

CHAPTER 10

AMIDST PERIL AND PROGRESS

Conservation of diversity and patent law

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Abstract. Medicinal and aromatic plants are biological, cultural and industrial resources. The diversity from which they stem is in peril, though. The manner in which they are patented and exploited by the bio-industry upon their modification is controversial. It disregards interests of countries and communities that provide them. This is affected by the global regulative framework, devised pursuant to the neo-liberal policies that steer globalization. Patent law is part of that framework. Reformulation of ethical principles, policies and laws should lead to integrative protection of ecological, cultural and commercial interests. The Convention on Biodiversity should do just that. Its implementation is hampered by conflicts with said framework, and particularly patent law. Some of the issues may be resolved politically, for example in the course of the Doha Development Agenda, but fundamental issues remain. This article addresses the context of these problems, some initiatives to rebut them, suggests alternative routes for their resolution, and concludes that diligence is required in respect of legal change when we are in the thick of peril and progress.

Keywords: plants; diversity; pharmaceuticals; exploitation; sustainability; distributive justice; globalization; ethics; access and benefit sharing; patent law; disclosure requirement

NATURE, CULTURE AND PLANTS

The cultural and ecological spheres on this planet are closely interwoven, and the same applies to human interests related to the resources they provide – the materials and knowledge, and ultimately products and services so attained¹. Phenomena that originate in one or the other sphere often have a dual character. Indeed “...every culture has manifested its own ecological microcosms in some form of art or mythology...” (Tobias 1995, p. 212). Central to Aboriginal cosmology is the ‘Tjukurrpa’ – a moment of creation when the ancestors engage in epic struggles transformed in animals, humans and plants –, which is, i.a., evoked in ceremonies, as to let strengths of the ancestors take over the dancers and singers. Also, the ‘stories’ contained in artistic expressions reveal the nature of the ancestral beings and their powers, which are related to natural phenomena. Every expression so

manifests the great creative evolution of the landscapes, but also provides practical knowledge for human survival (Isaacs 2002). The interrelation between referenced spheres is shared by man all over the world. Nature inspires and teaches: “Polynesians always looked to the summits of rock peaks for divine grace. In Bora Bora, the spirits inhabit not the water but spectacular Mount Pahia ... the Asians cultivated their own paintable mountains, inhabitable gardens, symbolic waterfalls and sacred caves. Ancient Egyptians beheld their Nile as a divine refuge. The Greeks made pilgrimages to God-inhabited groves, sun-drenched oracles and religious springs. Romans converted their nature gods into cult figures and painted them on the walls of country villas, while later medieval Europeans and Persians built elaborate walled-in gardens, complete with unicorns, lions, lambs and hydraulic phenomena” (Tobias 1995, p. 212). Plants may equally be perceived as biological and cultural resources, and agricultural and medicinal knowledge pertaining to those plants emanates from the same duality. It is as much affected by the ecosystem in which the peoples that develop it reside as by their cultural principles and conduct (Maffi 2000; Slaughter 1996).

DEGENERATION OF BIOLOGICAL AND CULTURAL DIVERSITY

Cultural and biological resources are in peril. Whereas culture and nature have always engaged in a mutually intense love affair, which – as is most often the case – manoeuvred between egoism and altruism, the balance may have become disturbed. Man’s egoism may have turned into narcissism. This occurred gradually, and it seems likely that each civilization has contributed somewhat to the narcissistic transformation (Ponting 1991). However, we may have reached a moment in time in which the consequences of that transformation will inevitably turn on ourselves. In respect of cultural diversity, it is expected that about 90% of the 5,760 languages spoken today will be replaced by the dominant languages – e.g., English, Chinese and Spanish – by the end of the 21st century. Such will have deleterious consequences because “... the extinction of each language results in the irrecoverable loss of unique cultural, historical and ecological knowledge ... every time a language dies, we have less evidence for understanding patterns in the structure and function of ... the maintenance of the world’s diverse ecosystems” (UNESCO 2003, p. 4-6). Biological diversity (‘biodiversity’) faces similar threats: “Over the past few hundred years, humans have increased species extinction rates by as much as 1,000 times background rates that were typical over Earth’s history. ... The distribution of species is becoming more homogenous. ... Between 10 and 50% of higher taxonomic groups (mammals, birds, amphibians, conifers and cycads) are currently threatened with extinction. ... 20% of bird species, 23% of mammals, 25% of conifers are currently threatened with extinction. ... 32% of amphibians are threatened with extinction. ... 10-20% ... of current grassland and forestland is ... to be converted to other uses between now and 2050, mainly due to the expansion of agriculture and ... cities and infrastructure ...” (Millennium Ecosystem Assessment 2005b, p. 2-5). Simultaneously, “Everyone in the world depends on nature and ecosystem services to provide the conditions for a decent, healthy and secure life ...

human activities have taken the planet to the edge of a massive wave of species extinction, further threatening our own well-being ..." (Reid 2005, p. 2). It is alarmingly clear that the manners in which humans exploit cultural and biological resources "may so alter the living world that it will be unable to sustain life ..." (Suzuki and McConnell 1997, p. 4). Of course, exploitation of these resources as such is a culturally neutral activity – humans depend on and interact with nature and each other for survival. However, the ways that supposedly entail so much risk have arisen in the 'West' – Europe and the United States –, root in elements of the complex of Greek-Roman and Judeo-Christian ways and ideas, but truly started to blossom during the European Enlightenment. It is from this complex of ideas, methods and developments that contemporary ways of exploitation commenced to flourish – upon industrialization in the 19th century and subsequently by the development of advanced technologies in the following century (Tobias 1995, p. 212-215; Cahn and O'Brien 1996, p. 131-206). Defining characteristics of the contemporary culture(s) of Europe and the United States may be a separation between the worlds of instrumentality and self-consciousness and dissociation of humanity from non-humanity (Touraine 2004, p. 154). Indeed, a normative division between man and his means (e.g., technology) and also between man and plants and animals (i.e. nature) may be widely embraced by societies in Europe and the United States, as well as a separation of 'objective' knowledge such as science, and 'subjective' knowledge such as morality. These perceptions of course affect all types of human activity within those societies, such as scientific, political, artistic and legal endeavours (e.g., respectively, Achinstein 2004; McClelland 1996; Tobias 1995; Drahos 1996). Whereas these perceptions have freed many from tyranny and oppression, and have positively contributed to the world in several respects – i.e. by human rights, in medicine and so forth –, they may also have led to a 'denial of nature', narcissism and – as it certainly appears from time to time – parasitic behaviour (Tobias 1995, p. 214). It may not be surprising that this behaviour first affected diversity in the west itself – where cultural and biological resources have been impoverished most rapidly, resulting in extensive homogenization and depletion. Presently, most cultural diversity can be found outside the western world. Out of about 6,000 cultures in the world, approximately 5,000 are considered indigenous². Indigenous cultures make up about 80% of the world's cultural diversity. Most indigenous cultures can be found outside the western world. The same applies to biodiversity. Both cultural and biological diversity are largest in countries with a tropical climate that did not industrialize to a great extent (e.g. Wullweber 2004, p. 18-36; Aguilar 2001, p. 242 ff)³. It is in those countries that the most negative impacts of exploitation are felt and the gravest losses are encountered. Of course, cultural and biological diversity have always been subject to change and loss. However, loss did not necessarily result in deterioration. On the contrary, loss was often followed by gain. Physical barriers – hills, mountains, seas and distances – offered protection against possible negative 'foreign' influences – both natural and man-made – and also allowed for local evolutionary adaptations that ensured a continuous and diverse genetic and cultural drift (Cavalli-Sforza and Cavalli-Sforza 1996; Sykes 2001). However, with the advent of globalization, loss of those very barriers and dispersion of the 'western way', it becomes rather difficult to sustain

diversity. The next paragraph addresses the phenomenon of globalization in relation to the bio-industry.

GLOBALIZATION AND THE BIO-INDUSTRY

Globalization is characterized by rapidly emerging relationships between states, corporations, communities and individuals from different geographical and cultural confinements. It leads to a society "... without borders and spatial boundaries ..." (Slater 2003, p. 51). Global interactivity is of course enhanced by information technology – such as the World-Wide Web. But also better modes of transportation, and thus the means to move people and objects around the globe, profoundly add hereto. Neo-liberal economic ideologies drive the process of globalization (Held and McGrew 2003, p. 299-420). It may not be surprising that, whereas globalization was devised politically, its first outlooks had a corporate character (Youngs 2003, p. 4-5). Industries benefit profoundly from the opening-up of markets (and thus countries and cultures) that is demanded by neo-liberalism. The knife cuts both ways: companies have greater access to productive resources and have more markets to sell the products deriving therefrom. In respect of the internationalization of production, it is noted that the various productive elements (resources) that enter into the manufacture of a product (capital, labour, knowledge and materials) come from more and more sources, which are increasingly hard to identify and track (Narula 2003, p. 20-26, 109-162). Simultaneously, industries themselves also transform for globalization (Held and McGrew 2003, p. 299-378). The bio-industry – broadly comprising companies, universities and research centres involved in research and development of products and services deriving from or consisting of biological material – may be illustrative (cf. Narula 2003, p. 35 ff; Dutfield 2003, p. 105 ff). The products and services it delivers – e.g., a pharmaceutical developed by biotechnological means – are often the outcome of global endeavours. Indeed, the resources that enter into the development of these products come from many, sometimes unidentifiable, sources and at low costs. The productive resources of biotechnology are capital, labour, biological material (including genetic and other biochemical compounds) and knowledge (Janssen 1999, p. 313-321). They are accessed, collected, researched and ultimately developed into products in a variety of countries and communities throughout the world. Presently, R&D by the bio-industry may require resource contributions from developed, developing and even least developed countries and the cultures that thrive in those countries⁴. Insofar as relevant for the topic at hand, these contributions may comprise different knowledge inputs (ranging from the knowledge of a molecular biologist to that of a traditional indigenous healer) as well as different material inputs (ranging from a medicinal plant cultivated by a local farmer to a synthesized compound delivered by a medicinal chemist).

CULTURAL AND BIOLOGICAL DIVERSITY AND PHARMACEUTICALS

Cultural and biological diversity are crucial for all human and thus also industrial and commercial endeavours (Millennium Ecosystem Assessment 2005a). This relation is particularly clear in the areas of medicine and health. Many pharmaceuticals derive from plant-related material and the medicinal knowledge (most commonly called traditional knowledge) of cultural communities (many of which are of indigenous origin) (e.g. Patrick 2005, p. 271-274; Schuler 2004, p. 160; Laird 2002, p. 247 ff). The pharmaceutical industry acknowledges these relations. Nevertheless, industry representatives often stress the relative importance of both natural compounds and traditional knowledge and correctly indicate that the process from raw material and knowledge to product is complex, time-consuming and costly (e.g. McCabe 2003). Furthermore, it is often argued that in-house compound libraries remain the primary source for the identification of active principles (lead compounds) (cf. Cordell 2000, p. 465-468). Conversely, others expect these libraries to become exhausted – the recombination of a limited number of compounds is restricted and not endless –, which necessitates the acquisition of new biological material (Patrick 2005, p. 275 ff). Also, the advancement of biotechnology allows for much more effective use of biochemical compounds than was the case before, and should result in new types of pharmaceuticals and therapies. Hence, industries should “tap natural diversity” (BIO 2004, p. 46). Therefore, the overall expectation is that both traditional knowledge and *in vivo* biological material will increasingly be accessed and used by the pharmaceutical industry (Patrick 2005, p. 172; Millennium Ecosystem Assessment 2005a, p. 25 ff; Verpoorte 2000, p. 253). The pharmaceutical (and in fact the entire bio-)industry is mostly situated in and/or steered from referenced western countries. Of course, important resources for biotechnology are provided as well from within these countries (money, labour and knowledge concerning the identification, modification and application of compounds, and worked material) (BIO 2004, p. 3-16; Powell 2001, p. 251-266). However, it is contested that the global ‘collaboration’ in biotechnology pays off only selectively. Supposedly, it progresses in an inappropriate fashion that solely benefits the bio-industry and negates economic interests of biodiversity-rich countries and traditional-knowledge-holding communities. The knowledge and material provided by the developing world and its communities are obtained at low cost by the bio-industry whereas the outcomes of R&D – pharmaceuticals – become subject of intellectual property (particularly patent) rights, and may be commercialized exclusively by the right-holders. This perspective turns on distributive justice. Moreover, some find that industrial and commercial activities – such as R&D, exploitation of pharmaceuticals, and the technological progress so achieved – should be conducted in a manner that is not neutral but contributive to other societal needs – such as conservation of diversity. This perspective hinges on the sustainability of these activities. The global regulative framework profoundly affects the manner in which human activities may be conducted and, thus, the issues of distributive justice

and sustainability (e.g. Shiva 1998). Intellectual property is a prominent part of that framework.

INTELLECTUAL PROPERTY AND GLOBAL LAW AND POLICY

‘Intellectual property’ is a term used to describe a variety of legal regimes that have different goals, structures and workings, but equally apply to intangible objects. These regimes are, i.a., the laws on copyrights, patents, trademarks, industrial designs, geographical indications and plant breeders’ rights. Intellectual property laws may apply to a variety of cultural and biological resources, albeit in a certain form and/or application only. For example, copyrights may apply to a painting depicting a medical treatment. Patents may encompass a biotechnological invention consisting of a modified biochemical with medicinal properties, and originating in a medicinal plant. The author and inventor, respectively, may be bestowed with exclusive rights in respect of the object concerned, as to exclude others from commercially exploiting such. Intellectual property law has western roots – it originates in Europe (Idris 2003, p. 7-75; Drahos 1996, p. 13-118; Brinkhof 1990). The regimes of intellectual property law were among the first ones to be inserted into the global regulative framework administered by the World Trade Organization (WTO). Globalization of the market economy requires global “... defining and protecting [of] property rights; setting rules for exchanging those rights, establishing rules for entry into and exit out of productive activities; and promoting competition by overseeing market structure and behavior and correcting market failures” (Flanders 1996, p. 80, 88-109). The TRIPs Agreement (1994) does all this for intellectual property – it globalizes the minimum standards for conveyance and enforcement of these rights. It has so extended the western way of conveyance of proprietary rights to certain forms and/or applications of cultural and biological resources to about the entire world, i.e. member states of the WTO (Matthews 2002)⁵.

The WTO resides over more than 140 treaties in a variety of fields, including labour, finance and, as indicated, intellectual property⁶. The neo-liberal policies that feed this framework necessarily led to an emphasis on the economic side of things and perhaps added to aforementioned deepening of the gaps between the worlds of self-consciousness and instrumentality indeed. This approach roots in the belief that problems in non-economic domains, such as culture and ecology, will only be solved upon economic development. Its proponents necessarily adhere to a ‘Brechtian view’ on mankind. Thus, as Jenny explains in the Dreigroschenoper about the preconditions for human survival: “*Ihr, die auf unsrer Scham und eurer Lust besteht / Das eine wisset ein für allemal: / Wie ihr es immer dreht und wie ihr’s immer schiebt / **Erst kommt das Fressen, dann kommt die Moral** / Erst muß es möglich sein auch armen Leuten / Vom großen Brotlaib sich ihr Teil zu schneiden*”⁷. Translated into terms of governance this implies that the enhancement of the economic domain (wealth) should subsequently lead to enhancement of other ones (welfare). However, the intermediate outcomes of globalization may challenge this assertion – dispersion of wealth is not an easy task. The International Labour

Organization concludes that "... the income gap between the richest and the poorest countries in the world increased significantly" during the past decades (ILO 2004, p. 36). The World Economic and Social Survey of 2005 shows that globalization has unevenly affected economic developments around the world. Whereas it has contributed drastically to economic development of some countries – for example China – it has hampered such enhancement on the sub-Saharan and Latin-American continents (DESA 2005). Also, the narrow focus on dispersion of wealth may not contribute to welfare. Hence, the United Nations Educational Social and Cultural Organization (UNESCO) finds that "... globalization, in its powerful extension of market principles, by highlighting the culture of economically powerful nations, has created new forms of inequality, thereby fostering cultural conflict rather than cultural pluralism", and concludes that it is a threat to cultural diversity (Garzon 2002). The Millennium Ecosystem Assessment Synthesis report concludes that globalization has weakened the connections between ecosystems and cultural diversity and that such contributes profoundly to the loss of biodiversity (Millennium Ecosystem Assessment 2005b, p. 120 ff). It also finds that during the past decades of globalization "... humans have changed ecosystems more rapidly and extensively than in any comparable period of time in human history, largely to meet rapidly growing demands ... This has resulted in a substantial and largely irreversible loss in the diversity of life on Earth" (Millennium Ecosystem Assessment 2005b, p. 2; 26-70). The causes of such loss are, among other things, industrialization, urbanization, pollution and climate change. Underlying causes are mostly attributed to rapid economic developments, overpopulation and drastic changes in consumption and production patterns. The Millennium Ecosystem Assessment shows that the fears about the consequences of man's parasitic use of biological resources described before are justified. It issues "... a stark warning. Human activity is putting such a strain on the natural functions of the Earth that the ability of the planet's ecosystems to sustain future generations can no longer be taken for granted" (Millennium Ecosystem Assessment 2005b, p. 2). It is conspicuous that a struggle between commerce, culture and ecology is going on. Realities of governance may be far more complex than the proponents of economic globalization acknowledge. Developments may not unfold through patterns of singular causalities, but may rather have a cyclonal character, in which multitudes of converging causes collectively push towards a certain outcome. Indeed, "... things ... are not isolated, unique, simple ..., but are ... complex ... and varied" (Eden 2001, p. 119). Perhaps Jenny was wrong.

DISTRIBUTIVE JUSTICE AND SUSTAINABILITY: THE GOOD AND EQUITABLE

The economic make-up of the global regulative framework may so harm the common good and equity (Williams 2003, p. 88). The issues of distributive justice and sustainability in respect of R&D and exploitation of pharmaceuticals by the bio-industry exemplify this. However, whereas deciding on the good and equitable may have always been hard, globalization has made it even more complex. Globalization

mingles values in an unprecedented fashion (Ahmed 1992, p. 26). Ethical imperatives are shuffled; many communities may suddenly be confronted with the individual internal one (i.e. Kant's categorical imperative), leaving the idea that it comes from God, religion or the state. Conversely, many individuals may find that their imperative – their autonomous responsibilities, virtues, and honours – is challenged in a globalizing world and they acquire insights into other (communal, cosmological etc.) ones. This may lead to confusion. Simply put; the Dutch adolescent may struggle with the proper manner to fulfil his social responsibilities and has to manoeuvre between the virtues of his environmentally friendly behaviour in Amsterdam, whilst maintaining consumption patterns that add to environmental problems in other (producing) regions of the world. The Aboriginal adolescent may struggle equally well. He may find it hard to reconcile communal duties and holistic approaches (e.g., the 'Tjukurrpa' concept), with the enhancement of his individual pursuits, his studies of, for example, reductionist physics, and the emancipation, assimilation and social mobility that necessarily follow. Presently, human beings are confronted with a dual complexity. Our imperatives – the source of our attitudes and judgments – are challenged by intermingling, while we simultaneously face serious problems that call for the wisest of decisions and that all need to be dealt with at the same time but seem impossible to reconcile (Morin 2004, p. 43-46). Particularly in respect of the topic at hand, one may, for example, find that biotechnological progress is good (but homogenization of knowledge, methods and means is bad), commercial exploitation of biological resources is good (but depletion and pollution are bad), accessing cultural and ecological spheres for that purpose is good (but disruption and deterioration of cultural and biological diversity are bad), stimulating the ones involved and deliver beneficial products by rewarding their efforts through proprietary rights is good (but not rewarding other ones' contributions and excluding them is bad), and conservation of resources within those spheres is equally good (but not making use of those resources is bad). Max Weber's 'polytheism of values' surely applies here, and we are challenged by a world that calls for irreconcilable attitudes (Weber 1915). More than ever, the pretexts for those attitudes must be derived from perhaps contradictory sources. In view hereof, a lot of attention is given to the re-formulation of ethical principles in a globalizing world. Similarly, new perceptions on the interconnections between science, technology, culture and ecology, and, of course, law call for reconsideration of their respective manners, goals and directions (e.g. Bindé 2004, p. 105-178; Ong and Collier 2005; Dunning 2003; NCB 2002; Beauchamp and Childress 2001; the studies of the European Group on Ethics in Science and New Technologies⁸; Norton 1986). Intellectual property certainly is among the fields of law that are particularly scrutinized in this respect.

How should one pursue to redirect the contemporary make-up of globalization, and implement such change in law? How should one re-direct law and enhance distributive justice and sustainability? As to the latter, one may observe that cultural and biological diversity are so crucial to human existence that it touches upon mankind as a 'moral community', which shares a primary collective interest in conservation (cf. Röling 1985, p. 137). The precautionary principle, which prescribes that one could better be safe than sorry, received due attention in this

respect (O'Riordan et al. 2001). Some plead for the formulation of a '*contrat culturel*' or a '*contrat naturel*' – as to recognize the cultural and natural domains as separate legal entities (respectively, Mayor and Bindé 2001; Serres 1990)⁹. Hence, whereas biological and cultural resources were previously regarded as phenomena with solely instrumental value, they should perhaps be approached as having intrinsic value as well and thus not be considered objects that exist primarily for the benefit of mankind. Enhancement of their standing by furthering Kant's concept on intrinsic value would move them into the centre of gravity of ethical, political and legal discourses¹⁰. The nexus between the global and the local necessarily is also at the forefront of these contemplations. Globalization appears very different looked at from within a developed or a developing country or from within a corporate laboratory or a traditional-knowledge-holding community. The need for protection of local interests and needs is increasingly acknowledged (e.g. Klein 2000)¹¹. Hence, globalization should be transformed into 'glocalization'¹². This requires a flexible approach towards (intellectual property) law too (e.g. Duffy 2002). These (and other) considerations lead to initiatives to re-direct the make-up of the global regulative framework. Some of the legislative endeavours may exclusively aim at bolstering one or the other interest in one or the other domain. The recent conclusion of the Convention for the Safeguarding of the Intangible Cultural Heritage (2003), and the conclusion of the Convention on the Protection of the Diversity of Cultural Contents and Artistic Expressions (now called the Convention on Cultural Diversity) (2005) may be indicative of steps in the direction of a cultural contract¹³. The Convention on Biological Diversity (1993) may be reflective of attempts to come to a natural contract. It also aims at recombining interests that became dissociated; it interlinks the natural contract with 'contracts' of a different kind. It interconnects the need for conservation of biological and cultural diversity, the interest in attaining products and services from such diversity through, among other things, biotechnological means, and the commercial interests and proprietary means concerned therewith. This convention shows the first signs of what may be called a '*contrat holistique*', in which the interconnections between ecological, cultural and economic domains and their global and local faces are safeguarded in an integrated fashion.

THE CONVENTION ON BIOLOGICAL DIVERSITY: ESSENTIALS OF A HOLISTIC CONTRACT

The goals of the Convention on Biological Diversity (CBD) are "... the conservation of biological diversity ... 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 ..." (art. 1)¹⁴. The conservation of biological resources should thus be achieved through a variety of market-economic measures. For that purpose, art. 3 provides that "States have ... the sovereign right to exploit their own resources ..." Hence, the commercial value of biological resources is acknowledged and an exclusive right therein conveyed to the country in which they can be found (the country of origin). Traditional-

knowledge holders' entitlement to their knowledge and its applications is recognized in art. 8(j), which provides that states shall "... respect, preserve and maintain knowledge ... and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity ... and encourage the equitable sharing of the benefits arising from the utilization of such knowledge ...". It should be emphasized that art. 8(j) does not provide a property-like right to traditional-knowledge holders – compared to the national sovereignty granted over biological resources. It entitles them to have a piece of the pie (to share equitably). The nexus between conservation and exploitation (the ecological, cultural and commercial domains) is provided by articles 15 and 16 CBD. Art. 15 (1) provides that "... the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". Access to the genetic resource should be obtained with prior informed consent (art. 15(3) and (5)). Art. 15(7) provides that "... each Contracting Party shall take ... measures ... with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial ... utilization of genetic resources with the Contracting Party providing such resources ... upon mutually agreed terms". Benefits that could be exchanged include technology. Art. 16(2) CBD provides that "access to and transfer of technology ... to developing countries shall be provided ... under fair terms ... In the case of ... patents ... such ... shall be provided on terms ... which are consistent with the ... protection of intellectual property rights" (see also art. 16(3)). Art. 16(5) CBD provides that contracting states must ensure that intellectual property rights are supportive of the goals of the CBD. The latter provisions are crucial for achieving the goals of the CBD, but hamper its implementation. As discussed before, the TRIPs Agreement defines minimum standards for intellectual property protection in compliance with previously existing laws and practices in Europe and the United States. Therefore, the following paragraph outlines the workings of European patent law insofar as relevant for the topic at hand.

PATENT LAW, INVENTIONS AND RESOURCES

"European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step" (Article 52 (1) of the Convention on the Grant of European Patents (1973); hereafter EPC)¹⁵. The patent applicant has to disclose the invention concerned (article 78 (1) (b) and 83 EPC). The patentee has the exclusive right to – briefly stated – exploit the invention commercially (art. 53 DPA 1995). This right lasts 20 years (art. 63 EPC). It is assumed that the opportunity of acquiring exclusive rights will spur potential inventors to devote resources to R&D. Simultaneously, by disclosure of information on the invention, other potential inventors can make use of it and further develop the particular field of technology. Upon lapse of the patent, everybody can make use of the invention previously encompassed thereby. These provisions clearly indicate the goal of patent law – technological progress and deliverance of beneficial products and processes by making use of the (presupposed) individual and egocentric

motivations of potential inventors. The correct workings of patent law hinge on the appropriate balance between public accessibility and private exclusivity, i.e., the flow between the public and private domains (Drahos 1996, p. 119-144; Belder 2006). The delineation between these domains is determined by the collective application of the requirements for patentability and the exclusions therefrom – and greatly affects the extent to which the interests of countries that provide biological resources and providers of traditional knowledge can be acknowledged and safeguarded through patent law. An important exclusion from patentability is provided by article 52(2) sub a EPC, which states that discoveries cannot be patented. An invention is not just anything useful, not any idea which can be reduced to practice. It should reveal a teaching for a planned and targeted action with technicality. The technicality entails the control of the forces of nature (Kraßer 2004, p. 120-121). The focus on (and interpretation of what constitutes) inventions delineates the scope of this proprietary regime, which is on certain intangibles. Of course, these intangibles may relate to previously existing and/or be manifested in and/or become known through tangible objects (Koopman 2005b, p. 525; Drahos 1996, p. 119-139). The outcomes of many biotechnological endeavours may be patentable inventions. It could concern (partial) DNA sequences, promoters and enhancers, proteins, vectors, genetically modified micro-organisms, cells, plants and animals, and a variety of processes used in the course of such modification or the application of biotechnological products (NCB 2002, p. 25). Plants that derive from breeding and selection cannot be patented pursuant to the EPC, but may be subjected to plant breeders' rights. In short, this exclusion derives from art. 53 b EPC, providing among others that plant and animal varieties and essentially biological processes for the production of plants and animals are excluded from patentability (Van Overwalle 1996)¹⁶.

A mixture of herbal substances, such as mostly used by traditional healers, is generally not considered to reveal a technical teaching. Arguably, it is merely 'making use' of nature, and as such is a discovery¹⁷. Nevertheless, even if one would conclude that the traditional knowledge, or its application, is an invention, it would still remain unpatentable. Pursuant to article 54 (1) and (2) EPC, novelty is determined according to the state of the art, which comprises everything made available to the public by means of a written or oral description, by use or in any other way, before the patent application is filed. Often traditional knowledge is not held secret as is common in a competitive business environment but – predominantly treated as a cultural object – rather openly used. Hence, it is not novel. Article 56 EPC states that an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in that art. One may very well imagine that the western-trained expert (e.g., a pharmacologist, microbiologist, botanist or biotechnologist) finds the medical application of a certain herbal substance obvious once he has inquired its biochemical structure and properties. Here, one is confronted with different ways of looking at what substantively is the same. Moreover, a problem may appear with the disclosure of the invention. Cultural knowledge is often not documented, let alone published. Simultaneously, this knowledge is expressed in a cultural and not solely in a 'technological' context. Hence, it could very well appear in songs, plays and so

forth. Modes of expression are not dissociated, as to have distinct artistic and scientific features, but are mixed¹⁸. However, patent offices focus on technological information that is classified according to the International Patent Classification System in about 60,000 classes of technology. Here, a cognitive problem appears – how should the patent office understand and verify the artistically expressed medical knowledge? Conversely, how should the traditional healer pursue to rewrite his knowledge according to specialist biological and chemical scientific standards and languages? Last, a problem with individualizing and identifying the ‘inventor’ appears (article 58 EPC and article 8 Dutch Patent Act 1995). Cultural knowledge is developed intra- and inter-generationally, and is most likely regarded as a communal creation. If it occurs that such knowledge amounts to a patentable invention, it may not be easy to attribute it. Hence, most traditional knowledge cannot be patented as such (Koopman 2005b, p. 527-529). Conversely, given the fact that it has been communicated and/or used openly, and therefore belongs to the state-of-the-art, anyone may, for patent law purposes, learn about and apply it – it belongs to the public domain. Inventions may have a causal relation with the cultural knowledge but may be regarded as novel and inventive anyhow, because of technological modifications. This turns on the closeness of the knowledge concerned (WIPO 2004b, p. 36-37). A causal relation does not necessarily reflect upon the perception and valuation of the various steps and/or contributions leading up to the final result – the invention. Development of an effective, standardized and safe pharmaceutical is, as was indicated before, a highly complex process, not only requiring the input of different types of knowledge, but also of different types of natural and modified material (e.g., synthesized chemical compounds). By the time the invention is completed and patentable, the relation with the initial cultural knowledge is usually remote and indirect¹⁹. This applies even more so to biological material. Biological material *per se* – for example an aromatic plant (its genes and other compounds) obtained in a biodiversity-rich country, with or without assistance of a traditional-knowledge holder and at the start of the R&D process – can never be subject of patent law. It concerns tangible objects, which may be owned and controlled as such. I may own a plant and The Netherlands has sovereignty over (the genes in) the plants on its territory (albeit probably not for private ownership). But neither these plants nor their genes are inventions. Material *per se* does not embody any technical teaching as to control forces of nature. The fact that such material (i.e. the tangible plant) may be used in the course of inventing (i.e. the intangible R&D) and can be related to the embodiment of the invention (i.e. the tangible pharmaceutical, transgenic plant and so forth) is irrelevant (Koopman 2005b, p. 530-531). Facilitation is not important for patent law purposes.

Given the fact that the patent holder has exclusive rights to exploit the invention commercially and reap the benefits, he is legally entitled to ignore the CBD. He does not have to deal with “fair and equitable sharing of the benefits” (articles 3, 15 and 16 CBD). On the contrary: the underlying assumption of the patent regime is that if inventors have to share benefits, they will not devote their resources to R&D – which this regime thus stimulates by conveying exclusivity to them. If states want to fulfil their obligations pursuant to the CBD, they necessarily have to change their

patent laws. How could one proceed, and solve the asymmetries between the CBD and the TRIPs Agreement?

INTEGRATION OF THE CBD IN THE GLOBAL REGULATORY FRAMEWORK

The TRIPs Council of the WTO addresses these questions in the course of its Doha Development Agenda²⁰. The Doha declaration states that members of the WTO “... recognize the need for all our peoples to benefit from ... the multilateral trading system ... The majority of WTO members are developing countries. We seek to place their needs and interests at the heart of the Work Programme adopted in this Declaration ... We are convinced that the aims of ... an open and non-discriminatory multilateral trading system, and acting for the protection of the environment and the promotion of sustainable development can and must be mutually supportive”. Several provisions in the TRIPs Agreement may be used for this purpose. Art. 7 provides that “... intellectual property rights should contribute to ... social and economic welfare ...”. Art. 8 (1) allows for the adoption of measures “... necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic development ...”. Clause 2 of that provision allows for measures to prevent abuse of intellectual property rights. Art. 27(2) allows for exclusions “... from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect the *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”. Art. 27(3) allows for exclusions from patentability pertaining to “... plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”. Hence, the TRIPs Agreement has some room for protection of interests related to the topic at hand, and particularly amendment of patent law in view of the purported distributive justice and sustainability issues (Picciotto 2002; McManis 1998). Proposals for using this room are mostly set forth by the World Intellectual Property Organization (WIPO) and the Secretariat of the CBD. The next paragraph addresses some of these proposals.

SOME APPROACHES TO THE IMPLEMENTATION OF THE CBD

The Conference of the Parties to the CBD has set forth the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization in 2002²¹. These Bonn Guidelines could give providers of genetic material and/or knowledge (read: countries of origin and traditional-knowledge holders) and the acquirers and users (read: western countries and the bio-industry) direction in the drafting of agreements that comply with both the CBD and

the TRIPs Agreement. These Material Transfer Agreements (MTAs) should safeguard ethical and users' interests of traditional-knowledge holders, regulate the acquisition and enforcement of intellectual property rights in common consent, provide accurate descriptions of the genetic material and related knowledge, and specify the manners in which such may be exploited (articles 42-44 A). Pursuant to articles 44-50 A, MTAs would also provide for specified manners of benefit sharing. However, the Bonn Guidelines go further than providing suggestions for MTAs only. They also propose to link the patentability of an invention, consisting of or made through the use of biological material and/or traditional knowledge, directly to prior informed consent of provider countries and/or communities and fair and equitable benefit sharing (articles 1 and 2 C). More than 100 countries have implemented regimes for the protection of ecological, cultural and commercial interests in biological resources and/or traditional knowledge that more or less correspond with the Guidelines (Ten Kate and Laird 2004, p. 138). For example, Costa Rica, Brazil, Peru and India have implemented legislation for that purpose²². Despite the differences among national and regional approaches, many similarities exist (Greer and Harvey 2004, p. 151-155; Dutfield 2004, p. 138-158; Ten Kate and Laird 2004, p. 139-141). Generally, access to material and/or knowledge is conditioned upon prior informed consent of a national office governing the country's biological resources and/or traditional-knowledge holders. Furthermore, biological samples and/or knowledge can only validly be transferred and legitimately used if proper benefit-sharing agreements are concluded, allowing the communities and/or country of origin a share in the proceeds deriving from the commercial exploitation of the material or knowledge concerned. Most importantly, these statutes generally indicate that within the countries concerned, no intellectual property rights can be obtained if the aforementioned requirements are not fulfilled. They impose material requirements that have substantive effect on the patentability of the inventions concerned. Sometimes, violating the requirements of these statutes is a criminal offence and may be prosecuted accordingly. Also, countries pursue to sanction violations by fines²³. Furthermore, many of these statutes make use of the previously outlined exceptions to protection of intellectual property allowed by the TRIPs Agreements. Some have inserted additional exclusions from patentability into their patent statutes. These exclusions may encompass DNA sequences and/or any plant or animal material. The Costa Rican patent law is an example of this approach. These statutes have national effect only, though. A company that violates such a law and manages to 'escape' the country, could still acquire patents and continue with its activities abroad – in the user countries, the western world, where the most important markets can be found anyhow. European user countries have generally taken a narrow approach to implementation of the CBD²⁴. They prefer to maintain strong patent protection for their industries, while at the same time fulfilling their CBD obligations. The main focus is on the disclosure requirement. As discussed before, the patent applicant has to disclose the invention for which the patent is sought (art. 78 (1) under b and 83 EPC). From the fact that traditional knowledge and biological resources generally do not reflect on the invention concept it follows that, most of the time, applicants do not disclose information related to the origin of those resources in European applications. The only situation in which they may be

held to disclose is when the resource is necessary to carry out the invention, and is not readily available (for example with unknown or rare biological material). The manner in which they obtained material and/or knowledge – with or without prior informed consent and benefit-sharing agreements – does not relate to the invention concept and is therefore irrelevant for examination of the patentability of an invention. Proposals pursue to broaden the disclosure requirement as to include the obligation to disclose prior informed consent and benefit-sharing agreements. Proposals of user countries generally pertain to a formal requirement (not sanctioned by rejection of patent applications and/or withdrawal of patents) instead of the substantive one included in referenced statutes of developing countries (WIPO 2004b; Koopman 2005b, p. 534-536; Dutfield 2004, p. 111-112). Among the countries that actively pursue implementation of the CBD in this respect are Norway, Denmark, Portugal, Switzerland and Belgium²⁵. Many of the aforementioned legislative initiatives violate the minimum standards for intellectual property protection set by the TRIPs Agreement and the need to implement the CBD with respect for intellectual property protection (art. 16 (2) CBD). Only a narrow formal disclosure requirement – one that is not supported by sanctions such as rejection of patent applications – would be in compliance with the TRIPs Agreement. The European Commission thus envisages such requirement²⁶. Requirements that affect the conveyance of patents violate TRIPs. The same applies to requirements that affect the validity of patents (withdrawal sanction), because their administrative appearance cannot negate their substantive effect (Contra De Carvalho 2000, p. 394-401)). Negotiations in the course of the referenced Doha Development Agenda should lead to clarity on the appropriate interaction between the CBD and TRIPs Agreement. This may not be necessary in respect of a distinct initiative, which pursues the establishment of a *sui generis* intellectual property regime for traditional-knowledge holders. Pursuant to the TRIPs Agreement more intellectual property is allowed – not less. Hence, WIPO envisages an additional regime (Dutfield 2004, p. 117-118; Wendland 2002, p. 101-108). It would apply to: “... tradition-based ... scientific works ... ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge ...” (WIPO 2002). It concerns documented and concrete knowledge, with which the community concerned has a cultural association. Right-holders would have the right to prevent reproduction and fixation of literary and artistic expressions, and exploitation of technical elements. Unlike contemporary patent law, the regime would necessarily convey enduring rights – rights would remain valid as long as the cultural association exists, which of course could be thousands of years (WIPO 2004a, Annex I, p. 5; 2001, p. 22, 226 ff). Other approaches to safeguarding the interests acknowledged in the CBD may have a complementary and/or soft law profile. They may call for use and application of other intellectual property regimes, such as pertaining to copyrights, trademarks, geographical indications and (secret) know-how (articles 9-14; 15-21; 22-24; 39 TRIPs, respectively) (WIPO 2003; Janke 2003). These regimes may offer leeway for protection of the interests concerned. However, like patent law, they cannot truly safeguard the commercial, cultural and ecological interests of biodiversity-rich countries and traditional-knowledge holders, since they do not apply to the

substantive resources but only to some derived expressions, representations, embodiments and applications (cf. Von Lewinski 2004; Blakeney 2002; Van Overwalle 2002). Other initiatives include the formulation of practice guidelines. Several botanical gardens adhere to the Common Policy Guidelines for Participating Botanical Gardens that correspond with important elements of the Bonn Guidelines (Laird and Posey 2002, p. 16-38)²⁷. Moreover, contractual approaches allow participants to negotiate and flexibly manoeuvre among the interests concerned. Many contracts have already been concluded during the past years. Several model contracts have been formulated that one could adhere to (Guerin-McManis and Kim 2002, p. 235-236; Singh Nijar 1996p. 40-46)²⁸. The International Cooperative Biodiversity Group projects aim to conduct bio-prospecting activities in a variety of developing countries, among which Peru and Surinam, in compliance with articles 8(j), 15 and 16 CBD and through a combination of contractual instruments, such as MTAs and agreements for the sharing of intellectual property rights and revenues²⁹. These initiatives may in fact provide leeway for day-to-day problems encountered by the various groups involved in biotechnological innovation, and may inspire the redirection of the regulative framework – ultimately the only way to come to structural solutions.

REMAINING ISSUES

Apart from the thorny interaction between the TRIPs Agreement and the CBD, several substantive issues remain to be addressed. One of those issues pertains to the fact that the national sovereignty conveyed to countries of origin (art. 3 CBD) may not correspond with the characteristics of biological material, which is often dispersed across countries and regions. The same necessarily applies to traditional knowledge. Hence, European patent EP 436 257 B1, which related to the Neem plant (*Azadirachtin indica*), was revoked for lack of novelty – prior knowledge and use in India (see note 19). However, the plant thrives and is cultivated throughout Asia, the Middle East and Europe (Puri 1999, p. 9-22). Of course, such availability also bears upon the bargaining power that providing countries, countries of origin and communities would have in negotiating access and benefit-sharing agreements with the bio-industry. Conversely, it may reduce the legal and thus commercial certainty of the transactions – parties to agreements may be confronted with claims of other countries and communities that are inappropriately left out of the arrangements. However, the primary question is whether conveying exclusive entitlement to a singular country and/or community would be equitable. Would it lead to distribution of benefits to the countries and/or communities that should receive them and thus repair the purported distributive-justice issue? Some of these problems may perhaps be solved by establishing a global bio-collecting society – an interesting idea that was proposed recently. Such a society may reduce transactional problems, may manage rights and agreements, and may distribute material, knowledge and benefits among the participants (Dutfield 2004, p. 121-122). Also, several biodiversity-rich countries have joined ranks in the Like-Minded Megadiverse Countries Group, which represents their interests³⁰. However, how

should such a society and/or group monitor i.a. flows of material and knowledge? Most of the material and knowledge concerned has not been described (cf. Patrick 2005, p. 172; cf. Sittenfeld 2001, p. 18). Attempts are made to describe the world's cultural and biodiversity and include them in databases and registries³¹. Given the fact that contemporary knowledge about and descriptions of these resources were attained over thousands of years and represent only a small portion of what is expected to be out there, this appears to be an insurmountable task (e.g. Wilson 2001, p. 141-143). In the unlikely situation that this task would be fulfilled anyhow, one may wonder how one should keep track of material and knowledge in the long and diverse chains of activities, in which a large variety of industrial, cultural and other participants are involved. How to keep track of the thousands of steps made from plant to pharmaceutical? Proposals are made to develop a certification system that would deliver certificates of origin, to be disclosed during the patent examination procedure³². However, such scheme requires additional measures (e.g., customs regulations), may incur large costs and bureaucracy, and may not be appropriate in respect of 'porous' resources such as genes and knowledge (Cunningham et al. 2004, p. 3-4; Barber et al. 2003; Glowka 2001). Also in respect of the envisaged *sui generis* intellectual property regime, several issues remain to be addressed. They include concurrence with existing intellectual property regimes, delineation of the eligible subject matter, and the extent in which such regime allows for protection of cultural interests instead of commercialization of cultural resources only. Shouldn't the laws of traditional-knowledge holders' communities – i.e. indigenous and customary law – be given some standing? (Koopman 2005a, p. 261-263, 273-275). Particularly in respect of patent law, the following problems remain to be addressed. First, opening up such regime for claims to biological material as such (i.e. in unmodified form) would negate the distinction between the tangible and the intangible, which is paramount to the contemporary legal regime. One may even conclude that this distinction is fundamental to the contemporary organization of society and is manifested in all kinds of law (e.g., also criminal law). One only has to think about the difference that is generally and also legally attached to human thought, intention, expression and action. The first two do not necessarily involve interaction with man's environment, the latter two always do – and may lead to changes that can be observed and judged by other persons within such environment. Also, changing patent law to this extent negates the fundamental distinction between discoveries and inventions on which this regime turns. Perhaps it would be appropriate to re-associate these categories, but in my opinion that would require a more fundamental reconsideration of laws than is envisaged presently by the proponents of these alterations. Second, in respect of the proposed accommodation of patent law to the interests of traditional-knowledge holders, I stress that patent law is not structured to stimulate the creation of any type of knowledge. It applies to novel, inventive, industrially applicable inventions (a particular type of technology). A similar remark could be made in respect of other intellectual property regimes. Although protection of the interests of traditional-knowledge holders through patent law (or broader; intellectual property law generally) may be justified, this cannot be attained by pragmatic and rather isolated changes (i.e. amendment of the disclosure requirement) and/or adding a new category of intellectual property (i.e. *sui generis*

protection for traditional knowledge). In my opinion, this would result in a drastic re-direction of this regime, which may have severe consequences. Would potential inventors still have the necessary incentives to devote (at least partially) their resources to R&D? Will they be able to continue their commercial activities in view of the various uncertainties and issues related to the implementation of the CBD described above? (Koopman 2005b, p. 529-530, 532, 535; McCabe 2003). Moreover, one may wonder whether such redirection may even work. The question must be asked whether patent law – or perhaps intellectual property law – is the appropriate means to the end. Is this regime fundamentally suited to serve the needs of inventors, biodiversity-rich countries and traditional-knowledge holders simultaneously? Isn't the make-up of this regime tailored to protecting the collective public interest of technological progress by means of protecting the individual private interests of the first group only? Is it possible to change the make-up of this regime and rebalance egoism with altruism and individualism with collectivism, without first reconsidering its principles and structure? Generally, we may have to contemplate how much attention is given to one or the other legal instrument. Is patent law (or generally intellectual property law) really the instrument on which integrative attempts for protection of referenced interests should be based? Aren't we so trying to let the rowing boat tow the vessel? A related question may be thrown up in respect of the overall aim of the CBD and the access and benefit-sharing concept. Should we really subject (our capabilities for) conservation of biological and cultural resources to the mechanisms of the market economy? Perhaps this may not lead to appropriate protection of the cultural and ecological interests related to them (e.g. GRAIN 2005; Martinez Alier 2002). One could even assert that this would amount to a total absorption of the cultural and ecological domains by the economic one, instead of mingling and re-balancing them. Hence, the 'economic contract' would not be complemented by cultural and/or natural contracts, but the latter would be inserted into and remain subordinated to the former. This may lead to an enrichment of that contract, but not to a substantive re-orientation – one that is necessary in view of the, if I may say, shocking accounts of the loss of cultural and biological diversity, and the almost apocalyptic consequences that most certainly derive therefrom. Whereas it is clear that the manner in which commercial, ecological and cultural interests are safeguarded in the contemporary age of globalization should change – perhaps through '*contrats holistiques*' such as the CBD – we first have to rethink policy priorities, the frameworks that were built on them, and the standing of legal instruments for that matter. The questions set forth in respect of patent law are illustrative. Of course, these questions do not at all imply that patentees that use biological and cultural resources should not contribute to the conservation of the diversity from which these resources stem. The Dutch expression "*voor wat, hoort wat*" ("you give some, you take some") surely applies. The primary question would be whether one wishes to oblige them to adhere to such a duty by means of patent law. Alternatively, one could think of the law of taxation: every corporation that generates revenue by making use of biological and/or cultural resources is taxed and the sums so collected may be distributed by collecting societies. This tax could then apply to exploitive activities in all kinds of fields – i.e. amusement, tourism, construction, biotechnology and so forth.

CONCLUSION

Plants are biological, cultural and industrial resources. They stem from the great cultural and biological diversity present on this planet. This diversity is in peril because of unsustainable economic policies and practices. Contemporary manners of exploitation originate in the western/developed world and spread as a result of globalization. The benefits that derive from exploitation of said resources may be dispersed unevenly, though. Whereas the bio-industry is steered from within the developed/western world, some of the material and knowledge provided for R&D and exploitation of pharmaceuticals originate in non-western/developing countries and cultural communities. The sustainability issue is thus paralleled by an issue of distributive injustice. Both issues are affected by the global regulative framework. Intellectual property law, including patent law, is part of that framework (i.e. the TRIPs Agreement). The (application of the) requirements for patentability imply that traditional knowledge and biological material as such cannot be patented and that the related interests are disregarded. No matter their relevancy for R&D of pharmaceuticals, which are patentable. The global regulative framework hinges on economic policies: *“Erst kommt das Fressen, dann kommt die Moral”*. However, assessments show that this assumption may be wrong. Conversely, economic, ecological and cultural domains should be enhanced in an integrated fashion. The CBD pursues to do just that, and may be a first attempt to come to a *‘contrat holistique’*. It turns on the concept of access and benefit sharing in respect of biological and cultural resources, and the benefits arising out of their commercial exploitation. This concept may conflict with the TRIPs Agreement. Although the TRIPs Agreement leaves room for protection of the interests involved, it sets minimum standards for intellectual property protection. An obligation for patent applicants to disclose agreements that indicate that they acted in compliance with this concept, sanctioned upon rejection of the application, violates those standards. It may be too early to consider imposition of such obligation anyhow. Too many problems remain to be solved. The multiple origin and evolving character of both biological material and traditional knowledge complicates the exclusive entitlement of countries of origin and cultural communities, and tracking of contributions in the course of R&D. The presupposed injustice of the exclusivity of patentees may be complemented by new injustices for the exclusivity of a country or community to widely held resources. Such availability hampers implementation of the benefit-sharing concept, and is expected to result in legal uncertainty for the bio-industry, biodiversity-rich countries, and traditional-knowledge holders alike. In respect of the latter, I doubt whether their cultural interests are sufficiently safeguarded by this concept. I suggest to give due attention to their laws too. Whereas the contradictions between the CBD and the TRIPs Agreement may to some extent be solved in the course of the Doha Development Agenda, fundamental issues remain to be addressed in respect of patent law. The CBD’s benefit-sharing concept negates the distinctions between the tangible and the intangible and between discoveries and inventions – paramount to patent law. Similarly, it negates that this regime is made

up to apply to a certain type of knowledge, complicating any pragmatic change for acknowledgement of other types of knowledge, i.e. traditional knowledge. Moreover, aligning patent law with the CBD ignores that patent law was set up to enhance technological progress only. It may not be suited to accommodate the broader interest in cultural and biodiversity equally well. At times, it appears as if we are expecting the rowing boat to tow the vessel. Law may set the stage for human activities, but it is human beings who should perform on it. Now, we have to think about which law may set which stage. One may be wary of the CBD's benefit-sharing concept in general. Should the interests of conservation of cultural and biological diversity really be subjected to the mechanisms of the market economy? Wouldn't this lead to absorption of the ecological and cultural domains by the economic domain, instead of reconciling them with each other? These doubts do not in any way imply that patentees should not actively contribute to conservation of cultural and biological diversity. Everybody should be involved in changing the hazardous tide, and aim for a sustainable and just world. However, we should aim at the appropriate target; should that target be patent law or, for example, the laws of taxation? From an overall point of view, I do expect the CBD to provide some basis for integrative protection of commercial, ecological and cultural interests though. It will at least induce us to try, which is essential because the challenges faced must be overcome. However, we should not frivolously turn to drastic legal changes, as proposed in respect of patent law. We should not sacrifice legal certainty to rebut legal shortcomings – without first solving the underlying substantive problems. Besides, legal uncertainty may be the biggest shortcoming of any law. The precautionary principle calls upon us to deal carefully with cultural and biological diversity, but also demands prudence in this respect. We should behave thoughtfully, especially when we are amidst peril and progress, and cannot readily determine which is what.

ACKNOWLEDGEMENTS

The author thanks the organizers of and participants in the Frontis Workshop on Medicinal and Aromatic Plants for the inspiring presentations and exchanges. Special gratitude is owed to Prof. Geertrui Van Overwalle. Reactions are very welcome via j.koopman@law.uu.nl.

NOTES

- ¹ Culture may be defined as the “whole complex of distinctive spiritual, material, intellectual and emotional features that characterize a society or social group. It includes not only the arts and the letters, but also modes of life, the fundamental rights of the human being, value systems, traditions and belief” (Garzon 2002, p. 3). Biological material may comprise genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (art. 2 of the Convention on Biological Diversity). At <http://www.biodiv.org> it is emphasized that the formulation of definitions is still a work in progress. Hence, terms such as biological resource, biological material, genetic resource, genetic material, biochemical compound are often interchangeably used. For the purposes of this article, it is most important to keep in mind the character of the material – all of it is biochemical. (See generally Young 2004, p. 1-4).

- ² “Indigenous communities ... are those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories ... consider themselves distinct from other sectors of the societies now prevailing in those territories. They ... are determined to preserve, develop and transmit to future generations ... their own cultural patterns, social institutions and legal systems” (Cobo 1986). See also the reports hereon by E. Daes at: <http://www.ohchr.org/english/issues/indigenous/documents.htm>.
- ³ These countries are often situated in the southern hemisphere. *In vitro* material mostly originates there too, but is predominantly held in collections in other countries now (e.g. Kloppenberg 1988; Mooney 1983).
- ⁴ On these categories, see the reports at <http://www.unctad.org/Templates/Page.asp?intItemID=2101&lang=1>. One should bear in mind that ‘western’ countries are generally developed and situated in the North, whereas developing and least-developed countries, in which most cultural and biodiversity can be found, are situated in the South. Of course, this generalization negates exceptions to the rule, such as Japan (non-western but highly developed) and Australia (western, developed but also possessing a lot of cultural and biological diversity). Said generalization has, however, induced people to depict one and other as a geopolitical North-South conflict.
- ⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights. At: http://www.wto.int/english/docs_e/legal_e/legal_e.htm#TRIPs
- ⁶ At <http://www.wto.org>.
- ⁷ Berthold Brecht and Kurt Weill. *Dreigroschenoper* (1928). *Ballade über die Frage: Wovon lebt der Mensch?*
- ⁸ At http://europa.eu.int/comm/european_group_ethics/index_en.htm.
- ⁹ In the past centuries, the relations among human beings, and the manner in which they organize themselves, were profoundly determined by a singular supreme political entity – the nation state –, inspired by Rousseau’s ‘*contrat social*’ (Rousseau 1772). Of course, globalization has changed the role of the state, exemplified in the competencies of supranational institutions such as the WTO, and arguably based on an ‘economic contract’.
- ¹⁰ Intrinsic value is a concept used to insulate and isolate those to whom intrinsic value is attributed from one another and their environment. Kant first promulgated the concept in respect of human beings: “Suppose that there were some thing the existence of which in itself had absolute worth ... I say, man and ... every rational being exists as an end in himself and not merely as a means to be arbitrarily used by this or that will Such beings are not merely subjective ends – whose existence ... has a worth for us – but are objective ends ... beings whose existence ... is an end” (Kant 1785, p. 318). Hence, other things, such as non-human organisms and non-living objects would not have such value. The selective and subjective attribution of intrinsic value has been scrutinized extensively, particularly in view of non-human organisms (e.g. Water Science and Technology Board 2004, p. 33-58; Cliteur 2001, p. 89-111).
- ¹¹ See also the No Logo website at: <http://www.nologo.org/>.
- ¹² The Development Gateway focuses on *glocalization*. At: <http://topics.developmentgateway.org/glocalization>.
- ¹³ Texts available at, respectively, http://portal.unesco.org/culture/en/ev.php-URL_ID=16429&URL_DO=DO_TOPIC&URL_SECTION=201.html and http://portal.unesco.org/culture/en/ev.php-URL_ID=11281&URL_DO=DO_TOPIC&URL_SECTION=201.html.
- ¹⁴ See on the (complexities of) definitions previous note 1.
- ¹⁵ At <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>. A European patent consists of a bundle of national patents. Although some of the requirements and effects are set forth in the EPC, others are determined by national patent statutes. A patent granted pursuant to the EPC conveys rights pursuant to the national patent statutes (art. 64(1) EPC). Therefore, reference is made to the Dutch Patent Act of 1995 (stb. 1995, 51, amend. 1998, stb. 632; at <http://www.wipo.int/clea/en/fiche.jsp?uid=nl020>) (hereafter DPA 1995).
- ¹⁶ Note that differences exist in this respect between the EPC and the patent regime of, for example, the United States. In respect of plants see (Van Overwalle 1999). In respect of animals see (Koopman 2002). See for compatible provisions in the TRIPs Agreements articles 27, 29 and 36.
- ¹⁷ Here, one is confronted with the epistemological hierarchy of knowledge on which patent law hinges. This hierarchy necessarily distinguishes between social knowledge (comprising traditional knowledge), science and technology. Only the latter may be subject of patent law. This hierarchy

(and the manner in which it is reflected in patent law) can be criticized. One may wonder whether it can be upheld in view of the relevance of traditional knowledge for biotechnological R&D. Perhaps we must reformulate the invention/discovery and the technology and nature concepts (Koopman 2005a).

¹⁸ Particularly indigenous communities may not adhere to and anticipate the divisions that are upheld in the western world in this respect. Hence, artistic expression may be subject of a copyright, whereas – as discussed before – technological inventions may be patented (e.g. Idris 2003). On the cultural backgrounds, see (Grosheide 2002, p. 1-15; Drahos 1996, p. 13-40). With respect to this topic see (e.g. Van Overwalle 2002, p. 251-257).

¹⁹ The use of closely related traditional knowledge renders a biotechnological invention unpatentable, for lack of novelty and/or inventivity. However, the lack of description of the cultural knowledge increases the chance that its use goes unnoticed in the patent examination procedure. The fact that this knowledge is not widely inserted in and disseminated through the dominant scientific and technological discourses also causes patent offices to make mistakes. A notorious example is the European patent (no. EP 436 257 B1) that was granted for a “... novel insecticide and ... fungicide derived from a neem seed”. This patent encompassed cultural knowledge, which had been applied for hundreds of years in India, and that – for purpose of acquiring the patent – was ‘technicized’ by the patent applicant. However, patent law provides procedures through which these bad patents can be contested and subsequently restricted to their actual novel and inventive elements or even revoked or annulled (Articles 99 and 138 EPC). Eventually, this also happened with this patent, which was revoked because of lack of novelty and inventivity (Commission on Intellectual Property Rights 2002: 76). Some of these cases have been widely described (e.g. Dutfeld 2004, p. 52-59). Given the sheer number of patents that in the past decades have been granted on biochemical inventions, the conclusion seems to be justified that these examples are only the tip of the iceberg – and not incidental mistakes.

²⁰ Adopted on November 14, 2001 and amended afterwards. At http://www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

²¹ See UNEP/CBD/COP/6/20 and COP Decision VI/24. At: <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24>.

²² Costa Rica has implemented the Ley de Biodiversidad, A.L. No. 7788 (1998), available at <http://www.grain.org/brl/costarica-leybiodiversidad-1998.cfm>; Brazil has implemented its Ley PM 2.186-16, 2001, at <http://www.planalto.gov.br/ccivil/mpv/2186-16>; Peru has implemented the Ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica, C. no. 26839, 2002, at <http://www.indecopi.gob.pe>; India has implemented the Biological Diversity Act, B. 93/2000, 2002, at <http://www.nifindia.org>. Many (of these) countries have in fact implemented a variety of statutes and regulations. At: <http://bch.biodiv.org/laws/laws.aspx>.

²³ The Brazilian approach is illustrative of these manners of tackling the unauthorized use of those resources. In 2003, a German national was suspected of committing biopiracy and arrested in Brazil (Astor 2003). Brazil intends to impose fines on biopirates, which may amount up to \$20 million. See <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2174&language=1>.

²⁴ It is noted that the U.S. has not ratified the CBD.

²⁵ For the developments in Belgium see Van (Van Overwalle 2004, p. 367-369). The state of several national initiatives can be inquired at: <http://www.biodiv.org/programmes/socio-eco/incentives/default.asp>.

²⁶ At: http://www.wipo.int/tk/en/genetic/proposals/index.html?meeting_id=7683.

²⁷ At <http://rbgkew.org.uk/conservation>.

²⁸ For an inventory see <http://www.wipo.int/tk/en/databases/contracts/summaries/index.html>. See also the documents and links provided at http://www.nativeweb.org/resources/law_legal_issues.

²⁹ See <http://www.nih.gov/fic/programs/icbg.html>. A case study about the ICBG is available at <http://www.biodiv.org/doc/case-studies/cb-abs-icbg-pdf>.

³⁰ At: <http://www.megadiverse.org>.

³¹ See for example the databases of the Global Biodiversity Information Facility at <http://www.gbif.net/portal/index.jsp>. For a national initiative, see the information provided by ProBioAndes on Peruvian native plants and uses at <http://www.geocities.com/probioandes/>. See also WIPO's portal on databases on traditional knowledge and genetic resources at <http://www.wipo.int/tk/en/databases/tkportal/>. WIPO pursues to enable patent examiners to include traditional knowledge in their examination of the novelty and inventivity of inventions for which

applications are filed by the making available of these databases. See also the database at <http://www.wipo.int/globalissues/databases/tk/index>.

³² Comparable to the CITES certification system. At: <http://www.cites.org>.

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