Revue générale de droit

The International Legal Regime for Biotechnology Patenting: an Appraisal from the Standpoint of Developing Countries

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Volume 31, numéro 2, 2001

URI : https://id.erudit.org/iderudit/1027794ar
DOI : https://doi.org/10.7202/1027794ar

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Éditeur(s)

Éditions Wilson & Lafleur, inc.

ISSN

0035-3086 (imprimé)
2292-2512 (numérique)

Découvrir la revue

Citer cet article

Badimboli Atibasay, J.-F. (2001). The International Legal Regime for Biotechnology Patenting: an Appraisal from the Standpoint of Developing Countries. *Revue générale de droit*, *31*(2), 291–325. https://doi.org/10.7202/1027794ar

Résumé de l'article

L’essor de la biotechnologie s’accompagne notamment de promesses de prospérité économique. Ainsi, le débat sur la propriété des ressources phytobiologiques et des produits qui en dérivent, ainsi que le partage des bénéfices, est de nouveau d’actualité. Il y a lieu d’attribuer la véhémence du débat au lien établi, dans le cadre de l’Organisation mondiale du commerce, entre la propriété intellectuelle et le commerce international. C’est donc dans ce contexte qu’il faut soupeser les prétentions des pays développés pour une protection adéquate des droits des inventeurs dans les pays en développement, et ceux de ces derniers pour la sauvegarde des intérêts locaux.

Mais seulement, les réponses apportées à ces prétentions dans les accords multilatéraux en matière d’innovations biologiques, soulèvent des controverses. En effet, on y décèle des divergences d’approches au regard des intérêts des parties impliquées. Par conséquent, les dispositions pertinentes sont teintées d’ambiguïtés, voire de possibilités de conflits.

Parmi les différentes solutions examinées, la révision projetée d’un des accords en question offrirait, aux pays concernés, l’occasion de clarifier les textes, en vue de faciliter la prévisibilité quant aux conséquences juridiques de leurs initiatives dans ce domaine.

The International Legal Regime for Biotechnology Patenting: an Appraisal from the Standpoint of Developing Countries

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ABSTRACT

The development of biotechnology, which promises many economic opportunities, has revived the debate over the ownership of biological resources and its derivatives, as well as the sharing of the benefits which derive from its multiple applications. At the core of the debate, is the recent marriage between intellectual property rights (IPR) and international trade, within the framework of the World Trade Organization (WTO). In this context, the need of developed countries to prevent trade distortions due to the lack of adequate IPR

RÉSUMÉ

L'essor de la biotechnologie s'accompagne notamment de promesses de prospérité économique. Ainsi, le débat sur la propriété des ressources phytobiologiques et des produits qui en dérivent, ainsi que le partage des bénéfices, est de nouveau d'actualité. Il y a lieu d'attribuer la véhémence du débat au lien établi, dans le cadre de l'Organisation mondiale du commerce, entre la propriété intellectuelle et le commerce international. C'est donc dans ce contexte qu'il faut soupeser les prétentions des pays développés pour une protection adéquate des

* An earlier draft of this paper was written in partial fulfilment of a Master's program at the University of Ottawa. I am grateful to professor Mistrale Goudreau for her assistance in focussing on this interesting topic and for her useful comments. Of course, I am solely responsible for all the arguments and possible mistakes.

protection in developing countries, is weighed against the need to promote local interests in these countries. However, the legal impact of recent multilateral agreements, which address biological innovations, is still subject to controversy. An assessment of these instruments reveals divergent approaches to the issues which divide the parties concerned. This results in ambiguities and conflicts with respect to relevant provisions of these agreements.
From a wide range of possible solutions discussed, industrial and developing countries might consider to review the disputed provisions in a way that attempts to harmonise the agreements and render legal implications of their respective initiatives in this area more predictable.

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Parmi les différentes solutions examinées, la révision projetée d'un des accords en question offrirait, aux pays concernés, l'occasion de clarifier les textes, en vue de faciliter la prévisibilité quant aux conséquences juridiques de leurs initiatives dans ce domaine.

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INTRODUCTION

Biotechnology holds high prospects of improvement in agriculture, medicine and research.[1] Indeed, it promises to enhance food resources through genetic engineering, and make a wide range of products available — crops, fertilizers, pesticides, drugs, vaccines, and so on. However, despite this widespread acceptance of the prospective benefits of biotechnology, the grant of patents in this area raises some critical questions. For example, the debate continues as to what should or should not constitute patentable subject matter, as well as the possible effects of genetically-engineered organisms on human life and the environment.[2]

Therefore, when it comes to international trade, particularly with regard to multilateral agreements, one of the biggest issues deals with the protection of Intellectual Property Rights (IPR) in developing countries. Here, economic and legal questions tend to prevail over ethical considerations.[3]

1. N.D. HAMILTON, "Who owns Dinner : Evolving Legal Rights for Ownership of Plant Genetic Resources", (1993) 28 *Tulsa L. J.*, pp. 587-657, pp. 689-90, discussing the benefits of biotechnology.

2. P. BLUNT, "Selective Breeding and the Patenting of Living Organisms", (1998) 48 *Syracuse L. Rev.*, pp. 1365-1390, pp. 1375-76, discussing the arguments pro and con the application of genetic-engineering on living organisms.

3. *Id.*, pp. 1375-76, noting that "[t]he risks involved in the development and the introduction of genetically organisms into the world at large will be balanced against the expected return on investment [...].

Seemingly, this is because the issues are raised, for the most part, in terms which oppose the "haves" and "have-nots", and the parties ultimately aim either to attain and maintain a competitive edge on the international market or to meet development goals. Worth recalling is that one major effect of IPR is to grant monopoly rights to those who invent new processes or products, for a certain period of time before their inventions are passed on to the public domain. Faced with this reality, farmers and indigenous communities in developing countries with huge biological endowments, are becoming increasingly critical of the patenting of plant varieties and its derivatives. Since biotechnology extends to both farming and genetic engineering,[4] by promising new economic prosperity and industrial uses, it will quite possibly continue to impact on the political and legal split between developed nations and developing countries.[5]

In this paper we submit that intellectual property law, as it stands at present with respect to the patenting of biological innovations, fails to strike an appropriate balance between inventors' rights and local communities' rights in developing countries. This is due to the fact that conflicts still persist in recent international agreements which have attempted to address competing interests of the parties involved. This statement is also based on the assumption that developing countries are actually willing to exploit their biological resources; but, they find current international standards of patentability quite challenging.

Therefore, we start, in Section I, by locating the source of the current debate in the "customary" link between IPR and trade, which has been codified in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement).[6] The assessment of the rationale behind this marriage

4. D.S. TILFORD, "Saving the Blueprints : The International Legal Regime for Plant Resources", (1998) 30 *Case W. Res. J. Int'l L.*, pp. 373-446, p. 376, arguing that "[t]oday, biotechnology is helping both farmers and medical researchers sift through the available genetic options to produce more precisely tailored crops and drugs".

5. *Id.*, p. 397, arguing that the field of biotechnology "promises [...] the battle over genetic resources".

6. April 15, 1994, [hereinafter TRIPS Agreement], *Marrakesh Agreement Establishing the World Trade Organization*, [hereinafter WTO Agreement], Annex IC, Legal Instruments — Results of The Uruguay Round, vol. 31; 33 *I.L.M.* 81 (1994).

then leads us to examine the nature and legal foundations of complaints made by inventors from developed countries, on the one hand, and their counterparts in developing countries, on the other.

In Section II, we look at the way the North-South political and legal controversy has been addressed in recent international legal instruments designed to protect IPR. Moreover, we pay special attention to the underlying principles as well as the outstanding drawbacks. Starting with an opening note on the *Paris Convention for the Protection of Industrial Property,*[7] we focus our analysis on the *International Convention for the Protection of New Plant Varieties,*[8] as well as the aforementioned TRIPS Agreement, and the *United Nations Convention on Biological Diversity.*[9]

We concentrate, in Section III, on conflicts between the various social and political actors; by making a critical evaluation of the relationship between the aforementioned agreements, as well as by discussing recent trends which are quite possibly laying down new perspectives with respect to the design of an appropriate law. Therefore, the call for harmonization in the end, reflects our purpose: we do not intend to question the legitimate objectives of the agreements, but to situate them within the context of developing countries' emerging interests.

I. SOCIAL ECONOMIC IMPLICATIONS OF BIOLOGICAL INNOVATIONS

The debate over biological innovations involves so many aspects that it gets somewhat confusing. Although a more rigorous approach requires separating what constitutes the IPR

7. March 20, 1883, 21 *U.S.T.* 1583, 828 *U.N.T.S.* 305 [hereinafter Paris Convention].

8. December 2, 1961, 33 *U.S.T.* 2703. This system, which is monitored by the Union for the Protection of New Varieties of Plants [hereinafter UPOV], has been amended several times. Recent versions retained for discussion in this paper are those of 1978 and 1991 [hereinafter UPOV Convention (1978), UPOV Convention (1991)].

9. June 5, 1992, S. Treaty Doc. N° 103-20 (1993) [hereinafter CBD].

issue from what is not,[10] it seems difficult to ignore the weight of the socio-economic problem when examining the relationship between the North and the South; particularly because the international legal instruments which we will analyse in the next section, set up a link between patent protection and international trade. In this section we propose to examine assumptions that justify the relationship between IPR and social economic development. We will then provide a summary explanation of divergent opinions of the parties involved, with regard to the need to protect biotechnological innovations.

A. WHY LINK PATENT PROTECTION TO INTERNATIONAL TRADE?

In any event, three assumptions seem to lay the foundation for a link between IPR and economic development : adequate IPR are beneficial to the developing countries in the long run, inadequate IPR cause financial losses to industrialized nations' businesses, and constitute a non-tariff barrier to trade. For example, the idea that IPR can be beneficial to the economy of developing nations certainly finds widespread support,[11] but some authors are sceptical about applying a

10. F.M. ABBOT, "Protecting First World Assets in the Third World : Intellectual Property Negotiations in the GATT Multilateral Framework", (1989) 22 *Vand. J. Transnat'l L.*, pp. 689-745, pp. 697-98, arguing that the IPR issue deals with designing a mechanism to protect intangible wealth transferred from developed countries to developing countries, therefore, it seems erroneous to base the debate on the benefits likely to be drawn by developing countries as a consequence of their cooperation.

11. See generally R.T. RAPP, R.P. ROZEK, "Benefits and Costs of Intellectual Property Protection in Developing Countries", 24 J. *World Trade*, pp. 75-102, pp. 77-81, arguing that the more effectively a country provides patent protection, the quicker it is likely to achieve economic development (p. 78). To support this assumption, they present an index of patent protection which ranks the level of protection on a scale of zero to five. Five corresponds to countries that fully comply with minimum standards proposed in the *Guidelines for Standards for the Protection and Enforcement of Patents of the U.S. Chamber of Commerce Intellectual Property Task Force* (p. 79), while zero applies to countries with no patent protection at all. The conclusion, following a "regression analysis" is that Western countries with a strong patent law experience greater economic development. But see A.S. GUTTERMAN, "The North-South Debate Regarding the Protection of Intellectual Property Rights", (1993) 28 *Wake Forest L. Rev.*, pp. 89-139, p. 118, n° 207, observing that "the scores were based solely on the laws as written and did not account for actual enforcement experience".

cause and effect logic in this issue and even assert that the international patent system is not fit for developing countries.[12] The outcome of the altercation is that developing countries adhere to the patent system hoping that it will arguably prompt investments[13] and transfer of technology;[14] but, at the same time, they fear "adverse economic consequences for themselves in general and for research and development in agriculture in particular".[15] Their reluctance is further justified by the fact that patents are overwhelmingly owned by foreigners and "insignificant number of inventions [are] induced by [the] patent system" in their countries.[16]

The second assumption is that North-based firms experience financial losses due to inadequate IPR protection in developing countries. Its justification extends from the fact that counterfeiting is an unfair trade practice, since it prevents

12. A.S. ODDI, "The International Patent System and Third World Development: Myth or Reality?", (1987) 5 *Duke L.J.*, pp. 831-878, p. 842, relying on a critical study by E. Penrose in 1951, according to which "there is no justification for developing countries to participate in the international patent system". See also R.J. GUTOWSKI, "The Marriage of Intellectual Property and International Trade in the TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?", (1999) 47 *Buff. L. Rev.*, pp. 713-761, pp. 750-51, arguing that "the evidence of successful industrialization of countries in East Asia, particularly the 'four little dragons' (Taiwan, Hong Kong, South Korea and Singapore), reveals that the recognition of IPR is not essential to development, despite the rhetoric of developed nations [...] economic and political reform rather than legal protection of IP may transform underdeveloped nations".

13. K.W. MCCABE, "The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology", (1998) 6 *J. Intell. Prop. L.*, pp. 41-67, p. 64, arguing aptly that "[p]atent protection acts as a stimulus for investment, not necessarily because it offers an expectation of increased profits, but rather because it offers a mechanism to exclude competitors from copying the subject invention". See also R.J. GUTOWSKI, *loc. cit.*, note 12, p. 758, pointing to "compelling arguments" for developing countries to benefit from IPR in the long-run; namely the creation of "incentives for domestic and foreign researchers and entrepreneurs to invest resources in innovative technologies and solutions to problems indigenous to their countries".

14. A.S. ODDI, *loc. cit.*, note 12, p. 855.

15. M.G. BHAT, "Trade-Related Intellectual Property Rights to Biological Resources: Socioeconomic Implications for Developing Countries", (1996) 19 *Ecological Econ.*, pp. 205-217, p. 205; See also K.W. MCCABE, *loc. cit.*, note 13, p. 55: "[A]ssuming that the developed countries' arguments are correct and that strengthened intellectual property protection will stimulate growth, the developing country will also spend money to develop its infrastructure in order to support the economic growth predicted by the developed countries".

16. A.S. ODDI, *loc. cit.*, note 12, p. 855.

innovators from reaping investment returns,[17] as well as to the need for developed countries to keep a competitive advantage on the international market.[18] However, quantification of such losses is challenged either because of extrapolations,[19] or because the structure of the international economic system itself is unequal.[20]

The last and most important assumption, at least from the point of view of legal analysis, is that inadequate IPR constitute a non-tariff barrier to trade. That is the reason why, as Bhat writes, "in the Uruguay Round, IPR was linked for the first time with international trade to become what is known as trade-related intellectual property rights".[21] The initiative came from the United States, in an attempt to stop its competitors from carrying on unfair trade practices.[22] As a result, the TRIPS Agreement[23] embodies more solidly developed

17. K.W. MCCABE, *loc. cit.*, note 13, p. 48, arguing that "biological inventions are particularly susceptible to piracy because, while they typically require substantial expenditures to develop, they are often simple to replicate".

18. D. HARTRIDGE, A. SUBRAMANIAN, "Intellectual Property Rights : The Issues in GATT", (1989) 22 *Vand. J. Transnat'l L.*, pp. 893-910, p. 895 : "The established industrialized economies are losing comparative advantage in some traditional sectors and are consciously shifting their attention and resources into areas of greater comparative advantage-activities that are creativity-, research-, and knowledge-intensive, and therefore intellectual property-intensive".

19. A well-known example is a report produced in 1986 by the United States International Trade Commission, dealing with "distortions in U.S. worldwide trade associated with the protection provided by foreign countries to U.S. IPR". This report estimated that U.S. companies that responded to the questionnaire lost $23.8 billion in that year. Extrapolating that figure, it was believed that "worldwide losses to United States industries in 1986 ranged from $43 billion to $61 billion". See F.M. ABBOT, *loc. cit.*, note 10, p. 700, commenting on U.S. International trade Commission, Pub. n° 2065, *Foreign Protection of Intellectual Property Rights and the Effect on U.S. Industry and Trade* (1988) (Report to United States Trade Representative).

20. V. SHIVA, *Biopiracy. The Plunder of Nature and Knowledge*, Boston, South End Press, 1997, p. 11.

21. M.G. BHAT, *loc. cit.*, note 15, p. 208. However, it should be noted that the Uruguay Round materialized what was difficult to achieve in the Tokyo Round of Negotiations. The agreement on counterfeiting in that round failed because there was no "consensus on its incorporation into the final results of the round, since only the United States and the European Community were prepared to support it at that time". See D. HARTRIDGE, A. SUBRAMANIAN, *loc. cit.*, note 18, p. 897.

22. R. ACHARYA, "Patenting of Biotechnology : GATT and the Erosion of the World's Biodiversity", (1991) 25 *J. World Trade*, pp. 71-87, p. 72, discussing how the economic crisis of the 1970s led industrialised countries, namely the United States, to re-examine competition policies.

23. TRIPS Agreement.

countries' concern for a free flow of trade by means of patent protection. The TRIPS Agreement aims to "reduce distortions and impediments to international trade, and [...] to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not become barriers to legitimate trade".[24] From what precedes, it follows that the positions held by the parties in relation to the protection of biological innovations diverge considerably. We will now attempt to examine these issues.

B. CONCERNS OF INVENTORS FOR A STRONG PATENT REGIME IN DEVELOPING COUNTRIES

To begin with, the biotechnology patenting issue in developing countries derives from whether biological resources and its derivatives should be considered as a *common heritage of humanity*,[25] or as a matter subject to proprietary rights. To this respect, the opinion that prevails in developed nations is that plant breeders are entitled to monopoly rights over the products and processes which they claim as innovations. It is further argued that it does not cost much for developing countries to provide germplasm,[26] *i.e.* raw genetic materials and landraces. In addition, monopoly rights are the best incentive for research and advancement, likely to benefit developing countries as well.[27]

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24. *Id.*, preamble.

25. See *infra*, text accompanying notes 39-42.

26. K. BOSSELMANN, "Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity", (1996) 7 *Collo. J. Int'l Envtl L. & Pol'y*, pp. 111-148, p. 133, commenting on how transnational seed companies put an emphasis on the fact that industrial breeding techniques involve "highly technical labor" and "capital input", thus deserving protection. See also G.B. FRISVOLD, P.T. CONDON, "The Convention on Biological Diversity and Agriculture: Implications and Unresolved Debates", (1998) 26 *World Develop.*, pp. 551-570, p. 553 and E. CHRISTENSEN, "Genetic Ark. A Proposal to Preserve Genetic Diversity for Future Generations", (1987) 40 *Stanford L. Rev.*, pp. 279-321, pp. 299-300.

27. G.B. FRISVOLD, P.T. CONDON, *id.*, p. 553.

It is little wonder that the articulation of political and legal arguments under the new era of marriage between IPR and international trade have contributed in reviving traditional complaints by the biotechnology industry in the North, particularly in the area of pharmaceuticals. Nogués summarises this as follows: "Industrial countries complain that the domestic patent regimes of many developing countries are inadequate because: patent protection is too short; some industries such as pharmaceuticals are excluded; the legal enforcement of patent rights is weak; and too much emphasis is given to compulsory licensing".[28]

Now that we have pointed out the essential issues, it might not be unwarranted to refer to a number of important arguments. Firstly, while in industrial countries long patent terms allow inventors to recover returns for a period generally extended to twenty years, in developing countries, on the contrary, the term rarely exceeds five years.[29] Though in some cases the period of protection might be relatively long, exclusion of substances used as food, medicine, or drugs will, among other factors, weaken such protection, in the second place.[30] It is worth mentioning that, as a general rule, countries enjoy discretion to implement policies that aim at protecting the public interest. Not surprisingly, it took time before some developed countries accepted to grant patents for "chemical products" (Germany), "non-medical pharmaceutical compositions" (France), or "food products" (Austria).[31] Even in the last decades, some countries like Canada, which share substantial costs for their health care system, would easily

28. J. NOGUÉS, "Patents and Pharmaceutical Drugs: Understanding Pressures on Developing Countries", (1990) 24 *J. World Trade*, pp. 81-104, p. 83.

29. A.S. GUTTERMAN, *loc. cit.*, note 11, p. 93.

30. For example, India's patent law in force prior to the TRIPS Agreement provides 14 years, except for inventions intended to be used as food, medicine or drug. As Adelman and Baldia note, the latter are subject to seven years from the filing date or five years from the date of sealing, "whichever is shorter". Again, in the event of opposition, the patent might expire before the opposition is concluded. See M.J. ADELMAN, S. BALDIA, "Prospects and Limits of the Patent Provision in the TRIPS Agreement", (1996) 29 *Vand. J. Transnat'l L*, pp. 507-533, p. 523.

31. R.L. GANA, "Prospects for Developing Countries under the TRIPS Agreement", (1996) 29 *Vand J. Transnat'l L*, pp. 735-775, p. 746.

exclude drug products from patentability.[32] Likewise, it is argued that such a practice, as carried out in developing countries, is a deliberate mechanism designed to free-ride high research and technology-based inventions.[33]

Following along the same vein of statutory preclusion, one further assertion points to the fact that developing countries allow protection to pharmaceutical processes only, not to products. As Nogués explains, "[a] process-patent protects the product only if it is produced with it. Since small modifications of a formula create many ways of producing a chemical compound, process-patents are generally viewed as providing weak protection for pharmaceutical drug companies".[34] By way of consequence, this results in the proliferation of generic drugs, creating unfair competition and losses for the biotechnology industry from the North.[35]

Ultimately, companies from developed countries consider compulsory licensing in developing nations as an intrusion into their private rights. An additional drawback is what is known as "working conditions". With this, developing countries willing to promote the development of local manufacturers, require as a prerequisite to the grant of a patent, that the invention be used in the country for a specified period of time[36] or manufactured domestically, instead of

32. R. WEISSMAN, "A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries", (1996) 17 *U. Pa. J. Int'l Econ. L.*, pp. 1069-1125, p. 1081, discussing the Canadian patent law reform as a requirement of the *North American Free Trade Agreement*. See also M.J. ADELMAN, S. BALDIA, *loc. cit.*, note 30, pp. 510-11, discussing the rationale behind the practice to exclude certain products from patentability.

33. A.S. GUTTERMAN, *loc. cit.*, note 11, p. 119. See also R.T. RAPP, R.P. ROZEK, *loc. cit.*, note 11, p. 86.

34. J. NOGUÉS, *loc. cit.*, note 28, p. 83.

35. *Id.*, p. 86, providing a list of 48 developing countries which excluded the pharmaceutical industry from protection as of 1988. See also M.J. ADELMAN, S. BALDIA, *loc. cit.*, note 30, p. 525, discussing, for example, the case of Indian companies which "compete in the international race to exploit the huge generic drugs that is developing in the West".

36. This first variation of the "working requirement" urges the patent-holder to use the patent in the market, so that in can effectively benefit the public. Companies are therefore discouraged from locking up their patents in a way that would serve anti-competitive purpose. See R. WEISSMAN, *loc. cit.*, note 32, p. 1074.

simply being imported.[37] However, the point of view voiced by developing countries runs quite opposite to the preceding arguments.

C. THE NEED TO PROMOTE LOCAL INTERESTS AND INDIGENOUS RIGHTS

To say that biological resources are a common heritage as understood by industrial countries, is not a view shared by developing countries. The potential effect of biotechnology patenting on consumers on the one hand, and the belief that it is possible to capitalize on biological resources for local development on the other,[38] have made developing countries critical of the current patent system. Their response to the complaints of patent holders can be stated as follows : the ownership of biological resources rests with the source country, the international patent system overlooks the contribution of local communities, and conventional standards of IPR promoted by developed countries fail to recognize indigenous knowledge.

The difference with regard to the principle of "common heritage", as applied to the ownership of genetic materials, was well reflected in the 1983 Food and Agriculture Organization's (FAO) *International Undertaking on Plant Genetic Resources.*[39] In this Undertaking, developing countries' opinions prevailed over those of industrial nations. For example, it was stated that not only raw materials were to be considered as common heritage of humanity, but also "elite and breeders'

37. Under this alternative, if a pharmeceutical company, for example, sells imported drugs instead of producing them locally, the patent protection might be withdrawn, *ibid.* See also K.W. MCCABE, *loc. cit.*, note 13, p. 62, pointing out that if a patented invention has not been manufactured domestically, a third party can be granted a compulsory licence to use the patented invention.

38. A.E. CARROLL, "Not Always the Best Medicine : Biotechnology and the Global Impact of U.S. Patent Law", (1995) 44 *Am. U. L. Rev.*, pp. 2433-2493, p. 2478.

39. *International Undertaking on Plant Genetic Resources*, FAO Res. 8/83 UN Doc. 83/Rep (1983) 285 [hereinafter FAO Undertaking].

lines and mutants".[40] This meant that developing countries could have free access to investment-intensive elite breeding materials,[41] just as industrial countries enjoy free access to genetic raw materials from developing countries. Consequently, no wonder the FAO Undertaking could not have any binding effect. Nevertheless, the concept of a "common heritage" was later on rejected, with the official recognition of breeders' rights. Also, farmers' rights were agreed upon as imposing a moral obligation to compensate developing countries.[42]

Thus, the difficulty to reconcile breeders' rights, which create legal entitlements, with farmers' rights, which are moral by nature, leads to the equity issue. By means of illustration, the debate that is now extended to biotechnology inventions in general, started with the seed battle. As a result, what is at stake, as explained by Kloppenburg, is "the established asymmetry of germ-plasm flow. Plant genetic resources leave the periphery as the common — and costless — heritage of mankind, and return as a commodity — private property with exchange value [...]".[43]

Because this argument infers that traditional knowledge provides no added economic value, local communities can't

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40. According to article 2 of the FAO Undertaking, "plant genetic resources" include the reproductive or vegetative propagating material of:
   (i) cultivated varieties (cultivars) in current use and newly developed varieties;
   (ii) obsolete cultivars;
   (iii) primitive cultivars;
   (iv) wild and weed species, near relatives of cultivated varieties;
   (v) *special genetic stocks (including elite and current breeders's lines and mutants)* [emphasis added].

41. R.A. SEDJO, "Property Rights, Genetic Resources, and Biotechnology", (1992) 35 *J. L. & Econ.*, pp. 199-213, p. 200; See also N. ROHT-ARRIAZZA, "Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities", in B. ZIFF, P.V. RAO (eds.), *Borrowed Power. Essays On Cultural Appropriation*, New Brunswick, Rutgers University Press, 1997, pp. 255-287, p. 266; D.S. TILFORD, *loc. cit.*, note 4, p. 411.

42. For further discussion, see G.B. FRISVOLD, P.T. CONDON, *loc. cit.*, note 26, p. 556.

43. J.R. KLOPPENBURG, Jr., *First The Seed. The Political Economy Of Plant Biotechnology. 1492-2000*, Cambridge/New York, Cambridge University Press, 1988, p. 169. See also N. ROHT-ARRIAZA, *loc. cit.*, note 41, pp. 259-60; V. SHIVA, *loc. cit.*, note 20, pp. 67-69.

have a share in genetic innovations. Therefore, opponents from the South state that laboratory applications are a mere extension of the original knowledge acquired through traditional breeding systems and centuries of on-field experience,[44] in pursuit of the same purposes. One well-publicized example, among others, of appropriation of indigenous knowledge, is the Neem tree found in India and very rich in chemical properties, which is now being exploited by American and Japanese companies, without sharing the benefits with farmers.[45]

As a result, developing countries contend that they are unable to promote local communities' interests by complying with conventional IPR[46]. In addition, despite the "marriage" between IPR and international trade, the cultural gap with respect to the conception of IPR can be significant;[47] especially because in developed countries where patent rights aim to encourage innovations for technical advancement, and

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44. V. SHIVA, *id.*, p. 54 : "[G]enetic engineering and biotechnology only relocate existing genes rather than create new ones, the ability to relocate and separate is translated into the power and right to own. The power to own a part is then translated into the control of the entire organism".

45. V. SHIVA, R. HOLLA-BHAR, "Intellectual Piracy and the Neem Tree", (1993) 23 *The Ecologist*, pp. 223-227, p. 224.

46. K.W. MCCABY, *loc. cit.*, note 13, p. 53, noting that the TRIPS Agreement is unpolular in developing countries because it impedes the development of self-sustained pharmaceutical industries. For an illustration see M.J. ADELMAN, S. BALDIA, *loc. cit.*, note 30, p. 526, arguing that the protectionist regime set out in India, for example, aimed at "[s]elf-reliance through an indigenous industry that could break the foreign companies' stranglehold on both the availability and the prices of drugs".

47. M. BLAKENEY, "Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples : An Australian Perspective", (1997) 19 *Euro. Intell. Prop. Rights*, pp. 298-303, p. 300 : "[I]ndigenous peoples do not view their heritage in terms of property at all [...] but in terms of community and individual responsibility. Possessing a song, story or medical knowledge carries with it certain responsibilities to show respect to and maintain a reciprocal relationship with the human beings, animals, plants and places with which the song, story or medicine is connected [...] quoting E.I. DAES, *Discrimination Against Indigenous Peoples : Study On The Protection Of The Cultural And Intellectual Property Of Indigenous Peoples*, (1993) [complete reference omitted in the citation]. But see R.J. GUTOWSKI, *loc. cit.*, note 12, p. 754 : "[T]oday's truly global economy and the paramount importance of technology and information point to the strong link between trade and IP. Even concerns about ideological imperialism and insensitivity to cultural differences are less than compelling today given the global movement towards market economies and free trade".

disclosure in order to facilitate public use of innovations afterwards, prior publication, for example, destroys novelty.[48] Under this condition, it is difficult to protect innovations of indigenous communities, as will be further discussed in the following section.

II. THE LEGAL IMPACT OF RECENT INTERNATIONAL AGREEMENTS

The above sketch of the views of the interested parties has attempted to demonstrate that the patenting of plant varieties and its derivatives raises discord because there are crucial and divergent interests at stake. This has been exemplified by the failure of the FAO Undertaking to take IPR-related issues away from the realm of policy considerations, in order to enshrine them into an international legally binding instrument. Noteworthy is that the 1883 Paris Conventions was the first attempt to harmonize the intellectual property law, but the original text remained mute as to what constitutes patentable subject matter. Even if the London revision introduced the term "industrial property"[49] so as to include the agriculture industry,[50] practice has confirmed the opinion that the provision in itself is discretionary, rather than mandatory.[51]

Since then, harmonization efforts have been unsuccessfully carried out by the World International Property Organization (WIPO), which monitors the Paris Convention. Because the WIPO is a United Nations' agency, where developing countries are majority members, industrial countries are

48. M. BLAKENEY, *id.*, p. 299.

49. See Paris Convention, article 1(3) which reads as follows: "Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour".

50. J.J. CAMPBELL, "Effects of International Trends & Agreements on Biotechnology Patenting", (1993) 10 *Can. Intell. Prop. Rev.*, pp. 129-143, p. 130.

51. A.S. ODDI, *loc. cit.*, note 12, p. 866, asserting that the matters enumerated in article 1(3) don't have to be protected; "they are merely *protectable*" depending on national legislation [emphasis in the original text].

suspicious about its initiatives,[52] precisely in light of its alleged bias towards the transfer of technology to developing countries as well as its reluctance to include new plant varieties within the scope of patentable subject matter.[53] Partly due to this, there have been recent developments in three important fora,[54] with the following agreements : The Union for the Protection of New Varieties of Plants (UPOV) Convention,[55] the TRIPS Agreements,[56] and the United Nations Convention on Biological Diversity (CBD)[57]. We will now examine how the concerns of the interested parties have been addressed therein.

A. PLANT PATENTS IN THE UPOV CONVENTION

Created in 1961, the UPOV Convention was conceived to accomplish what the Paris Convention could not : to protect the legal rights of breeders.[58] Its successive amendments have encouraged a market-based system of ratification, whereby countries are bound only by the provisions of specific texts.[59] This point is important because there are fundamental differences between the 1978 text and the 1991 revision.[60] For this reason, some commentators and interest groups lament the fact that every revision of the UPOV Convention increases protection for breeders' rights, at the

52. D.G. SCALISE, D. NUGENT, "International Intellectual Property Protections for Living Matter : Biotechnology, Multilateral Conventions and the Exception for Agriculture", (1995), 27 *Case W. Res. J. Int'l L*, pp. 83-118, p. 107. See also D.S. TILFORD, *loc. cit.*, note 4, pp. 405-406.

53. *Ibid.*

54. D.G. DOTSON, "The European Controversy over Genetic-Engineering Patents", (1997) 19 *Hous. J. Int'l L.*, pp. 919-949, p. 923, arguing that "WIPO has continually refused to recognize genetically engineered life-forms as patentable subject matter and has instead relied upon the International Union for the Protection of New Varieties of Plants".

55. *Supra*, note 8 and accompanying text.

56. *Supra*, note 6 and accompanying text.

57. *Supra*, note 9 and accompanying text.

58. N.D. HAMILTON, *loc. cit.*, note 1, p. 605.

59. *Id.*, p. 607. See also J.J. CAMPBELL, *loc. cit.*, note 50, p. 131.

60. *Supra*, note 8 and accompanying text.

expense of farmers' rights.[61] A survey of this system reveals at least three contentious issues which we will now attempt to discuss.

The first point of contention stems from the difference in the mode of protection provided respectively in the 1978 and 1991 texts. In the UPOV Convention (1978), member countries had a choice to protect breeders' rights either by grant of a special title of protection (a certificate) or by grant of a patent, but in principe,[62] double protection was not allowed. As for the UPOV Convention (1991), it has removed the prohibition of double protection by providing simply that "[e]ach Contracting Party shall grant and protect breeders' rights".[63] Accordingly, developing countries fear that this is likely to encourage other countries to follow in the footsteps of the United States by granting plant patents.[64]

The second controversial issue is that traditionally, breeders' rights created a double exception : One, known as "research exemption", allowed other breeders to use a protected variety so as to create other varieties, or to market such new varieties, without paying royalties;[65] the second one, known as "farmer exemption", permitted farmers to use and save protected seeds for future production, without paying royalties.[66] Under the UPOV Convention (1991), breeders'

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61. N. ROHT-ARRIAZA, *loc. cit.*, note 41, p. 265; See also GAIA FOUNDATION & GRAIN, "Ten Reasons Not to Join UPOV. Global Trade and Biodiversity In Conflict", N° 2 (London/Barcelona, 1998) (visited Dec. 22, 1999) <www.grain.org/publications/gtbc/issue2.htm>.

62. UPOV Convention (1978), art. 2(1). However, the United States was excused to apply double protection. It granted breeders' rights under the *Plant Variety Protection Act*, 7 U.S.C. §§ 2321-2583 (1970) to "new sexually reproducing varieties", whereas it granted plant patents for "asexually reproducing plants" under the *1930 Plant Patent Act*, 35 U.S.C. §§ 161-164 (1992); See N.D. HALMILTON, *loc. cit.*, note 1, p. 595.

63. UPOV Convention (1991), art. 2.

64. As a matter of fact, the European Patent Convention contains a provision very similar to what is found in the TRIPS Agreement, to be studied below, which prohibits patents on "plant or animal varieties or essentially biological processes for the production of plants or animals". This prohibition has been interpreted restrictively, as applying only to "varieties *per se*"; thus, "utility patents can be granted in cases where claims are not for a variety *per se*". See N.D. HAMILTON, *loc. cit.*, note 1, pp. 606-607. For further discussion see *infra*, note 89 and accompanying text.

65. UPOV Convention (1978), art. 5(3). See also N.D. HAMILTON, *id.*, p. 598, discussing the scope of these exceptions.

66. N.D. HAMILTON, *id.*, p. 599.

rights have been reinforced,[67] while the grant of exemptions has been left to the discretion of the state authority in each Contracting party.[68] Accordingly, failure to provide for such exemptions would entail an obligation to make arrangements like licencing, for the use of a patented variety in research, or royalties, for its use in farming.

A third stumbling block is rooted in the fact that standards of protection have been strengthened in a manner that makes UPOV a patent-like system of protection. To be protectable, a bred variety has to be new, *i.e.* the "propagating or harvested material [...] has not been sold or otherwise disposed of to others"; uniform, that is "in its characteristics"; distinct, meaning "clearly distinguishable from any other variety"; and finally, stable, in the sense that "its relevant characteristics remain unchanged" in successive generations.[69] These conditions are criticized as creating a dichotomy between farmers' varieties and breeders' commercial varieties. Since the former can find it difficult to conform with the uniformity and stability standards, for example, they will eventually be denied protection.[70]

Looking at the UPOV system from the angle of developing countries, and leaving aside its conflicts with respect to the biotechnology industry, leads one to the conclusion that this system, especially the UPOV Convention (1991), serves the interests of industrial countries, but overlooks those of developing countries. To quote Hamilton, "[t]he greater economic protection afforded by patents on plant varieties explains why this form of protection is favoured by American biotechnology companies and why the U.S. has promoted "patenting" of plant varieties in various international trade agreements".[71] With this said, we will now continue our investigation of the issue under discussion by surveying the TRIPS Agreement.

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67. UPOV Convention (1991), art. 14.

68. *Id.*, art. 15(2). See also D.S. TILFORD, *loc. cit.*, note 4, p. 407, acknowledging that despite the "optional" grant of exemptions, "[t]he 1991 amendments serve generally [...] to strengten breeders rights".

69. UPOV Convention (1991), arts. 5; 6; 7; 8; 9.

70. N. ROHT-ARRIAZA, *loc. cit.*, note 41, pp. 265-266.

71. N.D. HAMILTON, *loc. cit.*, note 1, p. 599.

B. BIOTECHNOLOGY PATENTING IN THE TRIPS AGREEMENT

The Uruguay round of negotiations has been described as "[p]erhaps the most significant forum for the promotion of the Northern view of the ownership of plant genetics".[72] Indeed, if one weights its results against the back drop of the concerns of the interested parties, as discussed in Section I, one might come to the conclusion that developed countries are the true winners. For instance, except for the provisions whose applications are subject to the transitional period, developing countries can no longer escape from the obligation to protect patent holders' rights for a period of no less than twenty years;[73] nor from the requirement to limit such rights only under certain conditions,[74] even though national legislative bodies are free to define "the kind and extent" of exceptions to be granted.[75] In addition, any country willing to resort to compulsory licensing has an obligation to conform to severe restrictions.[76] However, whether the TRIPS Agreement truly disfavours developing countries with respect to biotechnology patenting, is a matter that can be ascertained only if one examines the substantive provision that deals with the scope

72. *Id.*, p. 613.

73. TRIPS Agreement, art. 33.

74. *Id.*, art. 30, stipulating that the exceptions to exclusive rights will "not unreasonably conflict with a normal exploitation of the patent and [will] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

75. C.M. CORREA, "Patent Rights", in C.M. CORREA, A.A. YUSUF (eds.), *Intellectual Property And International Trade: The Trips Agreement*, London/Boston, Kluwer International, 1998, pp. 189-221, p. 208.

76. TRIPS Agreement, art. 31. The general rule is that compulsory licencing applies only where the attempt to obtain authorization from the right holder on reasonable commercial terms and conditions proves unsuccessful; unless the demand concerns national emergency or similar circumstances, in which case the right holder has to be notified and remunerated, taking into account the economic value of the authorization. Besides, any decision relating to the authorization can be subject to a judicial or independent review. See also K.W. MCCABE, *loc. cit.*, note 13, p. 61, noting the extent of severe restrictions to compulsory licencing; C.M. CORREA, *id.*, p. 210, pointing out that the flexibility as to the grounds for granting compulsory licences is subject to the conditions specified by the TRIPS Agreement. M. HALEWOOD, "Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law", (1997) 35 *Osgoode Hall L. J.*, pp. 243-287, p. 263, noting that compulsory licensing provisions "are definitely more restrictive than was previously allowed for [...]."

and the conditions for patentability, namely Article 27. We will start by dealing with the scope of patentable subject matter before examining the conditions of patentability.

According to Article 27, Section 1, shall be patentable "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Then follows the prohibition, in the same provision, of discrimination regarding the "place of invention", the "field of technology", and regarding the fact that "products are imported or locally produced".[77] This provision is considered as the major concession made by developing countries, since it allows no restriction as concerns patentable subject matter.[78] Furthermore, it arguably tends to put an end to working requirements.[79]

In any case, under Section 2 of the same article, it is possible to exclude from patent protection, certain inventions on the grounds of *ordre public* or "morality", when it appears "necessary" to prevent their "commercial exploitation"; as well as "to protect human, animal or plant life or health or to avoid serious prejudice to the environment", except where such preclusion is "made merely because the exploitation is prohibited by domestic law".[80] This public health clause would apparently allow developing countries, for instance, to exclude some substances, such as pharmaceutical products, from patentability.[81] However, the weight to be attached to this provision

77. TRIPS Agreement, art. 27.1.

78. C.M. CORREA, *loc. cit.*, note 75, p. 191, commenting on article 27.1.

79. See discussion *supra*, notes 36-37 and accompanying text; K.W. MCCABE, *loc. cit.*, note 13, p. 62, arguing that the TRIPS Agreement "has effectively banned working requirements". See also R.L. GANA, *loc. cit.*, note 31, p. 756, observing that "[t]he TRIPS Agreement eliminates the use of working requirements as a condition to granting a patent". But see M. HALEWOOD, *loc. cit.*, note 76, p. 257, arguing that "within the *TRIPS* framework, pursuant to articles 8 and/or 30, a country could legislate local working provisions". Observing however, that "[t]he local aspect of the working requirement would be limited [...] by the fact that *some* importing of the patented subject matter would have to be allowed"; C.M. CORREA, *loc. cit.*, note 75, p. 203, concluding that "article 27(1) would not prohibit local production obligations[,] but just the discrimination in the exercise of rights against infringing goods, whether imported or locally produced".

80. TRIPS Agreement, art. 27.2.

81. R. WEISSMAN, *loc. cit.*, note 32, p. 1100: "Assuming the reason is legitimate, the exception will permit a country to deny patent to a particular drug or to all drugs".

must be assessed against the conditions laid down for its application. Firstly, it is stated that the exclusion must be "necessary"; secondly, it must aim to prevent "commercial exploitation" of such products; and thirdly, it must not rely merely on the prohibition of the excluded products in domestic law. It seems rightful to assume that these limitations are likely to narrow the permissive language of Article 28.2.[82] On the other hand, this provision does not provide any guidance as to how it should be construed.[83] Therefore, equally reasonable is the assumption that an attempt to rely on it might be challenged within the framework of the Dispute Settlement Body (DSB) of the WTO. With regard to the first paragraph of Section 3, it is stated that "diagnostic, therapeutic and surgical methods for the treatment of humans or animals",[84] also fall outside the ambit of patentable subject matter. This, in any case, runs parallel with preclusion of therapeutic methods in most countries.[85]

Turning our attention to Article 27, Section 3, it starts by specifying, in the first paragraph, the kind of products and processes which will not be patentable. These are, "plants and animals", and "essentially biological processes for the production of plants or animals [...]".[86] Whether the latter category

82. T.G. ACKERMANN, "Dis'ordre'ly Loopholes: TRIPS Patent Protection, GATT, and the ECJ", (1997) 32 *Tex. Int'l L. J.*, pp. 489-509, p. 492, discussing the scope of the exclusions in article 27.2.

83. The problem with the public health clause is two-fold: First, the exclusion must be "necessary", and second, it must aim to prevent " commercial exploitation" of the invention in question. Under GATT 1947 case-law, "necessary" has been construed as imposing an obligation on nations to resort to exceptional measures only if (1) another GATT-consistent measure is not available, and (2) the measure applied is "least-trade-restrictive". See R. WEISSMAN, *loc. cit.*, note 32, p. 1103. But the latter test appears to be "favored". See T.G. ACKERMANN, *id.*, p. 507. Thus, Weissman suggests "[a] less stringent reading of "necessary" — something closer to important, and with little or no attention to available alternative", R. WEISSMAN, *id.*, p. 1107. As concerns "commercial exploitation", it seems that a country would be justified to deny protection to foreign patent-holders only if commercial exploitation of the invention by domestic entities is not allowed either, R. WEISSMAN, *id.*, p. 1100. C.M. CORREA, *loc. cit.*, note 75, p. 193; T.G. ACKERMANN, *id.*, pp. 508-509. But how one defines "commercial exploitation" is quite an other issue. For further discussion of competing views, see T.G. ACKERMANN, *id.*, p. 509.

84. TRIPS Agreement, art. 27.3(a).

85. C.M. CORREA, *loc. cit.*, note 75, p. 194.

86. TRIPS Agreement, art. 27.3(b).

will in effect be excluded remains disputable. For example, professor Correa has suggested that if it is possible to interpret the exclusion of "plants and animals" broadly, as embracing animal races and animal plant species, the same can not be said about "essentially biological processes".[87] Referring, by way of analogy, to the patent law of the countries member to the European Patent Convention,[88] he argues that the criteria retained to interpret "essentially biological processes" is the degree of "human intervention".[89] As a result, "classical breeding methods are not patentable. In contrast, methods based on genetic engineering (*e.g.* the production of a 'transgenic' plant) where the technical intervention is significant, would be patentable".[90] As for "micro-organisms" and "non-biological processes" it is expressly provided that they shall be patentable.

Yet another hurdle for developing countries lies in the second subparagraph of Article 27, Section 3, which deals with "plant varieties" specifically. This provision mandates Members to provide protection for plant varieties "either by patents or by an effective *sui generis* system".[91] Since this provision also aims to assure that minimum IPR are provided for in developing countries, we have kept the discussion for the last section of this paper. Suffice to say along with professor Correa that "[t]his obligation is another important basis for

87. C.M. CORREA, *loc. cit.*, note 75, pp. 194-195, and by the same author, "The GATT Agreement on Trade-related Aspects of Intellectual Property Rights: New Standards for Patent Protection", (1994) 16 *Eur. Intell. Prop. Rev.*, pp. 327-335, p. 328 [hereinafter, C.M. CORREA, "New Standards"].

88. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 *U.N.T.S.* 199 [hereinafter, The European Patent Convention].

89. C.M. CORREA, *loc. cit.*, note 75, p. 195.

90. The analogy underlying this reasoning seems to be based on the similarity between article 27.3 of the TRIPS Agreement and article 53(b) of the European Patent Convention which reads as follows: "European patents shall not be granted [...] [for] plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof". For further discussion of the application of the "human intervention" standard by the European Patent Office, see W. MOSER, "Exceptions to Patentability Under Article 53(b) EPC", (1997) 28 *Int'l Rev. Ind. Prop. & Copy. L.*, pp. 845-850, pp. 846-849; H.C. THOMSEN, "The Exceptions to Patentability Under Article 53(b) EPC and Corresponding Laws of the EPC Contracting States", (1997) 28 *Int'l Rev. Ind. Prop. & Copy. L.*, pp. 850-857, pp. 852-855.

91. TRIPS Agreement, art. 27.3(b).

the expansion of the scope of intellectual property in the field most developing countries have neglected until now".[92]

With regard to the conditions of patentability, an invention must be new, involve an inventive step (non obvious), and be capable of industrial application (useful). Gana has rightly called these new standards a "deceptively simple terminology", contending that they "invoke a body of jurisprudence which has been carefully developed and applied by courts in developed countries for years"; and which, insofar as developing countries are concerned, represent the results of their "accession to international agreements, rather than the working out of ideas about the patent system emanating from the individual countries".[93] However strong this argument might be, the fact is that these standards hardly apply, if at all, to traditional breeding methods and indigenous knowledge. This view is not unsupported if we consider, for example, novelty. The fact that accounts of the uses of traditional medical remedies of indigenous communities have been published or used by scientists of all background, is quite well-documented.[94] Again, as many would argue, even if such publication manifestly destroys novelty and renders such remedies non-patentable,[95] it does not follow that pharmaceutical companies, for instance, will not be able to use such knowledge or substances in laboratory and patent their results.[96]

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92. C.M. CORREA, "New Standards", *loc. cit.*, note 87, pp. 328-329.

93. R.L. GANA, *loc. cit.*, note 31, p. 749.

94. M. BLAKENEY, *loc. cit.*, note 47, p. 299, referring to the practice of ethnobotanists and ethnopharmacologists. See also R. WEISSMAN, *loc. cit.*, note 32, p. 1090, noting that "corporate botanists and anthropologists rely on third world farmers and herbalists, especially from indigenous communities that make their home in or live off of the rain forests, to direct them to plants that they use in local medicines".

95. M. BLAKENEY *id.*, p. 299, arguing that publication "may have the effect of destroying the novelty of therapeutic claims". See also R.L. GANA, *loc. cit.*, note 31, pp. 749-750 : "Developed countries are likely to treat such traditional medicines or cultural knowledge as a product of nature or decide they do not satisfy novelty requirements".

96. R.L. GANA, *id.*, p. 750, arguing that it is possible for a pharmaceutical company to "take the raw formula or components of a native medicine and work on it until it satisfies the patentability requirements". See also R. WEISMAN, *loc. cit.*, note 32, p. 1090, asserting that "the pharmaceutical companies are able to synthesize chemical substances with mild alterations and patent them".

The preceding review of the TRIPS Agreement points to the conclusion that the concerns of developed countries have been given extensive consideration, whereas much remains to be done with regard to the interests of developing countries. Of course, there are a few exclusionary provisions, but it can be argued that their effects have been watered down considerably by somewhat ambiguous underlying conditions. Besides, the failure to consider farmers' rights or traditional knowledge of local communities suggests that such concepts do not fit, as yet, into the current regime of IPR. Now, if it is true that the TRIPS Agreement has failed to protect the interests of the latter, the CBD seems to have adopted quite a different approach.

C. INNOVATIONS IN THE CONVENTION ON BIOLOGICAL DIVERSITY

The CBD is the most known outcome of the UN Conference on Environment and Development (UNCED), held in Rio de Janeiro in June 1992. Many think of it as the major breakthrough managed by developing countries, but it is certainly an attempt to reconcile the interests of the North and those of the South with regard to biotechnology. Three objectives are contemplated: "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources".[97] The perception that the CBD meets the expectations of developing countries is premised on the ownership of genetic resources, access to technology, and IPR on biological innovations of indigenous communities.

The point about ownership of genetic resources is that the principle of "common heritage of humanity" has been rejected,[98] although some issues remain pending and their

97. CBD, art. 1.

98. See *supra*, Section I.C. for more on this topic. However, one commentator argues that the fact that the Preamble to the CBD states that the conservation of biological diversity is a "common concern of humankind" is meaningful, because States have now confirmed that biodiversity is a "commons", which entails an obligation to conserve it. See K. BOSSELMANN, *loc. cit.*, note 26, pp. 137-138.

discussion would extend the scope of this paper.[99] Instead, it is established that States have sovereign rights over their natural resources, and the authority to determine access to genetic resources.[100] One is tempted to think that measures taken in this sense, are limited only by "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 [these] genetic resources".[101] Except that the same article affirms that "[a]cces [to genetic resources] [...] shall be on mutually agreed terms",[102] thus creating an ambiguity as discussed below.

Next, we will consider the question of access to protected technology. On this point, the CBD is challenged by its opponents for stipulating that "[a]ccess to and transfer of technology [...] to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms".[103] Further still, developed countries "shall take legislative, administrative or policy measure [...] with the aim that [...] developing countries, which provide genetic resources are provided access to and transfer of technology which makes uses of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights".[104]

The history of the CBD itself shows that the language used in Article 16 was at the core of the United States' initial refusal to sign the Convention[105]. It was perceived as focussing

99. A thorny question concerns the retroactivity of the CBD with respect to germplasm collected from developing countries prior to its entry into force, and held by International Agricultural Research Centres (IARCs). The text does not shed light on the ownership of seed banks, but rather gives rise to controversies. For a discussion, see G.B. FRISVOLD, P.T. CONDON, *loc. cit.*, note 26, p. 558; see also N.D. HAMILTON, *loc. cit.*, note 1, pp. 630-631.

100. CBD, art. 15.1.

101. *Id.*, art. 15.7.

102. *Id.*, art. 15.4.

103. *Id.*, art. 16.2.

104. *Id.*, art. 16.3.

105. C.R. MCMANIS, "The Interface Between International Intellectual Property and Environmental Protection : Biodiversity and Biotechnology", (1998) 76 *Wash. U.L.Q.*, pp. 255-279, p. 262, discussing the Unites States's position with respect to the CBD.

on IPR "as a constraint to the transfer of technology rather than a prerequisite".[106] No wonder expressions like "equitable share", "fair and most favourable terms", rapidly triggered the Unites States' unilateral interpretation of the CBD, in order to satisfy the demands of the biotechnology industry.[107] Fears expressed by the latter being that the CBD urges inventors to transfer technology and disregard compensation; proposes the sharing of the income; and "creates the potential for sweeping forfeiture of intellectual property rights".[108]

Last, but certainly not least, is the recognition of indigenous and traditional knowledge. Article 8(j) calls on each Contracting party to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity". It also requires States to "encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".[109]

With these stipulations, it is expected that equity will finally find its way into the field of IPR.[110] As commented by

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106. *Id.*, p. 256, p. 262, quoting the *United Nations Convention on Biological Diversity*, in 3 *U.S. Dep't St. Dispatch* 423 (1992).

107. D.G. SCALISE, D. NUGENT, *loc. cit.*, note 52, p. 112, discussing the text of Message from the President of the United States Transmitting the Convention on Biological Diversity, with Annexes, Done at Rio de Jan[ei]ro June 5, 1992, and signed by The United States in New York, June 4, 1993, S. Treaty Doc. 20, 103d Cong., 1st Sess. (1993).

108. D.G. SCALISE, D. NUGENT, *id.*, p. 111. But see C.R. MCMANIS, *loc. cit.*, note 104, p. 263, challenging the attitude of "reading demons" into the text of article 16 : "[A]ny country that interprets Article 16 as requiring involuntary transfer of technology must be prepared for the counter-argument that the similar language in Article 15 requires involuntary transfer of genetic resources, a result no source country would happily accept", and the same author, quoting D. DUMANOSKI, "U.S. is Isolated in Opposing Biodiversity Treaty", *Boston Globe*, June 6, 1992, p. 4, quoted in R.L. MARGULIES, "Protecting Biodiversity : Recognizing International Intellectual Property Rights in Plant Genetic Resources", (1993) 14 *Mich. J. Int'l L.*, p. 322, p. 337. See also K. BOSSELMANN, *loc. cit.*, note 26, p. 139, describing article 16 as "the mirror opposite of Article 15 in that it attempts to define access to technology for LDCs [less developed countries] in the same way as Article 15 attempts to define access to genetic resources for DCs [developed countries]". In light of this ambiguity, it can rightly be argued that the rights provided for in the CBD in favor of developing countries, are difficult to enforce.

109. CBD, art. 7(j).

110. See *supra*, text accompanying note 43.

Date, "[t]he Biodiversity Convention creates IPR in traditional knowledge and urges unprecedented compensation and knowledge-sharing".[111] Again, such an optimism raises the question of the difficulty in protecting local communities IPR under conventional standards, especially when such rights refer to communal ownership.[112] This is where conflicts start arising between the CBD and the TRIPS Agreement.

III. ADDRESSING CONFLICTS BETWEEN THE INTERNATIONAL AGREEMENTS : IS THERE ANY WAY OUT?

As discussed previously, plant varieties are not excluded from protection under the TRIPS Agreement. To this effect, Members are required to "provide for the protection of plant varieties either by an effective *sui generis* system or by any combination thereof",[113] to make sure that minimum standards of IPR are catered to.[114] But, even though no specific reference is made to the UPOV Convention therein, the

111. V. DATE, "Global 'Development' and its Environmental Ramifications — The Interlinking of Ecologically Sustainable Development and Intellectual Property Rights", (1997) 27 *Golden Gate U. L. Rev.*, pp. 631-673, p. 662.

112. Two Australien copyright cases discussed by M. BLAKENEY illustrate this problem, *loc. cit.*, note 47, pp. 299-300. In *Yumbulul* v. *Reserve Bank of Australia*, (1991) 2 I.P.R. 481, representatives of a clan named Galpu, failed to prevent the Reserved Bank of Australia from reproducing the design of a Morning Star Pole on a commemorative banknote, considered by the clan members as offensive. The trial judge rejected the argument and held that "the artist who had created the pole had successfully disposed of his intellectual property rights in it through a legally binding assignment", see *id.*, p. 299. In *Milpurrurru* v. *Indofurn Ptg Ltd*, (1995) 91 CCH A.I.P.C. 39,051, the court held that the reproduction of Aboriginal artists' designs on carpets was a breach of copyright. But, damages could not be computed so as to include dead members of the clan, since, said the court, "the statutory remedies do not recognise the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories", *id.*, p. 300.

113. TRIPS Agreement, art. 27.3(b).

114. It is true, as McCabe notes, that "[o]ne reason the TRIPS Agreement was enacted, [...] was in recognition of the difficulty of negotiating worldwide patent protection through unilateral, bilateral, and multilateral agreements", K.W. MCCABE, *loc. cit.*, note 13, p. 63, referring to P. KATZENBERG, A. KUR, "TRIPS and Intellectual Property", in F-K. BEIER, G. SCHRICKER (eds.), *From GATT to TRIPS — The Agreement on Trade-Related Aspects of Intellectual Property Rights*, (1996), pp. 1-7 [complete reference omitted in the citation]. Nevertheless, it seems that this objective did not arguably materialize itself far beyond setting minimum standards of IPR. R.L. GANA, *loc. cit.*, note 31, p. 757, arguing that "[t]he function of the TRIPS Agreement is not to create a worldwide agreement on patent laws".

controversial expression "effective *sui generis* system" has been widely interpreted by many as limiting developing countries' choice of a system of protection to one that is already internationally available.[115]

In such an interpretation, the relationship between the TRIPS Agreement and the UPOV Convention seems to be taken for granted. And yet, this can stand only if it is ascertained that the UPOV Convention is likely to meet the goals of developing countries. Moreover, even if it is suggested that nations from the South are free to design a system of their own, provided that it be "effective", conflicts remain possible. In fact, the TRIPS Agreement does not define what is an "effective" system. So, to what extent are the UPOV Convention, the TRIPS Agreement and the CBD likely to conflict regarding biotechnology patenting? What options are worth exploring in an attempt to reconcile the respective interests of the parties?

A. WHERE THE AGREEMENTS CONFLICT

Following roughly the same pattern developed in the previous analysis, this subsection starts by comparing the UPOV Convention *vis-à-vis* the TRIPS Agreement and the CBD, then focusses on the relationship between these latter. Compared to the TRIPS Agreement, the UPOV Convention can be criticized for leading to results that counter the objective of free trade, by imposing non-tariff barriers and anti-competitive practices.[116] It further appears more objectionable when compared to the CBD. To be sure, drawbacks seem to derive from the fact that the UPOV Convention narrows farmers' rights as

115. K.W. MCCABE, *id.*, p. 58, discussing the UPOV Convention as a model *sui generis* legal regime. See also M. CORREA, "New Standards", note 87, p. 329 arguing that "[t]he reference to a *sui generis* regime naturally suggests the breeders's rights regime, as developed within UPOV [...]". Adding, nevertheless, that "the possibility is open to combine the patent system with the breeders's rights regime".

116. To give two examples cited by Gaia Foundation & Grain, strawberry plants from Argentina were barred access to Europe by a US breeder "because they would compete with plants produced in Europe under the U.S. licence". As concerns anti-competitive practices, "sugar cane breeders in Latin Americ[a] protect their varieties in neighbouring countries to prevent their exploitation there, and thereby protect their own exports", GAIA FOUNDATION & GRAIN, *loc. cit.*, note 61, Part. 4.1.

discussed earlier.[117] Farmers' right to save the seed, for instance, is consonant with the objective of conservation of biological diversity in the CBD. This objective, according to some authors, is particularly weakened by the fact that the UPOV Convention provides a patent-like protection. While this conforms with the TRIPS Agreement, opponents argue that "[t]he privatization of patented genetic resources accelerates the trend toward monocultural cropping".[118]

However, another view contends that "creation of new plant varieties by definition increases the actual diversity of species, and if genetic barriers can be eliminated through genetic engineering, there will arguably be an increase of botanical diversity as well".[119] Following this trend, the UPOV Convention would still be a good option for developing countries for two reasons: its field of application has been extended to "the entire kingdom [of plants] and not just species of interest to individual countries" and to "newly discovered as well as newly bred varieties".[120] Looking at the issue this way, developing countries would enjoy "competitive opportunities" and, at the same time, contribute to the increase of biological diversity.[121] In any event, this view, which might certainly be appealing to commercial breeders in developing countries, leaves unresolved the question of recognition of the rights of indigenous communities. While the CBD is quite explicit on this point, the UPOV Convention just as the TRIPS Agreement, remains silent.

With regards to the relationship between the TRIPS Agreement and the CBD, there are three possible areas of conflict: the principle of national sovereignty, the recognition of indigenous knowledge, and the acknowledgement of community rights. Firstly, the principle of national sovereignty established by the CBD, can be understood either as allowing developing

117. *Supra*, notes 66-67 and accompanying text.

118. M. RITCHIE, K. DAWKINS, M. VALLIANATOS, "Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge", (1996) 11 *St. John's J. Legal Comment*, pp. 431-453, p. 446.

119. C.R. MCMANIS, *loc. cit.*, note 105, p. 276.

120. *Ibid.*

121. *Ibid.*

countries to stop bio-piracy, very common in the past,[122] or as enabling them to enact legislation that excludes plant varieties from patentability[123]. In this way, the CBD would clash with the TRIPS requirement of biotechnology patenting.

Secondly, the CBD recognizes indigenous knowledge, which includes "innovations and practices",[124] as well as its contribution to the conservation and sustainable use of biological diversity. The problem is that, in light of this contribution, the CBD imposes on Contracting parties an obligation that has no equivalent in the TRIPS Agreement : to share the benefits of biological inventions. The TRIPS Agreement, instead, allows patents "in all fields of technology" without compensation.[125]

At any rate, if it is true that Article 7(j) of the CBD creates communal IPR as discussed previously, there is no need to insist that this is at odds with the TRIPS Agreement. Should indigenous communities, where "the knowledge is held by communities instead of just a single owner", claim their share for providing the "novel" information, such claims are irreconcilable with the individualistic view that prevails in the international patent system.[126] However, it might be possible to address these discrepancies. We will now explore some significant options.

B. TRENDS AND PERSPECTIVES

Groups involved in the debate concerning the agreements at issue are many; as are suggestions put forward so that countries privy to these agreements can fulfil their obli-

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122. One example is that some years back, Equador and Brazil tried, in vain, to prevent the exportation of Chinchona (from which quinine is derived) and rubber. See N.D. HAMILTON, *loc. cit.*, note 1, p. 627, quoting H. HOBHOUSE, *Seeds of Change : Five Plants Transformed Mankind*, (1985) and A. SMITH, *Explorers of the Amazon*, (1990), pp. 251-284 [complete reference omitted in the citation].

123. *Infra*, notes 128-130 and accompanying text.

124. CBD, art. 7(j).

125. GAIA FOUNDATION & GRAIN, "TRIPS versus CBD. Conflicts Between the WTO Regime of Intellectual Property Rights and Sustainable Biodiversity Management", *Global Trade and Biodiversity in Conflict*, N° 1, (1998), (visited Dec. 22, 1999) <http://www.grain.org/publications/gtbc/issue1.htm>.

126. V. TEJERA, "Tripping Over Property Rights : Is it Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPS Agreement?", (1999) 33 *New Eng. L. Rev.*, p. 967, p. 984.

gations. All in all, three options seem consistent with what we have discussed in this paper: *sui generis* systems of protection, contractual arrangements at a bilateral level, and the amendment of the TRIPS Agreement. The latter's requirement for a *sui generis* system of protection has had the effect of almost doubling membership in the UPOV system. For example, from January 1, 1994 to June 29, 1999 twenty new members have joined, which brings the total to 44 States.[127]

In any case, the *sui generis* option can also mean freedom of choice. India took the lead in 1997 by drawing up a draft legislation "to protect its biological resources from being exploited by foreigners without sharing the benefits with local people" and by setting up the National Biodiversity Authority (NBA) to implement the legislation,[128] but, only to meet strong opposition from the United States Government.[129] So far, most developing countries seem to have resisted the pressure as well, and many non-UPOV *sui generis* systems of protection are being drafted.[130] They aim to promote farmers' rights, to preserve local community rights, and to set up conditions for patentable matter in a way that serves local interests.

This option is more in line with the CBD, and actually, it is an attempt to fill the gap left by the TRIPS Agreement. As a result, some critics question its efficacy, since they think that it "tends to slow and even to block the flow of trade between nations".[131] In the second place, are contractual arrangements. Their possible justification is that "[t]he Biodiversity Convention provides the framework for the development of minimum standards for national regulation of transactions involving both the public and the private

127. States Party to the International Convention for the Protection of New Varieties of Plants. Status on June 29, 1999, (visited Dec. 22, 1999) <http://www.upov.org/eng/ratif/index.htm>.

128. K.S. JAYARAMAN, "India Drafts Law to Protects Bioresources", (1997) 390 *Nature*, p. 108.

129. V. TEJERA, *loc. cit.*, note 126, p. 981, discussing India's resistence to comply with the WTO's ruling.

130. GAIA FOUNDATION & GRAIN, "Beyond UPOV. Examples of developing countries preparing non-UPOV *sui generis* plant variety protection schemes for compliance with TRIPS", July 1999, (visited Dec. 22, 1999) <http://www.grain.org/publications/reports/nonupov.htm>.

131. V. TEJERA, *loc. cit.*, note 126, p. 982.

sector".[132] In fact, article 7(j) requires, for such dealings, "the approval and involvement of the holders of [...] knowledge, innovations and practices".[133] In practice, biological prospecting contracts, referred to as "gene-hunting", have been taking place between governmental or non-governmental entities located in the South and pharmaceutical or other research bodies based in the North. The former provide samples which will be analysed for possible applications in medicine, agriculture and industry, in exchange of royalties, and conservation facilities or potential commercial benefits.[134]

This option has been extensively encouraged by many commentators.[135] Despite a number of prospective advantages,[136] this solution poses first of all the question of developing countries' capacity to handle the hurdles and costs of possible action against multinational firms for violation of their rights resulting from screening contracts.[137] Then, the right to sell national resources is questioned by some environmental groups, for example, as well as some parliaments that consider biodiversity as part of the "national patrimony".[138] Another concern is that biological screening can turn into biopiracy, given the degree of opportunism. As Tejera asserts, "[c]ontractual relations between individual tribes will only succeed under a structured international trading system".[139]

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132. V. DATE, *loc. cit.*, note 111, p. 666.

133. CBD, art. 7(j).

134. The well-publicized example is the agreement reached in 1991 between Costa Rica's Instituto Nacional de Biodiversidad (INBio) and Mereck & Company, Ltd (Merek), a pharmaceutical firm based in the United States. Under this contract, INBio agreed to provide Merek with chemical extracts from wild plants, insects and microorganisms, "in exchange for a renewable two-year research and sampling budget of $1,135,000, and royalties on any resulting commercial profits", C.R. MCMANIS, *loc. cit.*, note 105, p. 270. For more examples and further discussion of such arrangements, see *ID.*, pp. 271-275; see also N.D. HAMILTON, *loc. cit.*, note 1, pp. 628-630.

135. D.G. SCALISE, D. NUGENT, *loc. cit.*, note 52, p. 118. See also R.A. SEDJO, *loc. cit.*, note 41, p. 209; V. DATE, *loc. cit.*, note 111, p. 669.

136. To name only a few, this solution appears sustainable because it is premised on contract rather than IPR. Then, it provides an incentive for developing countries to conserve genetic resources. And finally, it fosters equity. See K. BOSSELMANN, *loc. cit.*, note 26, p. 142, discussing the advantages of market solutions.

137. *Id.*, p. 143.

138. N.D. HAMILTON, *loc. cit.*, note 1, p. 629.

139. V. TEJERA, *loc. cit.*, note 126, p. 986.

The last option would be to amend the TRIPS Agreement so as to eliminate its conflicts with the CBD. First, it is consistent with the members' desire to review the controversial provision of Article 27 as stated in the TRIPS Agreement itself.[140] In principle, possibilities for such an amendment range from defining the term *sui generis*,[141] repealing Article 27.3 (b),[142] further suspending its implementation by developing countries,[143] to incorporating farmers' and local community rights[144] or establishing for such rights a new system of protection.[145] Depending on the direction to be taken, amendment looks like the best option for developing countries. It would not only highlight the extent to which both the TRIPS Agreement and the CBD are legally binding without

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140. See TRIPS Agreement, art. 27.3(b). The procedure is established in article 71, which enables the Council established under article 68, to "undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement". But the Council may need to refer to the Ministerial Conference, art. 71.2. See also K.W. MCCABE, *loc. cit.*, note 13, p. 63, commenting on article 71. It should be mentioned that the 3rd WTO Ministerial Conference, which started on 30 November 1999, in Seattle, ended inconclusively on 3 December 1999. At the time of writing this paper, the discussion has not been rescheduled yet.

141. Depending on the definition of this term, developing countries might want to oppose a clear reference to the UPOV's standards of IPR, or a requirement to join the UPOV Convention. See GAIA FOUNDATION & GRAIN, "TRIPS versus Biodiversity: What to do with the 1999 Review of Article 27.3(b)", (1999), (visited Dec. 22, 1999) <http://www.grain.org/publications/reports/TRIPSmay99.htm>. But see K.W. MCCABE, *loc. cit.*, note 13, p. 60, suggesting that "[a]lthough the 1991 UPOV Convention does not provide the level of protection that patents do, it may provide a common platform acceptable to both sides of this issue".

142. This would be the worse solution for developing countries. Beyond the appearance that plant varieties would cease to be referred to expressly, it actually implies the removal of the exception created. In such a case, plant varieties would fall within the ambit of section 27.1, which established patentability "in all fields of technology". See *supra*, notes 77-78 and accompanying text. This explains why transnational corporations have been urging the United States to lobby for the deletion of the exception that applies to plant varieties. See K.W. MCCABE, *loc. cit.*, note 13, pp. 57-58.

143. GAIA FOUNDATION & GRAIN, *loc. cit.*, note 141.

144. V. TEJERA, *loc. cit.*, note 126, p. 986.

145. Preparations for the 1999 Ministerial Conference: Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities. Communication from Bolivia, Colombia, Ecuador, Nicaragua, and Peru, WT/GC/W/362 (Oct. 12, 1999) (proposing the establishment of a multilateral legal framework that will grant effective protection to traditional knowledge).

colliding with each other,[146] but, in practice, it would bring clarity *vis-à-vis* the UPOV Convention and predictability as regards any measure the parties might wish to take.

CONCLUSION

Biotechnology patenting is a very complex and controversial issue. In the perspective we have adopted here, this is due to the fact that it opposes gene-endowed, but technologically deprived countries from the South, to gene-hunting, but technologically rich nations from the North. Moreover, this raises serious questions as to the ownership of genetic raw materiels, the protection of its derivatives, and sharing of the benefits.

As a result, the international intellectual property law in its recent developments, fails to address these issues harmoniously. It tends, instead, to keep pace with advancement in the biotechnology industry. For this reason, the UPOV system has been reinforced to provide patent-like protection to commercial breeders. This situation seems to leave traditional breeders behing, not just because farmers' privileges have been deleted, but also because the new standards of protection hardly apply to landraces and traditional knowledge.

As for the TRIPS Agreement, it is less concerned, in its objectives, with the need to harmonize IPR than by the desire to set up minimum intellectual property standards, so that greater protection can be afforded to industrial forces. Thus, it remains clear that plant varieties are patentable subject matter. The language in the TRIPS Agreement gives developed countries a better bargaining position, because if they cannot achieve biotechnology patenting under this regime, they can push toward the UPOV Convention. Developing countries on their side, have a strong hold on the CBD, which takes into account the rights of local communities, despite the ambiguity and vagueness of its wording.

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146. But see M. HALEWOOD, *loc. cit.*, note 76, pp. 280-281, stating that if these agreements deal with the same subject matter, "then, based on the *Vienna Convention, TRIPS* would prevail over the *CBD*, and parties to both agreements would be obliged to comply with *TRIPS* where the two agreements applied equally to any given legal initiative".

Therefore, the conflicts between these agreements stem from differences in their respective objectives. Consequently, this compels developing countries, for example, to perceive the issue from different angles all at the same time. Moreover, as providers of genetic materials, they fear bio-piracy believing that these resources have the potential to develop their economy; while, as consumers of protected technology, they fear being denied access to accessible markets as well as conservation consideration, in terms of local industry. Thus, it goes without saying that the way from fear to "fair dealing" passes through the harmonization of the TRIPS Agreement and the CBD. At any rate, whether the parties are willing to bridge the gap between them remains to be seen.

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