Interacting International Institutions: The Convention on Biological Diversity and TRIPs – Regulating Access to Genetic Resources

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1. Introduction to the biodiversity issue

The issue of biological diversity constitutes one of today’s greatest challenges, for the following main reasons:

- First, the concern about biodiversity stems largely from an increased awareness and scientific agreement that the current rate of species extinction is extremely high compared to the natural average rate.\(^1\)
- Second, as the new biotechnologies greatly enhance the potential utility areas of the world’s genetic resources, the economic interests linked to these resources are soaring.\(^2\)
- One combined effect of these two trends is a greatly enhanced interest in property rights and access to genetic resources.

A number of international instruments deal with the various facets of biodiversity management. The central treaty is the Convention on Biodiversity (CBD) that was signed in Rio de Janeiro in 1992 and provides an overall legal framework for the issue area. The CBD is not the first international treaty to address species or habitat conservation, but it is the first to address conservation and sustainable use of all biological diversity worldwide.\(^3\) Until the early 1980s, conservation work – whether national or international – was still focused on wild species of plants and animals. An important shift came when questions of access to, and control over, plant genetic resources were raised in the UN Food and Agricultural Organization (FAO) by governments of the developing world. Since then, the controversial issue of property rights and access to genetic resources has been dealt with in several international arenas, most importantly the CBD and the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) under the World Trade Organisation (WTO).

The Convention on Biological Diversity is built on a three-fold, interacting objective: “to ensure conservation of biological diversity, and sustainable use of its components; and to promote a fair and equitable sharing of the benefits arising out of utilisation of genetic resources” (Article 1). This idea of equitable sharing as an essential element of biodiversity

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\(^1\) For example, the average species lifetime of mammals in fossil records is in the order of one million years, which would mean roughly 0.5 extinctions per 100 years for the present mammalian fauna of nearly 5000 species. In fact, however, the current rate of extinction of mammals is roughly 100 times higher than this background rate. In other taxa the discrepancy may be even greater (Heywood, 1995:232). Heywood, V.H. (ed) (1995) Global Biodiversity Assessment (Cambridge: Cambridge University Press). Estimates of the number of existing species in the world vary from about 5 to 100 million, of which only some 1.7 million have been described scientifically. See Wilson, E.O. (ed) (1988) Biodiversity. Washington D.C.: National Academy Press. & Wilson, E.O. (1992) The Diversity of Life. (Cambridge, MA: Harvard University Press).

\(^2\) Biotechnology traditionally includes activities such as baking bread and brewing beer, where the interaction of different organisms (such as that between yeast and wheat) combine to create a new product. The concept of ‘new biotechnologies’ indicates more direct dependency on human intervention (recombinant DNA techniques and genomics).

\(^3\) Biological diversity is a broad concept that has been used to embody the variability among all living organisms, including diversity within species (genetic diversity), among species and among ecosystems. The CBD defines genetic resources as genetic material of actual or potential value.
conservation provides the backdrop for this study. The major bulk of the world’s terrestrial species is found in tropical forests in the South. At the same time, it is primarily the developed countries of the North that possess the technological and economical capacity to reap – through intellectual property rights – the ever larger benefits from the genetic variability employed in the agribusiness and pharmaceutical industries (Kate & Laird, 1999).

These actors have been pushing hard for a strengthening of intellectual property rights systems within TRIPs of the WTO. This situation made the issues of intellectual property rights to genetic resources, linked to the responsibility for costly biodiversity conservation, very central on the agenda during the CBD negotiations. The CBD aims directly at the skewed distribution of biological resources and biotechnology between the North and the South.

### 2 Intellectual property rights and genetic resources – co-evolving approaches

This paper deals with the co-evolution of the CBD and the TRIPs agreement. To recap briefly, the CBD entered the international negotiation arena in 1989, was signed at the 1992 UN Conference on Environment and Development in Rio de Janeiro, and entered into force in December 1993. The GATT Uruguay Round set out in 1988 and was concluded in 1994, including the TRIPs agreement, which was formally established along with the World Trade Organisation (WTO). By April 2002, 183 states have ratified the CBD and the WTO has 144 member states.

TRIPs is part of the common institutional framework established under the WTO and, as such, it must be adhered to by all states wishing to join the WTO. TRIPs follows the basic WTO principles of non-discrimination: National Treatment – treating one’s own nationals and foreigners equally, and Most-favoured-nation Treatment – equal treatment for nationals

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6 The concepts of developing and developed/industrialised countries, or “South” and “North”, tend to obscure significant political and economic differences within the two groups. Here, they also obscure the fact that most countries are heavily interdependent in their use of genetic resources. As large parts of the international debate on biodiversity have been formulated as part of a North-South conflict, and for simplicity, I shall nevertheless keep to this admittedly simplified dichotomy. The CBD treaty makes specific use of these concepts in designating duties and rights to the parties.
7 The TRIPS Agreement is Annex 1C of the Marrakech Agreement Establishing the World Trade Organization, signed in Morocco in 1994. It represents the third pillar of the WTO, along with trade in goods and services (GATT and GATS).
8 The CBD is governed by a Conference of the Parties (COP) and is supported by the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA). The CBD Secretariat is located in Montreal and has 36 professionals and 26 support staff (approved by COP for 2003-4).
of all trading partners in the WTO. The TRIPs agreement covers questions about giving adequate protection to intellectual property rights, how countries should enforce those rights adequately, and how to settle disputes on intellectual property between members of the WTO. Most importantly, TRIPs is an attempt to standardise the way intellectual property rights are protected around the world and to strengthen this harmonisation process in all technological fields – including biotechnology. Of particular interest for this study is the development and interpretation of TRIPs article 27.3 (b). The article maintains that plant varieties must be protected by patents or by a special system of its own kind – usually referred to as a *sui generis* system. A central conflict revolves around whether TRIPs really leaves it up to the Parties to design their own *sui generis* systems, or if they should preferably chose the breeder’s rights system provided by the International Union for the Protection of New Varieties of Plants (UPOV).

Some of the major ingredients in this interaction take us back to 1980. Originally, international transactions with plant genetic resources were based on the principle of *common heritage of mankind*. This principle was gradually undermined as patent legislation was reinterpreted to cover biological material. This was, among others, an effect of the rapid developments within the new biotechnologies, which made it possible to overcome what had previously been legal and biological barriers to patenting in biotechnology. In the FAO Undertaking of 1983, developing countries pushed through an agreement that all categories of plant genetic resources should be regarded as a common heritage of mankind. This signified an effort to keep all types of breeding material within the public domain, outside the scope of patents. This was in line with the basic principle of the international genebanks – that seeds should be freely available as a source of plant breeding and food security. International gene banks were stocked with seeds from the most commonly used food plants and these seeds were primarily collected from the extensive variation found in the South. In 1989, however, developed countries succeeded in establishing intellectual property rights as compatible with the

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10 http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

11 Intellectual property includes copyright, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and undisclosed information, including trade secrets.

12 The more widely used definition of the CHM implies that the resources should be freely available and accessible to all, regardless of economic and technological strength, and hence, outside the reach of intellectual property rights (Bilder, 1980). Bilder, R.B. (1980), “International law and natural resources policies”, *Natural Resources Journal*, vol. 20, pp. 451-486, July.


17 A sovereign right is not the same as a property right. National sovereignty implies that the state has the prerogative to regulate the area, e.g. by establishing property rights regimes to the resources in question.

18 The principle of national sovereign rights to control and exploit own resources had previously been decided at the UN Conference on Human Environment, in Stockholm in 1972; the Stockholm Declaration Principle 21.

19 These are a Commission for plant genetic resources, a never functioning Fund, and the Undertaking.

20 The 12 are Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa, and Venezuela.
output, has hampered the implementation of its objectives? The following examination of the relationship between the CBD and TRIPs is meant to provide some answers.

In this section we have seen how the CBD and TRIPs interact at the junction between biodiversity and biotechnology. The two regimes operate with different approaches to property rights pertaining to genetic resources – hence, different objectives drive the interaction. In the ensuing section we will examine the effects of the interaction, which are primarily making themselves felt in the implementation phase rather than at the output level. The third section provides a picture of how this largely disruptive relationship has been dealt with, first by the regimes themselves and secondly by related action at the international and national levels. Finally, we will comment on the adequacy of these responses in terms of reducing the disruptive effects of the conflicting approaches to property rights to genetic resources.

3. Disruptive effects of the interaction – access and benefit sharing

The changes in patentability pertaining to genetic resources originated with developments in biotechnology. It led to the successful demand by developed countries for all WTO members to provide and respect intellectual property protection, including in the field of biotechnology. The TRIPs does not create a single, universal patent system. What it does seek to achieve is to strengthen, expand the scope for, and harmonise the domestic patent legislation in each of the member countries. As multinational corporations seek patent protection around the world, they depend on each country’s patent office to grant those rights, and TRIPs has now laid down the ground rules for what must be protected – including plant varieties and pharmaceuticals. It is hence among the consequences of a strengthened and expanding patent system that we must look for effects of the interaction.

In the next sub-sections, we will look at the major controversy that applies directly to the policy objectives of the CBD and TRIPs – access and benefit sharing, and add a few words on the related subject of conservation. See also Table 4 at the end, on some differences between genetic resources used in agriculture and pharmaceuticals/medicine respectively.

3.1 Access and benefit sharing

Access to a rich variety of genetic resources is essential for plant breeding and food security in all parts of the world. Applying patents to genetic resources from the international

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21 Patent legislation is of a national character, and patent protection is applicable only in the country where it has been granted. One exception is the European Patent Convention (EPC) of 1973, which applies primarily in the European Communities, and which is administered by the European Patent Office (EPO). National patent legislation is largely drawn from international conventions, administered by the World Intellectual Patent Organization (WIPO).

22 See e.g. the Economist, June 23rd 2001, p. 26.

genebanks is thus seen as representing a threat to the basic principle of free exchange of germplasm, on which these genebanks are building.\textsuperscript{24} Barton and Berger (2001) conclude that ‘it may be very expensive or difficult for the public sector to gain access to patented technologies or to use protected varieties for research in developing new applications for the smaller crops or subsistence farmers’.\textsuperscript{25} On the same note, the FAO Commission on Plant Genetic Resources has warned, “if the patent system is applied universally to living matter, including plant and animals, and their genetic resources, then the principle of unrestricted access will be severely eroded”.\textsuperscript{26} Developing countries maintain that without the IPRs the question of benefit sharing would not arise and all genetic material could be freely available in the same way as it was historically.\textsuperscript{27}

The North-South divide arose to a large extent because patenting is a long and costly business that is primarily employed by large corporations.\textsuperscript{28} The developing world holds no more than one to three per cent of all patents worldwide.\textsuperscript{29} Patenting is hardly a tool for indigenous and local communities, even though these groups often harbour much knowledge about the use of biological resources. Biotechnological products in agriculture often build on local breeders’ lines, which represent the end result of the work of generations of farmers. Likewise, pharmaceutical products of biotechnology often build on traditional knowledge about the medicinal traits of biological resources, such as wild plants. This activity is often referred to as bioprospecting; alternatively as ‘biopiracy’ by those who fear that the owner countries will be unlikely to take part in the benefits derived.\textsuperscript{30} In either case, a patent will

\begin{footnotesize}
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\item \textsuperscript{24} Keystone International Dialogue on Plant Genetic Resources, 1990, “Final Consensus Report”, Madras Plenary Session, 14 February, Keystone, Colorado
\item \textsuperscript{26} FAO, 1993, Harvesting nature’s diversity, the Information Division.
\item \textsuperscript{27} Borring, J. (2001) “The International Undertaking on Plant Genetic Resources for Food and Agriculture: is it Now or Never?”, IPRGI Newsletter for Europe, No. 17, p. 5.
\item \textsuperscript{30} Such products may be in the form of genes that are useful to biotechnology, chemicals that are useful as for instance colours and enzymes, and structures and constructions from nature that can be used in industry. Fewer that one percent of flowering plants has been thoroughly investigated for their chemical composition (Sheldon & Balick, 1995:46). The diversity of marine species is largely unknown; the deep sea may rival tropical forests in species diversity. Microbial and insect diversity are other unexplored areas in natural product chemistry (Aylward, 1995:105, in Swanson, see below). Screening results from Shaman Pharmaceuticals revealed that of the samples that displayed promising chemical activity, 74% directly correlated with the original ethnobotanical use – traditional knowledge (Sheldon & Balick, 1995:58-59). Jennie Wood Sheldon & Michael J. Balick (1995) “Ethnobotany and the search for balance between use and conservation”, in
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reward only the one that provided the last piece of a long process of breeding or invention. There are, as yet, no alternative models to IPR laws for protection of traditional knowledge.\footnote{31} The knowledge in its traditional form and the non-systematically bred cultivars hardly fulfil general patent criteria, such as reproducibility, or the UPOV criteria of being “stable, uniform and distinct”. In effect, it is argued that patenting may be incompatible with the CBD policy objective of equitable sharing of benefits.\footnote{32}

\textit{3.2 The conservation and sustainable use aspect}

A related dispute concerns whether intellectual property rights represent a direct threat to genetic diversity. Supporters of intellectual property rights (IPR) argue about the need to introduce high-yielding plant varieties in agriculture and consider the use of plant breeders’ rights and patents to be preconditions for food security. Opponents argue that the precondition for food security lies in the conservation and sustainable use of the huge variety of (non-systematically bred) farmers’ cultivars. They go on to say that the patent and plant breeders’ rights criteria of reproducibility and “uniform, stable and distinct from existing varieties”\footnote{33} may lead to increased use of monocultures, which replace the diverse varieties. Moreover, it has been argued that patenting may work indirectly to reduce the genetic diversity, as patenting is largely an asset of the developed world and a handful of multinational corporations, which dominate the seed industry. Developing countries, where much of that diversity is found on farm, in situ, have few incentives to conserve their genetic heritage (NORD, 1992; Swanson, 1999, Fauchald, 2001).\footnote{34} For wild species, it is speculated whether the effect from IRP systems may indirectly weaken indigenous and local groups in their efforts to achieve bilateral agreements on bioprospecting (Gebhart, 1998).\footnote{35} The acquisition of benefits are dependent on the existence of appropriate policies and institutions in the country providing...
genetic resources, as well as appropriate legislation in the accessing countries (Rosendal, 2000; Fauchald, 2001).

These controversies over access, benefit sharing, and conservation indicate the potential for disruptive effects in the implementation of the two regimes. While concerns for equitable sharing and conservation constitute the core norms and principles debated within the CBD arena, the TRIPs is geared to promote the privatisation of genetic resources through individual rights. The existing system of intellectual property rights and patents does not accommodate non-western systems of knowledge and ownership, such as community or farmers rights. Hence, they can hardly contribute to enhance equitable sharing and, in effect, they provide little incentive for conservation in poor, but gene-rich, countries. We now go on to examine how the two regimes have been responding to this situation.

4. Institutional response to the interaction: Collective bridge-building and tacit ‘arms-races’

In the following we will start by examining whether there were responses at the international output level in terms of explicit changes in the texts in one or both institutions. It is important to keep in mind that both the CBD (1988-1993) and the TRIPs (1988-1994) were long in the making and that during their negotiation phases they represented both sources and targets for each other respectively. Their parallel negotiations were characterised by anticipation of what was taking place in the other forum. Second, we will examine subsequent responses within our two core regimes as well as draw attention to relevant activities in other international regimes. Third, we look into responses associated with the outcome level, which refers to behaviour change in the implementation phase.

4.1 Initial responses at the international output level – the treaty texts

Largely as a response to the general developments in patent legislation, of which the TRIPs negotiations constituted a significant part, the CBD reconfirmed national sovereign rights to genetic resources (§ 15.1) and equitable sharing of benefits from use of those resources (§ 15.7). Access to the resources shall be based on mutually agreed terms and be subject to prior informed consent (15.4 and 15.5). This is to make sure that the providers of genetic resources get their fair share of the benefits derived from their use. Article 15.2 declares that the parties shall facilitate access to the same resources. In the last phases of negotiations, and as a direct response to what was being negotiated in the Uruguay Round (TRIPs), the CBD was equipped with § 16.5. This paragraph says that IPR-systems should “not run counter to the objectives in

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the CBD”. Here, the diverging objectives constituting the two regimes are explicitly referred to.

At the same time, article 16.2 states that the technology transfer process is to be consistent with “the adequate and effective protection of intellectual property rights”. Article 16.2 implies that the CBD is sanctioning IPR, but only on certain conditions (art. 15.4, 15.5, and 16.5).

The principles that were being hammered out within the CBD negotiations did seep into the TRIPs agenda, as well. This was also partly due to the mitigating effect of the European Patent Convention (Art. 53(b)), which allowed for plants and animals to be excluded from patentability. The same compromise found its way into the final agreement on TRIPs:

• On one hand, it grants parties the right to exclude from patentability (Art. 27.3. [a]) diagnostic, therapeutic and surgical methods for the treatment of humans and animals, and (Art. 27.3.[b]) plants and animals other than micro-organisms.37
• On the other hand, it obligates parties to introduce some type of intellectual property rights also for plant varieties. TRIPs requires members to provide for the protection of plant varieties, either by patents or by establishing an effective sui generis system (a legal system of its own kind).

During the co-evolution of these two regimes, they have constituted a target and a source for each other respectively. The discussions on IPR in the GATT Uruguay Round had significant impact on the questions of access and benefit sharing pertaining to genetic resources, as debated within the framework of the CBD. In turn, feedback processes from the CBD negotiation rounds have affected the interpretation of the TRIPs agreement.

Briefly addressing the question of how one regime has been able to unilaterally influence the other, intentionality refers to the institution as a whole – in a word, the ‘collective will’ of the institution. The ability to influence is partly contingent on the respective institutional strength of the two regimes. Regime strength is also largely contingent upon the power and interests of the parties involved. One may ask whether the TRIPs was a strategic move by dominating northern countries, in particular the United States, to counter the objectives in the CBD. One interpretation of the developing countries’ relative success in the CBD could be that the USA stopped worrying about the output of the biodiversity negotiations, being confident that their interests would be secured by the TRIPs regulations in WTO. On the other hand, in the eyes of the USA negotiation team, it was the developing countries that were trying to ‘hollow out’ the TRIPs agreement by using the biodiversity convention (Raustiala, 1997:47).38 In the strict sense of ‘institutional influence’ applied in this project, we may regard the influence between the CBD and TRIPs as anticipated more than intended. The IPR issue forced a certain type of response in the CBD output, while the IPR-opposition had some small success in ‘harnessing’ TRIPs.

The main message is that the effects of the interaction did not greatly hinder the output in any of the two core regimes. Some concessions were made to move the two regimes in a more compatible direction, but the changes in outputs did not resolve the problem of their disruptive objectives. This corroborates the notion that the effects will be more likely to be felt in the implementation phase, rather than at the output level. We now go on to examine the responses that have taken place subsequent to the two outputs.

4.2 Subsequent responses within the core institutions

A remaining controversy is whether TRIPs art. 27.3 (b) really allows Parties to design their own *sui generis* systems\(^{39}\) or if *sui generis* implies the *plant breeder’s rights* system provided by the International Union for the Protection of New Varieties of Plants (UPOV). UPOV was revised in 1991 so as to resemble patent protection on a number of dimensions, most importantly by restricting the former provisions for farmers and breeders. Formerly, protection under the UPOV Convention of 1978 only pertained to the final product, the variety, and not to subsequent varieties bred on the basis of the protected one. Farmers were thus free to use such seeds for next year’s sowing (*farmers’ privilege*) and breeders and scientists could use UPOV-protected material for developing new products (*breeders’ exemption*), without paying royalties.\(^{40}\) As a response to the high level of conflict associated with TRIPs article 27.3(b), plans for its revision have been in the pipeline several times. So far, however, only the deadline for least developing country compliance has been altered. The deadline for compliance was prolonged at the WTO Doha ministerial meeting (November 2001) from 2005 to 2016.

Within the CBD, the Conferences of the Parties (COP) have subsequently put much emphasis on examining the relationship between the CBD objectives and the strengthened IPR systems under the WTO. COP has established a Panel of Experts on access and benefit sharing and an Ad Hoc open-ended Working Group on access and benefit sharing. To assist these bodies, COP5 called for Parties to provide case studies on the impacts of IPR on access and benefit sharing (UNEP/CBD/5/26). The COPs have also made repeated calls for closer inter-institutional collaboration by asking for the CBD Secretariat to be granted observer status in TRIPs meetings. In TRIPs, the US has repeatedly turned down these efforts on the grounds that they do not see the need.\(^{41}\) In 2002, the CBD Ad Hoc Working Group on Access and Benefit Sharing prepared the ‘Bonn Guidelines’, which encourage prior informed consent and mutually agreed terms by making concrete suggestions for how these principles could be included in bilateral bioprospecting agreements. The Bonn Guidelines were adopted at COP6 in Hague (2002).

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\(^{39}\) Proposed alternatives comprise *farmers’ rights, community rights or protection of traditional knowledge*.


\(^{41}\) Jan Borring, Special Advisor to the Norwegian Ministry of Environment, personal communication, April 2002.
The Bonn Guidelines may become legally binding following the recommendations from the World Summit on Sustainable Development (WSSD) in Johannesburg. During the last stretch of the WSSD, an agreement was reached to call for an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. Due to concern for implications regarding both the TRIPs agreement and WIPO, the Group of megadiverse countries argued successfully that they might have to restrict access to genetic resources for researchers, business and private investment unless there are clear rules on benefit sharing. The new regime is to be negotiated within the framework of the CBD and its Bonn Guidelines. Another significant and relevant output of the Earth Summit was the restated claim that WTO rules shall not override global environmental treaties.

In sum, most of the response activity has been in the form of collective decision-making within the CBD.

Wider ramifications – related activities at the international output level
The newly concluded FAO International Treaty on Plant Genetic Resources for food and agriculture (ITPGR, 2001) explicitly prohibits patenting of genetic material, ‘in the public domain’ and ‘in the form received’ from its multilateral system of genebanks. This multilateral system is aimed at solving problems of access to plant genetic resources in agriculture. It aims to ensure that plant genetic resources can be made available for research and plant breeding. The new system will hardly block patenting altogether. Even slight modifications of the germplasm may qualify for patent protection and the isolation and description of any particular gene may still count as an invention.

The access question remains less resolved in the pharmaceutical sector. Here, the name of the game for screening of genetic resources for medicinals is still bilateral agreements and bioprospecting deals. Some efforts at addressing these issues are underway. UNESCO has addressed traditional knowledge and intellectual property by developing model provisions on the protection of folklore. Secondly, UNCTAD runs the Biotrade Initiative, which seeks to assist developing countries to “develop, at the national level, an institutional environment to facilitate trade and investment, in products and services of biological diversity, as a means to attain the objectives of the CBD”. A third example is WIPO, which has studied and collected case studies on the protection of traditional knowledge.

Summing up, the response to the interaction has come in the form of collective decision making rather than any kind of inter-institutional response.

4.3 Responses at the outcome level: Domestic policies

42 Paragraph 42(o) in the Plan of Implementation, UN World Summit on Sustainable Development, Johannesburg, 26 August – 4 September 2002.

43 Paragraph 42(o) in the Plan of Implementation, UN World Summit on Sustainable Development, Johannesburg, 26 August – 4 September 2002.
Most of the developed countries have already complied with the TRIPs obligation of a strengthened patent system. The EU Patent Directive is a case in point, but the obstacles it has had to grapple with, mirrors those between the TRIPs and the CBD themselves. Several newly developed countries have also seen it in their interest to comply to TRIPs, in order to gain market access and investments and avoid trade sanctions (Sell, 2002). So far, the least developing countries have not complied with the TRIPs. Conversely, with regard to the CBD, it is the developing countries that are putting legislation into place, while the developed world is practically without examples of compliance in terms of equitable sharing.

Examples of activities relating to the TRIPs – CBD interaction in the North

Concurrent with the onset of the Uruguay Round, the (then) EC Commission started what would become a 12-year struggle to revise and harmonise the common patent system of the member states: The EU Directive on Patents in Biotechnology. The aim is to bring European patent legislation in line with USA and Japanese standards. During its long pipeline existence (1988-1998), several EU Member States (all of which are CBD Parties), environmental and farmers’ groups, as well as the European Parliament, all sought to bring the Patent Directive more into line with EU obligations under the CBD. The Directive was finally agreed to in 1998, but was immediately challenged. The final text of the Directive does go some way in reflecting the CBD objective of equitable sharing by maintaining in preamble (27) that the patent application should include information on the geographical origin of biological material. The Directive also makes concrete reference (in preamble 55) to the need to follow up the Community obligations under the CBD articles 3, 8(j), 16(2) and 16(5). Nevertheless, the Dutch government in October 1998 tabled a legal motion calling for the annulment of the directive. One of the main Dutch complaints was that a mere reference in the preamble was not sufficient to make the Patent Directive compatible with the CBD objectives. A few months later, Italy and Norway joined the proceedings in support of the Netherlands. The challenge was later dismissed by the EU Court of Justice, ruling that the Directive was not contrary to the CBD. This remains a contested issue; few countries have implemented the Patent Directive, and Belgium and Denmark have made specific amendments in their domestic patent legislation in order to bring them more into line with the CBD objectives.

Then in September 2002 the EU made a turn-around on the issue by tabling a plan to the TRIPs Council. The key proposal of the plan, which is fed into the TRIPs Council’s work on the Doha Development Agenda, is to make disclosures (in a multilateral system) of

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45 http://www.odin.dep.no/ud/publ/1999/bio-patent/patent.html

46 http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en. (Select Opinion at the top, enter “C-377/98” in the Case Number search box and hit the Submit button.)

47 Special advisor to UNEP, Norwegian delegation leader, director and chair of several working groups and scientific panels to CBD, Peter Johan Schei, comments: “But there is indeed a conflict and the EU patent directive is contrary to the intentions of the CBD.” (06.03.2002, Research Council of Norway, Conference on Sustainable Development.)
geographical origin of biological material used in biotechnology inventions. It is meant as an obligation for patent applications, although it is not meant to constitute a formal patentability criterion.\footnote{Communication by the European Communities and their Member States to the TRIPs Council on 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’, European Commission, Directorate-General for Trade, Brussels, 12 September 2002.}

The EU Communication also addresses the need to provide better protection of traditional knowledge and it recognises the right of subsistence farmers in developing countries to re-use and exchange seeds, even if these seeds are covered by intellectual property rights.\footnote{Welcoming the initiative, Trade Commissioner Pascal Lamy commented: “Many complex eco-systems could be mines of ‘green gold’ – medicines, new crop varieties and other benefits for the entire world. It’s only fair that the countries with such resources benefit from their exploitation”. http://europa.eu.int/comm/trade/miti/intell/pr170902.htm}

Drawing in the opposite direction are the so called “TRIPs plus” agreements.\footnote{See Graham Dutfield, “Biotechnology and Patents: What are developing countries doing about article 27.3(b)?”, Bridges, Post-Doha Ministerial Issue, 2001, Vol. 5, No. 9.} These are bilateral trade agreements primarily between the USA or EU and a developing country, which include requirements for higher patent standards than what the TRIPs demands.\footnote{See e.g. the Economist, 23. June 2001, p. 26.}

For instance, the trade agreements between the European Community and its Member States (EC/MS) and South Africa, as well as that between EC/MS and Mexico, assert that the Parties “shall ensure adequate and effective protection of IPR in conformity with the highest international standards”.\footnote{http://europa.eu.int/comm/trade/bilateral/mercosur/pr240702_en.htm OJ, L 31, 04/12/1999 p. 0003-02397 and OJ, L 276 28102000.}

The agreements ensure implementation in advance of the timetable set up in TRIPs.

There are also some examples of TRIPs implementation in the South. The Philippines’ Plant Variety Protection Act of 2002 is built on UPOV 1991.\footnote{http://www.gov.ph/news/default.asp?newsid=1471} This decision is controversial. A joint statement from Philippine farmers’ groups, indigenous peoples’ organisations, scientists and NGOs, reads; “For the past decade, the Philippines like many developing countries has been under tremendous pressure from industrialized countries and the global seed industry to allow for IPR on plant varieties in order to comply with the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO); among them, the need to provide Intellectual Property Rights (IPR) over plant varieties.”

\textit{Examples of activities relating to the CBD – TRIPs interaction in the South}

A number of developing countries are engaged in establishing some type of access legislation to control and share in the benefits derived from their genetic resources.\footnote{See http://www.grain.org/brl/index-en.cfm} Let us take a brief look at some examples:

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48 Communication by the European Communities and their Member States to the TRIPs Council on 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’, European Commission, Directorate-General for Trade, Brussels, 12 September 2002.

49 Welcoming the initiative, Trade Commissioner Pascal Lamy commented: “Many complex eco-systems could be mines of ‘green gold’ – medicines, new crop varieties and other benefits for the entire world. It’s only fair that the countries with such resources benefit from their exploitation”. http://europa.eu.int/comm/trade/miti/intell/pr170902.htm


54 See http://www.grain.org/brl/index-en.cfm
The ANDEAN IPR-regime (1996) constitutes the first time that a group of developing countries has set up a new intellectual property regime, which, while in the name of TRIPS, directly incorporates elements from the Convention on Biological Diversity. The new regime holds that TRIPs’ Article 27.3(b) should be amended in order to include the possibility that Members may require as conditions for patentability: (a) the identification of the source of the genetic material; (b) the related traditional knowledge used to obtain that material; (c) evidence of fair and equitable benefit sharing; and (d) evidence of prior informed consent from the Government or the traditional community for the exploitation of the subject matter of the patent.\(^5\)

The OAU Model Law represents an African alliance against TRIPs.\(^6\) It requires a permit and the prior informed consent of communities; payment of collecting fee; sharing of benefits from commercial products; community rights to control access to resources and knowledge, and partake of 50% of any benefits handed to the government under the access regime. Other examples include the Philippines Executive Order 247 and the Costa Rica Biodiversity Law. Currently, close to one hundred countries, mostly developing, are in the process of making legislation and institutional arrangements to control access to genetic resources and to handle bioprospecting deals.

Summing up, we have seen a broad spectre of activities relating to the interaction between the CBD and TRIPs. The next section will discuss how these activities may contribute to enhance or block synergies in the issue area with a view to implementation.

5. **Are the policy responses adequate to reduce or avoid disruptive effects?**

In section three we discussed the effects of the interaction. Section four dealt with the responses to these effects at the output level of the regimes and subsequent responses within international regimes, as well as responses at the outcome level in terms of domestic adaptation. In this section we discuss the adequacy of these responses, first with a view to the current institutional relationship between the two regimes and secondly with a view to how the interaction may affect implementation.

5.1 **The adequacy of institutional responses**

The responses that took place during the establishment of the CBD and TRIPs can be seen as a compromise or a stalemate at the level of international outputs. The situation was hardly resolved, as the basic objectives of the two regimes remain different. Subsequently, there have been several indications that the potential conflict is taken seriously. A number of

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\(^5\) Review of Article 27.3(b) - Communication from Brazil, Permanent Mission of Brazil, Geneva, WTO document IP/C/W/228, 24 November 2000.

\(^6\) The OAU Model Law on Rights of Local Communities, Farmers, Breeders, and Access; 2000. In addition, Bangladesh, Bolivia, Brazil, India, Peru and the Philippines also have legislation on access and benefit sharing.
regulatory obstacles to achieving mutual support between the two regimes remain, however. COP3 pointed out that national measures to promote technology transfer under CBD Article 16 might raise WTO *most-favoured nation* issues if Convention Parties and non-Parties were treated differently.\(^{57}\) It might also raise TRIPs issues if owners of proprietary technology were compelled to license technologies on grounds other than those prescribed in the TRIPs Agreement. Moreover, even though the conflicts are explicitly admitted and attended to, implementation of the CBD objectives may be hampered by the stronger regulatory force of the TRIPs:

- First, there is a consistent barrier to inter-institutional co-operation. The CBD has still not been granted observer status in TRIPs due to opposition from the USA.\(^{58}\) This is in spite of repeated efforts by the Executive Secretary of the CBD, on the call of several COPs, to achieve such status.
- Second, patenting in the biotechnology sector is a contested, though relatively small part of a larger issue area concerning international trade and patenting in all sectors. The driving forces in this much wider issue area are powerful and gaining in strength.
- Third, if WTO members refuse to sign up to TRIPs, they become liable to economic sanctions. The dispute settlement mechanism of the WTO rates among the strongest of such international instruments. This makes the WTO a more powerful instrument than the CBD, which carries no economic sanction mechanisms.
- Fourth, the WTO is a stronger institution in terms of its compliance mechanism, incorporating different sets of *timetables* for countries to harmonise their patent legislation.

Efforts towards inter-institutional co-operation have been repeatedly stopped. The WTO/TRIPs is stronger in terms of compliance mechanisms and in being controlled by the more powerful states. In effect, the interaction between the two international regimes may represent a potentially serious challenge for the operation of what may appear the weaker one, the CBD. On the other hand, there is ample evidence that the issue of the two regimes’ diverging objectives is recognised in the WTO and the CBD alike. More important, the external responses indicate a growing legitimacy of the CBD objectives:

### 5.2 Adaptation at the domestic level – increasing the conflict level

The interaction has spurred a great deal of response in terms of domestic access legislation. Several countries are adding as preconditions for granting a patent: the identification of source of genetic material and traditional knowledge used, evidence of fair and equitable sharing, and prior informed consent. TRIPs article 27.1 lists the prevalent patent criteria of novelty, inventive step, industrial application, and reproducibility. Any disclosure measures will come as additional requirements. It is not clear whether TRIPs may exclude Members

\(^{57}\) *Most-favoured nation* is a basic principle of the GATT/WTO regime, saying that any trade advantages conferred by one country to another must be given all GATT parties.

\(^{58}\) *Bridges* 3/7-2001:4.
from including such other requirements or if such activity would be incompatible with TRIPs. If such legislation were to be brought to the dispute settlement body of the WTO, it would have to address the WTOs competence to rule on domestic legislation passed to implement another international instrument – the CBD. 

So far, there has been no legal testing of the two regimes.

The proliferation of access legislation in the South has also brought up questions about the effects on conservation and innovation. Some argue that the emerging legal regimes to regulate access to genetic resources in the South are based on unrealistic expectations of benefits, and that they can hinder both bioprospecting and biodiversity conservation (Grajal, 1999). This is a growing concern, although the argument itself seems to build on an inherent contradiction. On one hand, it is argued that large-scale agribusiness and the pharmaceutical industries are virtually self-sufficient in genetic resources for their innovations. At the same time, complaints are increasingly being raised by the same sectors that the rapidly spreading access restrictions in the South constitute serious barriers to scientific conservation work as well as technological innovations.

Roughly speaking, there were initially two opinions about the relationship between the CBD and TRIPs. Some developed countries, including the USA, perceived no conflict between the two, while some developing countries viewed the two as essentially incompatible. While these rather extreme views still persist, an increasing number of developed and developing countries now acknowledge that the two regimes are likely to conflict in the implementation phase. They agree on the need to modify art. 27.3(b) of TRIPs (Cannabrava, 2001). In the meantime, the increasingly cumbersome access regulations in the South and the ‘TRIPs +’ deals established by the North can be seen as parts of an ‘arms race’, which is currently escalating. On the other hand, there are now several activities within the EU designed to increase mutual trust among the parties involved in transactions with genetic resources. These activities may indicate that the legitimacy of the CBD objectives on benefit sharing is gaining ground.

6. Concluding remarks

The case reviewed in this study involves fairly novel regimes; both the CBD and TRIPs are less than ten years into their implementation phase. This may have implications for the conclusions drawn, or rather the inconclusive nature of the indications so far. A significant trait is the overlapping membership in these global institutions, which operate in different


policy fields, but seek to regulate the same natural resource (genetic resources). The interaction is rooted in different objectives and is arguably leading to disruptive effects with regard to conservation of, access to, and equitable sharing of benefits from genetic resources. The nature of influence is arguably unintentional, but clearly anticipated. Within both arenas, the parties acknowledge that there are interactions involved. Most of the interaction has been handled through collective decision-making within each institution. At all stages, a great deal of interaction and responses has taken place by way of adaptation at the domestic level. In light of this, the continued refusal of TRIPs to allow the CBD secretariat observer status would seem to be counter-productive with a view to reaching adequate responses between the two. It would seem that more synergy could be achieved by opening up for greater inter-institutional co-ordination.

The interaction approach highlights how processes in other international fora may prompt issue linking. The CBD agenda and the issue linking taking place in the biodiversity negotiations greatly reflected the developments in the GATT Uruguay Round. This was seen most particularly in the early decision to include the issue of property rights to genetic resources, which established the link to domesticated biological resources and emphasised the need for equitable sharing of benefits. In contrast, in the early phases, the biodiversity issue was rather a by-line to the more general orientations of the trade organisation. Lately, however, the biodiversity issue enters the WTO equation in relation to access to raw material and technological innovation. The pressure to include links to these dimensions within the TRIPs agenda has been steadily growing.

This brings us to the question of whether the interaction between the CBD and TRIPs gives cause for worry. Prior to the CBD COP6, Klaus Toepfer, head of UNEP, stated “The interrelation between the WTO and CBD is extremely high on the (COP6) agenda.” He went on to say: “We don’t want to wait until we have conflicting cases. We want to do whatever is possible to solve the interrelations between them”.62 Seen in light of the inequality between subsistence farmers and transnational corporations, and the added strength provided by the patent system for the latter party, the situation is clearly problematic. The various responses to the interaction between the two regimes may to some extent be viewed as an ‘arms race’. Strengthened measures within one arena have in turn led to heavier ‘weapons’ being applied by the other, such as the ‘TRIPs +’ agreements, the strengthened EU Patent Directive, and the increasingly cumbersome access regulations emerging in many developing countries. The new FAO Treaty on plant genetic resources and the CBD Bonn Guidelines may turn out to have mitigating effects in this regard. Other constructive activities include the Danish and Belgian amendments to include disclosure of prior informed consent and mutually agreed terms in their patent legislation and the recent EU plan to make disclosure of origin of genetic material an obligation.

Finally, the examination of activities suggests that the quest for enhanced synergies is hard to separate from a debate of values when such different objectives clash. Policy measures may involve increased synergies in terms of facilitating technological innovation,

in terms of improving conservation, or in terms of enhancing international equity. Any one measure will hardly be able to achieve a top score on all dimensions, but there is clearly a need to increase bridge building and restore mutual trust in this issue area. The EU plan to the TRIPs Council constitutes one among the first few steps towards synergy. The question of how regimes develop legitimacy is crucial for future transactions with genetic material.
Table 4. The two main sectors within biotechnology and the role of genetic resources

<table>
<thead>
<tr>
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<th>Agriculture (plants)</th>
<th>Pharmaceuticals/medicine</th>
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<tbody>
<tr>
<td><strong>Regimes interacting with CBD</strong></td>
<td>FAO Treaty on pgrfa, CGIAR, IPGRI, WIPO, TRIPs, EU patent directive</td>
<td>TRIPs, WIPO, EU patent directive a.o.</td>
</tr>
<tr>
<td><strong>Resources in focus</strong></td>
<td>Plant genetic resources for food and agriculture: breeders’ lines, landraces, wild relatives, seeds and germplasm</td>
<td>All types of genetic material: gene sequences, micro-organisms, medicinal plants</td>
</tr>
<tr>
<td><strong>Basis for main controversy with regard to intellectual property rights (IPR) to genetic resources</strong></td>
<td>Farmers’ rights: farmers have played a central role in conserving, developing and distributing agrobiodiversity across the globe. Most products of biotechnology tend to consist of elite lines of plant varieties with biotechnology element constituting an ‘added extra’. The contributions of farmers fall outside the scope of IPR – it is hard to identify and confer rights to the historic contributions of farmers.</td>
<td>Traditional knowledge of medicinal traits in plants. Modern biotechnology has a role in isolating specific traits, the chemical elements, which may be reproduced in vitro. The contributions from traditional and local knowledge fall outside the scope of IPR – it is hard to identify and confer rights to those who have knowledge about the traits.</td>
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<tr>
<td><strong>Main avenue of access for users of genetic resources</strong></td>
<td>Through international genebanks or private seed collections. Broad screening of genetic resources in situ.</td>
<td>Bioprospecting deals, access through traditional knowledge, or broad screening of genetic resources in situ.</td>
</tr>
<tr>
<td><strong>Main complaints by those providing genetic resources</strong></td>
<td>Lack of fair compensation. Costly/reduced access to patented material (breeders’ lines, high yielding varieties)</td>
<td>Lack of fair compensation. Costly/reduced access to patented material (medicines and vaccines)</td>
</tr>
<tr>
<td><strong>The role and value of genetic resources</strong></td>
<td>The diversity of traditional varieties is crucial for food security and continued breeding in industrial agriculture. All countries depend largely on pgrfa that originate elsewhere. Loss of diversity and knowledge may result in reduced food safety.</td>
<td>Low volume, high value. Both the knowledge and the biodiversity are of fundamental importance for continued development in pharmaceutical sector. Loss of biodiversity and knowledge may result in loss of vital new medicines.</td>
</tr>
<tr>
<td><strong>Main actors and stakeholders in transactions with genetic resources</strong></td>
<td>States (state sovereignty, new legislation). Farmers (small-scale, developing countries). Genebanks (private, national and international). TNCs (Monsanto, DuPont/Pioneer, Rhone Poulenc/Limagrain, Syngenta).</td>
<td>States (state sovereignty, new legislation). Traditional healers and shamans, indigenous people. TNCs (Monsanto, DuPont/Pioneer, Novartis, Rhone Poulenc/Limagrain, Zeneca/ Cosun).</td>
</tr>
<tr>
<td><strong>Identification and location of the resource</strong></td>
<td>Specific useful traits for developing new varieties may be found ‘all over the place’, not only in genebanks and farmers fields – hence, it is hard to obtain a monopoly on traits. The product can be living biological material – such as a plant variety.</td>
<td>These ‘products’ have not been subject to much breeding or domestication. ‘Relatives’ may be found ‘all over the place’ – hence, it is hard to obtain a monopoly on a medicinal trait. The product is often non-living biological material – a pharmaceutical product.</td>
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