

ARTICLE:

BIODIVERSITY AND INTELLECTUAL PROPERTY

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I. INTRODUCTION

Genetic resources have become an issue of high priority to scientists, industry, politicians and even the public at large, for a variety of reasons. Although they form a warehouse of enormous use potentials for plant¹ and animal breeding, in food, chemical and environmental industries, and in pharmaceuticals and medicine,² their existence is increasingly endangered. Their current extinction rate is estimated to be a hundred to a thousand times faster than pre-human levels.³

Modern techniques, such as chemical prospecting and screening, as well as molecular mapping, offer new and economically-viable means for quicker discovery of valuable genetic information from biological material,

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¹ Cf. e.g., Tanksley and McCouch, *Seed Banks and Molecular Maps: Unlocking Genetic Potential from the Wild*, 277 *Science* 1063 *et seq.* (22 August 1997).

² Statistics for 1985 reveal that some US\$53 billion was spent world-wide for over-the-counter drugs extracted or derived from plants; in 1990 in the US alone an estimated \$15.5 billion was spent for such drugs (see Reid, *The Economic Realities of Biodiversity*, *Issues in Science and Technology*, Winter 1993/94, 48 *et seq.* (49)). For the role and value of natural product-derived drugs, cf. K. ten Kate and Laird, *THE COMMERCIAL USE OF BIODIVERSITY – ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING*, London 1999, pp. 40 *et seq.*

³ According to Pimm/Russel/Gittelman/Brooks, *The Future of Biodiversity*, 269 *Science* 347 *et seq.* (21 July 1995); cf. also World Resources Institute (WRI), The World Conservation Union (IURN) and United Nations Environment Programme (UNEP), *Global Biodiversity Strategy*, Baltimore 1992, pp. 7 *et seq.*; Ziswiler, *Die Biologie des Verschwindens*, *Universitas* 6/1993, pp. 575 *et seq.* For the main causes of the present state of development see the analysis of OECD, *Saving Biological Diversity, Economic Incentives*, Paris 1996, pp. 43 *et seq.*; Pimm/Lawton, *Planning for Biodiversity*, 279 *Science* 2068 s. (27 March 1998).

as well as for their commercial use.⁴ Nonetheless, the preservation and conservation measures so far⁵—apart from *ex situ* preservation in gene banks largely located in industrialized countries⁶—have remained relatively modest.⁷ Last, but not least, host countries of biological diversity—eighty percent of which is located in developing countries of the tropics⁸—have received little if any compensation or other form of benefits for the contribution the use of their genetic resources has generated to the overall wealth of either the global economy or the economy of any specific country.⁹

How can this situation be explained, when compared with the treatment of and the benefits derived from other natural treasures such as mineral ores or crude oil, which have made their “host countries” rich? The main reason for the seemingly discriminatory treatment of genetic resources, as compared with the treatment of other resources, is at the same time their natural strength and their legal weakness: plants, animals, insects, micro-organisms and other biological material are renewable resources, capable of self-replication or of being reproduced in a biological system. They perpetuate themselves via the information embodied in their genetic constitution, which they pass on to their progeny.¹⁰ As explained elsewhere, “the capability of

⁴ Cf. Eisner, *Prospecting for Nature's Chemical Reaches*, Issues in Science and Technology, Winter 1989/90, 31 *et seq.*; Alper, *Drug Discovery on the Assembly Line*, 264 Science 1399 *et seq.* (3 June 1994); Flam, *Chemical Prospecting Scour the Seas for Promising Drugs*, 266 Science 1324 *et seq.* (15 November 1994); Tanksley and McCouch, 277 Science 163 *et seq.* (22 August 1997).

⁵ See for the respective efforts, *e.g.*, Global Biodiversity Strategy, *op. cit.* note 3; World Resources Institute, National Biodiversity Planning, Baltimore 1995.

⁶ Cf. Plucknett/Smith/Williams/Anishety, GENE BANKS AND THE WORLD FOOD, Princeton 1987.

⁷ See Board on Agriculture, National Research Council (Ed.), MANAGING GLOBAL GENETIC RESOURCES - AGRICULTURAL CROP ISSUES AND POLICIES, Washington, D.C., 1993, pp. 117 ss; van Jarsveld/Freitag *et al.*, *Biodiversity Assessment and Conservation Strategies*, 279 Science 2106 *et seq.* (27 March 1998). For the efforts of the OECD countries to improve biodiversity policy *cf.* OECD, Saving Biological Diversity, *op. cit.* note 3, pp. 67 *et seq.*

⁸ See Raven and Wilson, *A Fifty Year Plan for Biodiversity Surveys*, 258 Science 1099 *et seq.* (13 November 1992); for the distribution of a great variety of species, their extinction rates and for efforts for their preservation, see the contributions published in Reaka-Kudla/D.E. Wilson/E.O. Wilson (Eds.), Biodiversity II, Understanding and Protecting our Biological Resources, Washington, D.C., 1997.

⁹ Cf. Global Biodiversity Strategy, *op. cit.* note 3, pp. 1 *et seq.*

¹⁰ Crespi/Straus, Intellectual Property – Technology Transfer and Genetic Resources, An OECD Survey of Current Practices and Policies, Paris 1996, p. 15. According to Edward O. Wilson “Biodiversity is defined as all hereditary based

self-reproduction of biological material as carrier of genetic information clearly reveals the limits of claiming the ownership; once acquired, either legally or not, it is impossible for the original owner to prove that the genetic information used was exclusively his or hers, *e.g.*, seeds recovered for use for further propagation, genes isolated for producing transgenic animals or plants, or for producing valuable proteins through cell culture, or for the synthetic production of valuable, active biochemical substances, and the like.”¹¹

Not surprisingly, the fact that host countries of genetic resources have not been able to gain from their exploitation¹² while the industrialized world has apparently been successful,¹³ has led to a long-lasting controversy between the North and the South on access, exploitation and preservation of

variation at all levels of organisation, from the gene within a single local population or species, to the species composing all or part of a local Community, and finally to the Communities themselves that compose the living parts of the multifacious ecosystem of the world.” (in Biodiversity II, *op. cit.*, note 8, p.1).

¹¹ Crespi/Straus, *op.cit.*, note 10, p. 16.

¹² According to a UN Commission 1994 Report, *Conserving Indigenous Knowledge: Integrating two Systems of Innovation*, the Losses of the Third World due to “Bio-Piracy” are estimated at US \$5.4 billion a Year (*cf.* Williams, “Bio-Piracy’s Costs Third World US \$5.4 Bn. a Year,” *Financial Times* of October 28, 1994, p. 5). However, it has to be noted that this experience is not limited to hosts of genetic resources in the South only. As it is known, the Taq polymerase, the enzyme, which is essential in the polymerase chain reaction (PCR), was found in a Yellowstone hot spring microbe. Whereas the drug companies Cetus and later on Hoffman-La Roche, which acquired Cetus, have earned hundreds of millions of dollars, the Yellowstone National Park has seen none of this windfall (*cf.* Pennisi, *Lawsuit Target Yellowstone Bug Deal*, 279 *Science* 1624 (13 March 1998)).

¹³ It is estimated that the value, for instance of the American soybean crop has experienced an annual increase of about \$3 billion over the past sixty years thanks to exploitation of biodiversity (via cross-breeding), *cf.* Jenks, *The Convention on Biological Diversity – An Efficient Framework for the Preservation of Life on Earth?*, 15 *Northwest Journal of Int. Law & Business* 636 *et seq.*, at 645 (1995). According to Chambers and Bertram, The U.S. Position on the Consultative Group on International Agricultural Research, in: Eberhart, Shands, Collins and Lower (Eds.), *INTELLECTUAL PROPERTY RIGHTS III. GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS*, Madison 1998, pp. 59 *et seq.*, at 61, roughly half the gains in U.S. agricultural yield from 1930 to 1980, were due to the use of genetic material from the germplasm collection held in the National Plant Germplasm System’s collections. For some other concrete examples of such benefits see Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 *J. Intell. Prop. L.* 141 *et seq.*, at 145 *et seq.* (1994).

world genetic resources.¹⁴ As a preliminary outcome of this controversy in 1983, an International Undertaking on Plant Genetic Resources was concluded, under the auspices of the United Nations Food and Agriculture Organisation (FAO).¹⁵ The concept adopted in this Undertaking, that plant genetic resources constitute *common heritage of mankind*,¹⁶ was then interpreted as embracing special genetic stocks, including elite and current breeders' lines and mutations.¹⁷ In two subsequently adopted resolutions, however, the FAO recognized that plant breeders rights are not incompatible with the Undertaking.¹⁸

Since 1983, the legal framework controlling the ownership, access and the exploitation of genetic resources has changed profoundly, thanks to the adoption of two international legal instruments: First, on June 5, 1992, the Convention on Biological Diversity (CBD) was signed in Rio de Janeiro,¹⁹ and second, only two years later, on April 15, 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was concluded, as Annex 1C to the Marrakesh Agreement establishing the World Trade Organization (WTO).

In order to understand the interrelationship of these two important instruments of international public law with respect to genetic resources, it is essential to realize the double legal nature of genetic resources: as *phenotypes*, *i.e.*, individual plants and animals, they traditionally constitute private (tangible) goods; as *genotypes*, *i.e.*, information embodied in the genetic

¹⁴ Cf. Mooney, *The Law of the Seed. Another Development and Plant Genetic Resources*, Development Dialogue 1 *et seq.* (1983); Plucknett et al., *op. cit.*, note 6; Straus, *Plant Biotechnology, Industrial Property and Plant Genetic Resources*, 21 *Intellectual Property in Asia and the Pacific* 21 *et seq.* (March-June 1988); Odek, 2 *J. Intell. Prop. L.* 141 *et seq.* (1994); Römpczyk, *Biopolitik - Der Reichtum des Südens gegen Technik und Kapital des Nordens*, Baden-Baden 1998, pp. 18 *et seq.*

¹⁵ Report of the Council of FAO, U.N. Doc. C 84/REP (1983).

¹⁶ On the history of the concept of the "common heritage" and its surrounding controversy see Baslar, *THE CONCEPT OF THE COMMON HERITAGE OF MANKIND IN INTERNATIONAL LAW*, The Hague/Boston/London 1998, pp. 9 *et seq.*, 307 *et seq.*; Lerch, *Verfügungsrechte und biologische Vielfalt*, Marburg 1996, pp. 91 *et seq.*

¹⁷ Cf. Sedjo, *Property Rights, Genetic Resources and Biotechnological Change*, 35 *Journal of Law & Economics* 199 *et seq.*, at 202 (1992), with further references.

¹⁸ Resolution 4/89 of November 29, 1989 and Resolution 3/91 of November 25, 1991, reproduced as Annex I and III to the FAO International Undertaking on Plant Genetic Resources, FAO Doc. CPGR/93/Inf. 2 (March 1993). See on these developments also Odek, 2 *J. Intell. Prop. L.* 150 (1994).

¹⁹ It entered into force on December 28, 1993. In the meantime over 160 States have ratified the CBD (see Römpczyk, *op. cit.* note 14, p. 19).

constitution of micro-organisms, plant or animal species, they *a priori* conform to the definition of public good.

As correctly pointed out by Sedjo, however, genotypes can possess exclusivity, too.²⁰ This holds true if access to them is limited by either tangible property ownership or by intellectual property rights, such as patents or plant breeder's rights. Whereas the CBD is primarily focussed on providing rules related to tangible property aspects of access to and exploitation of genetic resources as phenotypes, the TRIPS Agreement is concerned with international mandatory standards for protecting intellectual property rights, including those which relate to genetic information.

II. OBJECTIVES AND CONTENTS OF THE CONVENTION ON BIOLOGICAL DIVERSITY

A. Sovereign Rights of the States

In view of the complex of issues surrounding the preservation and exploitation of genetic resources, the issues covered by the CBD—which was concluded after some ten years of negotiations²¹—are also manifold. Most of them are for the first time specially covered in a binding universal treaty.²² This holds true for genetic diversity and the recognition of conservation of biodiversity as the common concern of humankind,²³ as well as for, on the one hand, the nexus between access and use of genetic resources, and on the other, transfer of relevant technologies, including those subject of patents and other intellectual property rights.²⁴

The starting point and basis of the ambitious objectives set forth in Art. 1 CBD, namely “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to

²⁰ Cf. Sedjo, 35 *Journal of Law & Economics*, 201, 208 (1992).

²¹ On the origin and history of CBD see Glowka et al., *A Guide to the Convention on Biological Diversity*, IUCN, Gland and Cambridge 1994, pp. 2 s.; Tinker, *Introduction to Biological Diversity: Law, Institutions and Science*, 1 *Buffalo Journal of International Law* 1 *et seq.*, at. 10 *et seq.* (Spring 1994).

²² It should be noted that the 1983 FAO Undertaking on Plant Genetic Resources has remained a non-binding instrument as far as the control over genetic resources was concerned (see Glowka et al., *op. cit.* note 21 p. 5, and Römperczyk, *op. cit.* note 14, p. 23).

²³ Paragraph 3 of the Preamble reads: “Affirming that the conservation of biological diversity is a common concern of human kind.” On the notion of Common Concept of Mankind cf. Baslar, *op. cit.* note 16, pp. 294 *et seq.*, 314 *et seq.*

²⁴ Cf. Straus, *The Rio Biodiversity Convention and Intellectual Property*, 24 *IIC* 602 *et seq.*, at 605 (1993).

genetic resources and by appropriate transfer of relevant technologies, and by appropriate funding,” is in the replacement of the *common heritage of mankind* concept by the explicit recognition of sovereign rights of states over their natural resources, which are referred to in the Preamble and twice in the main text.²⁵ According to the principle laid down in Art. 3 CBD, states have the sovereign right to exploit their own resources pursuant to their own environmental policies. However, they also have the responsibility to ensure that activities within their jurisdiction or control do not cause trans-border environmental damage. Also, they have to act in accordance with the Charter of the United Nations and the principles of international law.²⁶

Furthermore, the principle of national sovereignty is balanced by the obligation of Contracting Parties under Art. 15 (2) CBD to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties, and not to impose restrictions that run counter to the Conventions’ objectives. Thus, the right of states to control access to genetic resources is not an absolute right.²⁷

The objectives of equitable sharing of the benefits arising out of the utilisation of genetic resources, which are defined as “genetic material,” *i.e.*, any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value (Art. 2), are attained by Art. 15 and 16 of the CBD.²⁸ Whereas Art. 15 regulates access to genetic resources, Art. 16 addresses access to and transfer of technology. Taken together, these two provisions represent the “fundamental trade-off of the entire Convention and illustrate the political and economic strength of both the biodiversity-rich developing nations and the technology-based developed nations.”²⁹

B. Access to Genetic Resources

Under Art. 15 (1) of the CBD the authority to determine *access* to genetic resources rests with national governments and is subject to national legislation. However, this provision does not grant the State a property right over genetic resources, which can, depending on national laws, well be

²⁵ Cf. Glowka et al., *op. cit.* note 21 p. 3; Tinker, 1 Buffalo Journal of International Law 13 (Spring 1994); Jenks, 15 Northwest Journal of Int. Law & Business 650 (1995); K. ten Kate and Laird, *op. cit.* Note 2, pp. 13 *et seq.*.

²⁶ See for more details Glowka et al., *op. cit.* note 21 p. 26.

²⁷ See Doc. UNEP/CBD/COP 2/13, of October 5, 1995. No. 9.

²⁸ By decision II/11 of the Conference of the Parties to the Convention on Biological Diversity (COP) it has been reaffirmed that human genetic resources were not included within the framework of the CBD (*cf.* Doc. UNEP/CBD/COP/3/20 of October 5, 1996, No. 38).

²⁹ Tinker, 1 Buffalo Journal of International Law 16 (Spring 1994).

owned by another, for instance a private party.³⁰ The expression used, “their,” is to be understood as referring to natural resources under a state’s jurisdiction. It will be a complex task for national access legislations to distinguish between state-owned and privately-owned genetic resources, and to clearly indicate with whom a potential user will need to negotiate, and whether the outcome of such negotiations will be subject to governmental review, or whether the state will even have to be involved as a party of such agreements.³¹ As already mentioned, however, the exercise of the sovereign rights of the states over their genetic resources is qualified not only by their obligation to endeavour to create conditions to facilitate access to environmentally sound uses by other Contracting Parties, but also by the objectives of the Convention, since no access restrictions contradicting those objectives may be imposed (Art. 15 (2) of the CBD).

It is beyond doubt that, due to the prevailing interdependence of states in respect to genetic resources, the adoption of the respective rules in national laws of the Contracting Parties will to a large extent be responsible for the final success or failure of all endeavours of the respective state to benefit from the CBD regime. In view of the fact that large collections of genetic material had existed in a number of countries prior to the entering into force of the CBD, it is important to note that under Art. 15 (3) of the CBD the access and benefit-sharing provisions of Art. 15 and 16, as well as 19, which relates to handling of biotechnology and distribution of its benefits, are not applicable to resources acquired from the provider of genetic resources prior to the Convention’s entry into force, and to resources acquired illegally from the country of origin after CBD’s entry into force. Thus, Contracting Parties from which genetic resources stored in pre-existing *ex-situ* collections have no claims under the CBD to invoke the benefit sharing provisions for the past and future use of these genetic resources.³²

Paragraphs four and five of Art. 15 of the CBD contain some important ramifications indicating general conditions on which the access to genetic resources may be made dependent. By conditioning access on attaining

³⁰ Seemingly in the US, for instance, national parks can exercise ownership rights over genetic resources located in their territory (see Pennisi, 279 *Science* 1624 (13 March 1998)).

³¹ See Glowka et al., *op. cit.* note 21, p. 76, 80.

³² See Doc. UNEP/CBD/COP/3/20 of October 5, 1996, Nos. 41-44; Glowka et al., *op. cit.* note 21, pp. 77, 79. *Cf.* also Hawtin and Reeves, Intellectual Property Rights and Access to Genetic Resources in the Consultative Groups on International Agricultural Research, in: Eberhart, Shands, Collins and Lower (Eds.), *op. cit.* note 13, pp. 41 *et seq.*, at 49, and the “Guiding Principles for the consultative groups on International Agricultural Research Centers on Intellectual Property and Genetic Resources,” reproduced in Hawtin and Reeves, *ibidem*, pp. 55 *et seq.*, at 56.

mutually agreed terms, paragraph four implies the expectation of a negotiation between the Contracting Party granting access and an individual, a company, or an institution, such as a university or botanical garden, seeking access to and use of genetic resources. It will be a matter for national legislation to set out, for instance, minimum or general terms to be observed, or to leave a free hand to negotiators. Also, it will be to the national legislature to assign the task to coordinate and implement access agreements with other States and private parties having a national focal point, for instance, a government or university institution which could act as an intermediary on behalf of the government,³³ and which could play an instrumental role in successful exploitation of genetic resources of a respective country.

Under paragraph five of Art. 15 the access to genetic resources may be subjected to *prior informed consent* of the Contracting Party providing such resources. The phrase, "unless otherwise determined by that Party," reveals that imposing this requirement is an option rather than an obligation. As Hendrickx *et al* correctly emphasized, this has the consequence that a user is only required to submit to prior informed consent if the providing Party has taken steps to establish the necessary procedure in its legal system.³⁴ Here also it will be a matter for the national legislation to decide in what instances prior informed consent will apply, and also to specify minimum or general requirements of such consent. Since *prior informed consent* involves, in chronological order,

consent of the Contracting Party providing genetic resources

based on information provided by the Party interested in
access to and use of genetic resources

prior to consent for access being granted,

the provider has the authority to require information *inter alia* also on the subsequent use, etc. of genetic resources. The national access legislation could establish a variety of rules related to, for instance, the information required, access fees, export and biosafety restrictions, and also to

³³ Terms are mutually agreed-upon, if they are reciprocally accepted. See Doc. UNEP/CBD/COP/3/20 of October 5, 1996 Nos. 46-50; Glowka *et al.*, *op. cit.* note 21, p. 80. For more details see Henne, 'Mutually agreed terms' in the CBD: Requirements under public international law, in: Mugabe, Barber, Henne, Glowka and La Viña (Eds.), *ACCESS TO GENETIC RESOURCES-STRATEGIES FOR SHARING BENEFITS*, Nairobi 1997, pp. 71 *et seq.*

³⁴ Hendrickx/Koester/Prip, *The Convention on Biological Diversity - Access to Genetic Resources: A Legal Analysis*, 23 *Environmental Law and Policy* 250 (1993), cited according to Glowka *et al.*, *op. cit.* note 21, p. 81.

intellectual property rights and the sharing of benefits derived from genetic resources.³⁵

Two further principles related to research in and utilisation of genetic resources, in paragraphs six and seven of Art. 15 of CBD, should be mentioned here. On one hand, there is a general obligation of each Contracting Party to “endeavour” to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and whenever possible in, the provider country. It is clear that this provision is aimed at encouraging research into applications of genetic resources in host countries, and to establish and further develop their research and development capabilities.

On the other hand, paragraph 7 sets out that Contracting Parties shall adopt legislative, administrative or policy measures aimed at sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the provider country, upon mutually agreed terms. Clearly, the national legislation implementing this principle and the contractual practice subsequently based upon it will play a key role. Only a legislation which takes into account the interests of the potential users, as well as of the providers, of genetic resources in a balanced way will stimulate the environmentally sound use of biodiversity and secure adequate benefits from their exploitation.

Since the potential economic value of genetic resources is extremely difficult to estimate, especially in the medium- and long-term, parties will have to develop and employ considerable skills in negotiating the contract terms, as well as the mechanisms to monitor the later developments linked to the execution of agreements. The difficulty in adopting national legislation on access and exploitation of genetic resources is best demonstrated by the developments taking place in Brazil, where a prospective bill has met with massive criticism for envisioning too many restrictions and too-complicated rules.³⁶

C. Access to and Transfer of Technology

During the long-lasting debates between the South and the North on access to and exploitation of genetic resources, the counterclaim by developing countries that they be secured access to and transfer of technology was

³⁵ See for more details Glowka et al., *op. cit.* note 21, pp. 80 s. For some specific aspects of prior informed consent *cf.* Tobin, Certificates of origin: A role for IPR regimes in securing prior informed consent, in: Mugabe, Barber, Henne, Glowka and La Viña (Eds.), *op.cit.* note 33, pp. 329 *et seq.*

³⁶ *Cf.* Pennisi, *Brazil Wants Cut of its Biological Bounty*, 279 *Science* 1445 (6 March 1998).

one of the main reasons for tension. Art. 16 of the CBD, in which legal means for solving these problems are set forth, is therefore to be viewed as a compromise. Art. 16 issues have been very controversially discussed; its solutions have long seemed unacceptable to some developed countries, in particular the United States.³⁷ By adopting Art. 16, which has to be read and eventually implemented along with Articles 12 (Research and Training), 17 (Exchange of Information), 18 (Technical and Scientific Co-operation) and 19 (Handling of Biotechnology and Distribution of the Benefits), an obligation for each Contracting Party has been established to undertake "to provide and/or facilitate access for and transfer to other Contracting Parties" of:

- technologies relevant to the conservation of biological diversity;
- technologies relevant to the sustainable use of its components; or
- technologies that make use of genetic resources; and
- do not cause significant damage to the environment (Art. 16 (1)).

Thus, this obligation is limited to enumerated technologies directly linked to either the conservation or sustainable use of genetic resources or their exploitation, and which include genetic engineering and other modern biotechnology techniques.³⁸

Since Art. 16 (1) of the CBD applies to each Contracting Party, the obligation is incumbent not only on suppliers but also on recipients of technologies. The difficulty that Contracting Parties would be faced with, if mandatorily required to provide access to and transfer of such privately owned technologies, is reflected in the wording "to provide/or facilitate," which offers the Parties a choice, in which "facilitate" denotes the minimum obligation to be met. Many different ways have been indicated as to how to facilitate access to and transfer of the respective technologies, *e.g.*, through tax and other economic incentives, expanded intellectual property rights protection, or the purchase of intellectual property rights on behalf of

³⁷ See, *e.g.* Straus, 24 IIC 607 s. (1993); Burk/Barovsky/Monroy, *Biodiversity and Biotechnology*, 260 Science 1900 (25 June 1993).

³⁸ But *cf.* also Mugabe and Clarck, TECHNOLOGY TRANSFER AND THE CONVENTION ON BIOLOGICAL DIVERSITY - EMERGING POLICY AND INSTITUTIONAL ISSUES, Nairobi, Glasgow and Washington D.C. 1996, pp. 16, who plead in favour of a broad interpretation of this provision. In this context it should be noted that the modern biotechnology techniques, such as cloning from differentiated somatic cells, might not only offer solutions for conservation and sustainable use of genetic resources, but could also in the foreseeable future lead even to a revival of lost arts. As it has been reported, 1500 prehistoric microorganisms preserved in chunks of amber have already been revived (*cf.* Rohrbaugh, *The Patenting of Extinct Organisms: Revival of Lost Arts*, 25 AIPLA Q.J. 371 *et seq.*, at 373 (Summer 1997)). See also Cohen, *Can Cloning Help Save Beleaguered Species*, 276 Science 1329 s. (30 May 1997).

another Party.³⁹ In the latter case one Contracting Party could, for instance, acquire privately-owned patented technology and assign it or license it to one or more other Parties free of charge or on very favorable conditions.⁴⁰

Paragraph two of Art. 16 clarifies this obligation further by stating that the said access and transfer must be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms when mutually agreed. The CBD, by indicating that where patented or otherwise protected technology is at hand the terms have to recognize and be consistent with the adequate and effective protection of intellectual property rights, has established a link to the international regime of intellectual property rights and in particular its standards as set forth in the TRIPS Agreement.⁴¹

The link between the CBD and the TRIPS Agreement is even more explicitly emphasized in the third paragraph of Art. 16, under which legislative, administrative or policy measures, as appropriate, shall be taken by Contracting Parties, aimed at providing developing countries and providers of genetic resources access to, and transfer of, patented or otherwise protected technology which makes use of those resources, on mutually agreed terms and in accordance with international law. The subtle language of this provision establishes an obligation to create a framework permitting the transfer of technology making use of genetic resources to the provider-country Parties to the CBD on mutually agreed terms. In other words, this framework must also provide the basis on which mutually agreed terms can be negotiated and which must be in conformity with international law. Consequently, the legal framework at hand can not provide for, for instance, compulsory licences under conditions which would contravene the provision of Art. 31 of the TRIPS Agreement.

Due to the potential of intellectual property rights to have influence, either positive or negative, on the implementation of the CBD, Contracting Parties under Art. 16 (5) also acquire the obligation to co-operate in the area of intellectual property rights subject to national legislation and international law, "in order to ensure that such rights are supportive of and do not run counter to its objectives." It was this provision that originally prevented the

³⁹ Cf. Glowka et al., *op. cit.* note 21, p. 84.

⁴⁰ However, the phrase "or facilitate" makes it clear that Contracting Parties under the CBD are not obligated to direct their private sector to transfer technology (Tinker, 1 Buffalo Journal of International Law at 18 (Spring 1994), seemingly has some doubts as to the interpretation of this provision). Any interpretation according to which the Contracting Parties would be straight forward obliged to provide access to privately owned technologies, would strictly contradict the principles governing market oriented legal systems.

⁴¹ See Glowka et al., *op. cit.* note 21, pp. 86 s., and UNEP/CBD/COP/3/23 of October 5, 1996, Nos. 34 *et seq.*

United States from signing the CBD. In the U.S. view, the principle that it is appropriate or necessary to restrict intellectual property rights to encourage the transfer of technology from the private sector was unacceptable. Therefore, the United States originally made its acceptance of the Convention subject to deletion or amendment of Art. 16 (5), and acceptance of the basic principle that the terms of transfer of technology, or participation in research activities, must be those to which all Parties involved fully agree, as defined solely through the free market process.

In addition, the United States has strongly urged developing countries to take steps to encourage private investment and development, "most significantly by providing adequate and effective protection of intellectual property rights in the technology that stems from the development of genetic resources."⁴² When President Clinton eventually signed the CBD on June 4, 1993, the United States urged the Contracting Parties to establish adequate and effective legal protection of intellectual property in inventions based on genetic resources, to secure voluntary acceptance of conditions for the distribution of advantages as well as for the transfer of technology by all Parties involved, and not to impose restrictions on the development, sale or commercialization of the new technologies or products based on genetic resources.⁴³

III. THE TRIPS AGREEMENT

Much of the heat caused by Art. 16 (5) of the CBD⁴⁴ should have disappeared in April 1994, when the TRIPS Agreement was concluded. At that point, after intense and controversial discussions, Members of the WTO for the first time in history agreed on mandatory protection standards in the area of patents at an universal level. Since then, these standards constitute the *international law* to be observed under Art. 16 of the CBD, whenever access to and transfer of a patented or otherwise intellectual property rights-protected technology is at hand. Patent related provisions of the TRIPS Agreement have been negotiated by and large by the same parties as the CBD, and are to be understood as a preliminary outcome of the dialogue

⁴² See the report "PTO, Biotech Group Explains Objections to Earth's Biodiversity Treaty," 44 PTCJ, 120-121 (Nov. 1992).

⁴³ The statement released by Madeleine Albright, then U.S. Permanent Representative at United Nation, and the Counsellor of the State Department, Timothy Wirth, was reproduced in *Amerikadienst* No. 23, June 9, 1993, 1 *et seq.*

⁴⁴ See, *e.g.* Hathaway, *Yes: A Threat to Property Rights*, ABA Journal 42 (September 1992); Hackett, *No: A Competitive Disadvantage*, ABA Journal 43 (September 1992).

which followed the conclusion of the CBD,⁴⁵ and which will continue according to Art. 27 (3) (b) last sentence of the TRIPS Agreement in 1999.⁴⁶

As to the patent protection-related TRIPS provisions, mention should be made in this context only of the obligation of WTO Members under Art. 27 (1) to make patents available for any inventions, whether products or processes, in all fields of technology, provided that they meet the usual patentability requirements, *i.e.*, are new, involve an inventive step (are non-obvious) and are capable of industrial application (useful), as well as being sufficiently disclosed (Art. 29 (1)).

Although WTO Members are allowed to exclude from patentability certain categories of inventions, and developing countries, countries in transition to market economy, and least developed countries are offered transitory periods of five or eleven years, respectively, to comply with all patent protection related obligations (see Art. 65-66), the manoeuvring space under the TRIPS Agreement has been substantially narrowed. An invention may be excluded from patent protection, under the rationale that the prevention of its commercial exploitation is necessary to protect *public order* or morality in the territory of a Member, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. However, such exclusion may not be made merely because the exploitation is prohibited by the law of a Member. Consequently, whenever the commercial exploitation of an invention at stake is allowed, it may not be excluded from patentability under Art. 27 (2) TRIPS.⁴⁷ Moreover, Members may also exclude from patentability plants and animals, and essentially-biological processes for their production. However, they must grant patents on micro-organisms, as well as non-biological and micro-biological processes, including those for the production of plants or animals. Also, plant varieties must be offered patent, or an effective *sui generis* protection (Art. 27 (3) (b)). Thus, among the WTO Members the consensus exists that not only modern genetic engineering techniques for the production of animals or plants,⁴⁸ but

⁴⁵ Art. 16 (5) of the CBD has been interpreted as to imply a further dialogue on the impact of intellectual property rights on technology transfer (see Glowka et al., *op. cit.* note 21, at 91).

⁴⁶ The respective U.S. position is reflected in Lourie, *The U.S. Position on Developing Trade Agreements Concerning Intellectual Property*, in Eberhart, Strands, Collins and Lower, *op.cit.* note 13, pp. 77 *et seq.*

⁴⁷ See for more details Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in Beier and Schriker (Eds.), *FROM GATT TO TRIPS – THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS*, Weinheim 1996, 160 *et seq.*; Correa, *The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection*, 1994 EIPR 327, p. 328.

⁴⁸ See Straus, *op.cit.* note 47, p. 185; Correa, 1994 EIPR 328.

also biological material including micro-organisms have to be offered patent protection.⁴⁹

Although no definition of either the notion *technology* or that of an *invention* is contained in the TRIPS Agreement—and particularly undefined is the subtle distinction between patentable inventions and unpatentable discoveries⁵⁰—this may not, in principle, put in question the patentability of naturally occurring substances such as DNA, cell lines, *etc.* For if micro-organisms are mandatorily declared subject matter eligible for patent protection, then naturally-occurring biochemical substances, such as sequences of nucleotides (DNA), *per argumentum a maiore ad minus* are also to be regarded as subject matter for which WTO Members must offer product patent protection. Thus, information embodied in genetic resources can be excluded from patent protection only under the conditions set out in Art. 27 (2) and (3) of the TRIPS Agreement.

The lack of a definition of the concept of *invention* under the TRIPS Agreement does not lead to the general conclusion that WTO Members, no matter whether developed or developing countries (for the latter this applies only after the expiration of the transitory period), could legitimately follow a definition of invention that broadly excludes materials pre-existing in nature from patentability.⁵¹ Therefore provisions such as Art. 6b of Decision 344 of the Andean Group, which stipulates that substances pre-existing in nature

⁴⁹ Cf. Straus, *Genpatente - Rechtliche, ethische, wissenschafts- und ent-klungs-politische Fragen*, Basel and Frankfurt 1997, pp. 56 *et seq.*

⁵⁰ Cf. Straus, *op. cit.* note 47, p. 187; Correa, 1994 EIPR 329.

⁵¹ As advocated by Correa, *Implementing the TRIPs Agreement in the Patents Field - Options for Developing Countries*, 1 *Journal of World Intellectual Property* 75 *et seq.*, at 79 (1998); and by the study of the Secretariat of the United Nations Conference on Trade and Development (UNCTAD), (prepared with the assistance of Correa/Maskus/Reichman/Ullrich), *The TRIPs Agreement and Developing Countries*, Geneva 1996, No. 145 at p. 34, where it is explained that due to the fact that the TRIPs Agreement does not contain a definition of “invention,” domestic legislation may exclude the protection of “substances found in nature,” including cells and subcellular components, (such as genes)....” However, the authors of the UNCTAD study themselves had some doubts in their own interpretation as revealed by their observation in the preceding paragraph, where one can read: “However, adherents to the TRIPs Agreement must generally provide patent protection for microorganisms and for “non-biological and microbiological processes” on the doubtful premise that the patenting of microorganisms and microbiological processes does not entail the protection of life forms” (*ibid.* No. 144). In this context it is acknowledged, but cannot be examined any further here, that the specific requirements for products of nature to qualify for patent protection may vary in national laws and practices of WTO Members (see on this issue, *e.g.*, Kadidal, *Plants, Poverty, and Pharmaceutical Patents*, 103 *Yale Law Journal* 223 at 237 *et seq.* (1993)).

and their replications are not an “invention,” or that of Art. 6g of the Argentine patent law under which “any kind of life material or substances already existing in nature” does not constitute an “invention,” cannot be viewed as being in conformity with Art. 27 of the TRIPS Agreement. The same applies to the Brazilian patent law, which does not provide protection for “...the whole or part of natural living beings and biological materials found in nature, or isolated therefrom including the genoma or germplasm of any natural living being, and any natural biological process.”⁵²

Further, an important clarification of Art. 16 (5) of the CBD has been instituted by Arts. 28, 30, 31 and 33 of the TRIPS Agreement, in which are defined the rights to be mandatorily conferred on the patent owner, their term and exceptions, as well as limitations of those rights. Under Art. 28 (1) TRIPS Agreement, a product patent shall confer on its owner the rights to prevent third parties not having the owners consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; and, in case of process patent, to prevent third parties not having the owners consent from the act of using the process, and from the acts of: using, offering, for sale, selling, or importing for these purposes at least the product obtained directly by that process. The term of protection, set out in Art. 33, shall not end before the expiration of a period of twenty years counted from the filing date.

The severe concerns expressed upon the possibility of the CBD Contracting Parties to provide under Art. 16 (5) of the CBD far reaching liberal terms for granting compulsory licenses should have disappeared, in view of the rules on compulsory licenses under Art. 31 TRIPS Agreement. Those rules can be summarized as follows:

- consideration of the circumstances of each individual case is required (a);
- the (compulsory license) applicant must have attempted to obtain the consent of the right holder “on reasonable commercial terms and conditions,” such efforts having been unsuccessful “within a reasonable period of time” (b);⁵³
- the scope and duration of the use on the basis of the compulsory license must be limited to the purpose of which it was granted (c);
- the compulsory license shall not be exclusive (d);

⁵² This Latin American legislation is reported in Correa, *ibid.*, who is seemingly of the opinion that such exclusions do not contradict TRIPs Agreement obligations.

⁵³ Art. 31 (b) provides for exceptions only in the case of a “national emergency” or in “other circumstances of extreme urgency.” However, in such cases as well, the right holder must be notified “as soon as reasonably practicable.”

- it may only be assigned together with “that part of the enterprise or goodwill which enjoys such use” (e);
- use on the basis of the compulsory license shall be permitted “predominantly for the supply of the domestic market of the Member authorizing such use” (f);
- in as far and as soon as the circumstances that led to the compulsory licensing no longer exist and are not likely to recur, the license must be terminated, in such cases however, the Members must provide for adequate protection of the legitimate interests of the party that was entitled to the compulsory license (g);
- the right holder shall receive adequate remuneration according to the circumstances of the case, taking into account the economic value of the compulsory license (h);
- both the decision on the legal validity of the grant of compulsory licenses and the decision on remuneration payable in relation to a compulsory license are subject to judicial review by a court or to other independent review by a “distinct higher authority” in the Member Country (i, j);
- compulsory licenses with the purpose of remedying a practice that was held to be anti-competitive in court or administrative proceedings are subject to special treatment pursuant to Art. 31 (k).

In this context it also must be borne in mind that Art. 31 TRIPS Agreement must always be read together with Art. 5A of the Paris Convention for the protection of industrial property. However, for instance, the application for a compulsory license based solely on failure to work or insufficient working of the patent is only permissible after four years from filing of the patent application or of three years after the patent grant, depending upon which period is longer. Moreover, this means that where the patent holder is able to justify his/her inactivity with legitimate reasons, such applications for compulsory licenses must remain without success. Having regard from the prohibition under Art. 27 (1) TRIPS Agreement to discriminate on rendering the exercise of patent rights dependent upon whether the products were imported or manufactured locally, it may be assumed that sufficient exercise of the patent right may also be ensured by importation of patented products. Whether or not this holds true will depend on the circumstances of each individual case, as examined according to the standards of Art. 5A (4), Paris Convention.⁵⁴

⁵⁴ See for more details on compulsory licenses rules of the TRIPS Agreement Straus, *op. cit.* note 47, pp. 202 *et seq.*

IV. LEGISLATION IMPLEMENTING THE CONVENTION ON BIOLOGICAL DIVERSITY

The CBD is to be viewed as a framework agreement, because its provisions in many instances are phrased as overall goals and policies, and less so as precise rights and obligations.⁵⁵ Consequently, the eventual success or failure in achieving the CBD objectives in a respective country will to a large extent depend on its implementing legislation, and foremost on the laws related to access to genetic resources and sharing of benefits from those resources. As it has been already noted, due to its complexity, the respective legislation has been hotly debated since 1995 in Brazil, and the outcome of those debates is difficult to predict.⁵⁶ Similar developments are to be observed for Fiji, where in May 1996 a Draft Sustainable Development Bill was published,⁵⁷ and Australia, where access is currently governed by individual states, but where the export of genetic resources is controlled by federal laws.⁵⁸

As a result of extensive discussions in which representatives of local communities, agricultural research institutions, various ministries, environmental lawyers, NGO's and politicians have participated, in May 1995 the Philippines issued Presidential Executive Order No. 247, "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of

⁵⁵ Cf. Glowka et al., *op. cit.* note 21, at 1.

⁵⁶ Draft Bill of Law on Access to Brazilian Biodiversity No. 306 (*cf.* Doc. UNEP/CBD/COP/3/20 of October 5, 1996, No. 16).

⁵⁷ Cf. Doc. UNEP/CBD/COP/3/20 of October 5, 1996, No. 17.

⁵⁸ At the state level, West Australia has already passed the Conservation and Land Management (CALM) Amendment Act 1993. Under this Act, for instance, the Department of CALM is empowered to enter into exclusive agreements to commercialize flora. In May 1994 Australia established a Commonwealth-State Working Party (CSWP) on access to biological resources with the aim at developing a nationally consistent approach to managing Australia's biological resources (including genetic once) (*cf.* Doc. UNEP/CBD/COP/3/20 Nos. 18-20). The access and benefit sharing issue in Australia and New Zealand is particularly complex due to the rights of indigenous population established under national laws or treaties (see Robertson and Calhoun, *Treaty on Biological Diversity: Ownership Issues and Access to Genetic Materials in New Zealand*, 1995 EIPR 219 *et seq.*; Blakeney, *Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective*, 1997 EIPR 298 *et seq.*). It should also be noted here that the issue of the cultural and intellectual property of indigenous peoples has been discussed since many years also at universal level in the United Nations Economic and Social Council in a much broader context, which cannot be addressed here, and where, for instance, medical research and "bio-prospecting" is but one issue (*cf.*, *e.g.*, UN Doc. E/CN.4/Sub.2/1993/28 of July 28, 1993, especially pp. 90 *et seq.*).

Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes, and Other Purposes.” The Executive Order is based on Section I, Art. XII of the Constitution, which provides that fauna and flora are the property of the State and the State has control over their disposition, development and use. By this Order the Philippines’ law-maker has provided a framework for biological diversity prospecting activities, with obligations of acquiring the prior informed consent of both the Government and Indigenous Cultural Communities (Section 2), minimum terms for both commercial and academic research agreements (Section 5), requirements for benefit-sharing, and the establishment of an institutional structure to act as the Competent National Authority on these matters (Section 6 and 7). In June 1996, “Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources” followed. Under this implementing legislation the “Inter-Agency Committee on Biological and Genetic Resources (IACBGR)” was established as the Competent National Authority. Moreover, procedures were set forth for the application and processing of research and commercial agreements, including public-sector notification and sector consultation, as well as minimum terms and conditions for both research and commercial agreements.⁵⁹

A legislative approach similar to that of the Philippines has also been chosen by the five Latin-American States which form the so-called “Andean Pact.” In July 1996, the Commission of the Cartagena Accord adopted Decision 391, by which “the Common System on Access to Genetic Resources” was adopted and became binding on the Member Countries, *i.e.*, Bolivia, Colombia, Ecuador, Peru and Venezuela, by its publication in the Official Gazette on July 17, 1996. The Adopted System is intended to

regulate access to the genetic resources of the Member Countries and their derivatives, in order to: (a) Create the conditions for fair and equitable sharing of the benefits accruing from such access; (b) Establish a basis for the recognition and appreciation of genetic resources, their derivatives and related intangible components, particularly where indigenous, Afro-American and Local Communities are involved; (c) Encourage the conservation of biological diversity and sustainable use of biological resources containing genetic resources; (d) Promote the consolidation and development of scientific, technological and technical capacities at local, national and subregional level; and (e) Strengthen the negotiating capacity of the Member Countries.

⁵⁹ Cf. Doc. UNEP/CBD/COP/2/13 of October 6, 1995, No. 16, and Doc. UNEP/CBD/COP/3/20 of October 5, 1996, Nos. 11-12. For more details on the factual and legal situation of the Philippines reference is made to Barber and La Viña, *Regulating Access to Genetic Resources: The Philippines Experience*, in: Mugabe, Barber, Henne, Glowka and La Viña (Eds.), *op.cit.* note 35, 115 *et seq.*

Under decision 391, applicants seeking access are required to obtain the prior informed consent of, and share benefits with, the Competent National Authority, and indigenous Afro-American and Local Communities. The Competent National Authority is defined as the public state authority or body designated by each Member Country and authorized to provide the genetic resource or its derivatives and, consequently, to sign or inspect access contracts, carry out the actions envisaged by the Common System, and ensure compliance with them. In order to comply with their obligations under decision 391, Member States are obliged to pass their own secondary legislation. While Ecuador passed respective legislation on September 2, 1996, in other Member States legislation is still in process.⁶⁰

V. PATENT LAW ASPECTS

Whereas it is widely recognized that only national legislation on access to and benefit-sharing from the use of genetic resources of the provider countries (be they developing or developed countries) is needed to attain the CBD objectives, it is seemingly less understood that such legislation, focused as it is primarily on tangible property issues, will barely succeed if the intangible aspects and characteristics of genetic resources as *genotypes* are not adequately considered. Following two different aspects are to be borne in mind.

On the one hand, the only realistic and internationally viable way is the exploitation of genetic resources as *genotypes*—which is in conformity with the established legal order and the principles of market economy, and which has potential for generating medium and long-term benefits for the provider as well as eventually for the user countries. For such exploitation to be successful in commercial terms, however, requires that genetic resources—including information embodied in the genetic constitution of micro-organisms, fungi, plants or animals—become eligible for patent protection under the usual patentability requirements, in both the countries of use and

⁶⁰ *Cf.* for more details Doc. UNEP/CBD/COP/3/20 of October 5, 1996, Nos. 13-15 and Ruiz, Access Regime for Andean Pact Countries: Issues and Experiences, in: Mugabe, Barber, Henne, Glowka and La Viña (eds.), *op.cit.* note 35, pp.187 *et seq.* Mention should be here also of the fact that, for instance, Gambia with its National Environmental Management Act, 1994 (Law No. 13/94) and Cameroon with its Law 94/01 of 1994 established the basis from which access to their genetic resources can be regulated. Both countries have adopted the principle that genetic resources belong to the State and that nobody can exploit them for scientific, commercial or cultural purposes without authorization (*cf.* Doc. UNEP/CBD/COP/2/13 No. 18.). See also in this context K. ten Kate and Laird, *op.cit.* note 2, pp. 16 *et seq.*

provider countries—which in most instances will also be countries of use.⁶¹ This seems to be accepted also with respect to macro-economic aspects.⁶²

On the other hand, the question can be raised whether patent laws need to be amended in a way which would support the CBD objectives by taking into account the access legislation. It has been suggested that provisions should be introduced which would oblige the applicant for a patent to disclose the country of origin of biological materials and traditional knowledge in the patent application whenever this is relevant, and inform whether explicit consent for the use of these materials has been obtained.⁶³

Along the same lines, in July 1997 the European Parliament attempted to amend the EU Commission's proposal for a Directive on the legal protection of biotechnological inventions *inter alia* by introducing an obligation that inventions consisting of or using biological material originating from plants or animals shall only qualify for patent protection if the geographical origin of the material is indicated, and if the patent applicant provides evidence to the patent authority to the effect that the material was used in accordance with the regulations regarding access and export applicable in the place of origin of the material.⁶⁴ However, the suggestions of the European Parliament were rejected by the Commission and the Council for the reason that such a provision would go beyond the international commitments entered into by the Community and its Member States under the CBD. The Council further pointed out that the Patent Offices would not be able to verify that foreign legislation was complied with.⁶⁵

⁶¹ Cf. Straus, 24 IIC 614 s. (1993); same, *Biotechnology and Intellectual Property*, in Rehm & Reed in cooperation with Pühler and Stadler (Eds.), *BIOTECHNOLOGY*, second, completely revised edition, Vol. 12: Legal, Economic and Ethical Dimensions (Vol. Ed. Brauer), Weinheim/New York/Basel/Cambridge/Tokyo 1995, pp. 281 *et seq.* (at 296); Kadidal, 103 Yale Law Journal 243 *et seq.* (1993); Sedjo 35 Journal of Law & Economics 211 (April 1992).

⁶² See Sedjo, *ibid.*; Lerch, *op. cit.* note 16, p. 195 (No. 11).

⁶³ This is suggested by Watal, *The TRIPs Agreement and Developing Countries - Strong, Weak or Balanced Protection?* The Journal of World Intellectual Property, 281 *et seq.*, at 292 (1998). Watal advocates the view that respective provisions should be included in the TRIPs Agreement.

⁶⁴ See Doc. COM (97) 446 Final (August 19, 1997), amendment 76 (1).

⁶⁵ See Statement of the Council's Reasons, O.J. EC No. C 110/26 (at 29, No. 25) of 8.4.98, and the criticism expressed by Sterckx, *Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions*, (1998) EIPR 123 *et seq.*, claiming that the amendments proposed by the European Parliament were necessary "in order to make the E.U. Member States' patent laws meet the obligation" under Art. 16 (5) of the CBD, namely to ensure that such rights are supportive of and do not run counter to its objectives.

Under the eventually-adopted wording of the Directive,⁶⁶ it is acknowledged that Member States, when bringing into force the laws, regulations and administrative provisions necessary to comply with the Directive, must give particular weight to Articles 3 and 8 (j), the second sentence of Art. 16 (2), and Art. 16 (5) of the CBD (Recital 55). Moreover, it acknowledges that further work is in process at an international level to “help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPS Agreement and the CBD” (Recital 56). Consequently, Recital 27 stipulates, in a legally non-binding way, that “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.” However, this applies without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

In view of the decision III/17 of the Third Conference of the Parties to the Biodiversity Convention—to which reference is made in the Recital 56 of the EU Directive and which clearly reveals that the relationship between the CBD and the TRIPS Agreement is still under examination at an international universal level—the decisions of the EU Commission, Council and also Parliament in the second reading of the Directive seem adequate. The proper place to resolve whether and how intellectual property laws, in particular patent laws, need to be amended in order to be (possibly more) supportive of the CBD objectives to the benefit of all parties involved has to be in the framework of the WTO and the TRIPS Agreement. When discussing this issue, however, the parties will have to realize that only if, under the patent laws of all WTO Members, genetic resources as *genotypes* will be eligible for protection along the lines of the EU Biotechnology Directive⁶⁷ and the practice under the US and Japanese Patent Acts, as well as under the European Patent Convention,⁶⁸ an optimal legal basis for generating benefits (which are a precondition for their sharing) will be achieved.

This latter aspect seems to be completely overlooked by the lawmakers of those countries which, like Argentina, Brazil, or the Andean Group,

⁶⁶ Directive 98/44/EC on the Legal Protection of Biotechnological Inventions of July 6, 1998, O.J. EC L213/13 of 30.7.98.

⁶⁷ The Directive leaves no doubt that “Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.” (Art. 3 (2)). Art. 5 (2), which relates to the patentability of elements of the human body, including DNA sequences, is even more specific and stipulates that this is true even if the structure at hand is “identical to that of a natural element.”

⁶⁸ For simplicity, reference as to these practices is made here only to Correa, 1 Journal of World Intellectual Property at 76 *et seq.* (1998) with further references.

decided to the contrary.⁶⁹ Likewise for the endeavours of some institutions in potential provider countries—such as India’s Council for Scientific and Industrial Research—to prevent the “bio-piracy” of natural substances occurring in a country, by making specific information on such substances available to patent offices as reference guide.⁷⁰ If India, as it may be assumed, is interested in sharing benefit from the use of the substances at stake, its research institutions, alone or in co-operation with foreign academic and/or industrial research institutions, should make efforts to acquire patents and other intellectual property rights in such substances wherever legally possible and economical feasible. A balanced national access legislation would back respective efforts. Also, preventing patenting of such substances does not only result in limiting potential benefits, but also prevents investments necessary to develop modern drugs from naturally occurring substances—which is eventually to the detriment of those who need them most, namely patients world-wide. It should go without saying that a reference guide to medicinal plants and local knowledge of their use can barely help people in the country at stake, let alone in other more or less remote countries.⁷¹

⁶⁹ See *supra*, text accompanying notes 51 and 52. For more details on the Indian situation, including draft access legislation *cf.* Kothari, Access and Benefit-Sharing: Options for Action in India, in: Mugabe, Barber, Henne, Glowka and La Viña (Eds.), *op.cit.* note 35, pp. 201 *et seq.*

⁷⁰ See Correa, 1 *Journal of World Intellectual Property* at 82 s. (1998), reporting on the launch of a program of that Indian institution to analyze some 500 medicinal plants, in order to place the information on CD-ROM and make it publicly available (*ibid.*, note 16).

⁷¹ However, one should not overlook the specifics of the patentability requirements under the US Patent Act (in particular the novelty provision under Section 102), which do not entirely conform to the parallel provisions of patent laws of nearly all other countries, and which in connection with patents issued on chemicals extracted from the Indian *neem* tree in the United States of America led to a “neem paranoia in India.” Quite apart from the fact that as long as these differences exist, they should also be used in the context of interest to the benefit of provider countries, they may in fact to a certain extent discredit the intellectual property protection system and its underlying principles and should therefore be eliminated in the course of further harmonization of patent laws (see for more details on these issues Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 *IDEA* 371 *et seq.* (1996/97)). See also Wolfgang, *Patents on Native Technology Challenged*, 269 *Science* 1506 (15 September 1995).

VI. AGREEMENTS ON ACCESS TO AND USE OF GENETIC RESOURCES

In order for the desired results be generated, a complex network of contractual arrangements between a variety of institutions from provider and the use countries will be necessary—in addition to the complex legal framework under the CBD, the TRIPS Agreement, and the corresponding national implementing legislations. In this respect it will be essential to realize, especially for the provider countries, that such arrangements will have to cover a broad range of aspects, and that benefit-sharing involves not only the sharing of revenues from the final use of genetic resources and their derivatives (*e.g.*, pharmaceuticals, agrochemicals or high yield transgenic crops), but also and perhaps more importantly in the long run, building up of indigenous research and development capabilities in the framework of co-operation with institutions from use countries (which are necessary for a successful exploitation and sustainable use), as well as conservation of each country's own natural riches.⁷² Moreover, such contractual arrangements could and should take into account the interests and contributions of indigenous communities, which were instrumental for the preservation of genetic resources in the past and which therefore should equally benefit from the new developments.⁷³

⁷² These aspects are in particularly emphasized by Eisner, *Issues in Science and Technology*, Winter 1989/90, 31 *et seq.* See also Rosenthal, *Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources*, in *OECD Proceedings, "Investing in Biological Diversity," The Cairns Conference, Paris 1997*, pp. 253 *et seq.*, at 257. On monetary and non-monetary benefits *cf.* K. ten Kate and Laird, *op.cit.* note 2, pp. 64 *et seq.*

⁷³ Benefits which would accrue to indigenous communities in this context could at least in part be interpreted as a micro-economic recognition of their rights arising from the past, present and future contributions in conserving, improving, and making available plant genetic resources. Although this will not solve the general issue of the concept of "farmers' rights," which were defined by FAO as "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in centers of origin/diversity" and which according to the understanding of FAO are vested in the international community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the international undertaking (see resolution 5/89 of November 29, 1998, Annex II to FAO Doc. CPGR/93/Inf. 2 (March 1993)). Although it is beyond this paper to discuss the issue of farmers' rights, it should be noted, that suggestions have been made to recognize these rights by instituting a mandatory fund with a compulsory funding mechanism, which would provide annual funds in the amount of about US \$1.5 billion (see FAO Doc. CPGR/94/WG9/4 (February 1994) No. 40 and note 12).

Before the adoption of the CBD, in 1991 the first complex contractual arrangement of the kind was concluded between the U.S. pharmaceutical company Merck & Co., Inc. and the Instituto Nacional de Biodiversidad (INBio), a government chartered NGO of Costa Rica, which has been widely publicized. Under the agreed collaboration, INBio performs collection of plant specimens and extraction activities, while Merck concentrates on screening and post-screening activities and product development. The contribution of the provider is extracts of plants collected from rain forests in national parks. The contribution of Merck was an initial advance payment to INBio of US \$1.135 Million, including \$100,000 as contribution to Cost Rica's National Park Fund, \$120,000 for training, \$80,000 as extracting fee paid to University of Costa Rica, \$135,000 for lab equipment, \$100,000 as salaries, \$60,000 as contribution to biodiversity inventory, \$120,000 for supplies and expenses, \$285,000 for biodiversity inventory equipment, and \$135,000 for administration. In addition, royalty payments, assumed to be between 1% and 3%, should accrue to INBio, in the event that Merck develops marketable products in which it will also retain patents.⁷⁴

Since the adoption of the CBD, the international commitment to chemical prospecting has increased. In December 1993, an International Co-operative Biodiversity Group (ICBG) Program was established in Washington. It is funded and guided co-operatively by three U.S. government agencies, namely the National Institutes of Health (NIH), the National Science Foundation (NSF) and the US Agency for International Development (USAID). The program is aimed at stimulating the field of bioprospecting, providing models for the development of sustainable use of biodiversity, gathering evidence on the feasibility of bioprospecting as a means to improve human health through discovery of natural products with medicinal properties, conserving biodiversity through valuation of natural resources, training and infrastructure building to aid in management, and promoting sustainable economic activity of communities, primarily in less developed countries, in which much of the world's biodiversity is found. Countries participating in the first set of projects under this program include Argentina, Cameroon, Chile, Costa Rica, Mexico, Nigeria, and Suriname. Included in the Program are U.S. and foreign universities, botanical gardens, museums, conservation organizations, and diverse industries, such as American Cyanamid Co., Bristol-Myers-Squibb, Monsanto and Shaman

⁷⁴ See e.g. Roberts, *Chemical Prospecting: Hope for Vanishing Ecosystems?* 256 *Science* 1142 s. (22 May 1992); and Stone, *The Biodiversity Treaty: Pandora's Box or Fair Deal?*, 256 *Science* 1624 (19 June 1992); for the history of that agreement see Haeussler, *International Cooperation*, in Seidl (Ed.), *THE USE OF BIODIVERSITY FOR SUSTAINABLE DEVELOPMENT: INVESTIGATION OF BIOACTIVE PRODUCTS AND THEIR COMMERCIAL APPLICATIONS*, Brazilia/Rio de Janeiro, 1994, pp. 71 *et seq.*

Pharmaceuticals. Agreements concluded between these partners typically involve research and development contracts and benefit-sharing agreements, which go very much along the lines of the Merck-INBio contract, and also take into account the interests of local communities.⁷⁵

VII. CONCLUDING REMARKS

We are only at the beginning of a process, which hopefully will lead to the badly needed preservation and sustainable use of the biodiversity of our planet. Should biodiversity continue to decline at the current pace, one of the main sources of the research in all areas of biotechnology would gradually disappear. The endeavor to preserve biodiversity, however, is one of the most complex political, economic and scientific issues of the present day. It should be clear that its eventual solution is not only far beyond the reach and imagination of those in charge of intellectual property protection, but also beyond the best imaginable effects of intellectual property rights.⁷⁶

Nonetheless, under the prevailing legal and economic environment in the present globalized world, patents and other industrial property rights are seemingly the only means to help host countries to generate funds supporting biodiversity in conformity with the principles of the market economy. If the providers of genetic resources will adopt well-balanced legislation on access to, and benefit sharing from, the use of genetic resources, undertake all efforts to enable local researchers to actively take part in collaborative research activities with partners from the industrialized world, and adopt intellectual property protection legislation covering biological material at stake, then there are good prospects for some success. In parallel, industrialized countries should examine whether additional measures have to be taken to ensure fair functioning of the entire intellectual property system to the benefit of both the provider and use countries of genetic resources.

Finally, a warning seems appropriate: Even with the best possible legal framework and thoughtful contractual arrangements, all parties involved will need patience and must not have excessive expectations as to the generation of benefits and their sharing. It should be borne in mind that ten, fifteen or more years and investments of hundreds of millions of dollars are needed before effective financial benefits can be reaped from, for instance, a

⁷⁵ See for more details Eisner, 138 Proceedings of the American Philosophical Society 385 *et seq.* (1994); and Rosenthal, *op. cit.* note 72.

⁷⁶ Professor Thomas Eisner from the Cornell University, Ithaca, N.Y., has proposed that a special "Biotic Fund" of some US \$250 million be established. It should be partly financed from the revenues deriving from the commercial, patent protected, use of genetic resources. See for details Eisner, 138 Proceedings of the American Philosophical Society 388 *et seq.* (1994).

clinically-valuable drug discovered only after 10,000 to 35,000 plant or animal samples have been tested.⁷⁷

⁷⁷ And, one should bear in mind, the chances of a single compound becoming a drug once it enters the discovery process are generally estimated at one in 5,000-10,000 (*cf.* K. ten Kate and Laird, *op.cit.* note 2, at 34).