

Amending WTO intellectual property rules to prevent bio-piracy and improve patent quality

Summary

Developing countries have proposed to amend the World Trade Organization (WTO)'s Agreement on Trade Related Intellectual Property Rights (TRIPs) by requiring patent applicants to disclose the origin of biological resources and traditional knowledge used in patented products.¹ Disclosure would also require the patent applicant to show that the applicant had obtained Prior Informed Consent (PIC) and arranged for an Access and Benefit Sharing (ABS) plan, according to national legislation, before appropriating biological resources and traditional knowledge used in a patentable product. According to its proponents, a disclosure requirement would help ensure that TRIPs and the United Nations Convention on Biological Diversity (CBD) would be mutually supportive, particularly regarding ABS and PIC.

Introduction

India and others formally submitted the amendment to Article 29 of TRIPs (which concerns general disclosure of information required for a patent application) on May 31 for a decision by the WTO General Council by July 31.² In mid-June, Norway also submitted principles for a disclosure amendment (WT/GC/W/566) that differs from the developing country proposal on the vital issue of how to discipline WTO member non-compliance with the disclosure requirement.³ The Norwegian proposal may offer a basis for a possible compromise on mandatory disclosure. The European Union supports disclosure requirements, but not under WTO auspices.

Developing countries say a disclosure requirement would prevent bio-piracy and “bad patents,” which result when patents are granted to applicants who have misappropriated biological resources and traditional knowledge. PIC and ABS contracts could result in hundreds of millions, if not billions, of dollars being paid by patent holders to mega-biodiverse developing countries. For example, Kenya's biological resources were used for a patented diabetes medication whose sales totaled \$379 million in 2004. No royalties were paid, and no ABS or PIC was agreed with the Kenyan authorities.

Many developed countries, led by the United States, insist that a disclosure requirement would be of no use in preventing bio-piracy or improving patent quality. The U.S. says developing countries should not seek fulfillment of CBD objectives through a binding TRIPs requirement, but rather through ABS bilateral negotiations between transnational companies and developing countries, outside the reach of the WTO dispute settlement system.⁴ Ignoring the developing country arguments about TRIPs violations resulting from lack of disclosure, the U.S. argues that the WTO should do no more work on disclosure until WTO members have accumulated more experience with ABS agreements (IP/C/W/434, paragraph 26).

Arriving at a compromise on disclosure may prove crucial for completing negotiations on the WTO's Doha Agenda. Some developing countries, such as India, have indicated that they could not sign off on the Doha negotiations unless a disclosure amendment for TRIPs is included.⁵ Three chairs of U.S. Congressional committees have warned U.S. trade negotiators that they would not support a Doha package with the disclosure amendment, as it would require a change in U.S. patent law.⁶

The following analysis provides some background to the debate. It then briefly surveys the extent of biopiracy and estimates the potential economic benefits for developing countries from receiving royalties on biological resources and/or traditional knowledge used in patented products. The analysis then reviews the difficulties of preventing biopiracy and ensuring adequate compensation within bilateral legal processes. Finally, the broader problem of intellectual property enforcement and the high political and economic cost of not amending TRIPs is considered.

Background

The disclosure debate dates back to the WTO's founding. Developing countries agreed to TRIPs Article 27.3b) (on the patenting of biological resources) only on condition that the subparagraph be reviewed within four years of the entry into force of the agreement, i.e. a review beginning in 1999. The Doha Ministerial Declaration of November 2001 authorized WTO members to examine the relationship between TRIPs and the CBD. Four years of talk later, the Hong Kong Ministerial Declaration merely “took note” that the debate was going on. This situation is deeply disappointing to developing countries, who expect the review to be about how to make TRIPs compatible with and supportive of CBD provisions, particularly PIC and ABS requirements.⁷

Developing countries believe a disclosure amendment to TRIPs is essential to support the CBD objectives and the TRIPs objectives of improving patent quality.⁸ Disclosure can help prevent the granting of patents that lack complete information about prior art (a history of innovation pertaining to a product or

process) and therefore fail to demonstrate the patent application requirement of novelty (Article 27.1). However, the United States, (the main proponent of TRIPs and an antagonistic non-member of the CBD) believes there is no incompatibility between TRIPs and the CBD, and therefore nothing need be done to amend TRIPs (IP/C/W/434, paragraph 3).⁹ The U.S. has blocked allowing the CBD Secretariat to be an observer at TRIPs Council meetings.

Developing countries view the disclosure requirement as a binding means to implement the best endeavor intent of Article 7 of TRIPs, which states in part: “The protection and enforcement of intellectual property rights should contribute . . . to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” How are developing countries to obtain such “mutual advantage” when developed country firms and researchers own 97 percent of all patents granted, with transnational corporate branch offices in developing countries owning another 80 percent of the remaining 3 percent?¹⁰

Developing countries, though patent poor, are rich in the biodiversity and traditional knowledge used in developing plant varieties and in other biological resources used in patented agricultural and pharmaceutical products. They are seeking to turn the patent system to their advantage and to reduce their negotiating disadvantage in bilateral ABS contracts. Through a TRIPs amendment, they would have recourse to the WTO’s dispute settlement mechanism when members failed to notify disclosure and the failure resulted in so-called “bad patents.”¹¹

Some limits of patent searches and bilateral negotiations to prevent bio-piracy

The first step in determining whether patented products incorporate biological resources and/or traditional knowledge in violation of the resource country of origin’s laws is a patent database search. If the search shows that products incorporate biological resources and/or traditional knowledge, then source countries may seek revocation of patents on a case-by-case basis through the patent offices and legal system of the country in which the patent was granted. However, non-governmental researchers who have used patent databases to search for patents incorporating biological resources and traditional knowledge have found it difficult to demonstrate bio-piracy because of the lack of a disclosure requirement in the patent holder’s country that would mandate reporting the source country of the biological resource used in the patented product. Only by cross-checking patent databases with medicinal plant databases and scientific literature has it been possible to determine the source country of biological resources and/or traditional knowledge used in very lucrative patented products.

For example, one researcher found that a drug to treat Type II diabetes, patented by Bayer Pharma, was derived from a bacterial strain in a microbe from Kenya’s Lake Ruiru. The discovery of the biological basis of the drug was not found within a patent application but by comparing different applications. In 2004, sales of the drug totaled U.S.\$379 million, but the patent search could find no evidence of a PCI and ABS agreement. In another case, a patent search and review of scientific literature found that the U.S. Patent Office had granted a patent on a “new use” of a North African medicinal plant to treat diabetes, despite explicit

acknowledgement in the patent application that traditional healers had used and continue to use the plant to treat a “wasting disease” that the patent holder identifies as diabetes.¹² In these cases, the novelty or “inventive step” required by TRIPs Article 27.1 for granting a patent is very much in question. For developing countries, disclosure is one of the “appropriate measures” WTO members should use to prevent patent holder abuse of the patent system, as called for in Article 8 of TRIPs.

Without the pressure that a disclosure amendment would create, not least through possible WTO litigation against member non-enforcement of disclosure, preventing biopiracy is difficult, as many national disclosure rules are voluntary. Biopiracy resulting in “bad patents” are a disincentive for developing countries to invest in creating patented products from their own resources due to fear of violating a patent, however “bad.” Furthermore, bilateral attempts to discipline bio-piracy can take years, during which the patent holder continues to receive benefits. For example, the U.S. Patent and Trademark Office has deliberated for six years on whether to revoke the patent for a yellow bean of Mexican origin that was determined by an NGO to have been biopirated. If and when the patent is revoked, another legal process will have to start to try to get compensation from the patent holder who continues to receive patent benefits throughout the legal process.¹³

Developing country governments seeking to determine the extent of unauthorized and uncompensated appropriation of their biological resources and traditional knowledge may face additional difficulties to those experienced by non-governmental researchers. Government initiatives to stop biopiracy may be compromised by trade interests. Consider Peru’s dilemma. In July 2005 at a meeting of intellectual property officials from the mega-biodiverse Amazon River basin countries, Peru announced the initial results of a new patent database research project. Its patent searches had determined that about 500 products registered in U.S., EU and Japanese databases derived from seven plants native to Peru, whose uses were well documented in traditional knowledge. The government declared it would select certain patents for further examination to determine whether Peruvian laws pertaining to PCI and ABS had been violated. If the laws had been violated, Peru would seek revocation of the offending patent plus compensation for patent abuse.¹⁴

However, this project is now in question in light of the intellectual property chapter of the U.S.-Peru Free Trade Agreement (FTA) that will be submitted to legislatures for approval after the Peruvian presidential election in July 2006. According to the FTA’s “Understanding Regarding Biodiversity and Traditional Knowledge,” PIC and ABS “can be adequately addressed through contracts that reflect mutually agreed terms between users and providers” of biological resources and traditional knowledge. While Peru continues to advocate for a disclosure amendment at the WTO, in the FTA it has agreed to a position on disclosure that the U.S. believes precludes the need for a TRIPs amendment. For the U.S., ABS/PIC contracts obviate the need for disclosure, while for Peru, such contracts are merely supplementary to the disclosure that provides evidence in the event of a contract interpretation dispute.

The U.S. is exerting similar bilateral pressure on other developing countries in both trade agreements and investment agreements, where intellectual property is defined as a form of invest-

ment. Such U.S. bilateral investment agreements allow private corporations to sue states. Together with so-called “TRIPs plus” agreements, the investment agreements are a real threat to producing and providing essential medicines and technological goods, particularly for developing countries.¹⁵

Given the large financial stake U.S. companies have in unauthorized and uncompensated use of biological resources and traditional knowledge, it is no wonder the U.S. government and industry prefer bilateral agreements to a TRIPs remedy for biopiracy. A U.S. discussion paper characterized an ABS agreement between Costa Rica and Merck, a huge pharmaceutical corporation, as providing “dramatic benefits.” Yet the deal gave Costa Rica just US\$1 million and laboratory testing equipment in exchange for Merck’s exclusive right to test 10,000 soil, plant and animal samples that might be developed into patented products (IP/C/W/469, paragraph 34). Even taking into account the often high cost of bringing a pharmaceutical product to market, considering that just one sample can be essential to the development of a drug worth hundreds of millions of annual sales, getting 10,000 opportunities to make hundreds of millions from each sample is a good deal for Merck. Nor does the deal take into account the value of the traditional knowledge needed to harvest the sample at the time of the year and at the site when its active ingredients can be optimally tested.

Estimating the extent of biopiracy and commercial value of biopirated products

Estimating the commercial value of biological resources and traditional knowledge, and then calculating what would be fair compensation for their use in individual patented products is a matter for negotiation. However, some global estimates give an idea of the commercial value of unauthorized and uncompensated appropriation of biological resources and traditional knowledge. On the basis of 1994 data, the Rural Advancement Foundation International calculated about “three-quarters of all plant-derived prescription drugs were discovered because of their prior use in indigenous medicine.” Global pharmaceutical industry profits of about \$32 billion in 1994 resulted from sales of drugs derived from traditional remedies.¹⁶ The United Nations Food and Agriculture Organization (FAO) estimated that if source countries received one percent of plant derived pharmaceutical sales of \$235 billion in 1997, the royalty would approach \$2.4 billion annually.¹⁷

In 2004, global pharmaceutical sales were estimated at \$466 billion.¹⁸ Applying FAO’s 1997 estimate methodology to the 2004 sales total, the royalty paid out to the sources of biological resources and traditional knowledge in patented pharmaceutical products for 2004 would have amounted to roughly \$4.6 billion. Half of such remuneration, if received annually by developing countries from 2007-2015, would exceed the \$16 billion in benefits projected by the World Bank to result for all developing countries from the implementation the WTO’s Doha agricultural and non-agricultural market access agreements.

The value of unauthorized and uncompensated removal of biological resources for patented agricultural inputs is probably less than the global value of plant-derived pharmaceuticals. Nevertheless, its value is not insignificant. For example, a disease resistant trait in the Porto Alegre peanut, taken from Brazil, has been bred into U.S. peanut varieties, saving U.S. peanut growers about \$2 billion in crops that would have otherwise been lost

to disease from 1996 to 2005.¹⁹ FAO estimated in 1998 (before the takeoff in royalties for genetically modified seeds) that if the commercial seed industry were to remunerate the providers of biological resources for the improved varieties with one percent of annual global seed sales, source countries would receive about \$150 million per year. By this reckoning, with seed sales worldwide of about \$21 billion in 2004, a global ABS biological resource royalty for seeds would be worth \$210 million annually.²⁰ These estimates don’t take into account the value of publicly held biological resources in the 12 International Agricultural Research Centers. Companies can draw on that germ plasm to develop improved plant varieties, whose annual added value to crops in North America, Australia, New Zealand and Europe, was estimated in 1994 to be \$5 billion per year, according to the Rural Advancement Foundation International.²¹

The high cost of keeping disclosure out of TRIPs

More difficult to estimate than the value of unauthorized and uncompensated biological resources and traditional knowledge for patent products is the cost to the WTO’s credibility, to biodiversity and to development of keeping disclosure out of TRIPs. One June 20, the EU and U.S. issued a detailed joint “Action Strategy for the Enforcement of Intellectual Property Rights” in which they promise to fight piracy through the TRIPs Council, but without a mention of biopiracy. If the TRIPs Council adopts the European Union proposal (IP/C/W/448) to amend TRIPs to increase enforcement of copyright, trademark and patent violations, but does nothing to prevent bad patents based on misappropriated biological resources, what credibility can TRIPs retain among developing country members, especially the mega-biodiverse? What incentive is there for developing countries to crack down on the counterfeiting of luxury goods, while bio-piracy remains outside the purview of TRIPs and therefore of potential WTO sanctions?

The United States is right to argue that even with disclosure, developing countries would still have to negotiate bilateral PIC/ABS contracts to benefit from the use of their biological resources and traditional knowledge in patented products. However, it is wrong to contend that disclosure cannot aid in determining whether patents have been unduly granted and therefore cannot provide a disincentive to those who would patent or seek to commercialize without a patent products derived from biological resources and traditional knowledge. Combined with the U.S. Federal Trade Commission’s recommendation for a new administrative procedure to challenge questionable patents, a disclosure notification requirement could not only discipline biopiracy without costly litigation, but prevent it.²² Because the U.S. is most concerned that disclosure could result in revocation of patents granted, thus creating “uncertainty” in the patent system, it should carefully consider Norway’s proposal.

Norway argues that if an applicant cannot provide disclosure information, the patent application should be discontinued. However, the proposal continues, if a patent is granted on the basis of inaccurate or incomplete disclosure information, the remedy should not lie with revocation of the patent, but through criminal and/or administrative penalties. A disclosure amendment would not provide grounds to revoke patents as a result of a WTO dispute ruling, as litigation could only result from non-compliance with the disclosure amendment. But disclosure notifications to the TRIPs Council and litigation in the event

of non-compliance would pressure WTO members to provide information that is requisite for good patent quality and for ABS and PIC agreements. Patent revocation could only occur as a national remedy if the patent failed to meet the general patent law requirement, recognized in TRIPs, of an inventive step.

Conclusion: the need for a compromise now

A disclosure amendment would provide a more certain legal basis for subsequent innovation resulting from a wider range of biological resources cared for by custodians who would have a greater incentive to share their knowledge if it were compensated adequately. Of course, the steady erosion of global biodiversity and the world's dependence on a very narrow range of biological diversity (just 30 crops provide 90 percent of global caloric intake, with just three crops providing 60 percent²³) will not be remedied simply by a disclosure amendment to TRIPs. But by supporting proper compensation for the stewardship of biological resources and traditional knowledge, disclosure provides a legal structure to encourage diversification of crop and plant derived pharmaceutical research. Norway proposes that the disclosure amendment should be compatible with and supportive of not only the CBD, but also "the International Treaty on Plant Genetic Resources for Food and Agriculture and the Multilateral System established under it." (WT/GC/W/566, footnote 1).

If biopiracy continues undisciplined by multilateral rules and one-sided ABS agreements provide little incentive to conserve and sustainably use biological resources, then biological erosion will accelerate, in turn endangering global food security and a vital basis of future pharmaceutical innovation.

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