The campaign against "biopiracy": introducing a disclosure of origin requirement

The Issue

Developing countries rich in biodiversity, local communities and indigenous peoples, have been long struggling to establish ownership and maintain sovereign control over their genetic resources and traditional knowledge to protect them from misappropriation and unfair exploitation, particularly by foreign biotechnology-based industries. These developing countries consider that the current intellectual property system does not serve their interests in this respect, and thus call for changes both within and outside the intellectual property system.

A number of environmental and sustainable development NGOs have been supportive of the efforts of developing countries in multiple processes at the international level. NGOs have been long concerned with the adverse effects of biotechnology on health and the environment. Given that many new biotechnology products and processes are now protected by intellectual property rights, they have further concerns that access to the genetic resources may be facilitated for users without the consent and sharing of benefits with the providers, mainly in developing countries. Moreover, NGOs have effectively raised public awareness and sparked concern at the national and international level on the inequity in the access and use of genetic resources and traditional knowledge, in particular through their direct involvement and role in highlighting cases of alleged misappropriation, also known as "biopiracy".[1]

In this regard, NGOs have been closely involved in the growing discussion about the relationship between intellectual property rules, genetic resources and the protection of traditional knowledge. The main issue of controversy is the extent to which intellectual property systems are seen to be incompatible with objectives related to the conservation and sustainable use of genetic resources and protection of traditional knowledge. Developing countries and NGOs have historically been in favour of keeping genetic material and innovations based on it in the public domain or providing protection for these innovations through a *sui generis* system that differs from traditional forms of intellectual property rights.

This is because the intellectual property right system in relation to genetic resources and traditional knowledge, particularly in the framework of the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), that came into force in 1995 and is seen as largely favouring the interests of developed countries that generally seek access to genetic resources and associated traditional knowledge that lies mainly in developing countries. Thus, a large part of the debate has focused on ensuring a proper balance between intellectual property systems and other instruments to regulate access and benefit sharing at the international level.

One of the main issues of contention that has received wide attention from governments and NGOs is whether there is any conflict between the principles concerning access to genetic resources and benefit sharing enshrined in the Convention on Biological Diversity (CBD),[2] concluded in Rio de Janeiro in 1992, and the TRIPS Agreement. Developing countries and many environmental and sustainable development NGOs believe that there is a conflict between the CBD and TRIPS, and accordingly, consider that in order for TRIPS to be reconciled with the CBD, the TRIPS Agreement must be amended.

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The objectives of the CBD are the conservation of biodiversity, sustainable use of its components and the equitable sharing of the benefits derived from access to and use of genetic resources. The CBD reaffirmed that countries have the sovereign right to determine how and under what conditions their genetic resources may be accessed and used and calls for the equitable sharing of benefits arising out of the utilisation of genetic resources. It also established that access and use of genetic resources between the provider and user of such resources should be based on prior and informed consent (PIC) and mutually-agreed terms.[3] Furthermore, the CBD requires members to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities and encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.[4] The CBD also seeks to facilitate access to technologies developed through the use of genetic resources, an important objective for developing countries that may be interested in developing their own biotechnology-based industries.

Voluntary guidelines (Bonn Guidelines) have also been developed in the CBD context to help members implement the provisions of the CBD related to access and benefit sharing, particularly to establish legislative,

administrative or policy measures on access and benefit sharing or when negotiating contractual arrangements for this purpose.[5] However, there are several difficulties in implementing the CBD objectives. One problem identified by NGOs and developing countries is that the CBD has ambiguous wording and lacks credible enforcement mechanisms for its provisions. The Bonn Guidelines, being voluntary, also provide little guidance on how enforcement mechanisms and measures might be structured.[6] Moreover, until recently, few countries have had national legislation on bio prospecting and access to genetic resources and traditional knowledge and the sharing of benefits derived from their use.[7]

The TRIPS Agreement on the other hand, established minimum international standards of the protection and enforcement of intellectual property rights. It is the first international treaty that makes it possible to patent life forms, by establishing that governments can exclude plants and animals from patentability, but not microorganisms or non-biological and micro-biological processes.[8] Moreover, plant varieties must be protected under some kind of intellectual property right; either patents or a sui generis system. Given that developing countries only agreed to these conditions as a compromise during the TRIPS negotiations, it was established that these provisions would be subject to review, among other things, to ensure that the TRIPS Agreement and the CBD are supportive of each other.

The relationship between the TRIPS Agreement and the CBD is currently being discussed as an “outstanding implementation issue” under the Doha Round work programme, set up at the WTO Ministerial at Doha in 2001, expected to conclude in 2006.[9] In the context of ensuring that the CBD and TRIPS are mutually supportive, one of the proposals that has been made by many developing countries and supported by NGOs is for countries to adopt international disclosure of origin requirements that would require patent applicants to disclose the origin of the genetic material and traditional knowledge used in the invention, and show evidence that the provider gave prior informed consent and received a share of the benefits.

The campaign for disclosure of origin

The initial awareness-raising on the importance of establishing international rules to prevent the misuse of genetic resources and traditional knowledge was undertaken by environmental and sustainable development NGOs as far back as the 1970s. NGOs pointed to multiple cases of so-called “biopiracy” or grant of invalid patents over inventions based on genetic material and/or traditional knowledge, and highlighted concerns about the unequal exploitation of such resources.

Moreover, over the years governments and NGOs have put forth a number of initiatives to conserve and regulate the use of and access to genetic resources, as well as the sharing of benefits derived from their use. Some initiatives have clashed with other efforts to protect new biotechnological products and processes for intellectual property rights. For example, NGOs such as the Action Group on Erosion, Technology and Concentration (ETC Group), know formerly as RAFI,[10] and GRAIN[11] were very involved in laying out the framework for what would be the first international commitments to conserve genetic resources and ensure their benefits to all, embodied in the 1981 International Undertaking on Plant Genetic Resources for Food and Agriculture (IU) under the Food and Agriculture Organisation of the United Nations (FAO). The IU was meant to be a legally-binding convention that would counteract the privatisation of genetic resources by establishing their status as the "common heritage of mankind", at the time when the system of plant breeders rights (PBRs), a form of intellectual property protection on plants, was expanding under the Union for the Protection of Plant Varieties (UPOV).[12]

The Rio Declaration on Environment and Development and the subsequent adoption of the CBD in 1992 were the formal turning points of NGO participation on issues related to biodiversity conservation, including genetic resources. For example, before the UN Conference on Environment and Development in Rio de Janeiro in 1992 (Rio Conference), civil society held an important event that brought a wide range of civil society organisations and networks from Latin America, Africa, Europe and Asia together to think about the issues. The Gene Traders Conference in London on 14 April 1992 was organised by the NGO the Intermediate Technology Development Group (ITDG), now known as Public Action.[13]

The conference was convened in response to concerns over the decrease in worldwide biodiversity, to examine the threat to food security and develop strategies for NGOs to contribute to solutions.[14] The discussion focused on seeds and biotechnology, and broadly the effect of changes in technology and the application of intellectual property on seed and biodiversity conservation and food security. This helped to build a common framework for the NGOs to further work on genetic conservation in multiple fora, particularly in the context of the Food and Agriculture Organisation (FAO). NGOs that had engaged in these issues since the 1970s to early 1980s such as the ETC Group, GRAIN, and ITDG played important roles in the lengthy negotiation process over a twenty year period that culminated in the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture, also known as the Seed Treaty, concluded in November 2001, which came into force in June 2004. While the treaty was seen as an important step in the debate on conservation, sharing and use of genetic resources, the Seed Treaty outcome was not well received by all NGO groups.[15]

One of the reasons for the discontent is that since the early 1990s the focus of the international debate on genetic resources, traditional knowledge and intellectual property has shifted towards reaping commercial benefits that can be derived from the use of such resources, rather than their conservation. In this regard, the ideals embodied in the IU regarding the view that conservation of genetic resources as common heritage of mankind were overruled by the new CBD principles that established that countries are sovereign over their genetic resources, and thus they can freely decide how to conserve or use such resources for commercial benefit, including whether to provide patents for genetic material or not as an incentive for bio-prospecting research, and provided a framework for access based on the sharing of benefits derived from such use.

NGOs have also been involved in the debate on the pending TRIPS review of Article 27.3(b) in the context of the WTO Council for TRIPS, particularly concerning proposals by developing countries for an amendment to the TRIPS Agreement that would necessitate disclosure requirements in patent applications. Those that have been actively supporting the adoption of the disclosure requirement and helping to present different options to what the disclosure requirement might look like include Action Aid, the International Centre for Trade and Sustainable Development (ICTSD), the International Union for the Conservation of Nature (IUCN), Greenpeace, the Berne Declaration and the Centre for International Environmental Law (CIEL). The Quakers United Nations Office in Geneva (QUNO) has also played an important role in facilitating dialogue between the different parties involved and helping build common positions among developing countries on disclosure requirements.[16]

However, there is divergence of opinions among developed and developing countries, as well as environmental and sustainable development NGOs themselves, as to the desirability, efficacy, form and feasibility of the disclosure mechanism, and whether they would serve to promote the objectives of the CBD.[17] For example, the United States strongly opposes the introduction of disclosure requirements in patent applications, whether mandatory or voluntary, arguing instead for a contractual arrangements to regulate access and use of genetic resources and traditional knowledge and to establish arrangements to determine benefit sharing and prior informed consent. Moreover, some NGOs that have traditionally focused on the conservation objectives prefer alternative solutions that do not presuppose the possibility of patenting life forms, including genetic resources, and have suggested amending TRIPS to ban patents on life forms.

While the specific elements of the disclosure requirement are still being developed, and there is recognition that this is but one tool to prevent make TRIPS compatible with the CBD goals, developing countries and supportive NGOs are of the view that the obligation would serve the purpose of ensuring that patent applicants for inventions based on genetic resources or traditional knowledge to give due recognition to the source of origin and where appropriate, provide adequate compensation to the holder. In this sense, a disclosure requirement would seek to act as a transparency measure to allow biodiversity rich countries and local communities to monitor and control the use and sharing of benefits of genetic resources and traditional knowledge for inventions, new technologies and commercial products. A fundamental aspect of the proposals from developing countries is the inclusion of the disclosure requirement as an amendment to the TRIPS Agreement in order to ensure that countries would need to pass national legislation amending patent laws to include the obligation, and that such obligation would be mandatory under TRIPS, and hence legally enforceable.

Successes and lessons learned

In the ongoing debate on the relationship between genetic resources, traditional knowledge and intellectual property, in particular the need for disclosure of origin requirements in patent applications in the multiple for a dealing with these issues, there is evidence of progress for developing countries, and of important support provided to developing countries by NGOs in the process. Developing countries, who usually are not demandeurs in the negotiations related to intellectual property, have been able to construct a detailed proposal to pursue their interests related to the equitable use and sharing of benefits derived from inventions, products and processes based on their genetic resources and/or traditional knowledge. The disclosure of origin requirement is a defence mechanism aimed at asserting their offensive interest in the area which developing countries have managed to carry forward, with support from NGOs, during over 10 years of discussions and negotiations in multiple international fora.

Through their advocacy and campaigning activities, NGOs have been able to increase the public awareness of the importance and validity of the demands of developing countries related to the conservation, use and sharing of benefits derived from genetic resources and traditional knowledge. This has been significant in ensuring that these issues are maintained and prioritised in the agenda of the WTO, WIPO, FAO and CBD. They have also been instrumental in helping developing countries resist pressure from developed countries and bio-prospecting companies to give increased access to their biodiversity without proper arrangements regarding access and benefit sharing and prior and informed consent. At the same time, NGOs have been able to provide both developed and

developing country governments and negotiators with important sources of information concerning the extent of the problem, and have been pro-actively suggesting different alternative solutions. Moreover, NGOs have helped to maintain the coherence and increase the understanding among the different interrelated discussions taking place in the different international fora.

Some of the difficulties that NGOs have encountered in the process include the complexity of building expertise and understanding the very technical issues related to issues such as disclosure requirements in patent applications and the interrelationship between the patent system, the TRIPS Agreement and the principles and goals enshrined in the CBD. Moreover, it has been difficult for some NGOs who are more sceptical of the role of biotechnology related to biodiversity conservation and sustainability of agriculture and food systems, to understand that developing countries may wish to promote the application of new technologies in these areas for their commercial benefit.

There are also several lessons that derive from this case. Clearly, NGOs can continue to support the pro-active efforts of developing countries to reassert their legitimate interests related to biodiversity and agriculture. The fact that there are diversity of views and proposed solutions among NGOs to the problems related to the equitable access and use of genetic resources and traditional knowledge in inventions, products and processes has not been a handicap of the NGO contribution to the process, but rather has served to enrich the debate and the discussions.

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[1] Among the several reasons why a patent over a bio-invention may constitute a case of bio-piracy, are: 1) the patent examiner was not aware of the existence of the prior art or that it is already in the public domain, the parties involved had not authorised the holder to obtain a patent for the invention, the invention is not novel or inventive, or the proper arrangements for sharing the benefits of its commercialization or showing evidence of prior and informed consent have not been established.

[2] 188 countries are party to the Convention on Biological Diversity. The United States of America has not ratified the Convention.

[3] See Art 15 of the Convention on Biological Diversity.

[4] See Art 8(j) of the Convention on Biological Diversity.

[5] The Bonn Guidelines were developed at the Sixth Conference of the Parties of the CBD in May 2002.

[6] See M.J. Oliva and A. Perrault, "Prior Informed Consent and Access to Genetic Resources", Center for International Environmental Law, in *Disclosure Requirements: Ensuring the Mutual Supportiveness between the WTO TRIPS Agreement and the CBD,* IUCN, ICTSD, CIEL, IDDRI, QUNO, 2005, p.19.

[7] See Jayashree Watal, "Intellectual Property and Biotechnology: Trade Interests of Developing Countries", in R. Melendez-Ortiz and V. Sanchez (eds), *Trading in Genes*, Earthscan, 2005.

[8] See Article 27.3(b), the Agreement on Trade-Related Aspects of Intellectual Property Rights.

[9] See WTO document JOB(01)/Rev.1, October 2001.

[10] See www.etcgroup.com

[11] See www.grain.org

[12] See GRAIN, "International Undertaking on Plant Genetic Resources: The Final Stretch", October 2001, http://www.grain.org/briefings/?id=154.

[13] See http://www.practicalaction.org/

[14] See Koos Neefjes, The gene traders: security or profit in food production? : Proceedings of an International Conference "The Gene Traders: Security or Profit in Food Production?" 1992: London); Intermediate Technology Development Group; New Economics Foundation (1992).

[15] See for example "A Disappointing Compromise", Seedling Editorial, GRAIN, at http://www.grain.org/seedling/?id=174.

[16] QUNO also led the way in thinking about possible options for the review of Article 27.3(b). See G. Tansey, "Trade, Intellectual Property, Food & Biodiversity. Key Issues & Options for the 1999 review of Article 27.3(b) of the TRIPS Agreement", Discussion Paper No. 1, February 1999.

[17] For further discussion of the different positions, see for example *Disclosure Requirements: Ensuring the Mutual Supportiveness between the WTO TRIPS Agreement and the CBD,* IUCN, ICTSD, CIEL, IDDRI, QUNO, 2005.