monsanto), Syngenta, Aventis, and Dow. Together, they account for 60% of global pesticide market, 23% of commercial seed market and virtually 100% of the transgenic seed market (RAFI, September 1999).

As the seed industry became more concentrated, the share of biotechnology patents likewise consolidated on the few major companies. As a result of the wave of buyouts, the purchased firms' intellectual property rights came to be held by its 'mother firm'. Graff *et al.* (2001) found that the top seven seed firms own more than 80% of the total patents in agricultural biotechnology, whilst the three major ones held 55% of the total patents. DuPont and Pharmacia own a majority of all major types of patents: 38% of transformation technology patents, 31% of gene patents and 81% of germplasm patents, the latter merely reflecting the aggressive buyout strategies of these two firms in the seed industry. This

[70] See for instance, Barton (1998), Hayenga and Kalaitzandonakes (1999), Fulton and Giannakas (2001).

pattern raises concerns regarding potential entry difficulties for new firms in the agricultural biotechnology industry, as anyone trying to get in runs the risk of being blocked or considered to be infringing upon any of the biotech patents held by the major firms.

Thus, in both the product and innovation markets, the major firms have cornered a majority share, raising concerns of possible anti-competitive behaviour in the seed market and potential slowdown in the rate of agricultural biotechnology innovations.

Reasons for industry restructuring and the role of IPR. Noting that industry consolidation has led not only to concentration in the product market share (i.e. seeds) but also to concentration in the patents and specialized assets used for research and development in biotech, what was the motivation of giant firms in moving into the seed business? What role did intellectual property rights play in the seed industry transformation?

There are several competing reasons that may explain the restructuring of the industry. Some are unrelated (or only marginally related) to IPR, while others are centred on the intellectual property issue.

Non-IPR reasons. Strong demand complementarily between chemical and biotechnology products is one reason that might have motivated the amalgamation of seed and chemical companies. Consider a single firm producing both insecticides and pesticides and transgenic crops. Such a firm will be more profitable because it can price its products so that the use of the complementary product is encouraged. For instance, Monsanto tried a product-tying strategy when selling Roundup™ (a dominant herbicide with glyphosate as an active ingredient), with Roundup Ready™ crops which are glyphosate tolerant, to maintain their considerable market power in the glyphosate market (Hennessy and Hayes, 2000).

Innovation life cycle is another possible explanation for the consolidation exhibited by the agricultural biotechnology industry (Kalaitzandonakes and Hayenga, 2000). The idea is that it is typical that at the early phase of innovation – the fluid phase – that new entrants gain access, the total number of firms increases, and all of them engage in innovation and experimentation with product designs and operational characteristics. Over time, a specific product becomes the standard, and product innovation subsides, while process innovation may continue at lower cost. Finally, the rate of both product and process innovation dwindles. At each stage of the innovation life cycle, there is a corresponding change in the market structure. The number of firms peaks during the fluid phase and then eventually drops off to a few central players as the dominant design becomes established. The remaining firms emulate the features of the dominant product concept and compete on efficiency.

When applied to the agricultural biotechnology industry, Kalaitzandonakes and Hayenga (2000) note that the number of firms peaked in the early 1980s, as they competed in product innovation and various product forms, including transgenic plants and genetically engineered microorganisms. The dominant design emerged in the early 1990s – transgenic plants with a pesticide action – and consolidation began shortly thereafter.

Yet while the innovation life cycle appears to explain horizontal integration among firms engaged in biotechnology R&D, it does not sufficiently explain the vertical integration of pharmaceutical/chemical firms with seed companies.

IPR-related reasons. While non-IPR-related reasons may provide a partial explanation for the restructuring of the agricultural biotechnology industry, they raise sufficient questions to prompt a search for answers elsewhere. For instance, even as the innovation life cycle can explain horizontal mergers of R&D firms, it falls short of explaining the vertical integration in the life science industry. Thus, others have offered other explanations for the emergent market structure, which are directly related to intellectual property rights.

First, since IPR create monopoly power to its owner, a firm may want to erect barri-

ers to entry for potential competitors. This can be done by leveraging control over key intellectual properties to block potential imitation or minor innovation improvements (Lesser, 1998). By accumulating such blocking patents, the patent owner maintains its monopoly rents within a specific market and for a specific period of time. Thus, industry concentration can be motivated by the desire to control IPR, which results in the maintenance of a firm's monopoly power, and therefore provides an explanation for the industry consolidation.

Another reason why firms may want to accumulate patents by buying companies with IPR is to be able to use them as bargaining chips in negotiations with other firms. That is, knowing the high propensity of patent infringement in the biotechnology industry, having a number of patents give firms the necessary leverage or threat to sue back if they, in turn, are sued for infringement. Patent ownership then protects firms from rival patents or enables them to negotiate for the utilization of certain key technologies on an equitable basis (Joly and de Looze, 1996). Thus, what happens in a concentrated market structure where a few firms own most of the patents is an implicit cross-licensing among the firms (Barton, 1998). Without a sufficient number of potentially infringeable patents, a firm is more vulnerable to being sued for infringement by other companies.

A third IPR-related explanation for industry consolidation is the economies of scope in research or the desire to exploit complementarities in the use of specialized assets in biotech R&D. Graff *et al.* (2001) argue that the mere desire to accumulate patents to block entry would have led to an increase in the sheer number of owned patents, rather than in an increased diversity of patents. Since the increased industry concentration shows that major firms have accumulated not only a greater number of patents but also a more diverse one, an explanation can be found in the mutual complementarities of these assets. For example, the isolation of a gene leading to a gene patent will have a greater value if there are enabling technologies to use these genes; or if the firm owns a large array of elite germplasm into which those genes can be inserted. This explains the vertical integration of many biotechnology firms into the seed sector, as superior germplasm were essential complementary assets for agro-biotechnology.

The question is: why were so many mergers necessary for the exploitation of complementarities, when other possible contractual arrangements, such as licensing or joint ventures with the seed companies, exist? The fourth IP-related explanation relies upon the low appropriability of intellectual property rights in biotechnology and high transaction costs in contractual arrangements to provide an explanation for industrial consolidation in the agro-biotechnology industry.

The high transaction costs in licensing arrangements are due to the value allocation problem from these arrangements. Since firms do not know completely the full potential utilization of the resulting innovation, it is difficult to establish the correct cost and benefit sharing arrangement. Because of the difficulty of arriving at optimal licensing contracts, an acquisition alternative is thus often preferred.

Low appropriability of intellectual property rights and significant patent overlap comes about when firms have similar technology profiles. The weak differentiation of profiles is, in turn, due to the large size of a common knowledge base from academic research and publicly funded research programmes. Thus, it happens many times that different patents are merely based upon different procedures that are aimed at the same applications, e.g. gene insertion on different crops using gene gun technology or microprojectile methods. Consequently, in the face of similar patents, the probability of litigation is strong, and so is the incentive to merge or enter into cross-licensing agreements.

But why integrate vertically into the seed sector? Since crop biotechnologies demonstrate a significant degree of technical imitation and high-quality proprietary germplasm, being a key complementary asset for commercialization, this facilitates

a stronger market position than biotechnology know-how and IPR on specific genes. This strategy of vertical integration into the seed business and ownership of germplasm has become an almost necessary strategy for technology firms in the face of contested intellectual property rights (Joly and de Looze, 1996; Hayenga and Kalaitzandonakes, 1999).

To summarize, demand complementary between chemicals and seed, as well as the innovation life cycle, offers possible explanations for the trend of consolidation in the agrochemical/agrobiotech industry. But the existence of intellectual property rights appears to have had much to do with the vertical integration. In particular, firms have had incentives to buy firms with IPR: (i) to block entry of potential competitors; (ii) as a bargaining chip for an equitable use of rival technologies; (iii) because of complementarities of key intellectual assets like transformation technologies, genes and germplasm; or (iv) because of high transaction costs in licensing agreements along with low level of technology differentiation and intellectual property appropriability.

3.4 Conclusions[71]

The intellectual property system as it is reflected in the TRIPS agreement has been developed over centuries, predominantly by, and for the purposes of, industrialized countries. Arguably, most forms of protection are not adapted to the needs of TK holders. This is particularly true for patent protection, which constitutes a complex and costly legal tool, especially with respect to its international component. It requires considerable expertise and financial resources to acquire and manage these intellectual property rights, as well as the will and capacity to commercialize the protected products and processes. Appropriate corporate, institutional and contractual structures are necessary to take full advantage of this system. Furthermore, when patent protection shall contribute to reach certain policy goals such as biodiversity and equity, it needs the implementation of corresponding competition laws and policies. This type of IPR must therefore be radically adapted in order to satisfy the aspirations of TK holders that go beyond the grant of mere 'defensive rights' to prevent the most visible dysfunctions of the system. The same is true, however to a lesser degree, for Plant Breeders' Rights and *sui generis* protection systems. It is therefore questionable whether classical forms of IPR are appropriate for the purposes of TK holders in the light of the economic and non-economic concerns at stake. One may rather explore new concepts such as the '*domaine public payant*' to address both the demand from TK holders and from society at large in order to fulfil policies that are able to balance private and public interests.

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