

CIEL

Center for International Environmental Law

U.S. Office: 1367 Connecticut Ave., NW, Ste. 300, Washington, DC 20036 · Tel: +1 (202) 785-8700 · Fax: +1 (202) 785-8701

Geneva Office: B.P. 21 (160a Route de Florissant), CH-1231 Conches, Geneva, Switzerland · Tel/Fax: +41 (22) 789-0738

Writer's Direct E-Mail: ddownes@igc.apc.org · *Organizational E-Mail:* cielus@igc.apc.org

Web: <http://www.econet.apc.org/ciel/>

The 1999 WTO Review of Life Patenting Under TRIPS

Revised Discussion Paper -- November 1998

The 21st century is heralded as the “information age.” If we are indeed becoming a society in which information is the most valuable resource, then an overriding question will be, who controls the information? Who are the information haves and the have-nots? Intellectual property law, which defines ownership rights over information, is one of the main ways our society resolves these questions.

Historically, intellectual property rights such as patents and copyrights have been extended to inventors and creators as a reward for innovation, and as an incentive to disclose information to the public and promote innovation by others. Intellectual property in some form is almost universally recognized as an essential policy tool in market economies. The benefits to society of the legal right are, however, carefully balanced against the cost to society of granting it.

This balancing must take into account that the right is a time-limited exclusive right to control commercial use and sale of a valuable product -- a right which allows the holder to raise price and to reduce supply of the patented product to consumers. Patents on inventions that are particularly improved or innovative may confer market dominance or even a monopoly to the owner. Thus, the scope of these exclusive rights – in terms of time, technology covered, activities covered and geographical application – must be carefully defined to maximize benefits to society through a balancing of interests in stimulating innovation, avoiding excessive market dominance, and maximizing the free availability and exchange of information needed for a creative, innovative, and equitable society.

Today, the balance seems to be shifting. Intellectual property laws are defined through closed, secretive international negotiations dominated by industry – and are then brought to national legislatures as faits accomplis, without democratic deliberation. Combined with the technical, arcane nature of the intellectual property legal specialty, this has helped corporate interests to avoid public scrutiny and expand their control over developments in applications such as electronic information, biotechnology or pharmaceuticals. Industrial country governments promote corporate interests in expanded intellectual property rights in the name of maximizing national competitiveness in a global marketplace. The resulting boon to private investors – embodied in international treaties such as the trade agreements administered by the World Trade Organization – has been called an “information land grab” (Boyle 1996).

This paper outlines public interest concerns that citizens' groups need to air at the WTO, where many of the decisions are now being made about the contours of this “land grab.” The WTO needs to open up to public scrutiny and input in the context of three upcoming intellectual property debates. The first is the 1999 review of whether to require WTO members to recognize patents on life forms. The second is the review in 2000 of all WTO rules on intellectual property. The third is the possible inclusion of intellectual property on the agenda for upcoming trade negotiations. Governments need to respond to public input on the following needs:

1. The need to address environmental and indigenous goals and issues;
2. The need to avoid overly broad biotechnology patents;
3. The need to ensure that intellectual property does not reduce market competition;
4. The need for the WTO to promote development equitably in North and South;
5. The need for countries to manage investment in biotechnology;

6. The need to minimize the impact of unilateral pressure between trading partners;
7. The need to address environmental and ethical concerns about intellectual property.

The 1999 "TRIPS Review" of Life Patenting

At the WTO, the next step in this expansion of ownership over information may be the extension of WTO rules to require governments to recognize patents over life itself. Should living organisms or parts of organisms such as genes be considered "inventions" that can be patented under intellectual property law? Many citizens' groups in both the developed and developing world are concerned about the economic, social, environmental and ethical impacts of life patenting. Moreover, many developing country governments are concerned that the control of the nature and distribution of new life forms by multinational corporations may affect their development prospects and food security. Life patenting raises concerns about consumer rights, biodiversity conservation, environmental protection, sustainability of agriculture, indigenous rights, scientific and academic freedom, and, ultimately, the economic development of many developing countries dependent on new technologies.

The question of life patenting will come up in 1999 under the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Negotiated in the Uruguay Round of trade talks, the TRIPS Agreement is the most important international law on intellectual property. It sets minimum standards for national protection of intellectual property rights and procedures and remedies for their enforcement. Its enforcement measures -- including the potential for trade sanctions against non-complying WTO members -- are unprecedented in the field of international intellectual property.

The TRIPs Agreement requires countries to recognize patents on most products and processes, including pharmaceuticals, modified microorganisms, and "microbiological processes" (Article 27.3(b)). Currently, however, it does not require countries to recognize patents on plants or animals, or "essentially biological [but not microbiological] processes for the production of plants or animals" (*ibid.*). Under Article 27.3(b) of the TRIPS Agreement, each country has the discretion whether to recognize these patents. Countries may protect plant varieties either through patents or an "effective *sui generis* system" or both. This exception exists because many other countries rejected the US demand for patenting of plants and animals, on economic, legal or ethical grounds.

In 1999, the TRIPs Council of the WTO will review Article 27.3(b) of the TRIPs Agreement. It can be expected that the United States will seek to remove this discretion and to require countries to recognize patents on plants and animals. Other industrialized countries may side with the US, especially since the European Union recently decided to extend patents to cover life forms (EU 1998). A number of developing countries, on the other hand, are likely to oppose the removal of the exception.

Why the WTO Should Maintain the Life Patenting Exception

WTO Members should resist the proposed extension of TRIPS to life patenting. They should work through the WTO TRIPs Council to maintain the discretion about plant and animal patenting that the current language of Article 27.3(b) allows, as well as the right to develop *sui generis* systems for plant variety protection. They should also consider expanding the exception to cover microorganisms. Maintaining this discretion is essential for a number of reasons:

1. Maintaining Flexibility to Address Indigenous and Biodiversity Goals. First, it gives countries the space they need to experiment with various approaches to implementing Article 8(j) of the Convention on Biological Diversity, which requires protection of the traditional knowledge, innovations and practices of local and indigenous communities. Given the complexity of the issues, countries badly need to develop experience resolving them through pilot projects and programs, and this will require a phase of experimentation. Requiring all countries to uniformly recognize life patenting, and requiring uniform systems of plant variety protection, would hinder countries from gaining the experience needed to

implement Article 8(j) effectively.

2. Avoiding Trends Toward Overly Broad Biotechnology Patents. The scope of biotechnology patents in countries such as the United States (that are furthest along the road of patent expansion) is frequently too broad, which could actually stifle, rather than stimulate, productive innovation with consequent effects on international competitiveness and consumer health and welfare. There is significant concern about over-broad patent claims in the US itself (e.g. Eisenberg 1992, 1994). Even US industry groups have opposed some of the furthest extensions of rights sought in recent patent applications (Eisenberg 1992.) This suggests that the rest of the world is better off taking a “wait-and-see” approach” in which they can learn from the US experience, rather than rushing into a decision whose benefits are unproven.

3. Maintaining Competitive Markets. The competitive impacts of intellectual property rights counsel against expanding international obligations to protect them at this time. The combination of expanded international intellectual property protection with shifts in market dominance in the global economy raises significant concerns about market competitiveness (Anderson 1998). The over-broad patent claims in biotechnology, with continued blurring of the lines between invention and discovery, intensify the risk of anti-competitive impacts. On the other hand, some argue that intellectual property rights in the hands of small firms or newcomers to a market may sometimes serve as a tool to enhance competition.

In any case, there is currently a policy imbalance within the WTO. The WTO provides powerful protection of intellectual property through the TRIPS Agreement. While the TRIPS Agreement permits Members to take “appropriate measures” to prevent the abuse of intellectual property rights or practices that unreasonably restrain trade, there is no international set of competition disciplines to guard against market abuses, in large part because of US opposition. No further expansion of intellectual property should take place without a thorough examination of the competitive impacts and the possible need for competition disciplines to manage them. The first step should be for the TRIPS Council to evaluate these impacts as part of the overall review of the agreement in the year 2000. In addition, the TRIPS Council may need to define the types of measures needed to control anti-competitive abuses. More generally, the WTO needs to develop rules for ensuring the competitiveness of global markets. It should certainly not expand intellectual property requirements until a counterbalancing effort on competition is underway.

4. Preventing Greater Disparities Between North and South. The proposed extension of TRIPS to life patenting would further unbalance the Uruguay Round bargain in favor of industrialized countries and against developing countries. The protection afforded by the TRIPS agreement expands exclusive intellectual property protection in time (from 17 years in the US to 20 years under TRIPS); in scope (the TRIPS Agreement covers “any invention” -- broader than most preexisting national systems); and in geographical application (to all WTO Member countries). The increase in prices that will result from recognition of patents on products such as pharmaceuticals will reduce the access of poor people in the developing world to them, with resulting declines in health quality and life expectancy, at least in the near term.

As intellectual property rights are predominantly owned and controlled by corporations in industrialized countries, the protection of these rights worldwide entails a significant transfer of revenues from developing to industrialized countries. The concessions offered to developing countries in the Uruguay Round to offset this transfer – including reduction in agricultural subsidies, better market access and special and differentiated treatment – have not yet been honored by industrialized countries. Until they are, the WTO should not add to its requirements for intellectual property protection.

5. Managing Investment in Biotechnology. Countries may also wish to avoid expansion of intellectual property rights in order to limit the flow of private investment into biotechnology, until they have a proper regulatory framework in place to control its environmental impacts. In countries where

internal development of biotechnology products is a possibility, this would be one way of implementing the Biodiversity Convention's precautionary approach and its requirement that its Parties protect against environmental impacts of genetically modified organisms and maintain economic incentives for conservation. If investment flowed too quickly into this industry, there would be a vested interest against regulation and in favor of externalizing environmental costs so that society as a whole, rather than the producers of biotechnology, takes on the risks. By definition, intellectual property rights are designed to encourage private sector investment in technological development. Hence, avoiding the extension of intellectual property to modified organisms remains a reasonable policy choice for countries until an effective biosafety protocol is negotiated and enters into force, and effective national regulations and institutions are in place. Of course, this policy would supplement rather than replace environmental regulation of biotechnology products themselves.

6. Counterbalancing Unilateralism on Intellectual Property. Finally, the WTO should not raise TRIPs standards while major trading nations are still applying unilateral pressure to force trading partners not only to meet TRIPs standards but to go beyond them. This is another serious problem that disturbs the balance of tradeoffs which persuaded developing countries to sign the Uruguay Round agreements. For instance, the US has threatened Argentina with trade sanctions on the ground that Argentina's protection of intellectual property rights is not strong enough. Yet some US demands seemed to seek *stronger* protection than TRIPs requires. For instance, the US complained that Argentina's new patent law delayed extension of patents to pharmaceuticals until 2000, although developing countries do not have to phase in patent protection of new product types under TRIPs until a total of 10 years after TRIPs entered into force, well after the year 2000.

7. Addressing Environmental and Ethical Concerns. Life patenting raises significant environmental (UNEP 1996) and ethical issues for many people in many countries. There are concerns that patents on crop varieties, for instance, augment the incentives in favor of monocultures and the use of expensive inputs such as fertilizer associated with many improved crop varieties; this in turn causes environmental harm. In addition, many people in many societies feel that the structures of genes, animals or plants -- the structure of life itself -- should be kept free from commodification and market transactions, as an ethical matter. The private ownership and marketing of these fundamental structures of life violates religious and moral principles in a number of cultures. The WTO should not adopt a blanket rule when so many perspectives and concerns are yet to be considered.

Why the WTO -- as Part of Civil Society -- Should Examine Broader Concerns About Intellectual Property

The reasons discussed above for maintaining the exception to life patenting raise broader concerns about intellectual property. Thus, they argue for a broader discussion within the WTO about the social, environmental, economic and political implications. Yet this discussion cannot be left to the WTO alone, or to intellectual property specialists.

As Lester Thurow wrote recently in the Harvard Business Review (1997), "[i]t is clear that the invention of a new gene for making human beings different or better cannot be handled in the same way as the invention of a new gearbox." Decisions about the evolution of intellectual property cannot be left for technical analysis by specialists or closed international organizations. They must be debated by a full range of institutions and experts, and a full range of representatives from different groups within civil society. "[D]ifferent cultures and different parts of the world look at intellectual property rights quite differently There are real differences in beliefs about what should be freely available in the public domain and what should be for sale in the private marketplace" (Ibid.). Thus, the debate must seek to engage and respond to the different values and interests involved.

In the WTO and elsewhere, we are seeing the beginning of "a scramble among the powerful to grab valuable pieces of intellectual property, just as the powerful grabbed the common lands of England"

in advance of the Industrial Revolution (Thurow 1997). This is not a formula for a just and prosperous “information society.” Instead, we need a “socially managed enclosure movement for intellectual property rights” (ibid.), in which society as a whole defines the legal rights and duties that will govern the most important resources and exchanges of the future. As steps toward such a movement, we recommend the following:

- A full and public discussion within the TRIPS Council and the 1999 WTO Ministerial Conference of the public interest questions raised by intellectual property.
- A commitment by WTO Members to discuss fully and openly the public interest concerns involved in intellectual property, and to carry out a thorough review of the TRIPS Agreement in 2000, *before* starting negotiations on additional intellectual property requirements.
- A commitment in the WTO to address related issues alongside intellectual property policy, such as laws and policies needed to maintain healthy competition and limit anticompetitive impacts of intellectual property in the global market place.
- Involvement of other relevant institutions, such as UNESCO, the World Health Organization, and the World Intellectual Property Organization, and full participation by citizens’ groups.

For more information, contact David Downes in CIEL’s Washington office, or Matthew Stilwell in CIEL’s Geneva office.

Sources

Parts of this paper are adapted from: David Downes. 1997. Using Intellectual Property as a Tool to Protect Traditional Knowledge: CIEL Discussion Paper. Washington, D.C.: Center for International Environmental Law.

Anderson, Robert D. In press. “The Interface between Competition Policy and Intellectual Property in the Context of the International Trading System.” *Journal of International Economic Law* 1(4): _____.

Boyle, James. 1996b. “Sold Out.” *New York Times*, Mar. 31, 1996. Web: <http://www.wcl.american.edu/pub/faculty/boyle/sold_out.htm>

Eisenberg, Rebecca S. 1992. “Genes, Patents, and Product Development.” *Science* 257:903-908.

Eisenberg, Rebecca S. 1994. “Technology Transfer and the Genome Project: Problems with Patenting Research Tools.” *Risk: Health, Safety & Environment* 5:163-175.

(EU) European Union. 1998. *European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions.* Available through search function on EU web site, <<http://europa.eu.int>>.

Thurow, Lester C. 1997. “Needed: A New System of Intellectual Property Rights.” *Harvard Business Review* September-October 1997.

(UNEP) United Nations Environment Programme. 1996. Convention on Biological Diversity. Conference of the Parties. *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits From Its Use: A preliminary study: note by the Executive Secretary.* [Montreal]: UNEP. UN Doc. No. UNEP/CBD/COP/3/22. Web: <<http://www.biodiv.org>>.

November 7, 1998