



Protecting and sharing biodiversity and traditional knowledge: Holder and user tools

Geertrui Van Overwalle

Centre for Intellectual Property Rights, Catholic University Leuven, Belgium

Received 15 June 2004; received in revised form 18 October 2004; accepted 25 October 2004
Available online 11 May 2005

Abstract

The present paper deals with the question how legal protection of biodiversity and traditional knowledge can be accommodated and how the results from the use and exploitation of biodiversity and traditional knowledge can be shared. The aim is to cast the various contributions in this volume in a wider framework, by describing and evaluating current intellectual property (IP) protection systems, intellectual property-similar regimes and protection and sharing initiatives outside intellectual property. © 2005 Elsevier B.V. All rights reserved.

Keywords: Biodiversity; Traditional knowledge; Intellectual property rights; Patents; Plant breeder's rights; Farmer's rights; GURTs; ABS regimes; *Sui generis* regimes; Fair and equitable sharing

Abbreviations: ABS, access and benefit sharing; Bonn Guidelines, Bonn Guidelines on Access to Genetic Resources and Benefit-sharing, agreed by the Conference of the Parties (COP) in the Hague on April 19 2002; CBD, Convention on Biological Diversity; CCIPR, Collective Community Intellectual Property Right; COP, Conference of the Parties; EPC, European Patent Convention; EPO, European Patent Office; EGE, European Group on Ethics in Science and New Technologies; EIPR, European Intellectual Property Review; GURTs, Genetic Use Restriction Technologies; ITPGRFA, International Treaty on Plant Genetic Resources for Food and Agriculture; IP, intellectual property; IUCN, International Union for Conservation of Nature and Natural Resources; NHBMs, non-human biological materials; TIP right, Traditional Intellectual Property Right; TRIPs, Agreement on Trade-Related Aspects of Intellectual Property Rights; UPA, Utility Patent Act; UPOV, Union pour la Protection des Obtentions Végétales; USC, United States Code; USPTO, United States Patent Office; WIPO, World Intellectual Property Organisation.

E-mail address: geertrui.vanoverwalle@law.kuleuven.ac.be.

0921-8009/\$ - see front matter © 2005 Elsevier B.V. All rights reserved.
doi:10.1016/j.ecolecon.2004.10.014

1. Introduction

The present paper deals with the question how legal protection of biodiversity and traditional knowledge can be accommodated and how the results from the use and exploitation of biodiversity and traditional knowledge can be shared. The aim is to cast the various contributions in this volume in a wider framework, by describing and evaluating current intellectual property (IP) protection systems, intellectual property-similar regimes and protection and sharing initiatives outside intellectual property. The term protection in the current survey should be understood in the common sense it is given in an intellectual property law context and does not refer to the concept of protection in environmental law, nor to the concept of preservation.

The paper first addresses some of the major concepts used in the current debate: biodiversity, (traditional) knowledge, holders and users (Section 2). The paper then embarks on a wide and in-depth tour d’horizon of the legal instruments which can serve to protect biodiversity and traditional knowledge, seen from the perspective of biodiversity and traditional knowledge holders (Section 3). Next, the legal tools are explored which can be helpful in sharing the benefits resulting from biodiversity and traditional knowledge, from the perspective of responsible users (Section 4). After this expansive survey of the various legal initiatives, the paper closes with some conclusions and recommendations (Section 5).

2. Major concepts

In the search for new pharmaceutical, biotechnological or agricultural products, two different but closely related components have to be distinguished: the use of a *tangible* element, biological material, and the appropriation of an *intangible* component, traditional knowledge. The World Intellectual Property Organisation (WIPO) takes the view that the term ‘traditional knowledge’ refers to both tangible and non-tangible components: the tangible component of traditional knowledge mainly refers to genetic resources, whereas the intangible component of traditional knowledge mainly refers to the knowledge (WIPO, 2001). However, for clarity’s sake and in view of the differing applicable IP regimes, it is better not to plug the notion ‘biodiversity’ into the notion of traditional knowledge, but to address them as two closely related, but different concepts.

2.1. Biodiversity

Article 2 of the Convention on Biological Diversity (CBD)¹ stipulates that ‘biological diversity’ means “the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity

within species, between species and of ecosystems”. ‘Biological resources’ include “genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity”. ‘Genetic resources’ means “genetic material of actual or potential value”. While the language of the CBD provides a broad scope for action, CBD discussion documents suggest that the parties are at present focusing on *non-human* biological materials (NHBMs) and their natural habitats (Polski, in this issue; Hassemer, 2004). Those resources thus encompass pharmaceutical as well as natural product resources and crop genetic resources.

In addition to the semantic discussion on the notion of ‘biodiversity’, there has been an interesting debate on the economic nature and value of biodiversity. Polski takes the view that NHBMs are components of “common pool resources” and are themselves “common pool goods” (see also Maier-Rigaud and Apesteguia, 2004). The question arises to which extent this economic qualification has/should have any effect on our thinking on intellectual property concepts in the field of biodiversity. This question calls for further investigation.

2.2. Knowledge

2.2.1. Traditional knowledge

A key concept in the current debate is ‘traditional knowledge’. At present, one interpretation seems to be commonly accepted. The term traditional knowledge is understood to comprise both aesthetic and useful elements, as well as literary, artistic or scientific creations. Consequently, categories of traditional knowledge include, inter alia, expressions of folklore in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of language; agricultural knowledge; medicinal knowledge (WIPO, 2001; Leistner, 2004). De Carvalho (1999, 2003) introduces an interesting distinction in this regard: ‘traditional knowledge *stricto sensu*’, encompassing the knowledge itself and ‘traditional knowledge *lato sensu*’, encompassing the former plus expressions of traditional knowledge.

Efforts have been made to classify the various types of traditional knowledge. In international discourse it is agreed that the term ‘traditional know-

¹ Convention on Biological Diversity (CBD), 5 June 1992. See <http://www.unep.ch/bio/conv-e.html>.

ledge' can be subdivided in three classes: traditional medicinal knowledge (TMK), traditional agricultural knowledge (TAK) and traditional ecological knowledge (TEK).² The class of traditional agricultural knowledge relates to knowledge leading to crop improvement.

A distinction is made between 'traditional knowledge' and 'indigenous knowledge'. Indigenous knowledge is a subset within the traditional knowledge category: indigenous knowledge is traditional knowledge held and used by communities, peoples and nations that are indigenous (WIPO, 2001; Stoll and Von Hahn, 2004).

An economic assessment of traditional knowledge, in its turn, seems less omnipresent. However, recently a classification of local knowledge is developed which might be fruitful for a law and economics perspective. Gupta distinguishes three contested domains of local knowledge: community knowledge, knowledge in the public domain and individual knowledge (Gupta, 2004, p.3).

2.2.2. *Contemporary scientific knowledge*

Obviously, it is important to reflect on the notion of traditional knowledge. However, it should not be forgotten that in many cases new pharmaceutical, biotechnological and agricultural products can only be developed by the additional use of advanced techniques and contemporary scientific knowledge. The current debate is in danger of risking to become unrealistic and asymmetric, if attention is solely paid to traditional knowledge and the role and nature of contemporary knowledge is systematically underrated.

In an IP setting, more in particular in a patent law context, knowledge is considered eligible for patent protection and subsequent temporary monopolisation of its use, if it constitutes an invention which is new, inventive and industrial applicable. The pivotal concept here is 'invention'. The European Patent Convention (EPC)³ does not provide a

statutory definition of the term invention. The EPC Implementing Measures, however, underline that the invention must be of technical character to the extent that it must relate to a technical field⁴, must be concerned with a technical problem⁵ and must have technical features in terms of which the matter for which invention is sought, can be defined in the claim.⁶ EPC case law confirms this interpretation and underlines that an invention must have a technical character, must provide a technical contribution to the art and must solve a technical problem. The same approach is taken in legal doctrine: inventions are considered creations in the technical field which contain a "technical teaching", what the Germans call "ein Lehre zum technischen Handeln" (Benkard, 1993; Remouchamps, 1970) or what in the United States is known as "teaching rules" (Bent et al., 1987). In conclusion, in a patent context, 'knowledge' is mainly considered to be 'technical knowledge'.

In the field of the life sciences, there is one area of technical knowledge which is of major importance, viz. biotechnology. The EPC Implementing Regulations stipulate that biotechnological inventions are inventions "which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used".⁷

The notion 'contemporary' knowledge and the relationship 'traditional'/'contemporary' knowledge are by far not fully explored here and call for further investigation.

2.3. *Holders and users*

According to article 2 of the CBD, a country providing genetic resources, means a "country supplying genetic resources collected from in situ sources, including populations of both wild and domesticated species, or taken from ex situ sources,

² Cf. WIPO (2001). Cottier and Panizzon (2004) reject an activity specific approach which differentiates among the various types of traditional knowledge. These terms artificially disaggregate components of a single reality.

³ European Patent Convention of 5 October 1973, see http://www.european-patent-office.org/epc/pdf_e.htm.

⁴ EPC Implementing Regulations Rule 27(1)(a), see <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG>.

⁵ EPC Implementing Regulations Rule (27)(1)(c).

⁶ EPC Implementing Regulations Rule 29(1). The invention, however, must not entail technical progress or useful effect (EPC Guidelines, C-1.3), see http://www.european-patent-office.org/legal/gui_lines/index.htm.

⁷ EPC Implementing Regulations, Rule 23 (b) (2).

which may or may not have originated in that country” (Sterckx, 2004).⁸ Next to the notion of provider country, the CBD also employs the concept of country of origin of genetic resources, meaning “the country which possesses those genetic resources in situ conditions.” Recently, the major provider countries have grouped themselves in the Group of Like-minded Megadiverse Countries.⁹

According to the World Intellectual Property Organisation (WIPO), traditional knowledge holders are “all persons who create, originate, develop and practice traditional knowledge in a traditional setting and context. Indigenous communities, peoples and nations are traditional knowledge holders, but not all traditional knowledge holders are indigenous”.¹⁰ The CBD talks about “users” of genetic resources and knowledge.

‘Users of genetic resources’ or ‘recipients’¹¹ are defined as those individuals or entities that actually import and utilize genetic resources, whether for commercial or purely scientific purposes. Examples include botanic gardens that collect, display, and conduct research on plant species from other countries; pharmaceutical and biotechnology firms engaged in drug discovery and product development based on genetic resources accessed from another country; and cosmetic and nutritional companies that import, process and sell a wide variety of consumer goods that are based on natural products (Tobin and Barber, 2003).¹² By analogy “users of traditional knowledge” might be defined as individuals or

institutions making use of traditional knowledge for commercial or scientific purposes.

The search for native micro-organisms or plants harbouring interesting properties has been termed differently: the search and subsequent exploitation is sometimes referred to as “bio-prospecting” (OECD, 1996; Posey and Dutfield, 1996), or even as “bio-piracy” (Odek, 1994; Posey and Dutfield, 1998) by “gene hunters” (Cantley, 1997). Thoughtful observers underline that the word “bioprospection” mainly refers to legitimate actions carried out in the framework of a law or an agreement, whereas the notion “biopiracy” refers to illegal operations (Hassemer, 2004).

Many countries are both ‘holders’ or ‘providers’ and ‘users’ of genetic resources and traditional knowledge. This has recently been confirmed in the Bonn Guidelines.¹³ However, there has been a tendency in the international debate to view developing countries as primarily providers, while more industrialized developed countries have been portrayed as users. Tobin and Barber (2003) correctly underline the inaccuracy of such generalizations and argue that in many cases industrialized countries, such as Australia, are also important providers, while some developing countries, such as Brazil, have highly developed biotechnology and agro-industrial capacities.

3. Holder tools

3.1. Protecting biodiversity

Initially, biological resources were considered to be the “heritage of mankind” (Bragdon, 2001). By the same token, until the end of the last century, genetic resources were loosely labelled as “common heritage”. This refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest. With regard to crop resources, this system implies open access and non-exclusion to seeds and plants

⁸ Sterckx correctly points to some problems arising from the use *ex situ* sources.

⁹ The Group’s member countries, and signatories to the Cancun Declaration, are Bolivia, Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Kenya, Mexico, Malaysia, Peru, Philippines, South Africa and Venezuela. They all subscribed the Cancun Declaration and are Megadiverse countries or have special characteristics in their biodiversity, as could be a high concentration of species or numerous endemism. For the full text of the Cancun Declaration, see http://www.unido.org/file-storage/download/?file_id=11803. For more on the Group, see <http://www.megadiverse.org>.

¹⁰ The term ‘knowledge holder’ is used in WIPO (2001), 26.

¹¹ The term ‘recipient’ is used by Siebenhüner and Suplie (in this issue).

¹² Cf. Polski (in this issue) who refers to various types of bioprospectors harvesting NHBMs: scientist collectors and entrepreneurs.

¹³ Bonn Guidelines on Access to Genetic Resources and Benefit-sharing, agreed by the Conference of the Parties (COP) in the Hague on April 19 2002 (COP 6 Decision VI/24, see <http://www.biodiv.org/decisions/default.asp?lg=0anddec=VI/24>).

from farmer's fields, with due recognition of prior informed consent (Brush, 2003).

The bioprospecting mechanism, the rise of intellectual property for living material, the commercialization of seed and the increased use of genetic resources in crop breeding have contributed to a change in the customary treatment of genetic resources as common goods and have led to extensive revisions to the common heritage regime. The demise of common heritage culminated in the CBD, where ownership over genetic resources was mandated to national, sovereign states.¹⁴ In doing so, the CBD brought about a paradigm shift by stipulating that States have sovereign rights over their own biological resources (Hassemer, 2004).

The sovereignty regime, establishing property claims over resources, led in its turn to the question whether states or citizens could claim intellectual property rights over biological resources (Van Overwalle, 1998; cf. Cottier and Panizzon, 2004). Close reading of the CBD preambles and provisions, leads us to believe that the CBD is not principally opposed against the grant of IP rights over biological resources. The CBD only demands that the results of research and development and the benefits arising from the commercial and other utilization of genetic resources are shared in a fair and equitable way. The fact that the third recital no longer employs the notion of "common good", but "common concern"¹⁵, is quite significant in this respect [see also article 15 (7)].¹⁶

¹⁴ See the recitals of the CBD, stating "Reaffirming that States have sovereign rights over their own biological resources". Also see article 3 CBD: "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction." Also see article 15.1 CBD: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". (Van Overwalle, 1998; cf. Cottier and Panizzon, 2004).

¹⁵ See for a survey of the drafting history: Mc Connell (1996). For an in-depth examination of the concepts "common heritage" and "common concern", as well as some related notions, see Durner (2000).

¹⁶ Cf. Chapter 15, Point 15.4 (d), Point 15.4 (g), Point 15.4 (j) and Chapter 16 - E - Point 16.39 (a) (vi) of *Agenda 21*.

At present, mainly two IP regimes exist to protect biological resources: patents and plant breeder's rights. In addition, biological systems have been evolved which have the same monopolistic effects as IP regimes: genetic use restriction technologies (GURTs) and governmental ABS systems are put into place. Only farmer's rights form a distant echo of the pre-CBD-era.

3.1.1. Patents

The general principle with regard to patentability is laid down in article 27 (1) of the TRIPs Agreement¹⁷, which stipulates that patents shall be available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.¹⁸ In the field of life sciences, biotechnology and genetic engineering the TRIPs Agreement contains an exclusion to this wide principle which is highly relevant. Article 27 (3) (b) first sentence stipulates that members *may* exclude from patentability "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". However, article 27 (3) (b) second sentence prescribes that "members *shall* provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof".

The flexibility of article 27 (3) (b) *first* sentence has led to a variety of approaches in the protection of biological material amongst provider countries. Some provider countries find patents on biological resources useful and do not opt for the implementation of the exclusionary TRIPs provision in their patent law. They have established patent protection for biological material, plants and animals mirroring the EU Biotechnology Directive. This Directive

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakech Agreement Establishing the World Trade Organization, signed in Marrakech, Morocco on 15 April 1994), see http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm. For a critical review of article 27 TRIPs, see Correa and Yusuf (1998). Also see Van Overwalle (1997b).

¹⁸ For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

officially proclaims that patent law is no longer restricted to inanimate objects, but is principally also accessible for living matter.¹⁹ As to the patentability of biological material, the Directive stipulates that inventions which are new, which involve an inventive step and which are susceptible of industrial application, shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (article 3). As to the patentability of micro-organisms, plant and animal varieties, the Directive stipulates that micro-organisms are patentable [article 4 (3)], and that inventions which concern *plants* or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal *variety* [article 4 (2)].²⁰ In offering patent protection for micro-organisms, the Directive aligns itself with TRIPs, whereas in providing patent protection for *plants* and animals the Directive clearly deviates from the regime put forward in TRIPs.

In countries which have adopted a EU-like patent friendly regime for biological material, the potential of the patent system is rather limited, for two reasons. First, biological material of plant or animal origin only leads to patent protection if it constitutes an invention. The invention concept implies that unmodified resources—“raw material” as such—cannot be considered patentable subject matter, but that biological material isolated by means of a technical process may constitute a patentable invention. Second, genetic resources will only be granted patent protection, if they meet the conditions of novelty, inventive step and industrial applicability. In many cases, these conditions will be hard to meet in developing provider countries which have limited technological capacities, whereas they might be more easily fulfilled in industrialized provider countries, such as Australia or Brazil, which have highly developed biotechnological expertise and

contemporary, scientific knowledge. Here, patents might remain beyond reach, as a result of *practical* impediments.

Other provider countries have used the maneuvering room in article 27 (3) (b) *first* sentence of the TRIPs Agreement to limit what constitutes patentable subject matter (Commission on Intellectual Property Rights, 2002). They exclude plant and animals from patent protection, adopt a restrictive definition of micro-organism, and even exclude genetic material where possible. A typical example here are the Andean Pact Countries, which stipulate that “shall not be considered as inventions: any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing”. The same is true of Brazil and Argentina. In those countries, patent protection is out of reach for *policy* reasons.

3.1.2. Plant breeder's rights

Article 27 (3) (b) TRIPs *second* sentence stipulates that Members *shall* provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. This provision has led to a variety of approaches in the protection of plant varieties in various countries. In Europe, protection of plant varieties by way of patents was explicitly excluded [see article 53 (b) EPC] and merely plant breeders' rights were available. In the United States protection for plant varieties was possible by patents, both under the Plant Patent Act and under the Utility Patent Act, as well as by plant breeders' rights (Van Overwalle, 1999). However, few provider countries offer protection for plant varieties, either by patents or plant breeder's rights.

The plant breeders' rights system has been created on the basis of the International Convention for the Protection of New Varieties of Plants of 1961.^{21,22} This Convention created a Union for the Protection of New Varieties of Plants, commonly known under

¹⁹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention, 213 *Official Journal EC- L*, July 30 1998, 13.

²⁰ For a comprehensive and concise overview of the current patent framework for biotechnological inventions in Europe and the U.S., see Van Overwalle (1997a,2003a).

²¹ The text of the 1961 Convention is available at <http://www.upov.org/en/publications/conventions/index.html>.

²² For more on plant breeders' rights, see Van Overwalle (1996) (references cited there).

its French abbreviation UPOV (*Union pour la Protection des Obtentions Végétales*). The initial 1961 Convention was substantially revised in 1991.^{23,24}

The UPOV Convention offers protection for plant varieties. A plant variety is defined as “a plant grouping within a single botanical taxon of the lowest known rank which grouping can be defined by features characterizing a given genotype or combination of genotypes, and is distinguished from any other plant grouping by the expression of at least one of the said characteristics” [art. 2 (i) 1991 UPOV Convention].

The potential of the plant breeder’s rights system to protect biological resources is rather limited for provider countries, and this for three reasons. First, plant breeder’s rights protection is only available for plant *varieties*, not for the plant world at large. Second, protection is only available if the standard conditions of distinctness, uniformity, stability and (commercial) novelty are met. Although this threshold is significantly lower than the patent one, conditions have to be fulfilled. Third, only few provider countries offer plant breeder’s rights protection in their territory: Argentina and Brazil do, but Peru or Costa Rica, for example, do not.

Both in Europe and the United States it was generally understood that the TRIPs words ‘effective *sui generis* system’ referred to the plant breeder’s rights system. At present it is widely recognized that the *sui generis* models can include other models as well, such as for example access and benefit sharing (ABS) mechanisms.

3.1.3. Farmer’s rights

Plant breeder’s rights have to be distinguished from so-called farmer’s rights. Farmer’s rights fit in a movement to re-establish a common pool regime for plants, recognizing that plant genetic resources for food and agriculture are a common concern of all countries, in that all countries depend very largely on plant genetic resources for food and agriculture that originated elsewhere.²⁵ Farmer’s rights do not aim at protecting crop genetic resources, but on the contrary, at preventing that resources are monopolized by a group or person. They do not fit in the catalogue of ‘holder protection tools’, but seek to regain status of non-protectability of common pool resources.

The major impetus for this aspiration is given by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), negotiated in 2001 and now signed by 79 countries.²⁶ The core provisions of this International Treaty install a common heritage regime for some 40 crop genera, which are placed in the public domain and are accessible for breeding and research (article 12) and benefit sharing mechanisms (article 13). Witness of the common concern approach is article 12 (3) (d), which prohibits to introduce IP rights on traditional knowledge and on plant genetic resources for food and agriculture.²⁷

3.1.4. Biological regimes

If a country fails to establish an effective and well balanced patent or plant breeder’s rights system, breeders might turn to other, non-legal mechanisms to assure their interests. A biological way to protect genetic material against unauthorized use by third parties is the development of genetic use restriction

²³ *International Convention for the Protection of New Varieties of Plants of December 2 1961, as Revised at Geneva on November 10 1972, on October 23 1978 and on March 19 1991*, Geneva, UPOV, 1991 (available at <http://www.upov.org/en/publications/conventions/index.html>). The UPOV 1991 Convention entered into force on April 24 1998. For more background on the 1991 UPOV Convention one might also consult the *Records of the Diplomatic Conference on the Revision of the International Convention for the Protection of New Varieties of Plants - Geneva 1991*, Geneva, UPOV, 1992, 577 p. [UPOV Publication no. 346(E)].

²⁴ The Member States of this Union are 54 states (Status on June 1 2004). Parties to the 1991 UPOV Convention are 29 states (Status on September 24, 2004). (See <http://www.upov.int/en/about/members/pdf/pub423.pdf>).

²⁵ See the recitals of the ITPGRFA.

²⁶ For the text and other details on the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), see <http://www.fao.org/ag/cgrfa.itpgrf.htm>.

²⁷ Article 12 (3) (d) runs as follows: “Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System”. However, the Treaty does respect *existing* IP rights. Article 12 (3) (f) specifically stipulates: “Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws”.

technologies, so-called GURTs.²⁸ The best known example are the terminator genes.

This type of protection regime is no real option for two reasons. First, it is probably out of reach for many provider countries, since highly advanced techniques are necessary to insert GURTs in plant material, and many provider countries dispose neither of the expertise nor the infrastructure to do so. Second, it is subjected to heavy criticism, for running counter to the traditional right of farmers to save seed (Dutfield, 2003; Fischer, 1999; Ohlgart, 2002).

3.1.5. ABS regimes

Another route to provide protection for genetic resources (and traditional knowledge) is the establishment of appropriate, national access and benefit sharing (ABS) measures. The legal basis for access and benefit sharing measures with regard to genetic resources, is article 1 CBD. Article 1 CBD enumerates the three objectives and specifies with regard to the third one that it aims at the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to *genetic resources* and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. In addition, appeal can also be made to article 15 (7) CBD, which states that appropriate measures should be taken “with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of *genetic resources* with the provider country of such resources”. Strictly speaking, the term “provider country”, refers to the state, not to the inhabitants of that state. Subsequently, the sharing envisaged, is the sharing between different states, not between individuals/groups within one state or individuals/groups of different states. Although the text is rather specific in scope in this regard, a more flexible approach seems to be widely accepted.

²⁸ See the *UPOV Memorandum on the genetic use restriction technologies* of January 10, 2003, submitted to the Secretariat of the CBD (see <http://www.eldis.org/static/DOC11879.htm>). This Memorandum has been superseded by the Position UPOV concerning Decision VI/5 of the Conference of the Parties to the Convention on Biological Diversity (CBD) of April 11, 2003 (http://www.upov.int/en/about/pdf/gurts_11april2003.pdf).

The principles enshrined in article 15 CBD are further elaborated in the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing, agreed by the Conference of the Parties (COP) in the Hague on April 19 2002²⁹, setting out practical ways and means of mutually agreed terms at the national level (also see Barber, 2002).

However well meant, such measures place the burden upon the government and can only be successful in practice if the national government involved is willing to espouse the interest of the indigenous peoples involved and protect such rights for them (Lewis and Ramani, 2003).

When ABS systems are designed, attention should be paid to prior informed consent procedures. The prior informed consent requirement is prescribed by the CBD, more in particular article 15 (5), which stipulates that “access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party”. Prior informed consent in the context of genetic resources is defined by the International Union for Conservation of Nature and Natural Resources’ (IUCN) guide to the CBD as “consent of the contracting party which is the genetic resource provider, based on full and complete information provided by the potential genetic resource user prior to consent for access being granted...” (Glowka et al., 1994). The prior informed consent requirement is also implemented in the Bonn Guidelines. Is this requirement going to be substantiated in the future or will it remain no more than just a “gently floating irrelevance” (see Sterckx, 2004; Van den Daele et al., 2003)?

3.1.6. Contracts

A number of provider countries have established national laws and regulations to control the access to their genetic resources. In many cases, those laws prescribe that contractual arrangements are the legal instrument to regulate access to genetic resources. These so-called ‘material transfer agreements’ are conceived in a variety of forms and deal with a wide scale of issues (also see Tobin, 2002; Putterman, 1996). Frequently, the modalities of access to genetic resources and use of traditional knowledge are negotiated in one

²⁹ COP 6 Decision VI/24, see <http://www.biodiv.org/decisions/default.asp?lg=0anddec=VI/24>.

and the same contract. Agreements have great potential in establishing access and equitable sharing. However, well-balanced contracts might remain beyond reach of provider countries lacking necessary negotiation skills.

3.2. Protecting traditional knowledge

There is a growing consensus that indigenous communities which are involved in the identification of therapeutic properties of native plants should be compensated for the exploitation of their traditional medicinal knowledge. However, there seems to be a lot of obscurity and uncertainty as to the appropriate legal instruments that should be used to give shape to the right to compensation. Overlooking past and presents efforts to establish an appropriate model that fits the contribution of indigenous communities, we can observe two approaches (Wendland, 2002a,b).

3.2.1. Positive protection route

A first approach, the so-called “positive protection” route, is based on the assumption that protection of indigenous knowledge is important to safeguard the rights of knowledge holders in view of commercial exploitation and benefit.

Various systems have been suggested as a positive protection system for traditional *medicinal* knowledge: patent law, copyright protection, database protection, utility models, geographical indications, *sui generis* systems, liability regimes, contracts and ABS systems.³⁰

There is a well-established IP tool, which offers adequate legal protection for traditional *agricultural* knowledge leading to crop improvement: the plant breeder’s rights system. The latter system will not be further discussed here.³¹

3.2.1.1. Patents. The suggestion has been made that indigenous communities which are involved in the identification of the therapeutic properties of native plants, should be compensated for the exploitation of their medicinal knowledge by way of patents. The premises, concepts, interpretation and requirements of patent laws, however, have largely been dictated by the

industrial and technological circumstances in Western economies (Blakeney, 1997; Moufang, 1998; Beier, 1992; Beier, 1994). In this context it is questionable whether the contribution of traditional knowledge from which a pharmaceutical product has been developed, can be the sort of contribution that will meet patentability standards (Posey and Dutfield, 1998).

Analyzing traditional knowledge in conventional patent terms reveals a series of intrinsic thresholds. A first problem is the observation that indigenous peoples do not view their heritage in terms of property at all, but in terms of community and individual responsibility. Possessing medicinal knowledge carries with it certain responsibilities such as to show respect and maintain a reciprocal relationship with the human beings, animals, plants and places with which the medicine is connected (Daes, 1995, paragraph 26 quoted in Puri, 1995; Wells, 1995). There are two catches in this observation, however. First, there is most probably not one, monolithic indigenous view on property, but a diversity of views on how to regulate property internally. Second, not much is known about internal protocols (WIPO, 2001, p. 220).

A second problem relates to the final goal of patent law. The principal rationale of patent law is to provide an incentive for inventiveness and creativity, commercialization and distribution, by offering the patent holder a period of time during which his rights are immunized from competition. Indigenous peoples have been reported to be not primarily concerned with the commercial exploitation of their knowledge and market economic values. This observation should probably be put in perspective because such a point of view would imply a monolithic indigenous view and because there might well be diverging views on the value of knowledge in indigenous communities.

A third obstacle is the notion of invention and innovation. Traditional knowledge does not fit into the conventional, technically oriented, invention concept of patent law (similarly, Cottier and Panizzon, 2004).

A fourth impediment is the novelty requirement. Two difficulties can be observed in this regard. First and foremost it is often said, that indigenous knowledge is existing, transgenerational, communally shared and considered to be in the public domain and, therefore, unprotectable (Posey and Dutfield, 1998; Cottier, 1998). Recent investigations, however, have shown that not all indigenous knowledge is

³⁰ In this paper the potential of utility models has not been discussed. For more details, see Van Overwalle (2002b).

³¹ This system has been discussed supra.

communally shared, and not all of it is considered to be in the public domain (see WIPO, 2001, pp. 57–65). Various healing methods have been reported to have been held under a secrecy regime. Second, it is often argued that a problem with the patent claims of indigenous peoples in relation to traditional medicinal knowledge is that ethnobotanists and ethnopharmacologists often publish accounts of the uses of plants by indigenous peoples (Blakeney, 1997; Huft, 1995). This may have the effect of destroying the novelty of therapeutic claims, especially in a European patent setting. The United States, however, handles prior art and publication from foreign locations differently than Europeans do. Moreover, the patents applied for often do not concern the precise use undertaken by the indigenous community. The rosy periwinkle case (Kadidal, 1993) might serve as a good example of this issue. The indigenous knowledge provided the lead and it is unacceptable that this was not recognized, but the patent was not on the particular use revealed by the indigenous community.

A fifth obstacle is the notion in contemporary patent law of the inventor as an individual, solitary and original creator, or a group of individuals (so-called joint inventorship), not collective entities (Blakeney, 1997; Posey and Dutfield, 1998). It is often claimed that for indigenous peoples knowledge and determination of the use of resources are collective: custodians of traditional medicinal knowledge and indigenous peoples in general, do not fit the individuality model and might therefore be denied patent protection (Stoll and Von Hahn, 2004). Once again, this observation should be put in perspective, since knowledge and determination of use are not necessarily collective. Diverging views exist within indigenous communities on this issue (WIPO, 2001, p. 219).

The concept of joint inventorship is only helpful at times, because it requires that each of the joint inventors must have contributed to the inventive conception, working on the same subject matter and making the same contribution to the inventive thought and to the final result (Janssens, 1996; Singer and Singer, 1989).³² One does not become a joint inventor by being the first to observe a useful property or effect of an invention. In order to claim joint inventorship,

some demonstrable role in the final conception needs to be established. In case of collaboration with indigenous peoples or shamans, the problem is that their cooperation with ethnopharmacologists may be considered to be too indirect to the process of joint invention (De Carvalho, 1999). However, some successful events in this context have been observed, more in particular in the Peruvian ICBG project (Rosenthal, 2003). In case of collaboration with scientific institutions joint inventorship might be exacted, as the experience with regard to INBio (Gámez, 2003; Tamayo et al., 2004) and the Belgian *Saponin* project³³ clearly show.

Additional to intrinsic impediments for traditional knowledge to fit the patent system, also practical problems come up. A first practical problem, is that patents are expensive: next to the cost of patenting, which is high, the costs of opposition proceedings and infringement actions should be added, which can also be very high (Blakeney, 1997; Posey and Dutfield, 1998). Acquiring and defending patent protection require substantial financial resources. These actions tend to be complex and time-consuming and well beyond the means of indigenous peoples. The securing and enforcement of patents will therefore often be prohibitively expensive for indigenous peoples. However, costs associated with the use of the patent system have been argued not to make the system inherently unjust, particularly if ways can be found to lower costs or to assist indigent persons and communities to use the system (WIPO, 2001, p. 222).

A second practical impediment relates to the lack of intellectual property expertise of traditional knowledge holders. Some leading authors take the view that fairness dictates that when poor and excluded people are confronted with the very complicated issues involving intellectual property, they should have access to expert advice and representation. In order to provide such advice, they took the laudable initiative to establish an independent international

³² Koopman (in this issue) speaks about ‘unrecognizable inventions’ in this respect.

³³ Saponins are natural surfactants found in many plants, but they are most abundant in the desert plants. Extracts from these plants are commonly used. The Belgian invention related to the use of antiprotozoal saponins. A European patent application was filed (EP 1.140.127) by the pharmaceutical company Janssen Pharmaceutica. All Belgian collaborators are named as inventor, as well as two Vietnamese collaborators (VAN TRI MAI and NGOC NINH TRAN) who are working at the National Centre for Science and Technology in Hanoi.

service and referral organization, the Public Interest Intellectual Property Advisors (PIIPA; Gollin, 2003).

3.2.1.2. Geographical indications. Moreover, geographical indications have been put forward as an alternative IP protection system as well. Although geographical indications are subject to a lot of terminological confusion and although doubts have equally been expressed as to the appropriateness of this type of IPR right to accommodate protection for traditional indigenous knowledge (Kur, 2004; Kur and Knaak, 2004), this highly technical route of protection is gaining wider interest.

3.2.1.3. Copyright protection. One-way of strengthening the position of traditional healers is to consider these people as colleagues and teachers, rather than as informants. By including traditional healers who have provided information for research as co-authors or by providing acknowledgement using their names, all parties benefit (Balick, 2003; Leistner, 2004, p. 71–73 and 80–86). The copyright system, more in particular the collecting society model, can also play a role when designing benefit sharing mechanisms (Drahos, 2000; Leistner, 2004, p. 82–85).

3.2.1.4. Database protection. Workers in the ethnoscience are collecting data and are using modern technology to catalogue and study this information. Data gathering may be useful with regard to long-term preservation of the actual knowledge and subsequent IP protection of the data collections might be worthwhile (Alexander et al., 2003). Various types of database management can be established: free access, access associated with a material transfer agreement, access subject to scientific evaluation, etc.

3.2.1.5. Sui generis solution : Collective Community Intellectual Property Rights (CCIPRs) /Traditional Intellectual Property Right (TIP right). On top of existing IP systems, a new IP tool has been suggested to fit the needs of indigenous peoples: the adjudication to knowledge holder countries of a special form of IP protection for traditional medicinal knowledge, a so-called *sui generis* solution.³⁴ Such an approach

could find a legal basis in article 27 (3) (b) of the TRIPs Agreement which provides for an effective *sui generis* system for plant variety protection. Strictly speaking, the wording of article 27 (3) TRIPs Agreement only refers to plant varieties and the relationship between TRIPs and the CBD was unclear and strained (see European Commission, 2000). However, the wording might be given a wider scope and a *sui generis* regime might be conceived for traditional medicinal knowledge as well, as a result of the Doha Ministerial Declaration. Paragraph 19 of the Doha Ministerial Declaration stipulates that instructions are given to the TRIPS-Council, “in pursuing its work programme including under the review of article 27 (3) (b) the review of the TRIPs Agreement... , to examine, inter alia, the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore and other relevant new developments raised by members pursuant to article 71.1” (for more see Gervais, 2003).

As to the designation of the new *sui generis* right, different names are in use in national laws and draft laws and various terms have been put forward in the literature as well. Leistner favours the notion of “Collective Community Intellectual Property Rights (CCIPRs)” (Leistner, 2004), whereas Cottier and Panizzon (2004) suggest the term “Traditional Intellectual Property Right (TIP right)”.

In devising the international framework of this new protection right, various issues will have to be resolved: protectable subject matter, protectability requirements (“a certain level of intellectual activity” (Cottier and Panizzon, 2004, p. 390), application procedure, right holders, scope of right (“both traditional knowledge as such and the product” (Cottier and Panizzon, 2004, p. 391), duration of right and management of rights.³⁵ Consensus will have to be achieved on this wide range of issues, before it will be possible to elaborate a blueprint of an adequate and widely acceptable *sui generis* regime.

3.2.1.6. ABS system. Access and benefit sharing measures, may focus, besides genetic resources, on traditional knowledge as well. The legal basis here is

³⁴ There is a vast literature on this subject. A selection: Blakeney (1997); Cottier and Panizzon (2004); Cottier (1998); Da Costa e Silva (1995); Leistner (2004); Posey and Dutfield (1998); Walden (1996).

³⁵ For some concrete and detailed suggestions, see Cottier and Panizzon (2004 p. 387); Leistner (2004 p. 141).

article 8 (j) CBD, stipulating that each signatory shall, as far as possible and as appropriate, “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such *knowledge*, innovations and practices.”

It is suggested that attention is paid to informed consent procedures as well. A major problem, however, is the appropriate representation of community interests.

3.2.1.7. Compensatory liability regime. Recently, eminent legal scholars have reflected on alternative regimes which enable entrepreneurs to appropriate the fruits of their investments in cumulative and sequential innovation without impeding follow-on innovation and without creating barriers to entry, in order to open new ways for stimulating investment in sub-patentable innovation without impoverishing the public domain. A system which meets these concerns is a compensatory liability regime (Reichmann, 2003).³⁶ Further research and experience should prove to which degree the proposed system is workable and useful in a biodiversity context.

3.2.1.8. Contracts. Still another attempt to give shape to the expectations and needs of indigenous peoples is the voluntary concluding of contractual arrangements between a variety of institutions from provider and user countries. Various elements should be taken into consideration when concluding those contracts: monetary as well as non-monetary benefits, informed consent as well as disclosure procedures, and last but not least, bilateral as well as multilateral scope.³⁷

A first aspect to be considered, is the nature of the benefits. Experience shows that contractual arrangements first and foremost deal with tangible aspects,

notably with monetary benefits. They focus on what—quite significantly—has been termed ‘the gold standard’. However, it has been repeatedly argued that contracts and partnerships can only be successful in the long term if both monetary and non-monetary benefits are shared.

A second element to take into account are certain principles and procedures. Agreements should be based on the principles of equality, mutual respect, partnership, mutually beneficial relations and the sharing of results. These principles can be realized by paying special attention to prior informed consent procedures. More than once, the question arises whether these basic principles should also entail disclosure requirements.

A third aspect to focus on is the scope of the agreements: do bilateral agreements suffice, should multilateral contracts be negotiated or is there a need for an international regime? Some claim that the greatest threat to sustainability is no longer biopiracy *per se* but something far more insidious: the biofraud inherent to all bilateral contracts between a corporation and only one supplier. These contracts fuel a price war denying everyone the possibility of garnering an economic rent (Vogel, 2000). A cartel has now been proposed as a solution. In such a cartel, the price of access is fixed and the benefits are distributed among all who could have supplied the same resource or knowledge. Negotiating multilateral contracts between knowledge holders and bioentrepreneurs is definitely a step in the good direction. It might even be better to consider an international biocollecting regime (Drahos, 2000).

3.2.2. Defensive protection systems

A second approach, the so-called “defensive approach” route, aims at the protection of indigenous knowledge, mainly in an effort to protect these assets against acquisition and exploitation by third parties.

3.2.2.1. Documenting. The major route to protect indigenous knowledge against the unauthorized use and unauthorized acquisition of patents over traditional knowledge by third parties, is the documenting of traditional knowledge (cf. WIPO, 2001, pp. 6, 217). There are two possible alternatives. First, knowledge holders may apply for patent rights with the single purpose of avoiding that others acquire rights in their

³⁶ A similar liability regime (“Take now, pay later”) has been launched by Calabresi and Melamed (1972).

³⁷ For an extensive and critical overview of all the elements at stake, see Van Overwalle (2003b).

knowledge. Second, traditional knowledge holders may publish the information and as a result of publication, the knowledge becomes part of the state of the art and is novelty destroying for future patent applications based on or related to this knowledge (De Carvalho, 1999).³⁸

The main aim of divulgence of traditional knowledge is the preclusion of unauthorized use by unauthorized others. The major aim is not to make profit by putting information at the disposal of others, although this might be an indirect side effect. It remains to be seen to what extent this profit making conflicts with the equitable sharing principle.

3.2.2.2. Secrecy. Another—informal—effective way of protecting knowledge against unauthorized use is secrecy. A secrecy regime is usually maintained with regard to a formula for a chemical compound, a process of manufacturing, a pattern for a machine or other device, but it could also be applied to the field of traditional medicine, e.g. with regard to healing methods or techniques for using certain ingredients of particular plants in well balanced amounts. Some traditional knowledge holders have pointed out that it is sometimes difficult to maintain secrecy within small communities, where close-range interaction and collaboration constrains the innovator's ability to conceal his innovation. Innovators often rely on modifications of traditional techniques, which have been passed on in the community from one generation to another. Therefore, minimal observation might suffice for would-be infringers to imitate the innovation (see WIPO, 2001, p. 61; Leistner, 2004).

3.2.2.3. Ritual or magical components. It has been reported that yet another—informal—way of protecting knowledge, is the use of ritual or magical components that form part of traditional medicine. Those rituals often allow traditional healers to control the use of their innovations in spite of full disclosure of their techniques and methods within the local community (cf. WIPO, 2001, p. 62). Some people have pointed out that rituals operate as a barrier against reverse engineering; in other words, rituals function as a mechanism that prevents the use and development of technologies based on imitation. Apparently, ritual

regimes can create exclusive rights similar in strength to patents, at least in the local context and within supportive cultural frameworks (Golvan, 1992; WIPO, 2001, p. 61).

3.3. Overview

Various systems have been suggested as a protection system for biodiversity and traditional (medicinal) knowledge: patent law, copyright protection, database protection, utility models, geographical indications, *sui generis* systems, liability regimes, contracts and ABS systems. These systems can be classified according to two different parameters: the legal (IP tool versus non-IP tool) and institutional (public law tool versus private law tool) nature. The latter distinction might be somewhat reckless. Indeed, intellectual property rights are usually considered to have a mixed, public/private law, nature³⁹ and contracts, liability rules, are commonly accepted to have a private law nature (Boukaert and Van Hoecke, 1991, p. 33), but of course their socle is strongly based in public law. As yet, it is not clear, to what extent the twin concept 'public'–'private' coincides with the twin distinction 'static'–'dynamic', put forward by Dedeurwaerdere (in this issue). This relationship calls for further investigation.

Applying the two parameters to biodiversity and traditional knowledge brings us to Fig. 1.

4. User tools

Since the entry into force of the CBD, attention on regulation of access and benefit sharing has tended to focus on measures taken by provider countries to implement adequate measures. Recently, however, greater attention has been given to the promotion of a range of measures which countries, particularly developed countries, could implement in their role as users of genetic resources and traditional knowledge accessed from provider countries.

³⁸ For further details, see Alexander et al. (2003); Leistner (2004).

³⁹ There is a vast amount of literature on this issue. We have consulted the following leading Dutch and Belgian authorities on this point: Asser and Scholten (1954), p. 34–36; Boukaert and Van Hoecke (1991), p. 33; Poortinga (1977), p. 244; Van Gerven (1975), p. 24.

		MIXED	PRIVATE
IP TOOLS	Existing	Patents * ° Plant breeder's rights * Copyright ° Database protection ° Geographical indications ° Utility models °	Secrecy °
	New	<i>Sui generis</i> regime (CCIP right, TIP right) °	
NON-IP TOOLS		ABS measures * °	GURTs * Contracts * ° Liability regime ° Documenting ° Rituals °

Fig. 1. Holder tools for protecting biodiversity* and traditional knowledge°.

4.1. Sharing the results of biodiversity and traditional knowledge through patent law

Various attempts are being made to modify patent law in developed user countries in order to meet various objections and public concerns relating to the patenting of traditional knowledge by user countries and to adapt the patent system in a way that the expectations and needs of source countries and indigenous peoples are better accommodated.

Patent law can be tailored better in a number of ways. Some adjustments can be made during the application procedure (pre-grant phase), whereas other changes can be implemented once the patent has been granted by the relevant bureaucracy (post-grant phase). At present, at least two options seem to be available for user countries in the pre-grant phase: the reassessment of the current novelty regime and the introduction of additional requirements for the grant of a patent, in particular the incorporation of a disclosure of origin and a prior informed consent requirement. Some routes are also available in the post-grant phase, notably with regard to tempering the effects of a granted patent, through the introduction of responsible governance of patent rights.

4.1.1. Pre-grant options

4.1.1.1. *Prior art screening.* For granting national patents, almost every country in the world has its patent system as well as a patent office or equivalent

bureaucracy to screen patent applications and to decide whether patents should be awarded. For granting European patents, the European Patent Office acts as a receiving and examination office. Notably national offices with an examination tradition as well as the European Patent Office have elaborated capacity and extensive expertise in prior art searching. In the field of biological resources, and especially in the field of traditional knowledge, patent officers have great difficulty in identifying prior art, since documents giving evidence of that knowledge are lacking or difficult to retrieve. This might lead to errors and “patent office wrongdoings” (see Koopman, in this issue). However, the Hoodia patent is a successful example of intensive prior art searching of the EPO officers, leading to documents illustrating prior traditional use and subsequently destroying novelty.⁴⁰

⁴⁰ European patent application EP 973.534. The patent application claims a pharmaceutical composition which contains an extract obtainable from a plant of the genus *Trichocaulon* or *Hoodia* containing an appetite suppressant agent; a process for obtaining the extract and a process for synthesizing compound and its analogues and derivatives is also provided. The invention also extends to the use of such extracts and compound and its analogues for the manufacture of medicaments having appetite suppressant activity. The invention further provides novel intermediates for the synthesis of compound. Prior art EPO searching revealed prior use of the appetite suppressing effect in a document from 1993. As a result the wide claims will be refused and the specific claims on the component are put on hold.

4.1.1.2. Disclosure of origin requirement. The introduction of a disclosure of origin requirement in patent law is a possibility for production of evidence in respect of access and benefit sharing rules, laid down in the Bonn Guidelines. In Europe, the origin requirement was dealt with in the European Union Biotechnology Directive of 6 July 1998⁴¹, in particular in recital 27 (see [Blakeney, 1998](#)). Recital 27 requires that “whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents”. Although recital 27 contains a praiseworthy principle, the wording of recital 27 is so noncommittal, that one can wonder if the recital will have any effect at all.

Notwithstanding the noncommittal language of the Directive, Belgium and Denmark took serious action to integrate the principle in their respective legislation. Denmark recently implemented the origin requirement in its patent act and Belgium intends to do so in the near future. The current Danish Patent Act stipulates that where an invention involves or uses a biological material of vegetable or animal origin, the patent application shall contain information about the geographical origin of the material, if the applicant for the patent has knowledge about this. If the applicant for the patent has no knowledge about the geographical origin of the material, this shall be indicated in the application. A lack of information about the geographical origin of the material or the applicant’s lack of knowledge about this does not affect the manner in which the patent application is treated or the validity of the rights that follow from the patent issued.⁴²

In the initial Belgian proposal, non-compliance with the disclosure requirement was severely sanctioned (see [Van Overwalle, 2001, 2002a](#)). The

proposal stipulated that the exploitation of an invention is contrary to ‘ordre public’ and morality, when the invention is developed on the basis of biological material that was collected or exported in breach of articles 3, 8 (j), 15 and 16 CBD. Consequently, an invention using plant or animal material imported in violation of the law of the country of origin, would run counter to Belgian public order and morality and the relating patent could be nullified.⁴³ A lot of protest was raised against this severe approach. The current Belgian proposal softens the origin requirement to a great extent: the origin should be mentioned *if known* and if the origin is not communicated, no sanction is provided.⁴⁴

The Belgian proposal and equivalent systems, aiming at including the origin requirement as a substantial rather than just a formal requirement, have met with some sympathy ([Cottier and Panizzon, 2004](#), p. 398–399), but also with a lot of criticism ([De Carvalho, 1999, 2000](#), p. 379–380). It is argued that the obligation to disclose the origin of genetic resources and/or traditional knowledge as a substantial requirement for granting a patent could infringe article 27 TRIPs Agreement. However, if the implementation of benefit sharing under the CBD framework is a matter of vital importance to countries both from an economic and a technological perspective, an origin requirement in patent law might not be contrary to TRIPs. A solution might be to take up the obligation as a procedural requirement, within the meaning of “reasonable procedures” of article 62 TRIPs ([De Carvalho, 2000; Hassemer, 2004](#), p. 209–213).

The European Commission took position in this discussion. The Commission announced on 12 September 2002 that it welcomes disclosure of origin requirement, production of evidence in respect of access and benefit sharing rules as long as this requirement does not constitute an additional formal

⁴¹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention, 213 *Official Journal EC-L*, July 30 1998, 13.

⁴² Order n° 1086 of 11 December 2000, entering into force 20 December 2000, amending Order n° 374 of 19 June 1998 on patents and supplementary protection certificates.

⁴³ Article 49 §1 (1) of the Belgian Patent Act of 1984 stipulates that a patent may be revoked by court if the subject matter of the patent falls within articles 3 or 4, or does not meet the requirements of articles 2, 5, 6 and 7. Cf. article 138 (1) (a) EPC that stipulates that a European patent may be revoked if the subject matter of the European patent is not patentable within the terms of articles 52 to 57.

⁴⁴ Belgian Parliament (*Belgische Kamer Van Volksvertegenwoordigers*), 2001–2002, DOC 50 1886/001.

or substantial patentability criterion and as long as it has no bearing on the patentability of the invention or the validity of the patent.⁴⁵ It is clear that the Belgian legislator, in his latest proposals, has aligned himself with the Danish approach and the European Commission's declaration.

4.1.1.3. Informed consent requirement. Next to the addition of an origin requirement in patent law, the suggestion has been made to introduce an informed consent principle in patent law as well. This principle, laid down in article 15.5 CBD and elaborated in the Bonn Guidelines, would imply that every patent applicant has to show evidence that he received consent was obtained from the government or local communities where the material originates from.

Initially the European Commission did not make any reference to the prior informed consent requirement for the use of biological material: the EU Biotechnology Directive of 1998 does not mention informed consent for the use of biological material. An informed consent requirement has been taken up in the Danish patent act, but has not been foreseen in the Belgian proposal. The Danish patent act stipulates that where an invention involves or uses a biological material of human origin, the patent application shall indicate whether the person from whom the biological material originates has given consent for the application to be submitted. The information concerning consent does not affect the manner in which the patent application is treated or

the validity of the rights that follow from the patent issued.⁴⁶

Meanwhile the European Union has underlined its desire to take into account the principles embedded in CBD. The European Commission recently stated that it welcomes the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing, agreed by the Conference of the Parties (COP) in the Hague on April 19 2002.^{47,48}

4.1.2. Post grant options: humanitarian use restriction

Regulation of some post-grant issues might contribute to achieve a better balance between the rights of inventors/investors and traditional knowledge holders. Humanitarian use has been defined as use in developing countries (according to FAO definition) by resource poor farmers who make less than US\$10,000 per year, leaving the company free to explore commercial prospects for the technology (Potrykus, 2001). To date humanitarian use licenses have been given to five major rice-growing countries namely the Philippines, India, China, Vietnam and Indonesia.

4.2. Sharing the results of biodiversity and traditional knowledge through alternative measures

4.2.1. Self standing regulations

Concerns regarding the patenting of inventions based on biological material of plant origin and local traditional knowledge can be taken care of within patent law, but can also be cured in other laws. This can be achieved by introducing a supplementary provision, prescribing that the origin of the plant material must have been disclosed and that the knowledge holder must have had an opportunity of expressing prior, free and informed consent to

⁴⁵ Communication by the European Communities and their Member States to the TRIPs Council on the Review of Article 27.3(b) of the TRIPs Agreement, and the Relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore—A Concept Paper, Brussels, European Commission - Directorate General for Trade (12 September 2002). Also see: Submission by the European Community and its Member States on Traditional and Intellectual Property Rights—3rd Session of the WIPO Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore (13–21 June 2002). Also see: Review of Article 27.3(B) of the TRIPs Agreement and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore—A Concept Paper, submitted by the European Communities under Paragraph 32 (ii) to the WTO (14 February 2003).

⁴⁶ Order n° 1086 of 11 December 2000, entering into force 20 December 2000, amending Order n° 374 of 19 June 1998 on patents and supplementary protection certificates.

⁴⁷ COP 6 Decision VI/24, see <http://www.biodiv.org/decisions/default.asp?lg=0anddec=VI/24>.

⁴⁸ Communication by the European Communities, Brussels, 12 September 2002 (see previous footnote). Also see the Submission by the European Community and its Member States on Traditional and Intellectual Property Rights, Brussels, 14 June 2002.

access, use and patenting. Such a provision can be issued by a government and carries an obligation to comply. This approach has been advocated by De Carvalho (1999) and has also been suggested by the European Commission.⁴⁹ However, it remains to be seen what type of information will be requested and what the legal consequence will be of failure to disclose. To have any effect, non-compliance, in casu the non-existence of a disclosure of origin and informed consent, should probably result in a regulatory penalty.

4.2.2. *Voluntary code of conduct*

User measures can also be designed outside patent law, by way of a voluntary code of conduct. A code of conduct is a standard setting forth principles to guide a company's performance. Although a 'standard' sets forth rules or guidelines, compliance is not mandatory. Often, one of the aims of a code is to protect the public image of a company, large corporations often aim at convincing consumers they act morally. Hence the penalty for nonconformity with a standard comes from the marketplace or the public and the threat of bad publicity (Echols, 2003).

Nowadays, the issue of informed consent and origin requirement has become a matter of great public concern. Yet, if the (national) government's hands are tied or political consensus is hard to achieve, private sector standards are an option: if it appears undesirable to implement the informed consent requirement through legal action, the establishment of informed consent concerning patent matters through voluntary codes of conduct might be considered.⁵⁰

4.2.3. *Voluntary certification*

In the context of user measures, a relatively novel and innovative user measure is voluntary certification schemes for institutions abiding by rules for access and benefit sharing. Such measures have been used to great effect for a wide variety of purposes under the International Organization for Standardization (ISO). Alternative specialized schemes have also been used

for some forest products, various fisheries and marketing of organic food. The government of Switzerland has launched a pilot project to test the feasibility of such a measure for promoting proper use of genetic resources (see Tobin and Barber, 2003; Van Overwalle, 2004).

4.2.4. *'Doctrine of unclean hands'*

As should be clear from the above, there are differing opinions with regard to the question whether requiring disclosure of origin and legal provenance of genetic resources and traditional knowledge is in fact in conformity with TRIPS. There is one area of the debate about which there appears to be more widespread agreement. This relates to the principle that the holder of a patent, which has been obtained following an illegal act, should not be entitled to benefit from his illegal act, through exercise of the rights obtained in the grant of the IPR. This is generally referred to as the application of the "doctrine of unclean hands". On the basis of article 8 (2) TRIPS Agreement, which authorizes WTO members to adopt appropriate measures to prevent the abuse of IPRs, it is argued that if genetic resources are directly or indirectly used in making a patented invention and have been obtained in a country that has adopted legislation requiring prior informed consent, then failure to obtain that consent would amount to fraud (Tobin and Barber, 2003; De Carvalho, 1999, 2000, p. 389–401).

4.2.5. *Unjust enrichment*

Another tool to remedy incorrect behaviour of users, is the doctrine of unjust enrichment. Unjust enrichment occurs where a party keeps money or benefits that, in fairness, belong to someone else. A person who has been unjustly enriched at the expense of another must legally return the unfairly kept money or benefits. This route is currently critically examined in the framework of bioprospecting.

4.2.6. *Import and transport regulations*

Last but not least, utilizing existing customs regulations and procedures to regulate the import of genetic resources is a measure that could encourage users to comply with their obligations. Detailed regulations govern the import of plant material, wildlife, and microorganisms in virtually all countries.

⁴⁹ Communication by the EU to the TRIPs Council, 12 September 2002.

⁵⁰ The author first elaborated this idea in earlier work relating to stem cell patenting, see Van Overwalle (2002c).

		MIXED	PRIVATE
IP TOOLS	Existing	Patents (Patent Office) * ° - Prior art screening	Patents (Patent proprietor) * - Humanitarian use restrictions
	New	Patents * ° (Patent proprietor) - Origin requirement - Informed consent requirement	
NON-IP TOOLS		Self standing regulations ° Voluntary certification ° Import and transport regulations *	Voluntary code of conduct °* Doctrine of unclean hands Doctrine of unjust enrichment

Fig. 2. User tools for sharing benefits biodiversity* and traditional knowledge°.

Governments regulate imports for many different purposes. Hence they have implemented obligations under international treaties and, in some cases, they have ensured that the item imported was obtained in compliance with the laws of the country of source (Tobin and Barber, 2003).

4.3. Overview

Various systems have been suggested to meet the fair and equitable sharing objective of the CBD. Classifying these systems according to both the legal (IP versus non-IP) and institutional (public versus private) nature leads to Fig. 2.

5. Conclusions

The legal protection of biodiversity and traditional knowledge and the equitable sharing of their benefits have gained wide concern in civil society. It has triggered stakeholders, government officials, politicians and scholars to screen various existing instruments and to develop new lines of thought.

Our purpose in the second section was to analyze the major concepts surrounding this debate. We learned that some concepts are well clarified and are based on a reasonably wide consensus ('traditional knowledge', 'holder', 'user'), whereas others concepts remain unclear in nature and scope ('biodiversity', 'scientific knowledge') and call for further study.

In the third section we embarked on a tour d'horizon of the legal instruments which can serve to protect biodiversity and traditional knowledge, seen from the perspective of biodiversity and traditional

knowledge holders. The term 'protection' was defined in its strictest sense, thus referring to intellectual property (IP) protection and property-similar regimes.

To protect biological resources, mainly two IP regimes came in sight: patents and plant breeder's rights. The potential of the patent system is rather limited. Biological material of plant or animal origin does not always qualify as an invention. Moreover, the conditions of novelty, inventive step and industrial applicability are often hard to meet in developing provider countries with limited technological capacities. Patent law is definitely out of reach in those provider countries which have opted for using the flexibilities of TRIPs and have principally excluded biological material from their patent laws. The potential of the UPOV type plant breeder's rights system to protect biological resources is rather limited for provider countries as well. Plant breeder's rights protection is only available for plant *varieties*, not for the plant world at large. Furthermore, protection is only available if the standard conditions of distinctness, uniformity, stability and (commercial) novelty are met and although this threshold is significantly lower than the patent one, conditions have to be fulfilled. Plant breeders' rights law is completely beyond reach in the many provider countries which do not offer plant breeder's rights protection in their territory.

Next to patents and plant breeders' rights, biological systems have been evolved which have the same monopolistic effects as IP regimes: genetic use restriction technologies (GURTs). This type of protection regime is not a real option, either. It is probably out of reach for many provider countries,

since highly advanced techniques are necessary to insert GURTs in plant material, and many provider countries do not dispose of the expertise or the infrastructure to do so. Besides, GURTS have triggered wide criticism and resentment, since they run counter to the traditional right of farmers to save seed. Access and benefit sharing (ABS) systems as elaborated in the Bonn Guidelines have also been screened. ABS measures are not an IP tool in the strict sense, but they offer a very valuable alternative. However, one demerit is that such measures place the burden upon the government and can only be successful in practice if the national government involved is willing to espouse the interest of the indigenous/local peoples involved and protect such rights *for* them. Last but not least, contracts were discussed. Agreements have great potential in establishing access and equitable sharing. However, well-balanced contracts might remain beyond reach of provider countries lacking the necessary negotiation skills, although the situation is improving.

To protect traditional knowledge, mainly two approaches can be observed: a so-called “positive protection” route and a so-called “defensive approach” route. Various systems have been suggested as a positive protection system for traditional *medicinal* knowledge: patent law, copyright protection, database protection, geographical indications, *sui generis* systems, liability regimes, contracts and ABS systems. The potential of the patent system is very restricted, since traditional knowledge hardly fits in the conventional patent concepts and prerequisites. The copyright system might offer some limited protection in terms of co-authorship. Database protection is a very valuable tool, since it combines two different objectives: preservation of knowledge and IP protection of data collections. Protection through geographical indications seems promising and should be subject to further investigation. The same is true for *sui generis* systems, ABS regimes and compensatory liability regimes. Contracts have great potential as well, but might turn out adversely for providers lacking negotiating expertise—an international biocollecting regime might be the optimal solution here.

A second approach, the so-called “defensive” one, aims at the protection of indigenous know-

ledge, mainly in an effort to protect these assets against illegitimate acquisition and exploitation by third parties. The major route here is in documenting traditional knowledge. This route deserves full support, since it combines two different, but important objectives: dissemination (and thus, indirectly, preservation) of knowledge and prevention of unauthorized acquisition of IP rights.

The third section of the present contribution aimed at taking stock of what is currently available for protecting biodiversity and traditional knowledge and at pointing to some areas of debate. A realm of old and new tools has appeared. This abundance of differing instruments might puzzle the reader who is not familiar with this field. A few observations might help to guide the reader through this jumble of tools.

The multitude of tools triggers a need to list the various tools in order of merit. The major objective set out at the start of the paper was how to accommodate *IP or IP-like protection* of biodiversity and traditional knowledge. The underlying assumption was that IP protection might be a way to protect the fruits of labour of biodiversity and traditional knowledge holders and that IP protection is important to safeguard the rights of biodiversity and knowledge holders in view of commercial exploitation and benefit. It has become clear that some instruments have, if any, limited potential in this regard. One only has to remind oneself of patents, UPOV type plant breeders’ rights and GURTs. Other regimes hold great promise. One simply has to think of *sui generis* regimes such as CCIPRs or TIPRs, ABS regimes, contracts, databases, geographical indications and compensatory liability regimes. An additional objective which might be helpful in getting priorities right, is the *preservation* of biodiversity and traditional knowledge. If one considers both protection and preservation to be equally important objectives, than database systems and geographical indication regimes hold a prominent place for the future. Further research should prove how those systems should be developed or optimized to tailor them to a biodiversity context.

The prioritizing of tools might lead to some preferential tools. It has to be underlined that the various instruments are not mutually exclusive. Whenever possible, all tools can and should be used

in addition to one another: IP instruments and non-IP instruments, legally binding instruments and non-binding instruments. A fully effective regime to protect biodiversity and traditional knowledge will depend on a number of complementary instruments: IP related tools and non-IP related instruments (Cottier and Panizzon, 2004).

The debate on the protection of biodiversity and traditional knowledge and the right tools is by far not over yet. Besides, various of the proposed tools are still in an embryonic state and show all the symptoms of law in making.

The fourth section explored the legal tools which can be helpful in sharing the benefits resulting from biodiversity and traditional knowledge, from the perspective of responsible users. A first series of tools aims at establishing sharing mechanisms through adjustments in patent law, either in the pre-grant or in the post-grant phase. In the pre-grant phase the reassessment of the novelty regime by patent offices and the introduction of additional requirements for the grant of a patent—in particular the incorporation of a disclosure of origin and a prior informed consent requirement—seem valuable options. All these adjustments are currently finding their way into patent practice and (patent) legislation. However, current legislative proposals show a difference with regard to the legal implications of not fulfilling the additional requirements. However difficult it may seem from a TRIPs point of view, the disclosure of origin and prior informed consent requirements need to be implemented as substantial patentability requirements, or at least as self standing regulations with substantial regulatory penalties. In the post-grant phase, one tool was recorded, notably the introduction of humanitarian use restrictions. This type of tool has been successfully used in various countries already.

A second series of tools aims at sharing the results of biodiversity and traditional knowledge through alternative measures. Attention has been drawn to self-standing regulations, voluntary codes of conduct, voluntary certification, doctrine of unclean hands, unjust enrichment and import and export regulations. It has to be admitted that some of those tools have a rather weak legal basis (e.g. unclean hands, unjust enrichment). They should not be viewed as real, compelling instruments, but merely as sincere

attempts to challenge current legal thinking and open up some theories for new applications.

References

- Alexander, M., Chamundeeswari, K., Kambu, A., Riuz, M., Tobin, B., 2003. The Role of Registers in the Protection of Traditional Knowledge. From concept to practice. UNU-IAS report. United Nations University Institute of Advanced Studies (UNU-IAS), Tokyo. Available at <<http://www.ias.unu.edu>>.
- Asser, C., Scholten, P., 1954. Handleiding tot de beoefening van het Nederlandsch burgerlijk recht. Algemeen deel/Tjeenk Willink, Zwolle.
- Balick, M., 2003. Traditional knowledge: lessons from the past, lessons for the future. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis.
- Barber, C.V., 2002. Developing and implementing national measures for genetic resources access regulation and benefit sharing. In: Laird, S.A. (Ed.), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*. Earthscan Publications, Sterling, VA.
- Beier, 1992. Gewerblicher Rechtsschutz, Soziale Marktwirtschaft und Europäischer Binnenmarkt. GRUR, p. 228.
- Beier, 1994. Patent und Ethik im Spiegel der technischen Evolution. GRUR, p. 541.
- Benkard, G., 1993. Patentgesetz. Beck'sches Kurz Kommentare, vol. 4. Beck, München.
- Bent, S.A., Schwab, R.L., Conlin, D.G., Jeffery, D.D., 1987. *Intellectual property rights in biotechnology worldwide*. Stockton Press, New York.
- Blakeney, M., 1997. Bioprospecting and the protection of traditional medical knowledge of indigenous peoples: an Australian perspective. *European Intellectual Property Review*, 298–300.
- Blakeney, M., 1998. Biotechnology, TRIPs and the Convention on Biological Diversity. *Bio-Science Law Review*, 144.
- Boukaert, B., Van Hoecke, M., 1991. *Inleiding tot het Recht*. Acco, Leuven-Amersfoort.
- Bragdon, S., 2001. CGIARs and Intellectual Property Rights. In: Llewelyn, M. (Ed.), *Plant Intellectual Property Rights Within Europe and the Global Community*, Proceedings International Conference 10–11 January 2001 Angers, France. PIP, University Sheffield, Sheffield.
- Brush, S.B., 2003. The demise of common heritage and protection for traditional agricultural knowledge. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis. Available at <<http://www.law.wustl.edu/centeris/Confpapers/PDFWrdDoc/StLouis1.pdf>>.
- Calabresi, G., Melamed, A.D., 1972. Property rules, liability rules and inalienability: one view of the cathedral. *Harvard Law Review* 85, 1089.
- Cantley, M., 1997. International instruments, intellectual property and the collaborative exploitation of genetic resources. *Phytochemical Diversity: A Source of New Industrial Products*. Royal Society of Chemistry.

- Commission on Intellectual Property Rights, 2002. Integrating intellectual property rights and development policy. London.
- Correa, C.M., Yusuf, A.A., 1998. Intellectual Property and International Trade: The TRIPS Agreement. Kluwer Law International, The Hague.
- Cottier, T., 1998. The protection of genetic resources and traditional knowledge: towards more specific rights and obligations in world trade law. *Journal of International Economic Law*, 555–584.
- Cottier, T., Panizzon, M., 2004. Legal perspectives on traditional knowledge. *Journal of International Economic Law* (2), 371–399.
- Da Costa e Silva, E., 1995. The protection of intellectual property for local and indigenous communities. *European Intellectual Property Review*, 546.
- Daes, E.I., 1995. Discrimination against indigenous peoples: study on the protection of the cultural and intellectual property of indigenous peoples.
- De Carvalho, N.P., 1999. From the Shaman's hut to the patent office. Search of Effective Protection for Traditional Knowledge. Magazine of the Associação Brasileira Da Propriedade Intelectual (ABPI), N° 41.
- De Carvalho, N.P., 2000. Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without infringing the TRIPS agreement: the problem and the solution. *Washington University Journal of Law and Policy*, 317.
- De Carvalho, N.P., 2003. From the Shaman's Hut to the Patent Office. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis.
- Drahos, P., 2000. Indigenous knowledge, intellectual property and biopiracy: is a global bio-collecting society the answer? *European Intellectual Property Review*, 245.
- Durner, W., 2000. Common goods. Statusprinzipien von Umweltgütern im Völkerrecht. *Nomos*.
- Dutfield, G., 2003. Opinion: should terminator technology be terminated? *European Intellectual Property Review*, 11.
- Echols, M., 2003. Solutions in Terms of Self-Regulation or Self-Imposed Moral Codes of Business Corporations. In: Vedder, A. (Ed.), *The WTO and Concerns Regarding Animals and Nature*. Wolf Legal Productions.
- European Commission, 2000. Study on the Relationship between the Agreement on TRIPS and Biodiversity Related Issues, Final Report for DG I, Brussel. Available at <http://www.europa.eu.int/comm/trade/miti/intell/ceas.htm>.
- Fischer, W.W., 1999. The impact of 'terminator gene' technologies on developing countries. Costs and Benefits to the Livelihoods of the Rural and Urban Poor Arising from the Application of So-Called 'Terminator Genes' and Similar Technologies in Developing Countries. Report to the UK Department for International Development. Available at <http://www.law.harvard.edu/faculty/ffisher/terminator.html>.
- Gómez, R., 2003. The link between biodiversity and sustainable development: lessons from INBio's bioprospecting program in Costa Rica. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis. Available at <http://www.law.wustl.edu/centeris/Confpapers/PDFWrdDoc/gamezfinal1.pdf>.
- Gervais, D., 2003. TRIPS, Doha and traditional knowledge. *The Journal of World Intellectual Property*, 403–419.
- Glowka, L.F., et al., 1994. A Guide to the Convention on Biological Diversity. IUCN, Gland, Switzerland.
- Gollin, M.A., 2003. Answering the call: public interest intellectual property advisors. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis. Available at <http://www.law.wustl.edu/centeris/Confpapers/PDFWrdDoc/gollinfinal.pdf>.
- Golvan, C., 1992. Aboriginal art and the protection of indigenous cultural rights. *European Intellectual Property Review*, 227–232.
- Gupta, A., 2004. The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Traditional Knowledge. Study jointly commissioned by WIPO and UNEP, Geneva, Nairobi (online at: http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_373.html).
- Hassemer, M., 2004. Genetic resources. In: Von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property*. Kluwer Law, The Hague, pp. 154–213.
- Huft, M., 1995. Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights. *Northwestern University Law Review*, p. 1718.
- Janssens, M.C., 1996. Uitvindingen in dienstverband met bijzondere aandacht voor uitvindingen aan universiteiten—Employee and university inventions (Summary). *Bruylant, Brussel*, pp. 24–26.
- Kadidal, S., 1993. Plants, poverty and pharmaceutical patents. *The Yale Law Journal*, 223–258.
- Kur, A., 2004. Use of collective marks and geographical indications. In: Von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property*. Kluwer Law, The Hague, pp. 63–64.
- Kur, A., Knaak, R., 2004. Protection of traditional names and designations. In: Von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property*. Kluwer Law, The Hague, pp. 227–254.
- Leistner, M., 2004. Traditional knowledge. In: Von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property*. Kluwer Law, The Hague, pp. 52–144.
- Lewis, W., Ramani, V., 2003. Ethics and practice in ethnobiology: analysis of the international cooperative biodiversity project in Peru. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis. Available at <http://www.law.wustl.edu/centeris/Confpapers/PDFWrdDoc/lewisramani.pdf>.
- Maier-Rigaud, F.P., Apestequia, J., 2004. The Role of Rivalry. Public Goods Versus Common Pool Resources.
- McConnell, F., 1996. *The Biodiversity Convention—A Negotiating History*.
- Moufang, R., 1998. The concept of 'Ordre Public' and morality. In: Van Overwalle, G. (Ed.), *Patent Law, Ethics and Biotechnology*. Bruylant, Brussel, p. 77.

- Odek, O., 1994. Bio-piracy: creating proprietary rights in plant genetic resources. *Journal Intellectual Property Law*, 141.
- OECD, 1996. Intellectual property, technology transfer and genetic resources. Survey of current practices and policies. Paris.
- Ohlgart, S.M., 2002. The terminator gene: intellectual property rights vs. the farmers' common law right to save seed'. *Drake Journal of Agricultural Law*, 473.
- Poortinga, E., 1977. Het onderscheid publiekrecht–privaatrecht. *Recht en Kritiek*.
- Posey, D., Dutfeld, G., 1998. Plants, patents and traditional knowledge: ethical concerns of indigenous and traditional peoples. In: Van Overwalle, G. (Ed.), *Patent Law, Ethics and Biotechnology*. Bruylant, Brussel, pp. 112–126.
- Potrykus, I., 2001. Golden rice and beyond. *Plant Physiology*, 1157–1161.
- Puri, K., 1995. Cultural ownership and intellectual property rights post-mabo: putting ideas into action. *Intellectual Property Journal*, 293–347.
- Putterman, D.M., 1996. Model material transfer agreements for equitable biodiversity prospecting. *Colorado Journal of International Environmental Law and Policy*, 145–173.
- Reichmann, J., 2003. Of green tulips and legal kudzu: repackaging rights in subpatentable innovation. *Vanderbilt Law Review*, 1743–1798 (Symposium Issue).
- Remouchamps, L., 1970. Octrooien, in *Algemene Praktische Rechtsverzameling*, Larcier, Brussel, p. 117.
- Rosenthal, J., 2003. Politics, culture and governance in the development of prior informed consent and negotiated agreements with indigenous communities. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis.
- Singer, R., Singer, M., 1989. *Europäisches Patentübereinkommen: Kommentar*. Carl Heymanns Verlag, Köln, p. 174.
- Sterckx, S., 2004. Patents and Biodiversity: Some Reflections on Tensions Between the Regulation of Patenting and the Convention on Biological Diversity. Mimeo.
- Stoll, P.T., Von Hahn, A., 2004. Indigenous peoples, knowledge and resources in international law. In: Von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property*. Kluwer Law, The Hague, pp. 8–32.
- Tamayo, G., Guevara, L., Gámez, R., 2004. Biodiversity prospecting: the INBio experience. In: Bull, A.T. (Ed.), *Microbial Diversity and Bioprospecting*. ASM Press, Washington, pp. 445–449.
- Tobin, B., 2002. Biodiversity prospecting contracts: the search for equitable agreements. In: Laird, S.A. (Ed.), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*. Earthscan Publications, Sterling, VA.
- Tobin, B., Barber, C.V., 2003. Options for developing measures in user countries to implement the access and benefit-sharing provisions of the convention on biological diversity. In the current proceedings. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis.
- Van den Daele, W., Döbert, R., Seiler, A., 2003. Stakeholder dialogue on intellectual property rights in biotechnology: a project of the world business council for sustainable development. *International Review of Industrial Property and Copyright Law*, 932–952.
- Van Gerven, W., 1975. *Handelsen economisch recht*. Antwerpen Standaard.
- Van Overwalle, G., 1996. Octrooieerbaarheid van plantenbiotechnologische uitvindingen—Patentability of plant biotechnological inventions (Extensive Summary). Bruylant, Brussel. 739 pp.
- Van Overwalle, G., 1997a. The legal protection of biotechnological inventions in Europe and in the United States. Current framework and future developments. University Press, Leuven. 78 pp.
- Van Overwalle, G., 1997b. TRIPs en het octrooirecht. *Intellectuele Rechten—Droits Intellectuels*, pp. 222–244.
- Van Overwalle, G., 1998. Octrooieerbaarheid van biotechnologische uitvindingen. In: Van Overwalle, G. (Ed.), *Octrooirecht, ethiek en biotechnologie—Patent Law, Ethics and Biotechnology—Droit des brevets, éthique et biotechnologie*. Bruylant, Brussel, pp. 33–63.
- Van Overwalle, G., 1999. Patent protection for plants: a comparison of American and European approaches. *IDEA—Journal of Law and Technology*, 143–194.
- Van Overwalle, G., 2001. Traditional medicinal knowledge, patents and the convention on biological diversity. *Revue de droit intellectuel. L'Ingénieur Conseil*, 161–182.
- Van Overwalle, G., 2002a. Belgium Goes Its Own Way on Biodiversity and Patents. *European Intellectual Property Review*, 233–236.
- Van Overwalle, G., 2002b. Protection of traditional knowledge: a critical synthesis. In: Grosheide, W., Brinkhof, J. (Eds.), *Articles on Cultural Expressions and Indigenous Knowledge*. Molegrafica series. Intersentia, Antwerp, pp. 251–268.
- Van Overwalle, G., 2002c. Study on the patenting of inventions related to human stem cell research. *European Communities, Luxembourg*. 218 p. Available at <http://europa.eu.int/comm/european_group_ethics/docs/stud-vanoverw.pdf>.
- Van Overwalle, G., 2003a. Legal and ethical aspects of biopatenting. A critical analysis of the EU biotechnology directive. In: Baumgartner, C., Mieth, D. (Eds.), *Patente am Leben? Ethische rechtliche und politische Aspekte der Biopatentierung*. Mentis, Paderborn, pp. 145–158.
- Van Overwalle, G., 2003b. Holder and user perspectives in the traditional knowledge debate. Paper Presented at the Conference on Biodiversity, Biotechnology and the Protection of Traditional Knowledge. Washington University School of Law, Saint Louis.
- Van Overwalle, G., 2004. Disclosure of Origin and Certificates of Origin. Paper Presented at the International Roundtable on the Practicality, Feasibility and Cost of Certificates of Origin. Unesco, Paris.
- Vogel, J.H. (Ed.), 2000. *The Biodiversity Cartel. Transforming Traditional Knowledge into Trade Secrets*. CARE, Proyecto SUBIR.
- Walden, 1996. Intellectual property rights and biodiversity. In: Bowman, M., Redgwell, C. (Eds.), *International Law and the Conservation of Biological Diversity*. Kluwer Law International, London, pp. 182–189.
- Wells, A.J., 1995. Patenting new life forms: an ecological perspective. *European Intellectual Property Review*, 111–118.

- Wendland, W., 2002a. Intellectual property and the protection of cultural expressions: the work of the World Intellectual Property Organisation. In: Grosheide, W., Brinkhof, J. (Eds.), *Articles on Cultural Expressions and Indigenous Knowledge*. Intersentia, Antwerp, pp. 101–138.
- Wendland, W., 2002b. Intellectual property, traditional knowledge and folklore: WIPO's exploratory program. *International Review of Industrial Property and Copyright Law*, 485–504 and 606–624.
- WIPO, 2001. Intellectual property needs and expectations of traditional knowledge holders (WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge—1998–1999), p. 25. Geneva.