## Journal of Peace Studies, Vol. 12, Issue 3, July-September, 2005

## **Biopiracy: Emerging Concerns of the Developing Countries**

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The issue of biopiracy has come into vogue recently but it is a mere extension of the debates that have divided the North and the South for decades. The concern of some developing countries about biopiracy surfaced around the same time when the world, particularly the developed countries, were raising a hue and cry about the dwindling rainforests along with their biological diversity.

Biological diversity is the variability among living organisms from all sources and includes diversity within species, between species and of ecosystems. Biodiversity is of extreme importance in the ecological, biological and cultural sense. When in the 1980s the unprecedented loss of biodiversity was noticed globally, many of the developing countries were also waking up to the fact that pharmaceutical, food and biotechnology companies from the developed countries were making huge profits from products developed from their plant genetic resources and were using their traditional knowledge associated with the various uses of the genetic materials, without acknowledgement and compensation. The age of biopiracy had already begun.

#### **Defining Biopiracy**

Biopiracy, in its present form, is an offshoot of the international intellectual property rights (IPR) regime. Biopiracy involves the unauthorised and uncompensated extraction of biological resources and associated traditional knowledge by Northern based biotechnology companies, seed companies, pharmaceutical corporations and Research and Development (R&D) establishments through the process of bioprospecting. Bioprospecting is the exploration, extraction and screening of biodiversity and indigenous knowledge for commercially valuable genetic biochemical resources.[1]

These genetic materials then undergo rapid and precise screening procedures that allow for the isolation of chemicals displaying a specifically targeted activity, be it of medicinal or agricultural value. In most instances, the traditional knowledge about the various uses of the genetic resources are also procured and based on such knowledge, the researchers produce profitable and patentable products with little innovation of their own. A patent allowing transnational corporations (TNCs) and R& D establishments to deprive the poor in the developing world from using their own biodiversity and knowledge to meet their needs for food and medicine is called biopiracy.[2]

The international IPR regime not only legalises such piracy but also effectively negates all the contrib-utions of indigenous cultures in developing the knowledge about the uses of biological resources and in nurturing the valuable plant genetic resources over the centuries. On the contrary, the IPR regime creates an order in which the original innovators, i.e. the indigenous people of stealing what they themselves had originally innovated and have been using for generations.[3]

### **Biopiracy and Bioprospecting**

Many in the developed world claim that biopiracy is an emotionally loaded accusation against bioprospecting. While it is true that ideally patenting of a product do not technically stop the traditional use of biological material, the current practice proves otherwise. In many instances of patenting, such as on neem and turmeric, there is hardly any difference between the patented process and product and the traditional use of neem and turmeric, thereby making the indigenous communities vulnerable to legal action for practicing their own traditional knowledge. The patent holder enjoys all rights to produce and profit from the same traditionally used biological resources, whereas the traditional knowledge systems are not protected by any IPR system.

It may be acknowledged that bioprospecting does not necessarily involve the use of traditional knowledge, but it is also clear that valuable commercial compounds derived from plants, animals and micro-organisms are more easily identified and are of greater commercial value when collected with the help of traditional knowledge and/or are found in territories traditionally inhabited by indigenous people.

Many developing countries are concerned about the current bioprospecting activities because the international legal and policy environment do not adequately ensure prior informed consent and equitable benefit sharing. Though bilateral bioprospecting agreements are sanctioned by the Convention on Biological Diversity (CBD), in vast number of cases, commercial bioprospecting agreements can't be effectively monitored and enforced by the provider communities and countries or by the CBD. Under these circumstances, many developing countries apprehend that bioprospecting is nothing more than legalised biopiracy.

Most of the biotechnology hub countries whose profits burgeon with on the supply of genetic resources from the tropical countries find it convenient to propagate the ideal nature of bioprospecting. It is their most effective key to the biological riches of the South. What most developing countries are opposed to is that while access is ensured in the bioprospecting contracts, very often benefit sharing is not equitable.

Many developing countries find the unregulated bioprospecting agreements as inherently inequi-table due to the dispropor-tionate negotiating strengths of the TNCs and their potential for misappro-priating and monopolising biolog-ical resources and traditional knowledge through the utilisation of IPR regimes. There are certain circumstances which substantiate these fears. In the first place, there is no international legal mechanism for rewarding the indigenous people on an equitable basis for safe keeping biodiversity. There are international mechanisms on the other hand to promote bioprospecting without laying down specific terms and conditions for benefit sharing. The CBD itself promotes such bilateral agreements but fails to provide a strong plan of action for sharing benefits with the local communities. Bioprospecting at its present form facilitates the flow of biological materials from the tropical countries to the North and further in their patenting. International regulation is a prerequisite to check the misuse of bioprospecting.

### The TRIPS Agreement and Biopiracy

By extending IPRs to biodiversity based products as well as life forms, the TRIPS Agreement has pushed biodiversity related traditional knowledge systems to destabilisation. It facilitates monopoly control of biodiversity related products which are otherwise in the public domain (Article 27 of TRIPS). This particularly affects the rural poor and the indigenous communities who depend on biodiversity for day-to-day survival. Biopiracy therefore commits a double theft. First it steals genetic material and traditional knowledge from their owners and secondly, through monopolisation of the same, robs the dependants of their means of subsistence. The TRIPS Agreement overlooks the contribution of traditional knowledge systems in developing and modifying valuable genetic resources and which are now being used as filter by TNCs and R&D establishments. A patent claim on products developed with minor modifications of the traditional process is cleared as an innovation, failing to acknowledge its 'prior use' traditionally.

The TRIPS Agreement has put all member countries under tremendous pressure to establish the patenting of life forms namely, microbes, genes, crops, livestock and even human cells. The real push behind this pressure is generated by the mega TNCs who want patent rights on these items to increase their profits from the global sales of food, drug and technology. Their stake mainly lies on the new markets and legal control over the basic technologies and resources of global food and health care systems.

The TRIPS Agreement has made it mandatory that patents given in one member country of the World Trade Organisation (WTO) will have to be recognised by all other member countries; so there is not much option left for farmers. The patent regime while assisting the seed companies to usurp global markets, hits at the root of sustainable agriculture that is crucial to 70% of the world's farmers who are in the developing

countries.[4] The monopolisation of seeds in the name of patenting 'invented' plant varieties alienates the farmers from their own seeds. On the other hand the crop varieties improved and developed by traditional farmers to the international seed industry is estimated to be US%15 billion annually.<sup>5</sup> There is therefore a strong ethical and economic cause to fight for the 'stolen harvest' of the farmers.

Patenting on life forms has been widely practised in the developed world since the mid 1980s. In 1987, US Patents and Trademarks Office (USPTO) had extended patenting to all altered or engineered animals stimulating within a few years, series of patents in the North to microbes, plants, animals and human cell lines and genes. The TRIPS Agreement has forcefully universalised this Northern practice. On the other hand, the most crucial question revolving around a wide range of ethical, economic and political concerns is being thrown out from the backdoor. The questions like whether it is right that corporations should own the biological underpinnings of life do not find any place in the global talks.

Building Compatibility between the TRIPS Agreement and the CBD: Combating Biopiracy

The adoption of the CBD was the first emphatic step taken by the international community towards conservation and sustainable use of biodiversity. The Convention was a landmark achievement for the Southern countries because they succeeded in winning sovereignty over their biological resources, which essentially meant the right to use their resources sustainably.

The CBD is significant for the developing countries also because it recognises the importance of traditional knowledge from the point of view of conservation and sustainable use of biodiversity.[6] More significantly, the CBD frames out a strategy for the practical realisation of the sovereignty and sustainable use principles through the requirement of fair and equitable sharing of benefits arising from the utilisation of biological resources, traditional knowledge and innovations.[7] This requirement embodies the essence of the Convention and has become the guiding principle for the developing countries to claim their rightful share of benefits arising from the commercial use of these resources and the traditional knowledge associated with them by developed countries' TNCs.

The TRIPS Agreement comes into conflict with the CBD as it facilitates patents on products derived from biological resources without acknowledging and compensating the original knowledge holders, thereby negating the provisions of the CBD. The TRIPS Agreement provides only corporates and individuals with IPRs, providing no scope for granting collective rights to local and indigenous communities for their time-tested knowledge.

Further, TRIPS does not require a patent holder to disclose the source of the genetic material on which the patent is granted, thus giving tremendous leeway to the patent holders to get away with the patent without having to compensate the holders of the resources and the knowledge.

The inconsistencies between the two agreements have become a matter of debate between the developing and the developed countries. Within the CBD Conference of Parties (CoPs), the relationship between the CBD and TRIPS has been most frequently and intensely discussed in deliberations on such topics as access to genetic resources, benefit sharing and traditional knowledge. But North-South differences are very acute on IPRs and hardly any breakthrough could be achieved in the CBD CoPs.

The developing countries then, shifted their attention to the TRIPS Council review process that had started since 1999 to build mutual supportiveness between the two treaties Though a level of understanding has been reached about the urgency of building compatibility, as mandated by the Doha Declaration Paragraph 31(i), the cooperation of the developed countries is not forthcoming in this regard. The developing countries face their biggest challenge from the U.S., which does not recognise that there exists any serious difference between the two treaties and it is therefore reluctant to take any measure to build compatibility between the two

The Doha Ministerial Declaration (2001) says that work in the TRIPS Council on the review of Article 27.3(b) or the whole of the TRIPS Agreement under Article 71.1 and other implementation issues (both inside and outside the WTO) should also look at: a) the relationship between the TRIPS and the CBD; b) the protection of traditional knowledge and folklore and: c) other relevant new developments that member governments raise in the review of the TRIPS Agreement.[8]

A group of developing countries, including India has been carrying forward the negotiations to review the TRIPS Agreement. In October 1999, twelve developing countries from Asia, Africa and Latin America submitted two joint papers to the General Council detailing the implementation issues they were seeking solutions to.[9] Several TRIPS related proposals were put forward. One of the papers argued that TRIPS is incompatible with the CBD and sought a clear understanding that patents inconsistent with Article 15 of the CBD, which vests the authority to determine access to genetic resources in national governments, should not be granted. Another proposal was that the Article 27.3(b) should be amended in light of the provisions of the CBD, taking into account the conservation and sustainable use of biodiversity and the protection of the rights and knowledge of indigenous and local communities.

Brazil, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe jointly submitted a paper to the TRIPS Council on June 2002 on the relationship between the TRIPS Agreement and the CBD and the protection of Traditional Knowledge.[10] The submission stressed the need to modify the TRIPS

Agreement arguing that the agreement contains no provisions to preventing a person to claim patent rights in one country over genetic resources that are under sovereignty of another country. Neither does it ensure a member's claim to enforce prior informed consent nor fair and equitable benefit sharing. The paper proposed that TRIPS be amended to provide that WTO member states must require that, 'an applicant for a patent relating to biological materials or to traditional knowledge shall provide as a condition to acquiring patent rights:

(a) disclosure of the source of and country of origin of the biological resource and the traditional knowledge used in the invention;

(b) evidence of prior informed consent(PIC) through approval of authorities under the relevant national regime; and

(c) evidence of fair and equitable benefit sharing under the relevant national regime of the country of origin.

The same group of developing countries, excluding a few, carried on with the demands based on the submission of June 2002. The group reiterated the previous proposals in June 2003 emphasising that disclosure of the source and country of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation and in some cases, prevent the issue of 'bad patents' awarded without due regard to prior use and knowledge with regard to the resource.[11]

These countries want to establish a link between the CBD framework with the norms of disclosure of a patent application in the TRIPS Agreement so as to institutionalise a mechanism for ensuring that patents are not granted, or are invalidated if granted in violation of the rights of the countries and communities over their resources and knowledge respectively. This group is also the strongest proponent of international mechanism to arrest biopiracy. The main shortcoming of national patent offices to prevent biopiracy and to ensure reward to traditional knowledge holders is that they do not ipso facto lead to similar action on patent applications in other countries.

In March 2004, Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela presented a 'checklist of issues' pertaining to all the three conditions which they demand to be fulfilled before obtaining a patent.[12] Another proposal by the group including Bolivia and Pakistan submitted in December 2004 focused on PIC, the second of the three elements identified in the 'checklist' prepared as the basis for future negotiations. The proposal paid particular attention to Article 15 of the CBD, according to which Contracting Party is obliged to disclose PIC for patents that involve the use of biological resources, unless otherwise determined by the country that provides those resources.[13] This submission follows a proposal by the same group of countries in September 2004, which focused on the first of the checklist's elements, namely disclosure of origin.[14] This proposal considers ways that disclosure requirements could improve patent examination and prevent 'bad patents'.

### **Equitable Benefit Sharing through Anti-Biopiracy Regime**

The developing countries are negotiating for an international access and benefit-sharing (ABS) regime which would legally bound the TNCs to share equitably, with the traditional knowledge holders and genetic material holders, the benefits arising out of the products developed from biological resources. It is perceived as the most effective shield against biopiracy as it would address the issue of ownership which is the critical linkage that makes the communities entitled to benefits. Most current national legislations do not determine ownership of genetic resources, making it very difficult to determine whether indigenous groups and local farmers have a right to participate in ABS.

Further the ABS regime would bind the WTO members to amend their IPR laws to include the following three principles: (a) Disclosure of country or origin of source of biological material or traditional knowledge; (b) Prior Informed Consent (PIC); and (c) Equitable Benefit Sharing (EBS). The ABS regime can be institutionalised and functional only when provisions of the CBD and the TRIPS Agreement are compatible. The negotiations in the CBD CoPs and the TRIPS Council hold equal stake for the developing countries.

Many biodiversity rich developing countries are coming together to realise an ABS regime. The Like Minded Mega Diverse Countries (LMMC) group formed in 2002, including Bolivia, Brazil, China, Columbia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela have already established itself as an important negotiating block in crucial international fora on biodiversity and traditional knowledge issues. One of the priority issue in the group is ABS regime and amendment in the TRIPS Agreement.

## Conclusion

While the tussle between the developing and the developed countries is on, biopiracy also goes on rampantly. The current regulations, guidelines and practices in place, including national legislations of thirty-six countries, have failed to prevent biopiracy. This demonstrates that we need a strong, legally binding international regime, a regime that must lead to the fair and equitable sharing of benefits and protect the inalienable rights of indigenous peoples and local communities over their territories, genetic resources and traditional knowledge. But not all countries, especially the developed ones, have recognised that biopiracy is still a major, unresolved problem and that amendment of TRIPS hold the key to its solution. So the developing countries have to carry forward a lone battle against the profit-oriented biopirates. The WTO Ministerial Conference in Hong Kong is a prospective platform for putting up an aggressive strategy on this issue. It will be fruitful if the developing countries are able to achieve a Ministerial Declaration on TRIPS, biodiversity and traditional knowledge keeping in mind an eventual amendment to the TRIPS Agreement.

- 1. 'Bioprospecting, "Biopiracy and Indigenous People", *RAFI COMMUNIQUE*, Rural Advancement Foundation International, Nov-Dec, 1994.
- 2. Vandana Shiva, *Campaign Against Biopiracy* (New Delhi, Research Foundation for Science, Technology and Ecology), 1999, p. 10.
- 3. Ibid.
- 4. Ibid.
- 5. Gurdial Singh Nijar, In Defence of Local Community Knowledge and Biodiversity: A Conceptual Framework and the Essential Elements of Rights Regime (Penang, Third world Network), 1996, pp. 233-234.
- 6. Article 8 (j) and Preamble, CBD, 1992.
- 7. Article 1, Article 8 (j) and Article 15, CBD, 1992.
- 8. DOHA WTO MINISTERIAL 2001: TRIPS, WT/MIN (01)/DEC/2.
- 9. WT/GC/W/354 and WT/GC/W/355.
- 10. IP/C/W/356.
- 11. IP/C/W/403.
- 12. IP/C/W/420.
- 13. IP/C/W/438.
- 14. IP/C/W/429.