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Developing Effective Aproaches to Access to Genetic Resources

by

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Executive Summary

Under current international law, governed by the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), biotech companies are free to make contracts with individual countries, obtaining the right to extract genetic resources in biodiverse areas and to use these resources in their product development.

In this new EEI Policy Paper Mr. Alan Oxley - who is former Australian Ambassador to GATT and its President- argues that the EU competitiveness could be threatened by a currently discussed new UN regulatory system for genetic resources. The proposed regime would according to the author limit the freedom to make contracts by making it more difficult to obtain patents and by imposing obligations on biotech companies to share their future profits.

The paper provides further background on this important issue and argues that a contract-based system is a better way to protect the world's environment and biodiversity than the proposed patent-based regime.

About the author

Alan Oxley is Chairman of the Australian APEC Study Centre. He was Ambassador of Australia to the GATT (the predecessor of the WTO) and Chairman of the GATT. He is an expert on international trade, environmental policy and development. He is host of the Asian Pacific page of www.techcentralstation.com and his commentaries are published in media in the Asian Pacific region including the Asian Wall Street Journal and the Bangkok Post.

1. Introduction

The UN Convention on Biological Diversity (CBD), ratified by more than 188 countries since being adopted by the 1992 Earth Summit in Rio de Janeiro, is the principal international legal instrument that governs "bioprospecting," (the processes for securing the right to search and acquire rights to genetic resources).

The CBD also establishes principles for sharing the benefits that derive from the use of those resources, often referred to as Access and Benefit Sharing (ABS).

The rules about bioprospecting derive from the three primary goals of that pact:

- The conservation of biodiversity,
- Sustainable use of the components of biodiversity, and

- Sharing the benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way.

The Convention affirmed sovereign rights of countries over their biological resources, with conservation of biological diversity as the common concern of mankind.

Until the last two decades, foreign prospectors had felt free to take biological resources from a country and use them to develop drugs and other commercial products, with none of the profits generally flowing back to the country of origin. While this served both the advancement of knowledge and of innovation, it did little tangible to directly advance protection of biodiversity in the originating countries.

The goal set by CBD of sharing benefits was developed in hopes of generating enthusiasm in each nation – and particularly in developing nations with the most biological diversity – to preserve their biodiversity, even to the point of sacrificing some kinds of economic development. The recognition of sovereignty of nations over their biological resources, much like those nations possess for mineral, timber, hunting and fishing rights within their borders, provides the foundation for biodiversity protection.

In fact, national ownership and control of biological resources already was serving as a basis for agreements between research organizations – both commercial and educational – and some countries, in particular Costa Rica, in which those organizations conducted their work.

But not until the Bonn Guidelines were approved in 2002 was a real framework for benefit sharing with recognition of sovereign rights over biodiversity really established.

The voluntary guidelines called for governments to set up competent authorities for allowing access to biological resources and the traditional knowledge of indigenous groups within them. It also set up principles for those seeking access to obtain prior informed consent of their use, and even provided outlines for ways in which both monetary and non-monetary benefits might be shared among parties, including national governments, local communities, indigenous groups and private property holders.

The guidelines, in short, provide a framework for contractual agreements for access to biological resources at minimal cost and use of biological resources with fair sharing of their benefits for all concerned. Coupled with clearer property rights within developing nations, they would serve as the means for creating a market based system of incentives to provide access to biodiversity and for selling access to biodiversity.

The European Union and many other countries are in the midst now of implementing the guidelines and its principles into their laws.

Now, parties to the CBD have decided to create a new international regime to control access and benefit sharing. The process for creating such a regime is underway now, including a meeting this month of the Ad Hoc Open-Ended Working Group on Access

and Benefit Sharing in Bangkok, Thailand. During this process, the question will be which path the CBD parties take in addressing ABS.

One path would be the development of a system of mutually agreed upon contracts and agreements between those institutions and groups seeking access to genetic resources and those nations, their communities and their property rights holders that are the source for them, which offers a market-based way forward to achieve the goals of the Convention.

An alternative, regulatory and more litigious path has been proposed as means to manage access to biodiversity and traditional knowledge by representatives of nations in the 17-member Like Minded Mega-diverse Countries (LMMC). It is estimated that 72 percent of the world's biodiversity is located among them. Their proposal is that the international patent system be regulated to prevent biopiracy and to enforce delivery of benefits from access to genetic resources to their societies.

They propose that intellectual property law, as governed by both the World Intellectual Property Organization (WIPO) and the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), be overridden by a new international regime. The idea is to impose conditions on use of patents on inventions developed from genetic materials.

Suggestions include approval for uses of products and processes patented from research on genetic materials. Others are to require in patent applications disclosure of the origin of genetic material as well as traditional knowledge in past use of such material.

The question that the world now faces is which path to take? Market-based contractual arrangements enforced by agreements under national laws or international mechanisms to regulate patent laws to enforce rules on access to genetic resources?

Which is the best way to achieve the goals of the Convention – to maintain biodiversity and allow for its sustainable use and encourage the sharing of its benefits for all of mankind?

Different stakeholders – nations, local communities, farmers, landholders, scientists, researchers – each have a unique perspective. Take the right path, and everyone wins. If they go down the wrong path, the whole structure will collapse, with no benefits to be shared and none of the goals reached.

It is the position of this paper that market-based approaches offer the best hope for achieving the goals, while an approach of regulating patents risks destroying benefits for everyone.

2. The Wrong Path

Proponents of making it a requirement to regulate patents see it as a counterweight to system created by WIPO and TRIPS. Some claim it amounts to a "strategy to foster a form of technological protectionism."

Protection of basic patents lies at the core of successful intellectual property as provided in the Agreements administered by the World Intellectual Property Organization (WIPO) and the Agreement on Trade related aspects of Intellectual Property (TRIPS) of the World Trade Organization. Basic protections of patent rights and intellectual property are needed among trading partners if one country with impunity isn't to have the right to simply steal the creations of another country.

The TRIPS agreement among other things, extended patenting to microorganisms and "modified" life forms, provided for patents and other forms of protection for plant varieties that are cross or genetically bred, extended patent rights for pharmaceutical products, with an increased duration of protection for patents to 20 years from the date of application.

In doing these things, though, critics of TRIPS say it has denied the contribution of indigenous peoples, farmers and local communities in the patenting of products derived from their plants or traditional knowledge.

But is further regulation of requirements for patents, for example on disclosure of the origin of material in the creation of the product a real answer to these concerns? How would they be enforced under an international trading system that seeks to minimize trade frictions and facilitate free and open trade? Would they diminish the capacity to encourage private enterprise to create broader benefits?

As the International Chamber of Commerce Commission has pointed out in its discussion paper, "Access and Benefit-Sharing for Genetic Resources" for the third meeting of the Ad-Hoc Open-Ended Working Group on Access and Benefit-Sharing: "The case that seems to drive much of the thinking is that of the patented pharmaceutical product based largely upon therapeutic properties extracted from genetic resources, identified through traditional knowledge of these properties, and that yields billions of resources."

However, as the ICC discussion paper notes, that usually is not the case. In fact, there rarely is a line drawn directly from a plant to a product without a lot of twists and turns in between.

The development of the cancer drugs vincristine and vinblastine from the rosy periwinkle plant in Madagascar, cited often as an example of how biodiversity and traditional knowledge is vital to the development of new therapies and how

developing nations aren't economically benefited in its protection, took just such a circuitous route.

The plant was traditionally used to fight diabetes, until the U.S. National Cancer Institute decided to screen it for anti-cancer properties in the 1950s and 1960s. Scientists from Eli Lily, enlisted in the search, separated 80 alkaloids from the plants, none of which worked to cure diabetes. But they did find the two powerful anti-cancer drugs – vinblastine, which in combination with other drugs produced an 80 percent cure rate for the once almost always fatal testicular cancer, and vincristine, which helped raised the survival rate for childhood leukemia from 5 percent to 84 percent.

Many begrudge Eli Lilly making $100 million a year on the drugs while Madagascar received no royalties, as at the time of Lilly's patents knowledge resources were considered "free access goods." But a question to ponder is this: What about all the costs Eli Lilly incurred in testing the 78 alkaloids that didn't work, not to mention the cost of millions of dollar spent on products for cancer and other diseases that never made it to market?

As Joseph A. DiMasi of Tufts University, Ronald W. Hansen of the University of Rochester and Henry G. Grabowski of Duke University reported in "The price of innovation: new estimates of drug development costs," in *The Journal of Health Economics* 22 (2003), the cost of developing new drugs and bringing them to market is becoming more expensive, not less so. It has climbed from $231 million in 1987 dollars, as reported at the time of their last study in 1991, to $802 million in 2000 dollars, or just about double even when taking into account general inflation.

Why the high cost? In one sense, all the low hanging fruit in drug development has pretty much been gathered. The pharmaceutical industry is now focused on solving health problems that are much harder to crack.

As a result, of every 5,000 medicines tested, the Pharmaceutical Research and Manufacturers Association of America reports, only five on average go to clinical trials. Of those, only one is eventually approved for patient use. And of those numbers, only a few become so-called blockbuster drugs.

To protect their intellectual property, pharmaceutical companies must seek patents for drugs fairly early in the process. Otherwise a company could go through all the expense of trials and get nothing for that work. Yet, getting a patent and delivering a medicine to the market takes years.

Adding requirements for certification of the origin of material or traditional knowledge for patent applications and to regulate the use of products based on these patents would further extend the patenting process, and raise the costs and increase uncertainty. It would provide additional grounds for litigation, in a field that suffers enough of it already.

Biotechnology isn't like ordinary manufacturing. Bioprospecting plants is not digging for ore, it's checking their genetic and chemical makeup using such things as microscopes, computers and pipettes. Its most important ingredient is intense amounts of knowledge and imagination.

And those clever enough to create new saleable high-tech products are likely clever enough to cover their genetic tracks. TRIPS is enforceable primarily because an actual product or process can be traced. Ingredients are harder to do so, and that will prove especially so in the case of molecular ingredients when only 2 million of the anywhere from 5 million to 30 million species are now known and catalogued to provide comparisons against.

Just as customs agents couldn't control smuggling in previous centuries, and nations today struggle mightily preventing the shipment of large amounts of illegal drugs, so patent officers won't be able to keep unscrupulous commercial enterprises from surreptitiously pirating genetic material from a country and sending it to some biotechnology firm.

A high tariff in the form of increased patent burdens, though, could discourage legitimate drug makers and other biotechnology firms from contracting to collect specimens in a country out of fear all of their medicines would become open to challenge even if the samples collected there produced no good results.

There also is a second question to ponder from the example of vinblastine and vincristine. Patents have a limited life. Those associated with the distillation of these active ingredients have expired, and the technology behind their creation is now in the public domain in the United States and elsewhere.

What happens if new drugs are derived from them? Would their origin trace back to the periwinkle of Madagascar for purposes of patenting them? Does Madagascar have a right in perpetuity not granted the original patent holder to benefits and royalties from its one time supply of periwinkle leaves?

To cut this Gordian knot, Switzerland has suggested that disclosure of country of origin for genetic material and traditional knowledge only be required under patent law in those cases where goods and services are directly derived from the genetic material or traditional knowledge.

But under world trading rules dedicated to the elimination of discrimination in trade, that might well deny biodiverse countries or individuals and groups within them from negotiating a better deal for themselves contractually – knowing that some plants may well offer derivative benefits further down the line.

Attempting to enforce a shared-benefit regime through the patent system risks creating only more litigation and friction where cooperation and trust between trading partners, enforced through flexible, appropriate contractual arrangements, is needed.

Benefits can be shared only if they are created. There can be no sharing of profits or benefits that don't exist. The pharmaceutical industry and biotechnology companies have an interest in maintaining sources of supply in genetic materials only if the rewards they receive are commensurate to the risks they take in developing new drugs and products. Creating more costly legal hurdles for them to jump through

raises their risks and reduces the market incentive for them to perform bioprospecting and develop new medicines.

And it is not only royalties and financial benefits that developing countries and their peoples will lose as a result. They will also lose investment in their own countries from the pharmaceutical sector.

Two Countries among the 17 members of the Like-Minded Mega Diverse Countries illustrate this point.

Thailand and Brazil seem headed in different directions. While both are on the U.S. Trade Representatives Watch List for inadequate protection of intellectual property, Thailand has moved to work cooperatively with intellectual property holders, including biotechnology companies, while Brazil is erecting more barriers to them.

In Thailand, patents granted through the Thai Patent Office are valid for up to 20 years. Patent protection is extended to pharmaceutical products, and methods from transgenic production of animals, plants and microorganisms are patentable as are the organisms themselves as long as a discernable new function or trait is documented.

Since Thailand's enactment of the Foreign Business Act in 1999, it has seen patent registrations grow from 110 in 1999 to more than 600 in 2002. Investment in biotechnology has grown apace, and the economy itself – which suffered a steep drop in 1998, has since averaged more than 5 percent annual growth, including 6.7 percent in 2003 and 6.2 percent last year. Its unemployment rate at 2.2 percent is among the lowest in Asia.

The effects of the tsunami of December 26 are expected to slow growth this year, but the future looks bright. It is negotiating a Free Trade Agreement with the United States that would include improving intellectual property protections that will serve its own budding biotech sector.

Brazil, by contrast, has shown antagonism to new foreign direct investment. Although it signed on to the TRIPS accord in 1997, it has done many things to limit its effectiveness in regards to protection of intellectual property.

The Lula government has threatened pharmaceutical companies with compulsory licensing of products. It has allowed the sanitary registration of unauthorized copies of pharmaceutical products relying on undisclosed tests and other confidential data, in apparent violation of TRIPS. It has established price controls on new innovative medicines. It has set up a new hurdle to patent applications requiring that they undergo a review by a new regulatory body that also sets prices.

While Brazil enjoyed an overall growth rate of 5.2 percent last year, the result of this antagonism to intellectual property rights over the last five years has been a rate of growth well below other developing countries, despite its wealth of resources. And unemployment in Brazil still hovers around 10 percent, while net foreign direct investment in Brazil is about half what it was five years ago.

Now Brazil is leading the effort to put more hurdles in the way of patent protections for intellectual property in the name of biodiversity protection.

But it is this path that, if followed, will only lead to more misery among the poor in developing countries of the world.

3. The Need for Cures

Broad claims have been made on patents denying people in developing countries access to essential medicines. Others have argued that pharmaceutical companies devote most of their research to developing lifestyle medicines for developed countries.

Those claims are given by some as a further reason to require disclosure of country of origin for genetic materials or traditional knowledge in patent applications for new medicines or therapies.

Such disclosure would do nothing to redress those problems, if they existed. And there is plenty of evidence that those claims are simply wrong. Indeed, the fact is that patent protection is vital to allowing the creation of and dissemination to poor countries the essential medicines they need.

Amir Attaran, fellow in the Royal Institute of International Affairs in England and a principle with Idealith Research in the United States, noted in his 2004 paper published in *Health Affairs*, "How Do Patents and Economic Policy Affect Access to Essential Medicines in Developing Countries?," that only 17 of 319 medicines considered essential by the World Health Organization are patentable. And most of those that are patented for severe diseases such as HIV/AIDS, Tuberculosis and Malaria medicines are available in poor countries either in generic form or at discounted rates or even for free from the pharmaceutical companies that own them.

"The patenting data prove that patents are an infrequent determinant of access to medicines, while the economic data leave little doubt that the failure of billions of patients to receive necessary therapies is largely a consequence of economic policies that are in need of study and reform by public health scholars," Attaran, a lawyer and immunologist, wrote.

The circumstances of HIV/AIDS in India make clear that the problem in combating that disease there is not a problem of patents, but of poverty. More than 20,000 pharmaceutical companies produce generic versions of patented drugs there under the exemption granted by TRIPS to developing countries for enforcing patent laws. Yet, as Barun Mitra wrote ("Misdiagnosing the Diseases of the Poor," *Indian Express*, Feb. 9), "[B]arely 1 percent of the estimated 3.5 million Indians with AIDS get any kind of treatment at all."

Nobody, though, will get medicines that aren't developed. And it is the development of patented medicines for populations in developed countries that helps support, both directly and indirectly, medicines for people in developing and poor countries. And placing barriers in the way of patents or access to biodiversity serves no one well.

Consider river blindness. Some 18 million people are infected with the parasite that causes it and 120 million in the poorest countries in the world are at risk. Merck, after developing a drug for parasites in animals from a soil sample obtained from Japan, took the time and did the human trials necessary to develop a drug Mectizan (ivermectin) that given in daily doses over 15 years kills the parasite.

Beginning in 1987, Merck made the medicine available for free. More than that, it worked with WHO and national and local health authorities to create a network to help deliver more than 250 million doses of the drug since then. All of this cost Merck hundreds of millions of dollars.

Similar campaigns to combat other diseases, including other forms of parasitic blindness, malaria and AIDS, have been taken up by other pharmaceutical makers.

Where did they get the hundreds of millions and billions of dollars to perform these services? From the profits they received from their patented medicines – lifestyle or otherwise – and the billions invested in them by stockholders, including many of the world's largest pension funds, because of their profits.

The belief that patents don't now serve the interests of poor nations, and that making patenting medicines more expensive would have no repercussions on health in the developing world is simply wrong.

Intellectual property patents are rarely an impediment to the delivery of essential medicines or therapies to people in the developing world. The profits generated by them in fact generate the development of new and better medicines and make it possible to deliver medicines for free or at low cost to the poorest people around the globe.

How can these benefits best be secured along with promoting protection of biodiversity as everyone wants? There is a model and it is nothing new.

4. The Right Road

There is a model for agreements. It is one of the most successful. It preceded implementation of the treaty and provided impetus for its approval.

In 1989, the National Biodiversity Institute (INBio) of Costa Rica was formed on the recommendation of the National Planning Commission as a "non-government, non-profit, scientific research institute of social orientation for the public good."

Operating under the auspices of a 21 member General Assembly of diverse background, INBio was charged with collecting, centralizing, maintaining and disseminating information about Costa Rica's impressive biodiversity. Although, accounting for only 0.4 percent of the world's surface area, Costa Rica possesses an estimated five percent of the world's biodiversity.

One of INBio's first actions to support its mission was to enter into an agreement in 1991 with Merck, a U.S. pharmaceutical products and services company. It allowed Merck to obtain genetic material and information for research on potential new products in return for $1 million in the first two years and royalties from any product that was commercially developed.

Is the arrangement perfect? No. Were there any windfalls? No. Can it be improved? Undoubtedly.

Greater involvement of local and indigenous communities as well as formal property holders would improve the sharing of benefits among all stakeholders. Equally important, Costa Rica could improve its intellectual property protections generally so that it does not undermine the very benefits it hopes will be shared.

But the contractual approach demonstrates the kind of flexible arrangement for benefit sharing that attempting to use an international patent system for support could only undermine.

As R. David Simpson wrote in a 2001 paper, "Bioprospecting as a Conservation and Development Policy," for an International Workshop on Biodiversity of the Organization of Economic Cooperation and Development, Costa Rica garnered royalties of one to three percent, according to industry sources, from products developed from its resources. All of this, unlike timber, mining and many industrial activities, without damaging biodiversity at all.

The benefits have been such that INBio has made new contracts with more drug companies that have produced several more millions of dollars for education, environmental programs and protection of biodiversity there.

Contracts can be tailored to suit different needs. A contract with an educational institutional for strictly research purposes can be made without up front payment. They encourage private companies to help in the cataloguing of new species, giving special access under easier terms in cases where the likelihood of finding new drugs or cures is truly small.

All this can be done without destroying the incentives for biotechnology companies to explore the biodiversity in the developing world, as a system of regulation of patents and use of them for enforcement would.

5. Conclusion

What the international community and industry now need to look at more closely is how to make a market-based system work better.

Industry, for example, could adopt a voluntary code of conduct on how to conduct bioprospecting and secure rights to access genetic resources. It could agree to submitting questions on contracts to binding arbitration. And it could agree to provide training and also build up capacity within countries so that they can better manage their biodiversity and derive additional benefits from it.

As for governments and the CBD, they can create a place where non-confidential aspects of contracts and agreements on access and benefits are shared, to increase transparency for the entire process. And they can take steps to bring greater clarity to their laws on property rights and protections, not only for foreign biotechnology companies but for the economic advantage of their own citizens.

Rights to secure genetic resources and patents and property rights on inventions based on them are not the enemy of biodiversity. They are the means by which it can best be protected. Clarity on property rights of all stakeholders and a system that supports mutually beneficial contracts is the best way to promote an equitable sharing of benefits from biodiversity.

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