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**Traditional Knowledge, Biodiversity,
Benefit-Sharing and the Patent System:
Romantics v. Economics?**

HANNS ULLRICH

BADIA FIESOLANA, SAN DOMENICO (FI)

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European University Institute
Badia Fiesolana
I – 50016 San Domenico (FI)
Italy
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***TRADITIONAL KNOWLEDGE, BIODIVERSITY, BENEFIT-SHARING
AND THE PATENT SYSTEM***

– *ROMANTICS V. ECONOMICS?* –

Hanns Ullrich*

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I. Introduction

At about the same time that, in the late eighties/ early nineties of the last century, intellectual property became the subject of world trade negotiations, which ultimately resulted in the provision by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) of globally available protection on internationally accepted “adequate” conditions, which, then, contributed so much to industry’s general intellectual property euphoria during the last decade, international negotiations in the less industry-friendly fora of environment protection led to the development of alternative concepts of intellectual property protection. At least on their face, these seem to support some sort of a counter-movement to free trade in intellectual goods. Indeed, ever since the United Nations Conference on the Environment and Development of Rio de Janeiro in 1992, the catchwords are well-known: Defence, possibly even protection of traditional knowledge, such as knowledge of nutritional or medicinal characteristics of plants, control of access to genetic resources as a matter of safeguarding biodiversity, and sharing in the benefits accruing from patents granted for biotechnological inventions which, somehow, are based on traditional knowledge and/or on genetic resources found in nature. Their common denominator is that they point to limitations on access to and use of knowledge or resources which hitherto have been considered to be in the public domain. Therefore, these catchwords generally are also understood as indicating an area of basic conflict between, on the one hand, the protection of the environment (i.e. natural resources) and of the (cultural) identity of people, as well as the promotion of developing countries and, on the other hand, the protection of intellectual, in particular of inventive activity, as well as the promotion of industrial innovation as part of techno-economic progress.

It is, however, precisely this broader background, which invites rash value judgements on issues, whose complexity and ramifications are intractable enough.¹ Therefore, rather than

* Prof. Dr. iur., M.C.J. (N.Y.Univ.); Professor em. Universität der Bundeswehr München; Professor, European University Institute, Florence. Paper presented at the conference on „Biotechnology and International Law“, Siena, 8-9 October 2004; to be published in F. Francioni, T. Scovazzi (eds.), *Biotechnology and International Law*, London, Hart Publishing.

dealing with traditional knowledge and international intellectual property law in general, this paper will examine only issues of biodiversity-related traditional knowledge² and of patent law.³

Biodiversity-related traditional knowledge may have a value of its own, and being knowledge, promise of its protection may be sought under the rules of intellectual property or by analogy to these rules. In general, however, biodiversity-related traditional knowledge derives its value from the genetic resources to which it applies. As these have their own market value and are subject to rules of law of their own, the following analysis will be subdivided accordingly in a first part on the defence or protection of traditional knowledge as such, and a second part on its activation in the context of the exploration or the exploitation of genetic resources. In both respects patents are the most important “counterparts” as they allow protection of inventions based on the discovery, isolation, modification or application of genetic resources. Also patent law is both the internationally most homogenous and the systematically most clearly structured field of intellectual property, and, for this doctrinal reason alone, best suited to illustrate conflicts of traditional property protection of intellectual goods with the new concept of narrowing the public domain by protecting traditional knowledge and the objects to which it applies.

¹ A typical example of such a judgement, which is obviously circular, is the characterization of – arguably or actually illegitimate – patenting of genetic plant resources as “bio-piracy” or “misappropriation” (see G. Stenton, *Biopiracy within the Pharmaceutical Industry: A Stark Illustration of how Abusive, Manipulative and Perverse the Patenting Process can be towards Countries of the South*, *Eur. Int. Prop. Rev.* 2004, 17). There can hardly be any piracy or misappropriation of subject-matter unless protection of this subject-matter by title to property has been recognized first.

² Traditional knowledge may also constitute or may be akin to copyrightable subject-matter, which is protected as intellectual property proper. Propositions to make a distinction between traditional knowledge relating “to the useful arts” (the term used by Art. 1, Sect. 8 Clause 8 of the US Constitution to determine the field of patent law) and “traditional cultural expression” (the concept followed by the World Intellectual Property Organization in its attempts to develop the basis for a system of protection) are not generally accepted (see J. Gibson, *Intellectual Property System, Traditional Knowledge and the Legal Authority of Community*, *Eur. Int. Prop. Rev.* 2004, 280). For the purpose of the present paper, however, the distinction may well serve as a working hypothesis.

³ Thus, issues raised by plant variety protection are left aside, however important they are even in the age of gene technology (see for a clear presentation of the impact of plant variety protection and its relationship to patent protection CIPR (Commission on Intellectual Property Rights), *Integrating Intellectual Property Rights and Development Policy*, London 2002, 59 et seq.); however, the problem of farmers' rights also concerns patent protection. Also related, but not dealt with here is the protection of indications of geographical origin, see CIPR, loc. cit. at 87 et seq..

II. The Status of Traditional Knowledge Under Existing International Patent Law

1. Defending Traditional Knowledge: Poor Romantics – Poor Economics

a) *Improper appropriation under the rules for acquisition of patents*

On balance, legal literature on the safeguard of traditional knowledge approaches it as an issue of defending, according to the exclusivity rules of intellectual property protection, the inherited forms of knowledge of indigenous peoples – generally those living in developing countries⁴ □ against uncontrolled appropriation for business purposes by industry – generally from developed countries. Whilst such an approach may be too narrow in view of the need for protection against other kinds of unauthorized use of traditional knowledge (rather than just that of indigenous peoples),⁵ it points indeed to a minimum standard of passive protection of traditional knowledge, namely to the limits set by the rules on knowledge acquisition as provided for by intellectual property law. These rules are generally intended to ensure the functionality of the system of protection. In the case of patents this functionality is directed toward stimulating invention for the sake of technological innovation. To this effect appropriate knowledge must be separated from knowledge

⁴ These have also been the focus of WIPO (World Intellectual Property Organization), Intellectual Property Needs and Expectations of Traditional Knowledge Holders, Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), Geneva, April 2021, Part 2 (available at <http://www.wipo.int/tk/en/tk/ffm/report/final/pdf/part2.pdf>), the only exception being North America.

⁵ Whilst in Continental Europe traditional knowledge is abundant in many regions, specific protection is lacking. However, as regards food and wines etc. it is indirectly protected by indications of geographic origin (i.e. not against imitation as such, see Council Regulation (EC) 2081/92 of July 14, 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, OJEC 1992 L 208, 1, as amended by Reg. (EC) 692/2003 of April 8, 2003, OJEC 2003 L 99, 1; B. O'Connor, J. Kireeva, Overview of the EC Case Law Protecting Geographical Indications, Eur. Int. Prop. Rev. 2004, 313); traditional knowledge regarding medicinal methods and products, or regarding handicraft, etc. may enjoy protection under the general rules of unfair competition law (trade secrets, slavish imitation) against copying. Therefore, it must be the relationship to indigenous peoples which makes all the difference, and this should be reflected by the law, see *infra* 2 c) (ii).

which is, and which should remain, within (or should return to) the public domain.⁶ Art. 27 of the TRIPs-Agreement internationally harmonizes the relevant rules by stipulating that patent protection should only be granted to that which may properly be considered an invention, and among these only to those which are new, involve an inventive activity, and are industrially applicable. The selective effect of these four conditions of patentability varies, first, according to the nature of the subject-matter for which protection is claimed, and, second, according to national law and practice, because TRIPs Members may implement the standards differently.

Thus, in the first respect, the concept of invention, which, as regards mechanical inventions, is normally of only marginal importance, has become the crucial distinguishing factor in biotechnology. Biotechnological subject-matter may, indeed, represent a mere discovery of substances found in nature rather than an invention, the latter being defined as an instruction of how to achieve a technical result by operation of the forces of nature.⁷ However, the isolation of such substances and their presentation in a form ready for use may transform the discovery into an invention.⁸ Whilst the distinction may be a fine one, and may be controversial both in concreto and in the general context of biotechnology patenting, it raises issues of the politico-economic definition of patent protection in general rather than of the determination of the status of traditional knowledge in particular. Therefore, it will not be dealt with here on its merits.⁹

In the second respect, however, traditional knowledge may be directly at stake. Indeed, whether traditional knowledge may be appropriated by way of taking out patents will

⁶ See R. Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, 76 Cal. L. Rev. 803, 806 et seq. (1988); H. Ullrich, Standards of Patentability for European Inventions, Weinheim 1977, 97 et seq..

⁷ See BGH of March 27, 1969, BGHZ 52, 74 – Red Dove; though applying a broader concept, the famous formula of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), ("everything under the sun that is made by man") is based on the same distinction; generally Kl.-J. Mellulis in Benkard Europäisches Patentübereinkommen, Munich 2002, Art. 52, annot. 50; W. Cornish, D. Llewelyn, Intellectual Property: Patents, Copyright, Trademarks and Allied Rights, 5th ed. London 2003, p. 208 et seq..

⁸ For an illustration see BPatG of July 28, 1977, GRUR 1978, 238 – Antanamid – (synthetization of products found in nature); of December 12, 1983, GRUR 1985, 276 (-Schichtkeratotrtransplantat, application-specific preparation of products found in nature, in concreto human tissue); EPO of December 8, 1994, case V 8/94, OJEP0 1995, 338 C – Relaxin – isolation and identification of DNA-fragment coding for a human protein), but see EPO-Technical Board of Appeals of June 14, 2000, case T 241/95, GRUR Int. 2001, 460 (Serotoninrezeptor/Eli Lilly - discovery of selective linkage of compound to receptor no invention).

⁹ Note, however, that the delimitation of the scope of patent protection also determines the pre-emptive or non-pre-emptive effects vis-à-vis the use and exploitation of traditional knowledge (see text infra at n. 21), and the opportunity and legitimacy of benefit sharing, see infra 2 c).

largely depend on how national law defines the standards of novelty and inventive activity, which condition the grant of protection to inventions. Thus, whilst, as regards novelty, the general rule is that any prior art defeats the patentability of an invention,¹⁰ national laws may exclude knowledge from the relevant prior art, which has not been disclosed in writing, but only orally or by use and has been so disclosed only abroad,¹¹ the reason being that bringing knowledge, which is not generally available or accessible, to public attention by patenting is meritorious enough.¹² Clearly, under such a national rule, foreign traditional knowledge, if not sufficiently documented in publicly available literature, may become the subject of such alienation/appropriation. And yet, it would be unwise to ask, as a matter of principle, for a modification of such a "loose" definition of prior art/novelty,¹³ let alone to ask for an international harmonization imposing a strict standard of novelty based on a broad definition of relevant prior art, since it may precisely be the developing countries that have an interest in a flexible standard of novelty.¹⁴

¹⁰ See for example Art. 54 of the Convention for the Grant of European Patents (European Patent Convention, available at <http://www.european-patent-office.org/legal/epc/e/ar54.html#A54>), which reads in relevant parts "(1) An invention shall be considered to be new if it does not form part of the state of the art. (2) The state of the art shall be held to comprise everything made available to the public by means of written or oral description, by use, or in any other way, before the date of filing of the European patent application". This standards is adhered to throughout Europe and in most African and Latin American jurisdictions.

¹¹ This is the case in the USA, see 35 U.S. C 102, which reads in relevant part:

"A person shall be entitled to a patent unless

- (a) the invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, or....." For a critique of Sect. 102 (b) see M.A. Bagley, Still Patently Unconstitutional: A Reply to Professor Nard, 88 Minn. L. Rev. 239 (2003) with references. Thailand, Sri Lanka, the Philippines, Peru, New Zealand, Japan, India, PR China seem to have similar rules (see J. Schade, Patent-Tabelle, 8th ed. Cologne 2001). Utility model protection, i.e. protection of inventions by "petty patents" (available upon mere registration) may also be obtained for inventions which are not absolutely new, see for example Sect. 3 German Gebrauchsmustergesetz of August 28, 1986, BGBl I 1456. However, not all subject-matter may qualify for such protection as, under some laws, processes or chemical compounds may be excluded from protection.

¹² Rediscovery of prior art, which has fallen into oblivion, may equally be held meritorious enough to warrant the grant of a patent, even if it is available in (old) patent literature, see CJEC of June 30, 1988, case 35/87, Thetford/Fiamma, Rep. 1988, 3585, (upholding the pre-1977 British limitation of patented prior art to patents granted during the last 50 years against claims of incompatibility with the Common Market's constitutive principles of free trade). New Zealand still seems to follow the old British concept, see J. Schade, loc. cit. at p. 114.

¹³ As suggested in strong terms ("facilitates theft") by G. Stenton, loc. cit. Eur. Int. Prop. Rev. 2004, at p. 20.

¹⁴ Generally, the requirement of absolute novelty seems to be favoured as a matter of blocking domestic patenting by foreign applicants (see UNCTAD, The TRIPs Agreement and Developing Countries, Geneva 1996, 32 et seq.), but the downside of this approach is that it may inhibit domestic patenting of "imported" knowledge. Note that the impact of limiting prior art to publications in writing occurring anywhere and to oral disclosure or to disclosure by use, which occur on the domestic territory, mainly depends on which market is at issue: The domestic market may always be kept free, but protection may be obtained on foreign markets (by any applicant, domestic or foreign!). Should developing countries not be more

Rather, the point to be made is another one: Patent applications, which are made, or patents, which have been granted in disrespect of novelty standards which require all knowledge to be included in prior art, whether published in writing or orally or by use and regardless of the place of publication, simply are invalid or can be invalidated. Moreover, even if prior art is defined narrowly by national law, traditional knowledge may be raised to the level of relevant prior art by way of documentation, and then can be relied upon as a ground for invalidation. Actually, this is what is done now in many places.¹⁵ To be sure, such a pro-active approach to defending traditional knowledge may not always be possible, and it requires an extra-effort,¹⁶ just as opposing invalid patent applications or bringing actions for invalidation may raise issues of standing and pose problems of costs, as it does for any smaller complainant. But, at least there is a base-line of defence against acts of appropriation which lack merit. This is generally recognized and requires general respect.

However, the novelty requirement will impede patenting of inventions based on traditional knowledge only if the invention, as claimed, is identically anticipated by a teaching of traditional knowledge – most likely a rare instance given that the invention frequently will represent an adaptation or a transformation of (possibly ill-defined) traditional knowledge. By contrast, the requirement of an inventive activity or of non-obviousness of the invention by reference to the prior art as a whole¹⁷ should constitute the greater obstacle to

concerned with patenting conditions on their markets than with those existing on foreign markets? Note also that patenting on the basis of traditional knowledge does not normally foreclose access to markets by products of traditional knowledge (see *infra* text at n. 21); the situation is different as regards designs, trademarks, and, possibly, copyright to the extent that traditional cultural expression is appropriated.

¹⁵ See WIPO, Non-exhaustive Inventory of Traditional Knowledge-Related Databases (available at <http://www.wipo.int/tk/en/databases/databases.html>); *id.*, Intellectual Property Needs and Expectations, loc. cit. part 2 (fact finding reports); WIPO also prepares an IP Management Toolkit intended to assist developing countries in the proper establishment of databases which, however, in themselves may not easily be compatible with concepts of safeguarding traditional knowledge, see J. Gibson, loc. cit., Eur. Int. Prop. Rev. 2004, at 284 et seq.; CIPR, loc. cit., p. 81 et seq. (which also points to the important factual issue that such databases will be consulted by patent examiners only if made a mandatory element of search and examination).

¹⁶ For frequently cited, but not necessarily typical examples see CIPR, loc. cit. at p. 76, 81; Chr. Heath, S. Weidlich, Intellectual Property: Suitable for Protecting Traditional Medicine? Int. Prop. Qu. 2003, 69, 77 et seq. Note that in procedures before the patent offices of most jurisdictions everybody has standing to intervene in the granting procedure or to oppose the grant of patents; likewise invalidation suits may be brought by everybody. Factual barriers, however, may be high in view of the technical expertise required, the intricacies of patent law, and the expenses to be incurred.

¹⁷ Meaning that "inventiveness" must be assessed not by reference to specific single items of prior art, but by reference to the entire knowledge resulting from relevant prior art for the ordinary expert in the art, see W. Cornish, D. Llewelyn, loc. cit., sub. 5 – 29 et seq., 5 – 42, 5 – 46 et seq.; B. Jestaedt, in Benkard, Europäisches Patentübereinkommen, loc. cit., Art. 55, annot. 30.

undue patenting, at least in theory. In practice, however, this defence against appropriation of traditional knowledge by patenting will only be available to the extent that the "inventive idea" of the new teaching is sufficiently related to that following from traditional knowledge. This may not be the case precisely where the particular merits or effects of the isolation, purification, synthesization, adaptation or application of the subject-matter are claimed as its inventive characteristics.¹⁸ Moreover, frequently it will be precisely the – possibly incremental¹⁹ – improvement on traditional knowledge, which is claimed as a patentable invention. Therefore, other avenues for defending traditional knowledge need to be explored as well. But before turning to them, a second line of defense should be noted, which is the limitation of the scope of patents which are acquired for or on the basis of traditional biodiversity-related knowledge.

b) Limiting the scope of protection of traditional knowledge by patents

Indeed, unless a teaching of traditional knowledge has been lawfully patented as such – which, as demonstrated, should occur in rare circumstances only²⁰ –, reasons similar to those just mentioned will normally keep traditional knowledge outside the scope of exclusivity of patents, which have been acquired for biodiversity-related inventions. This is so because the scope of their protection may not reach beyond what is claimed as a novel and non-obvious teaching. In particular, it is the very function of the claims to clearly delimit the invention from what is taught by the prior art.²¹ Consequently, fears that patents based on traditional knowledge might subsequently bar the use of traditional knowledge as if they were general monopolies are unwarranted.²² In the context of the patent/traditional-knowledge relationship there is also, therefore, no need to rely on general exceptions from

¹⁸ See references supra n. 8.

¹⁹ Most patents are granted for incremental rather than only for (the few) pioneer inventions; what counts is not the advance in the art which they bring about, but whether or not they would have been produced by routine engineering, see W. Cornish, D. Llewelyn, loc. cit., sub. 5 – 34; H. Ullrich, Standards of patentability, loc. cit. at p. 12 et seq., 35 et seq., 60 et seq., 97 et seq..

²⁰ Conceivably this might occur with respect to secret traditional knowledge, in particular if its author/inventor is not identifiable. Violation of such secrets will not necessarily constitute a trade secret violation within the meaning of Art. 39 TRIPs-Agreement, or may not be enforceable abroad or constitute a ground of patent invalidation or vindication, and possibly it may not be claimed by others than the true inventor, see Art. 60 et seq., 138 European Patent Convention.

²¹ See W. Cornish, D. Llewelyn, loc. cit., p. 230 et seq., 236 et seq.; for a comparative analysis see U. Scharen, in Benkard, Europäisches Patentübereinkommen, loc. cit. Art. 69, annot. 3, 11, 24 et seq., 65, 66 et seq..

²² See WIPO, Intellectual Property Needs, loc. cit., p. 222; misleading G. Stenton, loc. cit., Eur. Int. Prop. Rev. 2004 at 20.

patent protection, such as prior user rights,²³ or to provide for new ones by analogy from plant variety protection, such as farmers' privileges.²⁴ The latter, in particular, are a concern of patent protection in general as it is extended to gene technology, regardless of where knowledge of the presumed properties of genes is derived from. Therefore, it has been adopted in Europe concomitantly with such extension of protection,²⁵ and, if not already existent, it may be introduced by developing countries with respect to their territories in accordance with Art. 30 TRIPs Agreement.

c) Defensive acquisition of patents for traditional knowledge

The upshot of the preceding considerations then is that traditional knowledge is not so much put in jeopardy by illegitimate appropriation through patents as by economic substitution through knowledge, which has been developed more or less directly on its basis. The threat of substitution is all the greater as such derived knowledge may be more competitive in that it is – presumably most of the time – scientifically-enhanced knowledge, which may be and generally is exploited industrially both as regards production and distribution. Reactions to this real threat are of various kinds.

One such reaction is to make use of the existing intellectual property system as shaped by the TRIPs-Agreement. Whilst, at least in some instances of technology-related traditional

²³ But see WIPO, Intellectual Property Needs, loc. cit., p. 222. Under patent systems attributing the patent to the person who is first to file (see infra n. 28) a new invention with the patent office (which he/she legitimately possesses), an exception to the exclusivity is frequently admitted for those who actually and legitimately practiced the same invention before the application was filed, see Sect. 12 German Patent Act. The purpose of this exception is to accommodate for the social costs resulting from the enforcement of absolute exclusivity, particularly in view of the legitimacy of keeping new knowledge secret (patenting is an option, not an obligation; trade secret protection for patentable knowledge is generally recognized as an alternative, see for a discussion *Kewanee Oil v. Bicron*, 416 U.S. 470 (1974)). However, prior user rights are generally recognized only with respect to the territory of prior use, meaning that they may benefit indigenous people only on their local markets, not abroad.

²⁴ See for instance Art. 14 Council Regulation 2100/94 of July 2, 1994 on Community Protection of Plant Varieties (OJEC 1994 L 227, 1, as amended OJEC 1995 L 258, 3); as an exception to the exclusive right of the holder of plant variety protection, the farmers' privilege must be distinguished from farmers' rights to obtain compensation for their collective breeding efforts and achievements, see A. Girsberger, The Concept of Farmers' Rights, the Role of FAO and the TRIPs Agreement, in Th. Cottier, P. Mavroidis, Intellectual Property - Trade, Competition and Sustainable Development, Ann Arbor 2003, 455.

²⁵ See Art. 11 Directive 98/44 of July 6, 1998 of the European Parliament and the Council on the legal protection of biotechnological inventions (OJEC 1998 L 213, 13); the adoption of the farmers' privilege was one of the many, but not the most controversial issue during legislation, see R. Nott, The Proposed EC Directive on Biotechnological Inventions, Eur. Int. Prop. Rev. 1994, 191, 193.

knowledge, this may be a promising route as regards safeguarding the reputation of traditional knowledge by trademarks,²⁶ it generally will not be available as regards protection of the substance of such knowledge. Legally speaking, the very reasons that stand in the way of appropriation of traditional knowledge by non-indigenous applicants (e.g. applicants of developed countries) frequently also impede acquisition of patent rights by the original holders of traditional knowledge. This is obvious for the novelty requirement, precisely because much traditional knowledge is more or less widely known for generations, even though only particular persons may know (or be allowed) to practice it. Mostly this will be equally true of the requirement of inventive activity and industrial applicability. There are also additional obstacles, such as the informal, uncodified nature of traditional knowledge²⁷ or – at least in some jurisdictions²⁸ – the lack of individually attributable inventorship. No less important are the factual obstacles which beset the patent system not only in less affluent countries, namely the costs of patent protection, and the difficulties of its procedural accessibility, in particular if protection is sought on more than the local level.²⁹

²⁶ The use of collective or of certifications marks (see Art. 64 et seq. Council Regulation 40/94 of December 20, 1993 on the Community Mark, OJEC 1994 L 11, 1, as last amended, OJEC 2004 L 123, 88), which allow for control of the quality of goods sold by members of the collective is frequently recommended and actually followed in practice (see CIPR, loc. cit. at p. 19; WIPO. Intellectual Property Needs, loc. cit. at p. 224; J. Gibson, loc. cit., Eur. Int. Prop. Rev. 2004 at 282 et seq. summing up WIPO investigations on national laws). But the point to be made here is that such marks also may establish product fidelity and protect against loss of reputation resulting from the use of the designation of traditional knowledge for derivative products, very much like trademarks are used to prolong product fidelity after expiration of patents for pharmaceuticals.

²⁷ The difficulty will be less for medicinal products, see the Chinese example of handling applications even for examined patents, as reported by Chr. Heath, S. Weidlich, loc. cit., Int. Prop. Qu. 2003 at 90 et seq. (stressing that in China traditional medicine is a well established mainstream art); however, it may be doubtful whether it really represents traditional knowledge deserving a separate status such as indigenous knowledge, see infra n. 99; Generally the disclosure requirements of patent law (Art. 29 TRIPs Agreement), if handled properly in accordance with their public purpose, should pose serious hurdles for easy patenting of uncodified knowledge. The disclosure requirement represents, indeed, a part (however imperfectly put into operation) of the quid pro quo of the grant of exclusive rights: The exclusivity is granted to allow enterprises to abandon secrecy; the value of disclosure as a quid pro quo lies in the facilitation of the development of both substitute knowledge and improvements, see R. Kraßer, Lehrbuch des Patentrechts, 5th ed. Munich 2004, 34, 397; W. Cornish, D. Lewelyn, loc. cit. at 3 – 49 et seq., 5 – 84 et seq..

²⁸ Namely in those granting the patent to the "first and true inventor" (35 U.S.C.102(f),115,135) rather than to the first-to-file inventor (see Art. 60 (3) European Patent Convention, because in the latter system the true inventor need not necessarily be identified, unless inventorship is claimed (see Art. 4 Paris Convention for the Protection of Industrial Property of March 20, 1883, as last amended BGBl 1984 II 799).

²⁹ See WIPO, Intellectual Property Needs, loc. cit. at p. 222, 223; if, as will be necessary in most cases, international protection is sought, protection in Europe alone will be virtually unaffordable, see H. Ullrich, Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe, 8 Eur. L. J. 433,440et seq.,468 et seq.(2002).

d) *Sui generis protection as a sustainable outer line of defence?*

Some of these problems may be overcome by appropriate adaptation of domestic patent laws and procedure.³⁰ However, politically speaking, that may not even be desirable, since the availability of any “adapted” patent protection might prove not only to the benefit of domestic or indigenous applicants, but also to the benefit of those whom a (developing) country might wish to exclude from protection, since international convention law excludes any reservation of protection to nationals only (Article 2 Paris Convention).

Anyway, given the particularities of its acquisition by tradition, its definition by use, and its dependence on the cultural and ethnographic environment, traditional knowledge in essence seems to demand specific forms of protection. Proposals for such *sui generis* regimes of protection have, indeed, been made by doctrine,³¹ are considered within WIPO, and have been pursued by some countries.³² However, since they must be specific to traditional knowledge in all its breadth, and yet satisfy the needs of particular forms of knowledge, and since they should formally identify and protect subject-matter, which may be valuable and operative only in its context of application, there is no general acceptance of legislative initiatives which have been taken in some of the countries concerned, let alone international consensus on what a model law should look like.³³

³⁰ See *supra* n. 27.

³¹ See e.g. Th. Cottier, M. Panizzon, Legal Perspectives on Traditional Knowledge. The Case for Intellectual Property Protection, 7 J. Int'l. Ec. L. 371, 381 et seq., 387 et seq. (2004); A. Gupta, Conserving Biodiversity and Rewarding Associated Knowledge and Innovation Systems. Honey Bee Perspective, in Th. Cottier, A. Mavroidis, (eds.), loc. cit., p. 373, 382 et seq.; for a broad discussion see A.von Hahn, Traditionelles Wissen indigener und lokaler Gemeinschaften zwischen geistigen Eigentumsrechten und dem public domain, Berlin 2004, 311 et seq..

³² See WIPO, Revised Version of Traditional Knowledge: Policy and Legal Options, WIPO/GRTKF/IC/6/4 Rev. (Document of the Secretariat for the 6th Sess. of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, March 15-19, 2004 (available at www.wipo.int/documents/en/meeting/2004/igc/pdf/grtk_ic_6_4pdf); *id.*, Review of Existing Intellectual Property Protection of Traditional Knowledge, WIPO/GRTKF/IC/3/7 of May 6, 2002 (available at www.wipo.int/documents/meeting/2002/igc/pdf/grtkf/ic3_7.pdf); J. Gibson, loc. cit., Eur. Int. Prop. Rev. 2004 at 283 et seq.; C. Correa, Traditional Knowledge and Intellectual Property – A Discussion Paper, Quaker United Nations Office, Geneva 2001, at 14 et seq.; G. Dutfield, Protecting Traditional Knowledge and Folklore, UNCTAD/ICTSD Issue Paper No.1, Geneva 2003, 40 et seq.; as to protection schemes relating more specifically to the control of the use of genetic resources see *infra* 2b).

³³ See references *supra* n. 32 and CIPR, loc. cit. at p. 79 et seq..

Obviously also, a sui generis approach, however well conceived as an appropriately adapted "full property"-regime,³⁴ will at best serve local trade to the extent that there is demand for traditional subject-matter as such.³⁵ The substitution problem, however, will remain unchanged, and any hopes of conservation effects are misplaced per se. Property titles cannot preserve knowledge that becomes obsolete or that falls into oblivion. Property is a market institution, not a conservation measure.³⁶ It may be based on rationales other than setting incentives and rewards.³⁷ But in the absence of markets, where offer and demand actually meet, it is literally worthless. More precisely, where property is supposed to operate in a museum rather than on a market, all it will produce are high individual costs and few social gains.

This, of course, is pushing the argument to its extreme. To the extent that traditional knowledge is actually traded or at least put to use as it is, available or adapted forms of intellectual property may serve a defensive purpose as protection against acts of passing off non-genuine products or services. Possibly it may also help codify and formalize such knowledge, if that is compatible with its nature, and it may constitute a means to ensure its recognition and respect.³⁸ In this regard, there is ample support for it also in public

³⁴ Meaning property carrying an obligation "to preserve and maintain" the traditional knowledge, see the concepts discussed WIPO, Revised Version, loc. cit. at No. 41.

³⁵ See Chr. Heath, S. Weidlich, loc. cit., Int. Prop. Qu. 2003 at p. 86 et seq. with references.

³⁶ For a more elaborate presentation of this basic point of industrial property law see H. Ullrich, Intellectual Property, Access to Information and Antitrust: Harmony, Disharmony and International Harmonization, in R. Dreyfuss, D. Zimmermann, H. First (eds.), Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society, Oxford 2001, 365, 371 et seq. with references; for the historical, philosophical and economic underpinnings of patent protection in general see O. Granstrand, The Economics and Management of Intellectual Property, Cheltenham 1999, 17 et seq., 55 et seq..

³⁷ At least as regards intellectual property other than patents, such as copyright in literary and artistic works proper or purely aesthetic designs, but even as regards patent law, the basis for the legitimacy of granting protection for inventions is not merely utilitarian, see for a broad discussion P. Drahos, A Philosophy of Intellectual Property, Aldershot 1996, passim (himself defending an instrumentalist approach with the aim of keeping property within the limits of functionality). It is, however, grossly misleading to pretend that protection of trademarks or of geographic indications of origin do not follow an incentive/reward-rationale, but protect reputation (see for instance D. R. Downes, How Intellectual Property Could be a Tool to Protect Traditional Knowledge, 25 Col. J. Envtl. L. 253, 259 (2000)). This is simply confusing the operation of protection with its rationale, which, at least in the case of trademarks, is to encourage investment in market penetration and distribution. Likewise, indications of origin are not protected for the sake of preserving products of the past, but to allow competition on the merits in trade, i.e. investment in quality, which is to be recouped from the market. In short, intellectual property is an instrument of dynamic competition, not a stand-still arrangement.

³⁸ For an account and a juxtaposition of the arguments on how and why to protect traditional knowledge see WIPO, Intellectual Property Needs, loc. cit. at p. 213 et seq. ; G. Dutfield, loc. cit., Issue Paper No.1 at 25 et seq., 29 et seq..

international law.³⁹ It is, however, quite revealing that it is not these aspects, which have ultimately induced legislatures in at least some developing countries to take the concrete step of specifically protecting traditional knowledge. Rather, by limiting access to and use of traditional knowledge, in particular by attributing property-like control to communities, local authorities or eventually even the State,⁴⁰ these measures aim to elevate traditional knowledge to the level of a scarce resource, the use of which is reserved to those willing to pay, in order to use it indirectly as a raw material for the development, by value-adding transformation, of more readily, widely, and hopefully also more efficiently applicable knowledge. The typical examples of such approaches to tapping the profit potential of innovation at its up-stream source are presented by legislation on public and/or private "property" over traditional medicines,⁴¹ and, more particularly, by legislation on access to genetic resources, including traditional knowledge of their properties and applications, on disclosure of their use in the process of invention, and on sharing in the benefits of innovation resulting therefrom.

2. Activating Traditional Knowledge: False Romantics – False Economics

a) *The Convention on Biological Diversity*

Taken mainly by developing countries,⁴² such legislative measures, standing alone, would hardly be effective. It is the support, in fact the impulse, which they have received from

³⁹ See T. McClellan The Role of International Law in Protecting the Traditional Knowledge and Plant Life of Indigenous Peoples, 19 Wis. Int'l L. J. 249 (2001); Chr. Heath, S. Weidlich, loc. cit., Int. Prop. Qu. 2003, 72 et seq.; M. Leistner, Traditional Knowledge, in S. v. Lewinski (ed.), Indigenous Heritage and Intellectual Property, The Hague 2004, 49 106 et seq.

⁴⁰ See e.g. the Thai Traditional Thai Medicinal Intelligence Act as reported by C. Correa, loc. cit. p. 13.

⁴¹ See n. 40.

⁴² See supra n. 40; as to Australia see B. Sherman, Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery, Eur. Int. Prop. Rev. 2003, 301 et seq.; as to India see G. Srividhya, Biological Diversity: An Indian Perspective on North-South Issues, in K. M. Hill, T. Takenaka, K. Takeuchi (eds.), Rethinking International Intellectual Property, Proceedings of the 2000 High Technology Summit Conference, University of Washington, Seattle 2001 (CASRIP Publication No. 6), 225 et seq.; Chr. Heath, S. Weidlich, loc. cit. Int. Prop. Qu. 2003, at 92 et seq. (reporting at p. 94 et seq. also on the Philippines); extensively S. Verma, Access to Plant Genetic Resources and Intellectual property Rights: The Case of India, CASRIP Newsletter 2001 (Spring/Summer) 18, 23 et seq.; as to Africa see for the Organisation of African Unity's Model Legislation T. Kongolo, Biodiversity and African Countries, Eur. Int. Prop. Rev. 2002, 579, 582 et seq.; R. Wolson, Intellectual Property Rights and Biological Resources: current policies and legislative developments in South Africa, in Chr. Bellmann, G. Dutfield, R. Meléndez-Ortiz (eds.), Development Perspectives in TRIPs, Trade and Sustainability, London 2003, 264, 271 et seq.;

public international law,⁴³ in particular from the Convention on Biological Diversity (CBD),⁴⁴ which makes such legislation attractive. In view of the dramatic reduction of biodiversity due to both highly selective "industrialization" of the exploitation of genetic resources and their substitution by derived or synthesized products,⁴⁵ the Convention seeks to control access to genetic resources on the basis of the principle that "States have..... the sovereign right to exploit their own resources pursuant to their own environmental polices..... (Art. 3)". Within a rather vaguely defined framework of environmental responsibilities, such as the development of conservation programmes and policies, the monitoring and identification of biodiversity, the establishment of protected areas (in situ conservation) and the introduction or maintenance of research, training, education and awareness projects etc. (Art. 6-14), the Convention reasserts in Art. 15 that, in view of their sovereign rights over their natural resources, States have the authority to determine access to genetic resources in accordance with their domestic legislation. Whilst they "shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting States and not to impose restrictions that run counter to the objectives of this Convention" (Art. 15 (2)), such access "where granted, shall be on mutually agreed terms...." (Art. 15 (4)), and "subject to prior informed consent of the Contracting Party providing such resources...." (Art. 15 (5)). In addition "each Contracting

J. Otieno-Odek, Towards TRIPs Compliance: Kenya's legislative reforms, in Chr. Bellmann, D. Dutfield, R. Meléndez-Ortiz (eds.), loc. cit. at 277, 282; as to Latin America B. Venero Aguirre, The Peruvian Law on Protection of the Collective Knowledge of Indigenous Peoples Related to Biological Resources, in Chr. Bellmann, G. Dutfield, R. Meléndez-Ortiz (eds.), loc. cit. at 285 et seq.; F. Noviak, Biotechnology and Regional Integration Systems: Legislation and Practices in the Andean Community Countries, sub. 2.1 (this Volume); see also the overview by M. Leistner, loc. cit. in S. v Lewinski (ed.), loc. cit., at p. 120 et seq., and by M. Hassemer, Genetic Resources, *ibid.* p. 151, 188 et seq.; a database on national legislation has been set up by the Secretariat of the Biodiversity Convention (Database on ABS Measures, available at <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>). It should be noted that a more or less voluntary, heterogeneous practice of contractual arrangements on access and benefit-sharing has developed between States and large corporations, see CIPR, loc. cit. at 77; D. Bell, The 1992 Convention on Biological Diversity: The Continuing Significance of U.S. Objections at the Earth Summit, 26 *Geo. Wash. J. Int'l. L. Ec.* 479, 528 et seq. (1993); R. Kneller, Ownership of Inventions Derived from Natural Products and Human Tissues, and Sharing of Benefits from the Communalization of Such Inventions, in K. Hill, T. Takenaka, K. Takeuchi (eds.) loc. cit. at 218, 221 et seq.; M. Hassemer, loc. cit. in S. v Lewinski (ed.), loc. cit., at p. 205 et seq..

⁴³ See references supra n. 39.

⁴⁴ Agreed on the 5th of June 1992 at Rio de Janeiro (text available at <http://www.biodiv.org/default.aspx>); there are 188 parties (168 signatories) to the Convention, but it has not been ratified by the USA, which is the major nation in biotechnology; for the reasons of refusal, mainly related to the provisions on financing and on intellectual property see D. Bell, loc. cit. 26 *Geo. Wash. Int'l. J. L. Ec.* at 507 et seq. (1993).

⁴⁵ For a brief account of this by now generally admitted phenomenon see D. Bell, loc. cit. 26 *Geo. Wash. J. Int'l. L. Ec.* at 483 et seq. (1993); S. Biber-Klemm, Incentives to bring about Conservation and Sustainable Use of Genetic Resources in the Framework of the World Trade Order, in Th Cottier, P. Mavroidis, loc. cit., p.481, 484 et seq..

Party shall take legislative, administrative or policy measures..... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms" (Art. 15 (7)).

The Biodiversity Convention has its own financial resources and mechanism mainly "to enable developing country parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions....." (Art. 20 (2)).⁴⁶ It also has its own organisational structure in order to meet the long term needs of environmental protection measures relating to biodiversity, and to take the decisions necessary to implement the provisions of the Convention (Art. 23 et seq.). These are generally in the nature of framework rules.

The decision pertinent to the topic of this paper, Decision VI/24 of the Conference of the Parties,⁴⁷ which adopts the so-called "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization",⁴⁸ provides for development of an "Action Plan for Capacity-Building for Access to Genetic Resources and Benefit-Sharing", and deals with the "Role of intellectual property rights in the implementation of access and benefit-sharing arrangements". The – formally voluntary⁴⁹ – Bonn Guidelines more particularly "are intended to assist Parties in developing an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits" (No. 12). To this effect they propose a complete scheme of administrative organisation and tasks, of distribution of substantive responsibilities between granting and receiving States, users and providers, of how to

⁴⁶ Even in view of the undisputable fact that developing countries need to be enabled to protect the environment, and that the latter is a matter of common concern to all Parties it is surprising to read Art. 20 (4) of the Convention: "4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties". Given the additional claim of benefit-sharing in the commercial exploitation of the good to be protected, namely biodiversity, this provision underscores the ambivalence of the communitarian approach underlying the Convention.

⁴⁷ Adopted at the 6th Ordinary Meeting at the Hague, April 7-19, 2002 (available at [http://www.biodiv.org/decisions/default.aspx?m=\(OP-06gid=7198glg=0\)](http://www.biodiv.org/decisions/default.aspx?m=(OP-06gid=7198glg=0))), hereinafter abbreviated as "Bonn Guidelines".

⁴⁸ So called following their elaboration and adoption by an Ad hoc Open-ended Working Group on Access and Benefit-sharing in Bonn from October 22 – 26, 2001.

⁴⁹ See Bonn Guidelines, sub. No. 7, but remember Art. 20 (4) of the Convention (supra n. 46).

involve "stakeholders", of the procedure for granting access and ensuring benefit-sharing, and of the terms and modalities of access, of prior informed consent and benefit-sharing, as well as an indicative list of "mutually agreed terms" of the arrangements between Contracting Parties). As if all this and provisions on incentives, accountability in implementing access and benefit-sharing arrangements were not enough, "Elements for Material Transfer Agreements" in the form of a contract check list are suggested, and modalities of monetary or non-monetary benefit-sharing are detailed.

b) Intellectual property issues

Intellectual property comes into the picture of this bureaucratic paradise at several points.⁵⁰

- (i) Art. 8 lit j of the Convention extends the duty of environmental protection to traditional knowledge of indigenous and local communities, insofar as it is relevant for the conservation and sustainable use of biological diversity. The provision even establishes a duty to promote its "wider application with the approval and involvement of the holders of such knowledge..." and to "encourage the equitable sharing of the benefits arising from the utilisation of such knowledge". This seems to be an obligation on the Contracting Parties in its own right, which must be distinguished from rules on access to and benefit-sharing as they apply when traditional knowledge is necessary for the identification and understanding of genetic resources and, therefore, is used in conjunction with the latter as "associated traditional knowledge".⁵¹ Even though the two kinds of traditional knowledge are not really separable on a general level, in the following text traditional knowledge will only be considered under the aspect of access to and benefit-sharing in the use or exploitation of genetic resources.

⁵⁰ It is a paradise in permanent evolution, see Bonn Guidelines, sub. No. 6; see as to the on-going work Decision VII/19 of the Conference of the Parties (adopted at its 7th ordinary meeting, Kuala Lumpur, 9 – 20 and 27 February 2004) inviting Parties and the Executive Secretary to do further documentation work and charging the Ad hoc Open-ended Working Group on Access and Benefit-sharing with further implementation work; in addition, the Working Group has been mandated "to elaborate and negotiate the nature, scope and elements of an international regime on access and benefit-sharing within the framework of the Convention on Biological Diversity.....".

⁵¹ See Bonn Guidelines, sub. No. 9, 11 lit j, 16 lit d (ii), 31; see also A. v. Hahn, P.-T. Stoll, Indigenous Peoples, Indigenous Knowledge and Indigenous Resources in International Law, in S. v. Lewinski, (ed), loc. cit, p. 5, 28 et seq., 32 et seq..

- (ii) Second, such subjection of associated traditional knowledge to the rules governing access to and benefit-sharing in the exploitation of genetic resources primarily means compliance with the requirement of obtaining informed consent to access knowledge prior to actually doing so.⁵² Whilst such prior informed consent may be relatively easy to handle administratively as regards genetic resources as such,⁵³ in respect of traditional knowledge it will create specific practical, if not legal difficulties. It is not easy to ask for informed consent to access knowledge unless it is known what knowledge exactly one wishes to request access to.⁵⁴ Moreover, the holders of the knowledge will not always know what they are asked for, and proof of informed consent (and subsequently of the basis of benefit-sharing) will require some formalisation/codification of the knowledge. Whilst such details are a matter for further implementation of the Bonn Guidelines by Contracting Parties and/or national legislation and administration, prior informed consent clearly affords some extra formal protection to traditional knowledge,⁵⁵ and it even elevates it to the level of a proprietary asset.
- (iii) This, indeed, brings up a third intellectual property issue raised by Decision VI/24 and the Bonn Guidelines in response to a general desideratum of the holders of traditional knowledge and the protagonists of its protection,⁵⁶ which is to request that

⁵² The concept seems to need quite some implementation as to the kind of information that is necessary to make the consent valid, and as to what prior consent means in cases where the use made of the genetic resources is subsequently modified, see Bonn Guidelines, No. 24 et seq.; G. Srividhy, in K. Hill, T. Takenaka, K. Takeuchi (eds.), loc. cit. at p. 230; according to J. Straus, Biodiversity and Intellectual Property, *ibid.* at 141, 148 et seq. the necessity of obtaining prior informed consent and its criteria entirely depend on national law; however, it would appear that the Convention also sets limits to this requirement or else access to resources may be made unduly difficult, see Bonn Guidelines No. 26 lit. b.

⁵³ Basically the consent is given via an administrative act – the prospecting permit – by the competent national authorities, but it may become more difficult when "stakeholders", such as indigenous peoples and local communities, have to approve of prospecting. Still, it relates to the tangible "phenotypes" of genetic resources.

⁵⁴ This vicious circle, which is noted also by G. Srividhy, in K. Hill, T. Takenaka, K. Takeuchi (eds.), loc. cit. at p. 230, is well-known from trade-secret licensing, where it is overcome by the parties first agreeing on duties of confidentiality obliging them to maintain confidentiality even in case of failure of the negotiations; breach of such agreements may be sanctioned by penalties and the grant of liquidated damages; however, this may not be a reliable mechanism in the context of bio-prospecting, where transactions may involve many and/or inexperienced people.

⁵⁵ In particular, it may protect and complement customary rules, which, in view of their proper way of functioning, their perception and precarious status cannot effectively safeguard traditional knowledge, see Bonn Guidelines No. 31, A. v. Hahn, loc.cit. at 209 et seq., 326 et seq.

⁵⁶ See N.S. Gopalakrishnan, TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patent System, *Eur. Int. Prop. Rev.* 2005,11; B. Sherman, loc. cit. *Eur. Int. Prop. Rev.*

the applicant for a patent should fully disclose in his patent application both the genetic resources and the traditional knowledge, which, in conjunction with genetic resources or independently, constitute the subject-matter of or have been used in the development of his invention.⁵⁷ This petition seems to be quite innocent as, in patent law, the description of the state of-the-art against which the invention has to be assessed, is both a formal requirement and good practice, and as such mentioning the contribution made by others to the invention seems simply to represent the respect due to the moral right(s) of the holder(s) of such knowledge.⁵⁸ However, the petition is raised regardless of the quantum or the quality of the contribution made by traditional knowledge (or the genetic resource for that matter) to the invention⁵⁹ – it may even be public domain knowledge⁶⁰ –, and it is made for much more mundane purposes: It is intended to serve as a tracking tool to control proper benefit-sharing.⁶¹

It is in view of this purpose also that the request for origin disclosure regarding gene-technology related inventions is considered to be a TRIPs-problem: Behind the new formality lurks a problem of substance: disclosure of genetic resources, and, a fortiori, of traditional knowledge may not always be done easily with sufficient precision. In addition, if informed consent has not been obtained with sufficient specificity,⁶² the patent application may be invalid or the patent, as granted,

2003, at p. 304 et seq.; N. Pires de Carvalho, Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPs Agreement: The Problem and the Solution, 2 Wash. Univ. J. L. Pol'y 371 (2000).

⁵⁷ See Conference of the Parties (of the CBD), Decision VI/24, supra n. 47, sub. C (Role of intellectual property rights in the implementation of access and benefit-sharing arrangements) at No. 1, 2, 3, 4 (c); Bonn Guidelines, No. 16 sub. d (ii).

⁵⁸ For an analogy see the right of the inventor to be named in the letters patent as internationally recognized by Art. 4 of Paris Convention for the Protection of Industrial Property.

⁵⁹ Claims to joint inventorship are generally misplaced since the inventive activity normally does not lie in the discovery of a genetic resource or of its use, but in its isolation and presentation in purified or improved gallelic form (contra: B. Sherman, loc. cit., Eur. Int. Prop. Rev. 2003 at p. 306); a different matter is whether the grant of prior informed consent may be conditioned on the acceptance of joint ownership of patents, which, though onerous enough and likely to be excessive, is simply a matter of either highhanded administrative imposition or successful negotiation of modalities of benefit-sharing, see Bonn Guidelines, Annex II (Monetary and Non-Monetary Benefits) sub. 2 q.

⁶⁰ As to this problem see infra sub. c) (iv).

⁶¹ Decision VI/24, supra n. 47, sub. C1: "disclosure..... as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted". Note, that disclosure of origin without submission of evidence of prior informed consent would make little if any sense.

⁶² See supra n. 61, and note that prior informed consent is also required if, subsequent to the original consent, the use to be made of the genetic resources or the traditional knowledge is changed, see Bonn Guidelines sub. No. 27 (c), 34 (it being an open question how detailed the indication of "specific use(s)" must be).

invalidated. Moreover, the patent office is made the judge of whether disclosure was warranted or not in view of the quantum or the quality of the contribution made by the genetic resource or by traditional knowledge. Finally and most importantly, the perspective for assessing all these new hurdles for the patent grant, which is costly and cumbersome enough,⁶³ risks being that of benefit-sharing rather than consideration of the merits of the invention as a promise of innovation that does not follow by itself from the state of the art.

The Contracting Parties of the Biodiversity Convention have asked the World Intellectual Property Organisation to submit a technical study on possible modalities and the feasibility of the disclosure requirement, a draft of which WIPO has submitted on the understanding that it does not express a policy position on the part of WIPO.⁶⁴ The lengthy paper does, however, show the extreme technical complexities and the wide array of possible approaches to a disclosure requirement. They may reach from voluntary indication of genetic resources actually implied in the invention as claimed⁶⁵ to a mandatory requirement to examine the equities of benefit-sharing based on the use of genetic resources somewhere in the process of inventing. On such a scale, making the indication of the genetic resources used for the invention a mandatory requirement of patent validity amounts to full recognition of the principle of benefit-sharing whatever its legitimacy may be in general or in casu, and extending such mandatory disclosure to the existence of prior informed consent

⁶³ This consideration is downplayed by B. Sherman, loc. cit., Eur. Int. Prop. Rev. 2003 at p. 306; however, given that the reliability of patent granting procedures is already weak enough (see Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, Washington DC, October 2003, Chapter 5), that granting procedures in Europe take 2 1/2 to 4 years on average, that on average the overall costs of a patent granted under the European Patent system are about 30.000 € over the life time of the patent, that protection has to be sought worldwide, and that patent agents and, subsequently, patent examiners are engineers, who are not trained to check whether prior informed consent has been duly obtained under the law(s) of one or more distant countries and from the proper owners (so that additional legal advice becomes necessary), it should become clear that the disclosure requirement raises more than simply an issue of practicality.

⁶⁴ WIPO, Draft Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge (WO/GA/30/7 Add 1 of August 15, 2003), circulated by the Executive Secretary of UNEP sub UNEP/CBD/COP/7/inf/17 of December 15, 2003 (available at <http://www.biodiv.org/doc/meetings/cop/cop-07/information/cop-inf-17-en.pdf>).

⁶⁵ See recital 27 EU Directive on biotechnological inventions, supra n. 25, which reads: "..... 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;..... this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents". Note that this is not only a non-binding, but also a rather restrictive formulation in view of the difficulties of precisely locating the origin of genetic resources, and the uncertainty as to where, how, and to what extent it has been used in the process of invention.

would mark the transformation of the patent system from an institution for the grant of private property rights into an auxiliary instrument of administrative environment protection.⁶⁶ It is for this reason that a globally uniform disclosure rule, which reaches beyond technological information, is hard to foresee. In addition, the differences in national access regulations and patent procedures⁶⁷ alone would seem to stand in the way of a patent-law supported control of the importance of the genetic resources used as a basis for the requirement of consent and benefit-sharing, of the materiality of the consent, and of the adequacy of benefit-sharing.

It is, therefore, no surprise that, at the level of the World Trade Organisation, where the same issue is debated, only little progress has been made as regards the nature and scope of a technical disclosure requirement, and even less as regards a transformation of the patent system into an instrument of environmental and developmental policy by way of an extension of the disclosure requirement to evidence of prior informed consent and, ultimately, to evidence of benefit sharing.⁶⁸ Indeed, what is really needed is a thorough empirical economic investigation into the question of how much of an extra-load can reasonably be carried by the patent system without deterring its use.⁶⁹ Such an investigation should be extended to examining the question of whether the

⁶⁶ Much to the regret of some fervent advocates of the disclosure requirement, even India has refrained from taking this last step, and is satisfied with a technical disclosure requirement, see N.S. Gopalakrishnan, loc. cit. *Eur. Int. Prop. Rev.* 2005 at 17 et seq.. After all, the prior informed consent primarily concerns the impact a request for access to genetic resources may have on bio-diversity rather than the commercial implications of the applicant's innovation project as such.

⁶⁷ The WIPO Technical Study, *supra* n. 64, has not gone into the different problems the disclosure requirement will raise, on the one hand, under an examination system (such as in the USA, in the EU or in Japan) and, on the other, under a mere registration system (such as existing in most developing countries, but also in major developed countries such as France or Italy).

⁶⁸ See Para. 19 of the Declaration of the 4th Ministerial Conference held at Doha November 14, 2001; for the state of play see "TRIPs Council Update, Bridges-WTO News June 2004 (6) ; Note: "TRIPs Council Addresses Health, Biodiversity, in Bridges-WTO/MEA News, March 2004 (No. 3) p. 12 (all available at www.ictsd.org); WTO-TRIPs Council: Communication from the European Communities and their Member States: Review of Article 27. 3 (b) of the TRIPs Agreement, and the Relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore – A Concept Paper -, IP/WC/383 of October 17, 2002; F. Addor, Industrial Property – Quo Vadis? Where now after Cancun? Presentation made at the Conference on "Industrial Property - Quo Vadis? Lacco Ameno - Ischia, 5 – 7 October 2003 (available at <http://www.ige.ch/E/jurinfo/pdf/Ischia.pdf>); as regards requirements of evidence on prior informed consent and even on benefit-sharing as claimed by developing countries see Note, TRIPS Council Focuses on Benefit-Sharing for Genetic Resources, 5(5) BRIDGES BioRes of March 18, 2005 (available at www.ictsd.org/biores).

⁶⁹ Thus, industry may even turn to other areas of promising research, see Glaxo Smith Kline's public policy position as reported in Second Report of the European Community to the Convention on Biological Diversity, Thematic Report on Access and Benefit-Sharing, October 2002, Box 5 (available at <http://biodiv.org/world/reports.aspx?type=abs&alpha=E>).

instrumentalization of the patent system for additional, if not extraneous purposes⁷⁰ really is efficient in view of the actual – and legitimate⁷¹ – benefit-sharing that may reasonably be expected. After all, however important patent protection may be for the biotechnology industry, the number of block buster patents is not likely to be greater than in other areas of chemical and pharmaceutical patenting.⁷² With respect to those commercially successful inventions, however, evidence of acts of tapping genetic resources, if necessary at all, may be easier to gather ex post from general sources of information than ex ante via a Kafkaesque system of global bureaucratic control.

c) *Systems friction*

- (i) It may very well be that within WTO-TRIPs, either expressly or implicitly, much of the excess load of the biodiversity-related disclosure requirements for patent applications may be negotiated away so as to make them compatible with proper operation and functionality of the system of protection, and, therefore, acceptable within TRIPs.⁷³ This, indeed, is what happened or is likely to happen with other stumbling blocks, which developing countries and the defenders of biodiversity and traditional knowledge have rolled in the way of patent-protected innovation in order

⁷⁰ It has even been suggested that national patent offices should report to the authorities of the countries of origin on the patent applications made, see WIPO, Technical Study, supra n. 64 sub. No. 81. This is surprising not only as regards costs of such extra work, but also as regards patent law, since, within certain time limits, patent applications are made publicly available anyway.

⁷¹ See infra sub c) (iii).

⁷² See F. Scherer, The Innovation Lottery, in R. Dreyfuss, D. Zimmerman, H. First (eds.), loc. cit. at p. 3 et seq.

⁷³ See the distinction between patent-related and patent-unrelated disclosure requirements made in the "Additional Comments by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and traditional Knowledge in Patent Applications", WIPO Document PCT/R/WG/6/11 of April 21, 2004, follow-up in Further Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications of October 26, 2004, PCT/R/WG/7, Paper No7 (all available at http://www.wipo.int/pct/en/meetings/reform-wg/pdf/pct_r_6_11.pdf). The EU has made it clear that it is willing to accept a mandatory technical disclosure requirement regarding the use of genetic resources for an invention, but that non-observance may not affect patent validity, and that, at any rate, the introduction of new disclosure obligations for patent applications requires a revision of the Patent Cooperation Treaty, of the Patent Law Treaty and of the European Patent Convention (which actually means delaying the introduction and its implementation for many years, if not ad calendas graecas), see European Community and its Member States, Disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications, Proposal submitted to WIPO, December 16, 2004 (available at http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf).

to bring their interests to bear. Thus, whilst fears that exclusive rights might in turn be applied to block the use of the original plant genetic resources have apparently not been dispelled,⁷⁴ the distinction between that source and the patentable invention as such seemed to be solid enough to allow the conclusion and, actually, the entry into force of the FAO-supported International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR).⁷⁵ Likewise, the US concerns that the Biodiversity Convention's Art. 16 on technology transfer might ultimately be used to impose rules of compulsory licensing for patented biotechnological inventions seems to be exaggerated in view of the flexible and limiting language of the provision.⁷⁶ At the very least, the language leaves enough room for less rigorous implementation by agreement.⁷⁷ In fact, Art. 16 (3) does not even appear to represent the threat that must be feared most, since the "developing countries which provide genetic resources" and, therefore, wish to have "access to and transfer of the technology that makes use of those resources" already possess the leverage power to obtain technology access and transfer by virtue of their power to control access to the genetic resources and to request benefit-sharing in non-monetary form.⁷⁸

- (ii) The true problems of the relationship between protecting biodiversity, promoting development and protecting inventions, therefore, do not lie in the texts of the relevant conventions, agreements, and statutes, but in the frictions resulting from the interaction between the regulatory systems they establish. Fortunately, a discussion of these frictions is well beyond the scope of this paper. This is obvious, for the question why and how it may be expected that, by claiming participation in the

⁷⁴ See Bonn Guidelines No. 16 (a) (iii); COP/CBD-Decision VI/24, supra n. 47, sub. C 3 (a), and see text supra sub1. c), d).

⁷⁵ See Art. 12.3 (d) of the Treaty and the Declaration adopted uniformly by the European Community and its Member States (available at <http://www.fao.org/Legal/Treaties/033s-e.htm>). The Treaty entered into force on June 29, 2004 due to the deposit of ratification instruments by the EU and all its Member States individually (thus bringing the number to 40 States, the USA and many other developed and developing having not yet ratified or not even signed the Treaty). The Treaty, which contains rules on access to plant genetic resources and traditional knowledge and on benefit-sharing similar to those of the CBD, in substance follows in more concrete terms a different principle of multilateral access and benefit-sharing with respect to a limited number of specified crops (see Art. 10 et seq. and Annex I). It cannot be dealt with here. As regards the recognition of farmers' rights (Art. 9) see P. Stoll, A. v. Hahn, loc. cit. in S. v. Lewinski, (ed.), loc. cit. at p. 33 et seq., and reference supra n. 24.

⁷⁶ See for US-resistance D. Bell, loc. cit., 26 Geo. Wash. J. Int'l. L. Ec. at 517 et seq.; for a cautious construction J. Straus, loc. cit. in K. Hill, T. Takenaka, K. Takeuchi (eds.), at p. 149 et seq..

⁷⁷ J. Chen, Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship Between Biodiversity and I. P., in K. Hill, T. Takenaka, K. Takeuchi (eds.), loc. cit. at p. 167, 206 et seq..

⁷⁸ See Bonn Guidelines Nr. 45 et seq. and appendix II.

benefits accruing from patent protected innovation, precisely those effects on biodiversity may be compensated for of which the incentive- and profit-oriented patent-competition-innovation system is accused⁷⁹? This is a problem of environment protection, and, therefore, not of my domain. However, as a matter of logic one would expect a counter-productive result. Indeed, if there are any effects to be expected at all from this interaction, then it would appear that they take the form of synergies in the operation of the systems, meaning that the effects will be mutually reinforcing, and, therefore, detrimental to the very objectives of the Biodiversity Convention. Rather than contributing to the preservation of genetic diversity in situ as a self-sustained and evolving common resource, the combined effects of, on the one hand, providing incentives through patents and, on the other, giving way to the commercial interests of holders (and alleged protectors) of genetic resources through a promise of benefit-sharing, are likely to be technological concentration and commercial selectivity ultimately leading to a substitution of the use of the original genetic resources and its associated traditional knowledge by innovative “industrial” products and processes. Whether this is desirable from a development perspective, and if so, how much of the associated wealth creation will occur in developing countries and actually produce general welfare again is a matter outside my expertise.

Anyway, whatever beneficial effects may occur, they obviously depend on the efficient functioning of the patent system as a form of protection of the goose, which lays the golden eggs, in which a share is sought. Whether the patent system can hold such promise in general is doubtful enough.⁸⁰ Certainly, however, the Biodiversity Convention’s rules on access and benefit-sharing do all but improve its operation.

⁷⁹ See references supra n. 36.

⁸⁰ The patent system is not only struggling with itself (see Federal Trade Commission, loc. cit. chapter 4, 5; H. Ullrich, loc. cit. 8 Eur. L. J.433 et seq. (2002); J. Tirole, Protection de la propriété intellectuelle: une introduction et quelques pistes de réflexion, in J. Tirole et al., Propriété intellectuelle, Paris (La Documentation française) 2003, 11 et seq.), but overestimated as regards its economic effects by both its protagonists and its adversaries (see Federal Trade Commission, loc. cit. Ch. 2; CIPR, loc. cit. p. 19 et seq.; S. Macdonald, Exploring the Hidden Costs of Patents, Quaker United Nation, Office Geneva. Occasional Paper 4 (available at <http://www.geneva.quono.info/pdf/OP4.pdf>); P. Schalk, U. Täger, Wissensverbreitung und Diffusionsdynamik im Spannungsfeld von innovierenden und imitierenden Unternehmen, Munich (Ifo Institute)1999,101 et seq.); and, of course, it is not perfect. But eventual changes cannot be discussed here, see with respect to its adaptation to the needs of developing countries in general CIPR, loc. cit. at p. 114 et seq.; and as regards biotechnology in particular M. Taylor, J. Crayford, American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change, Washington D.C. (Resources for the Future) 2003, 56 et seq..

They mistreat rather than foster the golden goose. Ideally,⁸¹ the exclusive rights granted by patent law should allow enterprises to reap the rewards which the market offers for the inventions made through investment in the development of new and non-obvious knowledge. To this effect, the exclusivity is granted evenly for all inventions so that investors may decide freely into which inventive activity to invest. In this sense, a patent system is a policy neutral, market driven instrument to promote innovation in general. Framework regulations of the market, however, may influence that choice to the extent that they predetermine costs and profit potentials. Clearly, the higher the costs of an innovation, including the costs of patenting, and the more public or private taxes are levied on potential profits, the higher the profit potential itself must be.

Therefore, subjecting access to genetic resources to administrative burdens and prospecting fees, introducing onerous obligations of disclosure of genetic sources and of consent, setting restrictive standards for the making of agreements on benefit sharing,⁸² and requiring such benefit-sharing on both the State or regional and the local or communal level, necessarily means that the direction of innovation becomes biased toward inventions which promise high commercial yields. To the extent then that such innovation depends on or is at least influenced by the availability, the quality, and the actual scope and enforceability of patent exclusivity as a means to actually realize the profits expected, the perverse effect of a biodiversity-specific sub-system of patent protection will be, that due to its increased costs and burdens, it will in turn reinforce the tendency toward selective high-yield inventive activity. Commercially promising inventions thus become specifically promoted by both the general, cost intensive regulatory regime of biodiversity-related innovation and by the additional requirements which are introduced on its account into the patent system, and they are so promoted to the detriment of less rewarding or more risky, but

⁸¹ See P. David, Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History, in Wallerstein (ed.), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Washington D.C. 1993, 19, 32 et seq.; H. Ullrich, *Standards of Patentability*, loc. cit. at p. 105 et seq. with references.

⁸² For the complexity of contracting alone see WIPO, Secretariat, *Genetic Resources: Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts (WIPO/GRTK/IC/6/5)* of February 3, 2004 (submitted to the 6th Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, March 15-19, 2004); Bonn Guidelines No. 41 et seq. (Mutually Agreed Terms); Appendix I – Suggested Elements for Material Transfer Agreements.

possibly more advanced or more technically/pharmaceutically valuable inventions.⁸³ Likewise, large enterprises, which are better equipped to handle the administrative complexities of the procedure for the grant of access, to negotiate and manage the agreements on benefit-sharing, and to take out patents in accordance with the additional disclosure requirements, are favoured over smaller enterprises.⁸⁴ Whilst the former effect will not remain without (the afore-mentioned counterproductive) impact on biodiversity; the latter is likely to affect the attainment of developmental objectives. It seems, indeed, that the obsession of developing countries and of many defenders of biodiversity with big enterprise has possibly made them forget how much a policy of access control, which is focussed on benefit-sharing, may actually hurt smaller domestic industry. It is less able to efficiently handle the complex and burdensome system and to promise and actually make comparable profits on a global scale, but, nevertheless, it is subject to the same rules that apply to large foreign enterprises.⁸⁵

(iii) This, of course, is not at all meant to deny the need to control access to genetic resources as one of the ways of safeguarding the public interest in the sustainable preservation of biodiversity. But it is to highlight the problems of its combination with developmental policies, in particular when the latter are based on a rationale of self-interested profit-making. More specifically, benefit-sharing, if required beyond the interests applicants may have in associating local industry or laboratories to their prospecting, research and exploitation activities,⁸⁶ has little legitimacy and easily comes into conflict with the rationale of the patent system. It is, indeed, a problematic approach to give the Nation States, as a matter of global interest in biodiversity, full sovereign control over the genetic resources which happen to be

⁸³ At the limit, necessary inventions, such as those for orphan drugs, will not be made at all, as has been officially recognized in recital 18 of the EU-Directive on biotechnological inventions, *supra* n. 25. Note also that a biodiversity-specific sub-system of patent protection may produce a technology bias towards reliance on other technologies, which may or may not be more valuable as regards the substance of the inventions.

⁸⁴ As evidenced by the examples of benefit-sharing agreements typically cited, see *supra* n. 42.

⁸⁵ This follows not only from the non-discrimination/national treatment-principle (see Art. 3 TRIPs-Agreement), but also from the environmentalist objective of the CBO to safeguard biodiversity and its sustainable use (Art. 1): all must abide by the rules or else the objective will not be attained (see also the first recitals of the Preamble of the CBD stressing the common responsibility in the interest of humankind).

⁸⁶ For examples see references *supra* n. 42; such local cooperation in the very development of biodiversity-dependent innovation certainly merits to be supported as a matter of technology transfer and non-monetary *ex ante* benefit-sharing.

found within their territory, and to expect that they will exercise this control with a view to safeguarding this global interest. It is a no less problematic idea to seek to justify this approach by analogy to sovereign control over mineral resources simply because both are natural resources.⁸⁷ Both physical and territorial control essentially concern genetic resources only as phenotypes. By contrast, such territorial control is less directly related to the genotypes, which genetic resources embody, since these have a distinct value as information on genetic functions. It is, indeed, not the information support, but the genetic information as such which goes into a biotechnological invention, and it is not the preservation of genetic resources in situ or ex situ, but the inventive effort, however big or small,⁸⁸ which creates the plus value and establishes the interest of protecting and exploiting the invention. Moreover, as the commercial value of the patented invention is determined by the demand which exists or which the patentee succeeds to attract by distributional efforts on the market, there is no direct correlation between the genetic input, however direct and important, and the "monopoly" power or the profitability of the biotechnological invention.⁸⁹ Mandatory benefit-sharing, therefore, runs the risk of a lack of sufficient basis in a quid pro quo, and the more so the more commercially successful a patented invention is.

For all these reasons it would seem that genetic resources, which are used in the invention process, may not, as such, justify benefit-sharing, but only if their utility is duly supported by associated traditional knowledge. But instead of solving the problem, access control and benefit-sharing based on the use of traditional knowledge raise additional questions. Indeed, whilst recognition of traditional knowledge as an expression of culture and identity should be in as little doubt as is

⁸⁷ See with a less critical undertone J. Straus, loc. cit. in K. Hill, T. Takenaka, K. Takeuchi (eds.), at p. 142 et seq.. One should, indeed, not forget to ask a preliminary question, which should be an inquiry into the legitimacy of exclusive territorial control over global and globally needed resources.

⁸⁸ It is undisputed that, as a rule, inventions represent incremental contributions to a cumulative process of technological progress, albeit in different ways in different industries (see Cl. Long, Patents and cumulative Innovation, 2 Wash. Univ. J. L. Ec. 229 (2000), and references infra n. 94); therefore "small" inventions should not be discriminated against. It is quite another matter whether patentability criteria, in particular the non-obviousness standard are applied consistently and strictly enough, see Federal Trade Commission, loc. cit. Ch. 4.

⁸⁹ Contra B. Sherman, loc. cit., Eur. Int. Prop. Rev. 2003, 305 et seq.. Note that analogies to employer/employee relations regarding inventions are misplaced, first, because there is no universal principle as to how these relations should be regulated – to the contrary, national laws differ widely – and second, because the employee, by producing an invention, makes an individual, non-routine contribution to technological progress.

the recognition of the honour of discoverers of laws of nature or of authors of scientific theories, the claim to benefit-sharing is less convincing in all three cases, albeit for reasons which are not entirely the same.⁹⁰ In the case of traditional knowledge the connecting factor for benefit-sharing is a collective and rather diffuse merit, which typically (and literally) comes through tradition, i.e. is inherited, whereas discoveries and theories are essentially personal and innovative achievements. Benefit-sharing based on some use of traditional knowledge is unlimited in time as concerns the past, and also as regards the future. It will not expire as the patent lapses, but only as the profits come to exhaustion.⁹¹ This means that it follows a principle of participation rather than one of incentive and reward, as is the case for patent protection. Participation as a principle is well known in intellectual property law, but only as regards copyright, which precisely does not confer a monopoly right, neither over the artistic creation nor, a fortiori, over the idea underlying a work. It does, therefore, not establish absolute and permanent dependencies. Such absolute dependencies are familiar and recurrent in patent law, but there they are limited in time and based on inventive achievement. Introducing dependencies based on traditional knowledge, therefore, means the introduction of an element of friction and systems' incompatibility. This may be the more problematic as there is no mechanism in the protection of traditional knowledge, whether by customary law or by adapted intellectual property law,⁹² which would make the knowledge-base progress. With the exception perhaps of some biodiversity-supportive, evolving farming methods, traditional knowledge is generally essentially retrospective and conservatory.

⁹⁰ For the pros and cons of recognizing and rewarding discoverers of laws of nature by benefit-sharing, see F.-K. Beier, J. Straus, *Der Schutz wissenschaftlicher Forschungsergebnisse*, Weilheim 1982; for the merits of traditional knowledge as a basis for benefit-sharing see G. Ghidini, "Equitable Sharing" of Biodiversity-Based Innovation: Some Reflections Under the Shadow of a Neem-Tree, *Italian Intellectual Property* 2002,39, 40 et seq., who equates traditional knowledge with know how and argues for benefit-sharing via a local manufacturing requirement (which is, however, economically costly, contrary to the rationale of global patent protection and incompatible with the ubiquitous nature of traditional knowledge once it has been transformed into scientific knowledge).

⁹¹ The open-endedness of benefit-sharing raises many issues, such as whether benefit-sharing is still justified once the patents (which?) have expired, simply because the products are still successfully sold; should benefit-sharing also continue, if the products are sold under a trademark (whose attractiveness is due to the marketing efforts of the enterprise), or if they are sold in competition with identical/similar, but derived generic products, and should the manufacturer/distributors of such derived generic products be included in benefit-sharing? etc..

⁹² See supra text at n. 31 et seq..

(iv) This systems friction is not only a philosophical one between conservation and progress, or a pecuniary one in that an additional and perpetual financial burden is laid on the patent system. Rather it affects the very rationality of promoting invention and innovation by exclusive rights, which are specifically limited in time and scope. The idea underlying the patent system is that from the permanent flow of knowledge a segment may be carved out in view of the particular new use to which the inventor has brought the knowledge, but that after a while that piece of knowledge must fall back into generally available knowledge so as to contribute to the accumulation of human knowledge and to form part of the basis from which, by competition for inventions, new ideas may be developed for new uses.⁹³ The patent system, therefore, is not simply crafted like a parasite on the public domain, but symbiotically lives as much for it as it lives from it, and whilst the public domain is much broader than what inventions may contribute to it, its rationale as well goes a long way in support of technical progress. It is, indeed, based on the idea that knowledge creation is a sequential and cumulative process where the merit of new contributions is derived from prior insights, discoveries, and inventions,⁹⁴ and, therefore, deserves protection by exclusivities only to the extent that, in their absence, it would not be turned, or would not sufficiently be turned, into economic value. If that risk of underinvestment in the production and exploitation of knowledge does not or does no longer exist, all knowledge – old or new – should be free in view of both its derivative nature and of its characteristics of a natural public good. As it may be used without rivalry, and as it is not subject to consumption,⁹⁵ everybody should be free to put it to its or to his or her best use.⁹⁶

⁹³ The disclosure requirement of patent law (see supra n. 27) and the experimental use-exemption from exclusivity (see Sect. 11 (2) German Patent Act, similar rules exist under all national laws, in the USA in the form of a general fair-use exception under common law see also 35 US C 271 (a) (e)) serve that very purpose; they are intended to speed-up substitute innovation; for a general discussion see R. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017 (1989); D. Gilat, *Experimental Use and Patents*, Weinheim 1995, 17 et seq..

⁹⁴ For an elaboration on the famous reply by J. Newton (“... if I have seen far, it is by standing on the shoulders of giants.....”), which, in fact, repeats the same insight of several centuries before made by Bertrand of Chartres, i.e. an insight deeply rooted in our culture – and obviously one which is similar to that of traditional knowledge as a local public domain – , see H. Boockmann, *Wissen und Widerstand - Geschichte der deutschen Universität*, Berlin 1999, 47), see S. Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and Patent Law*, 5 J. Ec. Persp. 29 (1991).

⁹⁵ See P. David, loc. cit. in Wallerstein (ed.) at p. 25 et seq., with references.

⁹⁶ For the economics of public domain knowledge and its justification see D. Foray, *On the Creation of Fundamental Knowledge: Finding the Right Balance Between the Public and the Private Domain*, in O. Granstrand (ed.), *Economics, Law and Intellectual Property*, Boston 2003, 199; see also L. Eisenberg, loc. cit., 56 U. Chi. L. Rev. at p. 1048 et seq. (1989).

It is in view of this utilitarian, but longstanding and, indeed, inherited rationale alone that knowledge should not light-handedly be withdrawn from the public domain,⁹⁷ and certainly not when the bounds of such withdrawal are as indefinite, if not unlimited, as they are in the case of traditional knowledge. Not only does the definition of both traditional knowledge and of indigenous peoples or local communities, to whom it may be attributed, remain vague,⁹⁸ but the attribution itself is indefinite. The same or similar knowledge may exist elsewhere, and it may be truly public, namely propagated by non-initiated persons, or mixed with other, public knowledge. In addition, traditional knowledge in the various developing countries is of a rather different quality, it is not easily separable from more or less trivial know-how or from routine craftsmanship, and it cannot properly and legitimately be distinguished from similarly "inherited" traditional knowledge existing in various parts of developed countries.⁹⁹ If that is so, what distinctions can be made and what arguments would be left to defend against yet another extension of the access-control/benefit-sharing approach to any knowledge which, in one way or the other, may be attributed to some group or to an individual?

⁹⁷ Contra S. v. Lewinski, Final considerations, in S. v. Lewinski (ed.), loc. cit. at p. 391 et seq., more convincing A.von Hahn, loc. cit. at 349 et seq., who recognizes the inherent dynamics of the public domain, and proposes to recognize traditional knowledge by accepting an analogy to the concept of *domaine public payant*.

⁹⁸ See WIPO, Secretariat, Traditional Knowledge – Operational Terms and Definitions, Document WIPO/GRTK/IC/3/9 of May 20, 2002 (Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 3rd Sess. Geneva, June 13 – 21, 2002); A. v. Hahn, P. Stoll, loc. cit. in S. v. Lewinski (ed.), at p. 8 et seq., 15 et seq. (obviously, by including communal people, the concept has been extended as a matter of broadening the scope of relevant traditional knowledge, and possibly in view of an objective of environment/biodiversity protection, but at the cost of a loss of legitimacy in terms of fundamental rights and claims to non-inclusion in the public domain).

⁹⁹ It is not easy to distinguish on a conceptual level Chinese or Indian medicinal or agricultural knowledge from traditional knowledge that exists in many parts of Europe, and which relates to viticulture, beer-brewing, cheese production or, in fact, to homeopathic pharmacology; this similarity is best evidenced by proposals to grant traditional knowledge protection by indications of geographic origin, or by certification marks, see supra n. 26; Kur, and Kur, Knaak in S. v. Lewinski, loc. cit. at p. 63, 221 et seq..

III. Conclusion

It is conceded that preserving the purity of the patent system is not a principle of practical politics nor would it be a sound guide for interpreting and applying the law. The TRIPs-Agreement itself, however “protectionist” in nature, recognizes the interdependence between a market-oriented intellectual property system and market regulation in the interest of public policy. Whilst it is an open question, how flexible the TRIPs Agreement really is in this regard, it will not escape the claims “for the Establishment of a Development Agenda” which the World Intellectual Property Organisation actually has to face.¹⁰⁰ The Biodiversity Convention’s intellectual property rules point in the same direction. It is also to be welcomed that, within TRIPs, the various disclosure requirements, which have been formulated under the CBD, are not considered as a controversial issue that must be dealt with as a matter of trade policy, but as a problem of how to legally accommodate for political claims, which, as such, are founded in global socio-economic disparities. Such openness holds promise of a gradual transformation of the TRIPs framework of international intellectual protection into a law-based ordering of property, as distinguished from the pressure mechanism of (bi-lateral) TRIPs-plus policies.

However, to assert that the TRIPs-Agreement and the Convention on Biological Diversity may be implemented in a "mutually supportive" way, is rather misleading in view of the systemic conflicts between the exclusivity-based promotion of innovation, the privileged participation in its profit potential, and the ecologically motivated conservation of biodiversity in open nature. Given that, in addition, the developmental strategies underlying biodiversity-related patent policies of developing countries are not even consistent with their general patent policy – after all the former, to achieve their purpose, require strong and broad titles of exclusivity whereas the latter, in the interest of competitive follower strategies and of easy access to high technology, tends to favour soft

¹⁰⁰ WIPO General Assembly, Thirty-First(15th Extraordinary)Session, Geneva, September 27 to October 5, 2004: Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO, WO/GA/31/11; see also the civil society “Geneva Declaration on the Future of the World Intellectual Property Organization” of October 2004 (available at <http://www.cptech.org/ip/wipo/genevadeclaration.html>).

and narrow protection –, would it not have been more advisable to seek to achieve each policy objective separately in accordance with its proper requirements and possibilities? The specific causes and needs of safeguarding biodiversity as a matter of protecting the environment, just as the particular causes and needs of pursuing a definite developmental strategy with a view to improve socio-economic standards of living, are only loosely related to the broad reasons underlying patent protection as an incentive system for inventive activity in general. In fact, much of biodiversity-related innovation may not even meet the needs of developing countries, let alone those of indigenous peoples, and still be socially desirable.¹⁰¹ Whilst it may not be illegitimate per se to seek to take advantage from the bargaining opportunities offered by territorial control over genetic resources or by locally existing, and generally vulnerable, associated traditional knowledge, it would seem that such legitimacy is best maintained by adequately limiting the advantages sought, and by consistently defining the means used¹⁰² strictly in view of and by reference to the achievement of the public policy objectives that give substance to such legitimacy claims in the first place.

¹⁰¹ See A. von Hahn, loc. cit. at p.356 et seq. (pointing to the development of pharmaceuticals for diseases which do not exist in the country in question or which do not affect indigenous people).

¹⁰² See supra n.86, and also the proposals made by A.von Hahn, loc. cit. at 358 et seq. (introduction of a domaine public payant) or by P. Drahos, Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?, Eur.Int.Prop.Rev.2000, 245