Patenting Life?

(A Primer on the TRIPs Review)

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TRIPS

Article 27 Patentable Subject Matter

3. Members may also exclude from patentability:

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

1. What is TRIPS?

RIPS stands for Trade-Related Aspects of Intellectual Property Rights. It is one of the agreements signed at the end of the Uruguay Round of GATT negotiations in 1995.

The United States put intellectual property rights (IPR) onto the agenda of the last GATT round. They said that since developing countries don't have strong IPR regimes, US industries are losing unpaid royalties when their products are sold abroad. (You pay royalties to the Coca-Cola Company every time you buy Coke in a registered container, because they have a trademark on the logo.) In fact, American manufacturers argued that the rest of the world owed them about \$24 billion per year in unpaid royalties. At that time, developing countries were already paying \$18 billion per year to developed countries for technology transfer (Gaia/GRAIN, 1998c). If countries like the US actually paid the developing countries for access to their biodiversity – which the US pharmaceutical and farming industries rely on – the debt burden would be reversed. For example, the Botanical Research Institute

Who owes whom?

A study published by the UN Development Program (RAFI, 1994) shows that the real royalty pirates are the TNCs, not the developing countries. If a 2% royalty was charged on biological diversity developed by local innovators in the developing countries, the developed countries would owe over US\$300 million in unpaid royalties for farmers' crop seeds and over US\$5 billion in unpaid royalties for medicinal plants.

of Texas has already collected over 100,000 specimens in the most interesting and endangered areas of the country. From 1985 to

1992, Japanese pharmaceutical firms already applied for patents on Philippine medicinal plants like banaba, sambong and lagundi. The US pushed hard and TRIPS became part of the Uruguay Round package of agreements. It covers seven fields of intellectual property: copyrights, trademarks, geographical indications ("Scotch" whisky), industrial designs, patents, topographies of integrated circuits and trade secrets. For these seven areas, TRIPS lays down minimal standards of protection and enforcement procedures. TRIPS is

Some key rules of WTO

- The Uruguay Round agreements which established WTO formed a take-it-orleave it package. A country could not say it liked the Agriculture Agreement but not TRIPS. Nor can one express reservations on an agreement.
- National Treatment is a basic principle. Any right or privilege given to a national in implementing the WTO agreements must be available for nationals of all other WTO members. No discrimination is allowed.
- Dispute settlement is what gives the WTO "teeth" and makes it the most powerful international institution. If a country fails to honor a commitment, another WTO member can retaliate through trade sanctions. In case of disputes, bilateral negotiations between the countries are encouraged. If the parties don't settle the dispute within 60 days on their own, a panel of three experts will take an "independent" decision on the case. The ruling of the panel can be appealed, but the decision of the Appellate Body will then be final and binding.

also subject to the basic rules of the World Trade Organisation, which replaced the GATT.

2. What does TRIPS say about patenting life?

TRIPS is the first international treaty which makes it legal – and compulsory – to patent life. This is very controversial. Most biodiversity is found in developing countries. But the developed countries have sophisticated technologies – such as genetic engineering — to extract value from biodiversity. That is the reason they want patent protection on life forms. It would mean that major transnational corporations like Monsanto/Cargill or Pioneer/DuPont can take genes from the fields, forests and coastal waters of countries like the Philippines, manipulate them in their labs back home and patent them. If the Philippines applied the

same patenting rules, Filipinos would have to pay royalties on their own resources and knowledge!

TRIPS Article 27.3/b/ allows countries to exclude plants and animals from patentability. Developing countries in general will take advantage of this exclusion to prohibit such patents domestically. However, some developed countries, like the US, will not. That means that biopiracy—the patenting of the developing countries' genetic resources and traditional knowledge by the developed countries—will continue.

Also, *TRIPS requires that all countries provide patents on micro-organisms*. Micro-organisms are life forms. And depending on how it is defined, a plant cell can be considered a micro-organism yet it can grow into an entire tree. A patent on such a cell could extend to trees, even if you can't patent a plant. The Philippine Constitution (Art. XII, Sec. 2) states that the State is the owner of all "flora and fauna" and "with the exception of agricultural lands, all other natural resources shall not be alienated." Allowing intellectual property rights over fauna or flora is a strong form of alienation since IPRs are *exclusive mo*-

TRIPS Article 27.3(b) says that:

Countries may...

- exclude plants and animals from patentability; and
- exclude essentially biological processes for the production of plants and animals from patentability

Countries must...

- allow patents on micro organisms
- allow patents on non-biological and microbiological processes for the production of plants and animals
- provide for the protection of intellectual property on plant varieties, either through patents or an effective sui generis system

nopoly rights that prevent other people from using or producing something.

For most developing countries, it is not clear how TRIPS distinguishes between plants and animals, which do not have to be patented, and microorganisms, which must be patented. Nor is it clear why essentially biological processes do not have to be patented, but microbiological and non-biological processes do. After all, a microbiological process is an essentially biological process.

3. What is this "effective sui generis system"?

This is a big and unanswered question. While TRIPS allows countries to exclude plants from their patent laws, it does require that countries provide some kind of IPR over plant varieties. Plant varieties are what farmers use, so farmers will be most affected (Leskien and Flinter, 1997).

This phrase got into TRIPS because of the European Patent Convention, which prohibits patents on plant and animal varieties.

Sui generis is Latin for "special, unique". You have a sui generis law when it is a law that is specially created for its purpose. For example, the Europeans set up a system of plant breeders' rights (PBR) in the 1960s. Breeders had been asking for some kind of ownership over their varieties since decades. Europeans found that the patent system was not appropriate for plants since plants reproduce themselves. They therefore created the *UPOV* system – a sui generis system for plant varieties. UPOV stands

Plant varieties?

Farmers don't plant "rice". They plant specific "varieties" of rice with characteristics adapted to their soils, water availability and climate. Filipino farmers have developed over 3,000 varieties of rice. Worldwide, there are over 100,000 rice varieties stored in genebanks like the one at IRRI, most of them collected from farmers. The sad part is that farmers have been encouraged since the Green Revolution to discard their traditional planting materials and grow just a few high-yielding varieties from high-tech labs. This is genetic erosion and it makes farms very vulnerable to pest and disease since most farmers are using the same few varieties.

for Union for the Protection of New Varieties of Plants and it has 43 members today, mostly industrialised countries. Another example can be found in informatics. The European Union has recently created a *sui generis* system of protection of intellectual property over electronic databases, since copyright in the area presented some weaknesses in the age of the Internet.

The US is pushing developing countries to adopt UPOV as a *sui generis* system. However, this is extremely controversial [Gaia/GRAIN, 1998b]. UPOV is a legal system designed to reward breeders which service industrial agriculture. The current UPOV rules, as revised in 1991, give breeders exclusive commercial rights that extend to the products of the harvest of any farmer using their varieties. That means not only can they claim ownership of a harvest – say, of flowers for the perfume industry such as ilangilang – but also the product – the perfume itself. Also, while the earlier version of the UPOV Convention (1978) contained a provision that allows farmers to save their harvest for seed, this is deleted from the 1991 text. It is up to each member government to determine whether their farmers will have a "privilege" to save seed for the next growing season.

All of this is very harsh for developing country farmers, who are not used to being policed by transnational seed companies. But this is what would happen if UPOV were used as a *sui generis* model. The fact is, TRIPS makes no mention of UPOV. So there is no reason, other than political pressure from countries like the US, to use it as a model.

As to the word "effective", no one knows what that means. One sui generis law might be effective for farmers of developed countries but not for those in developing countries.

4. Are the rights of farmers, fisherfolk and indigenous communities protected under TRIPS?

Not at all. This is causing the most problems for developing countries. In the past decade or so, a number of important legal instruments have been created to try to protect the rights of farmers and indigenous peoples in relation to biodiversity: both in the physical form of "genetic resources" and traditional knowledge. Among these are the Convention on Biological Diversity (CBD), the United Nations Food and Agriculture Organization (FAO), the International Labor Organization (ILO), and the United Nations Working Group on Indigenous Peoples. As a signatory to these international agreements, the Philippines is accountable to several commitments. In particular, the CBD is a binding agreement to protect the rights of indigenous and local communities

against the possible negative impacts of bio-patenting. TRIPS ignores all that. (Tauli-Corpuz, 1999)

In the Philippines, there are several laws and regulations that would become obsolete if TRIPS pushes through. TRIPS would also be inconsistent with a number of laws. For example, the Intellectual Property Code of the Philippines (R.A. 8293) states that Community Intellectual Rights to biodiversity-related innovations should be protected. Despite its limitations, the Indigenous Peoples' Rights Act (IPRA, R.A. 8371) also refers to Community Intellectual Rights. So does the Traditional and Alternative Medicines Act (TAMA, R.A. 8423). The EO 247 regulates access to genetic resources through provisions on prior informed consent. But these rights have not materialised. If TRIPS allows TNCs or national researchers to take out monopolies on indigenous or

TRIPS vs CBD

The CBD came into force in 1994 and has been ratified by 170 countries. The US has refused to ratify because it might harm their intellectual property pursuits. Regarding IPR, the CBD says several things:

- All countries have national sovereignty over their genetic resources (Art 1). This means they should not be forced to patent them.
- All parties must protect and promote the rights of local and indigenous communities with regards to biodiversity and traditional knowledge (Art 8j).
- Access to genetic resources must be on the basis of prior informed consent and the sharing of benefits. TRIPS requires no mechanism to this effect. That means that a patent granted in the US on a microorganism from the Philippines will not necessarily indicate where the microorganism came from. This means that the Philippines cannot claim a share of the commercial benefits. The CBD will not function.
- IPR should not go against the objectives of the Convention (Art 16.5). In fact, IPR and the TRIPS Agreement, do not espouse the objectives of the Convention, i.e. "the conservation and sustainable use of biological diversity." Monopolies diminish the chances for sustainable use (Gaia/ GRAIN, 1998a).

farmer varieties, all this talk about community rights is pointless.

5. Can we back out of the TRIPS Agreement or change it in any way?

No one can back out, unless the Philippines pull out of the WTO altogether. However, there is a chance to change the agreement, if we act fast.

According to the built-in timeframe, developing countries are supposed to implement TRIPS by 1 January 2000. (Most of developing countries now scrambling to draft *sui generis* laws for compliance with Article 27.3(b), without knowing what those laws should say.) However, because Article 27.3(b) was a compromise, offering less than what the US wanted, it was agreed to revisit

Timeframe for implementation of TRIPS

1 Jan 1995
1 Jan 1996
-1999 - Developed countries must implement
Article 27.3(b) under review in TRIPS Council
Ministerial Conference (Seattle, 30 Nov – 3 Dec)
1 Jan 2000
- 2000 - Developing countries must implement
Entire Agreement under review in TRIPS Council
Least developed countries must implement

the text in 1999. This is called a "review". And reviews can amend an agreement.

The built-in 1999 review of TRIPS 27.3(b) is both a problem and an opportunity. It is a problem, because it means that countries are supposed to implement something the terms of which might change. But it is an opportunity if developing countries have a clear and common strategy to change TRIPS before they have to implement it (Tansey, 1999).

The 1999 review goes on in the TRIPS Council at the WTO in Geneva. All WTO members can participate. There have been three meetings so far this year and the fourth and last meeting will take place on October 20-21. This does not mean that the 1999 review has to end at the October meeting. It can drag on. But if the implementation deadline for developing countries is 1 January 2000, then the October 1999 session is critical to secure an extension of the deadline.

6. What arguments can we take to the TRIPS review?

As of July 1999, developing countries started tabling proposals for amendment of TRIPS Article 27.3(b). Kenya, Venezuela, the Least-Developed Countries and the African Group have so far submitted papers. The African Group's is the most comprehensive.

Key problems faced by developing countries in implementing TRIPS

- IPRs on life such as patenting and plant variety protection à la UPOV are controversial and contested, worldwide. Developing countries argue that even as a trade agency, WTO must face up to and resolve the major policy issues raised by TRIPS: the ethics of patenting life, how to prevent biopiracy, the need to protect the rights of farmers and indigenous communities, and the unclear relationship between IPRs and development.
- One assessment of the developing countries is that TRIPS conflicts with their rights and obligations under the Convention on Biological Diversity. They are therefore demanding reconciliation between the two treaties, through amendment of TRIPS.
- No one knows what an "effective sui generis system" is. Developed countries push UPOV, but UPOV is a highly biased system designed for industrial agriculture. Only in October 1999 will the WTO Secretariat present the non-UPOV sui generis options to the members of the TRIPS Council, as demanded by Malaysia.
- According to the World Bank, the cost of implementing TRIPS will be high and payoff is not clear. For example, in Mexico it will require at least US\$32 million, in Indonesia US\$15 million and in India US\$6 million. (Finger and Schuler, 1999)
- Developing countries are behind schedule. They need more time.

The main arguments that are being voiced are the following:

PATENTING LIFE

Findings

- There is no basis for distinguishing between plants and animals, which can be excluded from patent laws, and micro-organisms, which must be included in patent laws. In the Philippine constitution, microorganisms are not mentioned, only flora and fauna. The same holds for essentially biological processes and microbiological processes, respectively.
- Plants, animals, micro-organisms and biological processes are all part of nature. Therefore they are discoveries, not inventions, and should not be patentable. (Microbiological processes are essentially biological and have to be treated as not patentable.) After all, we do not invent genes, we merely recombine them.
- If developing countries prohibit patents on plants and animals while developed countries patent them, biopiracy will continue.
- There is no mechanism for sharing benefits from the patenting of inventions derived from developing countries' biodiversity or traditional knowledge.

Possible solutions

- 1. Reword Article 27.3(b) to state that "Plants, animals, micro-organisms, and their parts, at all taxonomic levels, as well as biological processes for their production, are not patentable."
- 2. Incorporate provision to share benefits.

Which of the possible solutions is better?

The first solution is best as it resolves biopiracy and responds to ethical objections against patenting life. Experience proves that the idea that IPR could be used to share benefits is not viable.

PROTECTION OF PLANT VARIETIES – SUI GENERIS SYSTEMS

Findings

- If plants are not patentable, or countries have the option to legislate to that effect, there is no basis for requiring compulsory IPR protection of plant varieties. The European Patent Office has ruled that patents on "plants" amount in reality to patents on plant varieties, and therefore should not be permitted (since European law bans patents on plant varieties).
- IPR on plant varieties will have similar negative effects on farmers, indigenous peoples and the rest of society as patents.

- "Effective sui generis system" is not defined in TRIPS. It is not UPOV, but some countries insist, for their own benefit, that it should be.
- There is no provision for protecting the rights of farmers, indigenous peoples or other local communities. There is also no provision for protecting traditional knowledge. Yet countries are committed to protect all of these under CBD, FAO and national legislation.

Possible solutions

- 1. Delete the requirement to provide protection for plant varieties.
- 2. Define sui generis systems but use flexible terms so that they allow for protection of communities' rights and traditional knowledge.

Which of the possible solutions is better?

Many civil society groups prefer to see the obligation to protect plant varieties removed from TRIPS. This is consistent with the **"no patents on life"** position. It doesn't stop countries from legislating their own *sui generis* regimes. However, *sui generis* laws are very tricky. The stakeholders must be fully involved in this discussion. Do indigenous peoples support the culture of exclusive monopoly rights? Do farmers want IPR? What do the religious leaders say about the moral and ethical dimensions of "owning life"? Would communities want to see their rights defined and disputed through WTO? Are their rights "trade related"? Because of these grave uncertainties, it is better to withdraw this issue from WTO and settle it elsewhere.

OVERALL

Findings

- There is lack of empirical evidence of a link between IPR and economic development
- There is very little that is "trade-related" in TRIPS.
- TRIPS conflicts with the Convention on Biological Diversity.
- Developing countries need more time and expertise to deal with TRIPS.

Possible solutions

- 1. Extend the deadline to conduct a thorough and substantive review of all the issues generated by TRIPS Article 27.3(b). This should be done prior to the implementation deadline of 1 January 2000 so that developing countries are relieved of their obligations to implement until five years after such a review is completed.
- 2. Remove TRIPS from the WTO.
- 3. Amend TRIPS to make it compatible with CBD, especially regarding benefit-sharing and community rights.

Which of the possible solutions is better?

All of these are good solutions and they are not mutually exclusive. Extending the review before countries have to implement the current text is a high-priority and urgent option, so that countries and all stakeholders can deal more properly with these issues.

For more information on how to get involved in these issues, please contact

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ANNEX Official country positions on the review of TRIPS as of September 1999

Stakeholder	Patenting (life forms & biological processes)	Sui Generis (plant varieties)
Kenya ¹	- Need five-year extension of transition period - Harmonise TRIPS with CBD	Need five-year extension of transition period Increase scope of 27.3(b) to include protection of indigenous knowledge and farmers' rights Harmonise TRIPS with CBD
Venezuela ²	- In 2000, introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognise collective rights	
African Group ³	Review should be extended + additional five year transition after that Review should clarify that plants, animals, microorganisms, their parts and natural processes cannot be patented	 Review should be extended + additional five year transition after that Sui generis laws should allow for protection of community rights, continuation of farmers' practices and prevention of anticompetitive practices which threaten food sovereignty Harmonise TRIPS with CBD and FAO
LDC Group⁴	- There should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological processes, are not patentable Incorporate provision that patents must not be granted without prior informed consent of country of origin - Patents inconsistent with CBD Art 15 (access) should not be granted - Need for extended transition period	Sui generis provisions must be flexible enough to suit each country's seed supply system Need for extended transition period
Jamaica, Sri Lanka, Tanzania, Uganda, Zambia ⁵	- No patenting plants without prior informed consent of government and communities in country of origin	
SAARC ⁶	WTO must amend TRIPS to prevent biopiracy and not deprive farmers of their rights	
EU ⁷	- No weakening of provisions - No extension of transitional periods	- Supports in principle incorporation of UPOV 91 into TRIPS
USA ⁸	- Eliminate the exclusion for plants and animals so that they must be patentable in all countries	- Urges incorporation of UPOV 91 into TRIPS

¹ WT/GC/W/23 of 5 July 1999

² WT/GC/W/282 of 6 August 1999

³ WT/GC/W/302 of 6 August 1999

⁴ WT/GC/W/251 of 13 July 1999

⁵ http://www.foe.org/international/wto/govt.html of 2 September 1999

⁶ SAARC Council of Trade Ministers resolved to this effect on 10 August 1999. Deccan Herald of 11 August 1999.

⁷ 113 Committee, 219/99, of 27 April 1999.

⁸ WT/GC/W/115 of 19 November 1998.

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