Bilateral trade agreements are the latest tool to spread patents on life worldwide. They may be used to force countries to provide patents on plants and animals or to join the UPOV Convention's softer system of plant variety rights. Or they may include an obligation to sign the little-known Budapest Treaty on the patenting of micro-organisms. This was the option chosen for Central America and the Dominican Republic, which, through their free-trade agreement with the USA, are having the Budapest Treaty forced upon them. But the debate is far from over, for many Costa Ricans are determined to stop this happening.

CAFTA and the Budapest Treaty The debate in Costa Rica

SILVIA RODRÍGUEZ CERVANTES

he free trade agreement between the United States, the Dominican Republic and Central America (US-DR-CAFTA - CAFTA for short) has been highly controversial in Costa Rica. In October 2007 the deal was ratified by a wafer-thin majority in a referendum widely regarded as unfair, and the Costan Rican legislature is now in the process of endorsing the "complementary agenda" (which includes the Budapest Treaty). Although the Costa Rican government has managed, so far, to get what it wants, the process has not been smooth. As soon as the text of the agreement was made public in January 2004, groups began to examine the content and scope of its nearly 3,000 pages. One of these groups, Pensamiento Solidario (Solidarity Thinking), soon found that countries joining CAFTA would be required to sign ten intellectual property treaties administered by the World Intellectual Property Organisation in Geneva. One of these is the little-known "Budapest Treaty on the

International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". It was signed in 1977 and came into force in 1980. Since then, the Costa Rican government has never shown any interest in signing it, and the scientific community has not felt any need for it. Today, the vast majority of Costa Ricans do not know anything about it, and yet it is being imposed on them.

What is the Budapest Treaty for?

The aim of the Budapest Treaty is to facilitate the process of obtaining a patent on a micro-organism. This "facilitation", however, involves a total overhaul of the way patents are granted when they are applied to life forms.

The first obligation on anyone seeking a patent is to provide a written description of his or her invention. This is not a problem for the inanimate objects or industrial processes for which the patent law was created to give property titles. At this time, no one



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argued that life forms, from micro-organisms to complex plants and animals, were "inventions", and therefore intellectual property rights were not applied to them. However, this changed with the move to extend intellectual property rights to biotechnology. It is practically impossible to describe a life form, however small, and even more difficult to do so following the guidelines for a patent grant application. Governments and corporations realised that the patent legislation would have to be rewritten.

The Budapest Treaty was thus established as an internationally accepted system to get over this problem. Instead of demanding that patent applicants make information available and provide a written description of the subject of their application, the Treaty requires applicants for patents over micro-organisms to deposit a sample. The US government came up with this solution, which was then adopted by the EU. The Budapest Treaty is now turning it into an international practice. It is doing this by setting up a network of International Depository Authorities (IDAs), of which there are 37 in different parts of the world, mostly in industrialised countries. By signing this Treaty, governments agree that the deposit of a micro-organism in one of the IDAs serves the purpose of "describing" the invention as required in the patent application, and, by doing this, the inventor automatically obtains recognition of his "invention" by all states party to the treaty.

The remaining requirements still have to be complied with, according to the rules of each national office. Indeed, every country still has the right (although this has been eroded as well) to grant or deny a patent under the principle of "territoriality"; this concept accepts that patents are national rights (with a few exceptions for regional systems).

Problems with Budapest

• Stifling information, innovation and scope to contest biopiracy

Patents are inherently dangerous to society, as they involve monopolies. One way of protecting society against this is to demand full disclosure of the invention when granting the patent; this means, when the patent expires, the invention passes into the public domain. In other words, you do not get a monopoly unless you disclose the invention. This is a basic principle of patent law. By weakening this principle to accommodate biotechnology, the Budapest Treaty creates an obstacle to the dissemination of information about inventions. There are other problems too. Article 9.2 says that the IDAs will provide no information about whether or not a micro-organism has been deposited with it under the treaty. Nor are the IDAs authorised to provide any kind of information on the subject of an application, except to an authority, individual or legal entity that is "entitled" to obtain a sample of the said micro-organism. In the case of individuals or legal entities, Article 11.2 of the Regulations say these must be "authorised parties" that comply with established requirements (Article 11.3). If deposit replaces description and the regulations restrict access, the whole idea of requiring disclosure in exchange for the commercial monopoly is sabotaged, and research and innovation become more difficult. This system creates huge problems for communities: how can an indigenous group appeal against biopiracy or other wrongly granted patents?

Sabotaging initiatives for benefit-sharing

There is currently a major debate going on at international level about making patent applicants present a certificate of origin attesting to where and how they got any biological material or related traditional knowledge used in their invention. This debate is conducted mainly among states party to the Convention on Biological Diversity (CBD) and members of the World Trade Organisation council on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Council). This "disclosure" requirement has been proposed by countries with the greatest biodiversity as a last-ditch measure to stop the arbitrary extraction of biological resources and indigenous knowledge by bioprospectors, research institutes, governments and companies from industrialised countries.

With this proposal, the so-called "megadiverse" countries implicitly accept intellectual property rights over life forms in exchange for some kind of "fair and equitable" sharing of the benefits that accrue from the use of the resources in question. This means that national regulations on bioprospecting, access and benefit sharing will be reinforced by another form of protection. Patent applicants will have to demonstrate to the appropriate intellectual property office that they have complied with all the requirements of the country of origin of the resource.

What does the Budapest Treaty have to do with this? Quite simply, micro-organisms form part of the immense biological wealth of developing countries, and Costa Rica, like others, is trying





The push for Budapest

GRAIN

Over the last 50 years the global seed and biotech industry, headquartered in the rich industrialised states, has been using all sorts of means to try to get broad and powerful patent protection – monopoly rights, which prevent anyone from using an invention without permission or payment – over life forms in as many markets as possible. A major step forward was the signing of the Marrakech Agreements setting up the World Trade Organisation in 1994. One of those agreements was the Trade-Related Agreement on Intellectual Property Rights (TRIPS). TRIPS obliges all WTO members – and most countries of the world are members of WTO – to provide patents on life forms, starting with micro-organisms. TRIPS is the first obligatory international treaty to force patents on life globally, and it has a strong enforcement measure in the WTO's dispute settlement mechanism.

However, TRIPS was a compromise between the US, which wanted patents on everything, and the EU, which wanted to maintain a softer monopoly system for seeds, and left some loopholes. As a result, plants and animals do not have to be patented as such. And plant varieties have to get some kind of commercial property rights, either a "sui generis" system or patenting or both, but it's not specified further than that.

In the wake of this, major industrial powers such as the US, the EU and Japan have been using bilateral free trade agreements and investment treaties to push even stronger life patenting rules in the rather aggressively "TRIPS-plus" provisions over biodiversity in the South. They do this in several ways:

- requiring the patenting of plants and animals under national law this is common under US FTAs
- requiring accession to the Union for the Protection of New Plants Varieties (UPOV) or at least implementation of the provisions of its Convention, a softer patent system for crop seeds – this is common for US, EU and Japanese FTAs
- requiring accession to the Budapest Treaty on patenting of micro-organisms this is common for US and EU FTAs

So the push for Budapest is happening through bilateral trade deals, such as CAFTA, which are all the rage now as further trade liberalisation talks at the WTO have been getting nowhere for many years.

Related GRAIN materials:

* For a tally of who is being pushed into Budapest through FTAs, see GRAIN, "Bilateral agreements imposing TRIPSplus intellectual property rights on biodiversity in developing countries", October 2007. http://www.grain.org/rights/?id=68

* "Japan digs its claws into biodiversity through FTAs", August 2007, http://www.grain.org/articles/?id=29

* developing country markets they want to penetrate further. FTAs in particular have been used to push "TRIPS-plus through the backdoor", July 2001. http://www.grain.org/rights/?id=41



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to defend this wealth by introducing regulations on bioprospecting. Such legislation would be in line with international conventions such as the CBD. And the last meeting of the TRIPS Council, in October 2007, showed increasing support for the proposal.¹ The Budapest Treaty, however, completely ignores these discussions and facilitates the appropriation of biological wealth without any regard for the megadiverse countries' proposal about certificates of origin (which is already weak and excessively conciliatory).

Given that all Central American countries that have signed CAFTA are members of the WTO and the CBD, which policies and instruments will govern access to biological material within their shores? Budapest? The CBD? TRIPS? National laws? A minimum of common sense would oblige parties to the Budapest Treaty to introduce mechanisms to link the treaty to all those other international pacts that are in some way relevant to the issues it deals with. But that is not on the table.

• No definition of "micro-organism": oversight or trickery?

Neither the Budapest Treaty nor the WTO TRIPS Agreement defines the term "micro-organism", even though it is crucial to both of them. This is a major omission that promotes legal uncertainty about the very essence of the Budapest Treaty and about what is and what is not patentable under

1 See "Mandatory Disclosure of the Source and Origin of Biological Resources and Associated Traditional Knowledge under the TRIPS Agreement", South Center Policy Brief No. 11, October 2007.

Not only micro-organisms

Lorelly Arce Badilla

The Ombudsperson was informed that those in favour of the Budapest Treaty, in their attempts to convince others of their good faith, claimed that the Treaty facilitated disclosure of the invention and that the deposit was a complement to disclosure. Those not in favour of the treaty argued from the start that the Budapest Treaty not only did not facilitate disclosure but replaced it, which would have important implications.

Some of those in favour of the Treaty refer to the disclosure that is currently requested in Costa Rica by the Registry of Property as "simple" and consider the replacement of the same by a deposit, as regulated by the Treaty, to be acceptable. It appears that their opinion today about the treaty's replacement of disclosure is similar to that of those who have opposed the treaty. What is certain is that this procedure replaces disclosure as conceived in our laws, and the idea of depositing prevails. In Costa Rica, disclosure is an indispensable requirement for any patent application, and is not "simple". Applications must, among other things, specify the invention in a sufficiently clear and complete way that it can be evaluated, and that any person with knowledge of the corresponding technical subject can implement the invention.

So to apply for a patent makes the procedure for deposit and application interdependent and, consequently, establishes a relationship between disclosure with the above-mentioned characteristics in our legislation and disclosure as indicated in the Budapest Treaty, which is only scientific and/or taxonomic and, what is more worrying, not obligatory. Moreover, the applicant making the deposit can indicate that he has no knowledge of the properties of the micro-organism, which may represent dangers to health and the environment; all this in accordance with the regulations of the Budapest Treaty.

The concerns set out above appear even more reasonable if it is considered that the Guide for the deposit of microorganisms under the Treaty states that the only obligation is that depositors identify the micro-organism they are depositing with a symbol or number. The important thing is that the insufficiency of disclosure offered under ratification of the Treaty would contribute to reducing requirements for patent applications as established in our legislation, as well as the fact that the little information offered by patent applicants would not allow others to exercise the right to oppose the granting of patents under all the conditions required and established in the country's legislation.

The Budapest Treaty obliges states to recognise deposits of micro-organisms at the International Depository Authorities and does not expressly require them to have an International Depository Authority or centre for the deposit of micro-organisms, which does not however restrict depositing at the international authority chosen for the deposit of microorganisms and other biological material. In other words, with or without the International Depository Authority, by ratifying the Budapest Treaty, the country will be creating conditions to facilitate the patenting of micro-organisms and other life forms, many of which are not currently permitted under Costa Rican legislation, for example, micro-organisms not genetically modified; DNA sequences; plants and animals; natural processes and cycles; inventions essentially derived from knowledge associated with traditional or cultural biological practices in the public domain; inventions that if they were to be exploited commercially as a monopoly, might affect agricultural processes, and products that are considered as basic for the food and health of the country's inhabitants. Costa Rican legislation prohibits the patenting of higher life forms, and the principles contained in Articles 20 and 21 of the country's Constitution are incompatible with the private appropriation of human beings, including of course, their genetic material.

Excerpts taken from: Criterio Tratado de Budapest Defensoría de los Habitantes al Presidente de la Comisión de Asuntos Internacionales. Asamblea Legislativa. Oficio DH 797–2007. 3 November 2007.







Article 27.3(b) of TRIPS. This is deliberate. In a significant intervention at a TRIPS Council meeting, the US government made clear that it has no intention of including a definition of microorganism in international patent law because "rapid changes in microbiology will make constant updating necessary".²

This lack of definition means that, in practice, virtually anything can be understood as a microorganism. And this is what is happening. If we look at the lists of deposits held by the Budapest Treaty IDAs,³ we find that biological and biochemical material, such as deoxyribonucleic acid (DNA), ribonucleic acid (RNA), human cell lines, embryos, nematodes, seeds and other organisms, are being deposited as if they were micro-organisms, even though they are not. All this clearly serves the interests of the patent-holders.

A debate over ethics in Costa Rica

Because of this sheer lack of logic in what qualifies as a micro-organism for deposit at the IDAs, the Costa Rica's ombudsperson (Defensoría de los Habitantes) issued a far-reaching report to the Legislative Assembly about the implications of having to sign the Budapest Treaty as a requirement of CAFTA. This report is written from a human rights perspective, one that gives precedence to life and human dignity over research and science. The ombudsperson concluded that by surreptitiously introducing human life forms into a context of intellectual property rights, the Budapest Treaty was in conflict with ethical principles as these are understood and practised in Costa Rica. The report highlighted the following issues as the most problematic: details of deposits are not published; no description of deposits is available; deposits have no certificate of origin; and there is no definition of "micro-organism".

On 20 November 2007, the Episcopal Conference of the Catholic Church in Costa Rica, after pressure from various groups and individuals and after months of silence, finally announced its position on the Budapest Treaty.⁴ Among the points it raises are the following :

The Episcopal Conference of Costa Rica shares the concern that the Budapest Treaty, currently before the legislature, by not excluding human gametes [cells whose nuclei unite with those of other cells to form new organisms] and embryos from the scope of "micro-organisms", can be interpreted, both now and in the future, to include them, harming both human dignity and human rights.

It also urged members of the legislature to approve the constitutional reform that is required to guarantee respect for human life, stating that:

In the event that a clear and written commitment is not made to guarantee approval of this constitutional article, the bill "Adherence of Costa Rica to the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure" should not be approved.

Conclusion

The questions raised by this debate are fundamental. How can Costa Rica support a Treaty that does not even honour the principle of disclosure that is supposedly part of the contract between inventors and society? How can the country adhere to a treaty with its subject matter undefined, which means that its content can be manipulated? Is this not to accept what lawyers call "legal insecurity"? How can one fail to question the lack of harmony and convergence between this Treaty and the relevant international treaties and conventions, and with the legislation on biodiversity and even with the terms and scope of intellectual property? In addition, how can the divergence between national legislation, which defines micro-organism, and the Budapest Treaty, which doesn't, be acceptable, especially when the Budapest Treaty allows anything, even an embryo or human cell cultures, to be deposited as a micro-organism?

For all these reasons, many groups in Costa Rica oppose signing the Budapest Treaty as it involves accepting the commercial values that underpin it, which are incompatible with ethical, environmental, socio-economic and legal considerations. In addition, it flies in the face of the major public debate on bioethics and the patenting of life that many of us in Costa Rica feel is long overdue. Even more, the international multilateral discussions on patenting are not exhausted, which makes it completely unreasonable to demand that countries make further provision for the patenting of life forms. This is an important discussion: our experience is a warning to other groups in other countries, who will face the same problem when their governments negotiate a free trade agreement with the USA or any other similarly demanding country. 🎽



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Part II: Specific requirements of Individual International Depository Authorities and Industrial Property Offices. 4 Costa Rican Episcopal

3 WIPO, Treaty of Budapest,

2 Secretariat of the Council for

TRIPS, "Review of the Provision of Article 27.3(b): Summary of

issue raised and points made",

IP/C/W369, WTO, Geneva, 9 March 2006, paragraph 13.

http://tinyurl.com/3e54u5

4 Costa Rican Episcopal Conference, "A la opinión pública. Comunicado sobre la aprobación del proyecto de ley 'Adhesión de Costa Rica al Tratado de Budapest sobre el reconocimiento del Depósito de Microorganismos a los fines del Procedimiento en Materia de Patentes'," *Diario Extra*, 27 November 2007.