

Volume 9

Perspectives on Intellectual Property

EDITED BY
EDITORS Dr Peter Drahos and
Professor Michael Blakeney

IP in
Biodiversity
and
Agriculture



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Perspectives on Intellectual Property: Volume 9

IP in Biodiversity and Agriculture

Volume editors: Dr Peter Drahos and
Professor Michael Blakeney

Perspectives on Intellectual Property is a series of books each concentrating on a particular aspect of intellectual property law. Each book has an international scope and a depth of analysis greater than can usually be found in journal articles. This series brings together a team of expert editors and contains contributions from a range of academic writers and specialist practitioners.

The *Perspectives on Intellectual Property* series is edited by Professor Michael Blakeney, the Herchel Smith Chair and Director of the Queen Mary Intellectual Property Research Institute, Queen Mary, University of London. This volume is co-edited by Dr Peter Drahos, Herchel Smith Senior Research Fellow in Intellectual Property at Queen Mary.

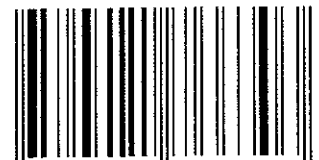
This volume contains a collection of papers focusing on the need for global intellectual property regulation to be integrated with the regulatory objectives to be found in the international regimes governing biodiversity, food and agriculture. The essays draw attention to this broad set of global regulatory agendas with which intellectual property systems, principally through the auspices of TRIPS and the WTO, are now irrevocably linked.

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Foreword

One effect of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been to raise the profile of intellectual property rights. The rules and practices which make up the institution of intellectual property have gained the attention of a wider audience and become more transparent as a result of their inclusion in the World Trade Organization (WTO) regime. International NGOs such as Greenpeace, Oxfam and Médicins Sans Frontières are much more conscious of the effects of intellectual property rights on the issues that matter to them than they were prior to TRIPS. Moreover, intellectual property is no longer just trade-related, because the WTO is no longer just a trade organisation. The WTO has become a key meeting place in the global village. It is a place in which environmental issues, labour standards and human rights issues are increasingly being linked to investment, competition and market access agendas. It has become a place in which global regulatory issues are discussed and decided.

Intellectual property rights are being required to serve much broader regulatory agendas than they have in the past. As the essays in this volume make clear the objectives of global intellectual property regulation have to be integrated with the regulatory objectives to be found in the international regimes governing biodiversity, food and agriculture. So, for example, it is accepted by states that the International Undertaking on Plant Genetic Resources must guarantee access to essential plant genetic resources in order for agriculture to progress. Progress in agriculture aids the goal of food security. Intellectual property rights, however, provide the basis upon which their owners may exclude others from access to, amongst other things, plant genetic resources. Clearly, if intellectual property regulation is to co-exist with and complement the regulation of food and agriculture, a great deal of dialogue and complicated international and national standard-setting will be required.

In the past the main regulatory objective of intellectual property rights has been to promote the allocation of resources to technological and cultural innovation. The use of intellectual property solely for this purpose is being questioned from a variety of perspectives. Intellectual property rights, as the literature on the Convention on Biological Diversity shows, are seen to be important in an equitable sharing of the benefits of the technological pie and not just in an increase in its size.

The controversy over biopiracy, which is discussed in some of the essays in the present volume, also shows that many people now expect intellectual property to serve distributive values. Environmental discourse through the agency of the Brundtland Commission has introduced the idea that technological development must be sustainable. Article 27(2) of TRIPS allows for the exclusion from patentability of inventions that seriously prejudice the environment. Future intellectual property regulation may be called upon to play a much greater role in managing technological change as opposed to simply promoting it.

Similarly, human rights discourse is challenging the neo-liberal agenda of market globalisation. One result of this has been a questioning by the Human Rights Commission of the extent to which the globalisation of intellectual property rights serves basic human rights such as the right to health and the right to education. The patent system, for example, seems to have been very efficient at delivering blockbuster life style drugs like Viagra, but much less efficient when it comes to allocating resources for the development of vaccines for tropical diseases like malaria. The many documented cases of biopiracy in which traditional knowledge and biological materials are used without permission by patent seekers over that knowledge and material hardly squares with Article 15 of the International Covenant on Economic, Social and Cultural Rights which recognises the right of everyone to take part in cultural life and to benefit materially from scientific productions of which he or she is the author. Intellectual property rights, by allowing for the commodification of the most basic biological information, have the potential to turn traditional groups into trespassers in their own cultures. The design of future intellectual property rights will have to pay much more attention, one suspects, to the international human rights framework.

The essays in this volume draw attention to a broader set of global regulatory agendas with which intellectual property systems, principally through the auspices of TRIPS and the WTO are now irrevocably linked. Traditional defenders of intellectual property rights may wish it were not so. However, the failure to engage meaningfully with the role of intellectual property in the regulation of food, agriculture, biodiversity, the environment and health will lead intellectual property into a crisis of legitimacy much deeper than the one it is currently experiencing. The papers in this volume address aspects of this crisis and suggest ways in which intellectual property regulation can progress.

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synthesized form as well as chromosomes, cells, tissue, organs and organisms, including cloned, transgenic and chimeric organisms, will not be allowed to be claimed as commercially negotiable genetic information or intellectual property by governments, commercial enterprises, other institutions or individuals.

The Parties to the treaty—to include signatory nation states and Indigenous Peoples—further agree to administer the gene pool as a trust. The signatories acknowledge the sovereign right and responsibility of every nation and homeland to oversee the biological resources within their borders and determine how they are managed and shared. However, because the gene pool, in all of its biological forms and manifestations, is a global commons, it cannot be sold by any institution or individual as genetic information. Nor can any institution or individual, in turn, lay claim to the genetic information as intellectual property.”

3. The TRIPS Reviews and the CBD: A Dress Rehearsal?

Peter Drahos

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His publications include *A Philosophy of Intellectual Property* (Dartmouth Press, 1996) and (with John Braithwaite) *Global Business Regulation* (Cambridge University Press, 2000). He is General Editor of the series *Globalization and Law* (Dartmouth Press).

The TRIPS Reviews and the CBD: A Dress Rehearsal?

I. Introduction

When exhausted trade negotiators put the finishing touches on the Final Act of the Uruguay Round¹ (Final Act) they probably thought that they were entitled to some rest. That Final Act brought together the most complex set of agreements in the history of international trade negotiations, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The complexity and range of these agreements meant that probably only a few players had any real understanding of them as a package. Most states at one point or another fell by the wayside because of a lack of technical capability, inexperience, ignorance or a lack of bargaining power. Most trade negotiators went home and told their domestic constituencies that they were winners. This is not surprising. No trade negotiator ever goes home saying he or she got a bad deal.

The Final Act, however, did not signal an end to the negotiating process. In fact it was only a beginning. Dotted throughout the agreements that make up the Final Act are obligations to continue negotiating on specific issues such as trade in services² or, as in the case of TRIPS, to review parts of the agreement. On top of this, trading nations have had to learn to work within a new institutional structure, the World Trade Organization (WTO), and a new dispute resolution process, a process that may yet see the evolution of a trade court that acts as a Supreme Court for the world. In addition, soon after the Final Act talk began of a new trade round, perhaps mini-rounds on issues like environment and trade, competition policy and trade, or perhaps another giant round with which to see in the new millennium. It depended on which person you talked to in the WTO. Attempts to launch a new multilateral trade round (MTN) in Seattle failed, spectacularly so. But in any case much of the real action in trade negotiations had shifted into free trade agreements (FTAs) amongst states. More than 100 FTAs have been registered with the WTO.

TRIPS also has an internal dynamic of review. The so-called "built-in-agenda" of TRIPS requires:-

- further negotiations in the Council for TRIPS on the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system (see Art. 23.4);

¹ Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, Marrakesh, April 15, 1994.

² Article XIX(1) of the General Agreement on Trade in Services obliges members of the WTO to

- Members to enter into negotiations aimed at increasing the protection of individual geographical indications (see Art. 24.1);
- the Council for TRIPS to review the application of the provisions on geographical indications, the first such review having to take place within two years of the entry into force of the WTO Agreement (see Art. 24.2);
- a review of Article 27.3(b) four years after the date of entry into force of the WTO Agreement (see Art. 27.3(b));
- the Council for TRIPS to examine during a five year period beginning from the date of entry into force of the WTO Agreement the scope and modalities of what are known as non-violation nullification and impairment complaints (see Art. 64.3); and
- the Council for TRIPS to review the implementation of TRIPS after January 1, 2000 and every two years thereafter. The Council also has the option of undertaking other reviews under this section (see Art. 71.1).

This is not the end of this process of reviews. The Council for TRIPS as part of its monitoring obligations under Article 68 has been reviewing the intellectual property laws of Members to make sure they are complying with their obligations under the Agreement. It is also worth noting in this context that a Member's intellectual property laws can also be reviewed under the WTO's Trade Review Policy Mechanism. Under this mechanism a Member's trade policies and practices are put under the microscope. A Member of the WTO is obliged to provide a report of its economy and face questions from other Members. In this way a Member's practices with respect to intellectual property can be scrutinised and questioned. All states at some point have to sit in this particular hot seat.³

There are two things to say about these reviews. First, they are an example of the way in which the WTO regime has locked states into a process of perpetual negotiation, a process that best suits states with high levels of negotiating capacity and resources. Secondly, the various reviews and monitoring work of the Council for TRIPS send the message to Members that their implementation of TRIPS is being watched by a WTO bureaucracy, a bureaucracy which gathers data on the performance of their obligations.

The remainder of this paper is divided in the following way. The TRIPS reviews are located in the context of the recent history of intellectual property protection for biotechnology. The second section of the paper briefly examines the United Nations Convention on Biological Diversity (CBD) and its connection with intellectual property. The third section discusses the options facing developed and developing countries when it comes to the CBD and the TRIPS reviews.

2. TRIPS in Context

TRIPS was an initiative of an international business coalition consisting of European, Japanese and U.S. multinationals.⁴ It was U.S. business that provided the leadership role. Essentially U.S. business saw the intellectual property issue as an investment issue. U.S. corporations wanted to be able to move their intellectual property portfolio to any part of the world to take advantage of various factors of production, safe in the knowledge that that portfolio would be protected on a worldwide basis. These companies had three broad objectives. The first was to globalise intellectual property protection. More states had to be persuaded to adopt intellectual property laws. The second objective was to begin a process of harmonising intellectual property laws to higher standards, thereby taking advantage of the principle of national treatment that had long been part of international intellectual property. The third objective was to create an enforcement mechanism that would ensure that states took their international obligations seriously. U.S. business was largely successful in fulfilling these goals. However, there were some comparatively minor disappointments.

One of these related to the provisions of TRIPS dealing with patents. During the Uruguay Round negotiations the U.S., along with Japan, had pushed for provisions on patent law that recognised very few restrictions on the scope of patentability.⁵ In this respect the U.S. was following a long tradition of patent expansionism in biotechnology that had been part of its domestic law since the nineteenth century. It was the U.S. Patent Office which in 1873 granted what was probably the world's first patent on a micro-organism when it granted a patent to Louis Pasteur for yeast.⁶ In the famous case of *Diamond v. Chakrabarty*,⁷ the majority of the U.S. Supreme Court took the view that it was for Congress to determine whether or not restrictions in the name of morality should be placed on the patentability of organisms. Their view was that it was the task of the courts to continue to adapt and expand the patent system unless otherwise directed by Congress. For ease of reference we might term this the amoral conception of patent law. The idea behind such a conception of patent law is to create the most expansive patent regime possible, leaving it to other areas of social regulation to deal with any social or economic problems that such a conception of patent law produces.

The patent provisions of TRIPS are, from the point of view of an amoral conception of patent law, somewhat disappointing. Amongst other things, Article 27(1) gives states the option of adopting a morality criterion in their law, and Article 27(3) allows states to prohibit the patenting of plants and animals. The main reason why the U.S. did not achieve as much as it wanted to on patents in TRIPS was that it did not have the strong support of the European Community and it had the

⁴ For the history see Peter Drahos, "Global Property Rights in Information: The Story of TRIPS at the GATT" (1995) 13 *Prometheus* 6.

⁵ See T.P. Stewart, ed., *The GATT Uruguay Round: A Negotiating History (1986-1992)* (Kluwer, The Netherlands, 1993), Vol. 2, p. 2294.

⁶ F.K. Beier, R.S. Crespi, J. Straus, *Biotechnology And Patent Protection* (OECD, Paris, 1985), p. 25.

³ In 1999 Argentina, Togo, Guinea, Egypt, the U.S., Bolivia, Israel, Philippines, Romania,

direct opposition of Canada.⁸ European negotiators were constrained by the language of the European Patent Convention (1973) (EPC) and Canada was opposed to the patentability of plant and animal life forms. It would be a mistake to think that the European Community is an advocate of a moral conception of patent law. It is true to say that there are express restrictions on patentability contained in Articles 52 and 53 of the EPC. But it is also true to say that the European Patent Office (EPO) has been progressively narrowing the operation of these restrictions. So, by way of quick example, despite the fact that Article 52 contains a prohibition on the patenting of software, the EPO was able to report in 1994 that it had granted more than 11,000 patents for software related inventions. The *Onco-mouse* decision⁹ reveals that the EPO is reading the morality criterion in Article 53(a) in a very narrow way. The restriction on the patentability of human treatment can be overcome by formulaic means.¹⁰ The exclusion of plant varieties under Article 53(b) of the EPC continues to be revisited. In a decision by the Enlarged Board of Appeal of the EPO of December 20, 1999 it was decided that product claims by Novartis AG—which encompassed a specific plant variety or plant varieties, but did not expressly mention them—were not caught by the restriction on the patenting of plant varieties in Article 53(b) of the EPC. The logic of this kind of literalism seems to be that if, for example, there were hypothetically a prohibition on the patenting of odd numbers, one could avoid it by claiming all numbers.

The reason why restrictions in European patent law on patentability are being narrowed through a method of mirrors relates to global investment. Most of the world's investment flows occur between the U.S., Japan and Europe. In the early 1990s, roughly 75 per cent of the total accumulated stock and 60 per cent of the flow of Direct Foreign Investment were to be found between the U.S., Japan and Europe.¹¹ There is intense economic rivalry between these three regions. The patent system has become an important signalling device in attracting these global flows. Markets are increasingly valuing companies based on their portfolios of intangible assets. Holding a strong suite of patents is one way of courting investors. From the point of view of the amoral conception of patents, to restrict the scope of patentability is to restrict the capacity of national patent holders to signal to the markets. The patent offices and patent systems of the U.S., Japan and Europe are caught up in a global regulatory ratchet being worked by international business to drive standards of patent protection up rather than down.¹² TRIPS, it is important to remember, constitutes a floor, not a ceiling. Article 1(1) allows Members to implement more extensive protection than is required by the Agreement.

⁸ See Jacques Gorlin, *An Analysis Of The Pharmaceutical-Related Provisions Of The WTO TRIPS (Intellectual Property) Agreement*, Intellectual Property Institute, 1999, 25.

⁹ Case T19/90 HARVARD/Onco-mouse O.J. EPO 1990, 4/75; [1990] E.P.O.R. 501 and O.J. EPO 1992, 558; [1991] E.P.O.R. 525.

¹⁰ A claim for a treatment of asthma using X would run into problems under Article 52(4), while a claim for the use of X as a medicine in treatment of asthma would probably survive.

¹¹ P. Hirst and C. Thompson, "Globalization, foreign direct investment and international economic governance" (1994) 1 Organization, 277, 290.

3. The CBD and TRIPS

The CBD is part of a pattern of global environmental regulation in which non-state actors, sometimes in alliance with a few states, push the global community into signing a framework convention. A framework convention typically establishes broad principles and imposes little in the way of specific obligations on a state. For cynics such treaties are dismissed as feeble symbolic victories. In their study of global business regulation Braithwaite and Drahos concluded, however, that such conventions have important uses.¹³ They can represent the beginnings of an evolution towards a more detailed regime of rule-bound obligations.

The CBD is still in the soft stage of its development. Its relationship to TRIPS at a non-legal level of abstraction is best characterised in terms of an opposition of principles, an opposition between the principle of sustainable development and the principle of economic growth. It is the latter principle that TRIPS serves. The justification for globalising and harmonising intellectual property rights is that such rights will strengthen the supply of innovation to the market. Economic growth, it is said, will be the result of improving dynamic efficiency through stronger intellectual property rights. Pushing markets in the direction of more technological innovation stands in stark contrast to the kind of economy that committed environmentalists want. For them, development is subject to environmental costs and to date states have done a poor job of costing the negative externalities generated by technology-based development.

The principle of sustainable development receives only muted recognition in the Final Act.¹⁴ It has no presence in TRIPS. Article 27 does recognise that the grant of patents might be restricted on the basis of environmental factors, but this is a long way from saying that the patent system must bow to sustainable development. There is no mention of conservation of biodiversity in the preamble to TRIPS. The CBD does refer to intellectual property rights in Article 16, obliging members to ensure that intellectual property rights do not undermine the objectives of the Convention.

Having said that TRIPS and the CBD are at the level of deep principle in opposition, there are, it needs to be said, other ways of characterising their relationship. Genetic resources or the information that these resources represent might be said to form an intellectual commons. One argument, an economic one, might be that the best way to preserve this commons is by means of a private property regime. The creation of property rights in the commons will give the holders of those rights an incentive to conserve resources for the purposes of future exploitation. Intellectual property regimes, it has been argued by some, can be used to foster biodiversity conservation.¹⁵

¹³ J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge UP, 2000), Chap. 26.

¹⁴ The Preamble to the Agreement on Agriculture in the Final Act notes that reform has to take into account the need to protect the environment, and the Agreement Establishing The WTO expressly recognises the objective of sustainable development in its preamble.

¹⁵ See, for example, Timothy Swanson, *The International Regulation of Extinction* (Macmillan Press,

Following on from this it might be said that the CBD and TRIPS are in fact complementary.¹⁶ In order to have a market in products and processes based on the use of genetic resources, the owners of those resources need to be clearly identified, as must be the scope of ownership. The rules of contract then determine the transfer of capital that the rules of property have created. The CBD itself envisages that the use of genetic resources will largely be determined through bargaining. However, it is very difficult for bargaining to take place in the absence of a well defined set of property rules. Whatever else one might say about existing intellectual property rights, they are well defined, primarily because they have been the subject of judicial deliberation for many decades, or hundreds of years in the case of the patent system. A vast body of technical jurisprudence surrounds their interpretation and implementation.

Does it follow, then, that we ought to use these well ordered regimes in order to support the kind of negotiations and bargaining that are envisaged by the CBD? The answer is not necessarily. Markets and bargaining can flourish in the absence of private property rights. Most western legal systems do not recognise a general right of property in information. This does not prevent people from selling information to journalists. What matters to bargaining is that agents have control over resources. Full blown private property rights are one way in which that control can be achieved, but by no means the only way. The CBD, if it is to achieve its purposes, will require regulatory systems that grant or recognise the control of genetic resources by individuals or collectives. However, these systems need not be existing intellectual property systems. Nor need these systems rest on the individualistic conception of private property to be found in western civil and common law traditions. They can instead recognise alternative conceptions of control based on notions of custody, stewardship and collective ownership. The Organization of African Unity's model law on access to biological resources is an example of the kind of creative juridical thinking that can be developed in this area.¹⁷ It, for example, recognises a complex sovereignty of a state and local communities over biological resources. It is, of course, crucial that these alternative systems provide certainty on the key issues of who has control over these resources for the purposes of negotiating access and the arrangements for benefit-sharing. Whatever norms are chosen must deliver certainty.

The CBD is not prescriptive in any detailed way concerning the type of regulatory system that is to fulfil its purposes. It simply establishes a set of open-ended principles that are to pattern the development of regulatory systems. These principles include a principle of

¹⁶ Those within the trade paradigm tend to see intellectual property rights and environmental regulation as complementary. In its summary of the work of the WTO Committee on Trade and Environment the WTO states the following: "WTO members state in the CTE Report that... [TRIPS]... plays an essential role in facilitating access to and transfer of environmentally sound technology and products".

¹⁷ The model law is published in The OAU's Model Law: *The Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, Organization of African Unity, Scientific, Technical, Research & Research Commission, Prof. I.A.

bargaining (mutually agreed terms—Art. 15.4), a principle of prior informed consent (Art. 15.5), a principle of benefit-sharing (Arts 15.6 and 15.7) and a principle of recognition of indigenous intellectual property (Art. 8(j)). Since the signing of the CBD a global dialogue involving states, international organisations and many hundreds of NGO actors has developed concerning the key issues of control, access and benefit sharing. This dialogue has led to different national and regional initiatives on the implementation of the CBD.¹⁸ The principles of the CBD have, it seems, spawned a diversity of regulatory life forms.

One important objective for states which are members of the CBD is to ensure that a TRIPS review does not deliver an outcome that endangers this diversity of regulatory development. The concern within the NGO community is that a TRIPS review will produce an outcome that entrenches existing intellectual property regimes in the national legal frameworks of countries. The basic fear is that such an outcome will strengthen the proprietary grip of global agri-chemical and pharmaceutical industries over biological resources upon which many depend. Centralising power in this way could have many unforeseen consequences relating to health, food and agriculture. One such problem might be the problem of perverse incentives. A market mechanism for the conservation of biodiversity might reduce the incentive to conserve biodiversity in relation to those genes that do not contribute to brand name products. The parallel that might be made here is with standards in personal computing. At one stage the market supported a number of different standards, but once Microsoft's standard became dominant the others were lost. Nor is it clear that the market chose the best standard. There is no *a priori* way to determine whether intellectual property rights will have this effect on biodiversity. As is usually the case with intellectual property, it is an empirical matter. One can say that the claim that intellectual property rights will aid the conservation of biodiversity is simplistic. Companies seeking patents on products derived from genetic resources are interested in conservation to the extent that they want their laboratories well stocked with raw materials. It hardly follows that they are interested in saving entire forests or indigenous cultures. It is the CBD that presents the world with a genuine opportunity to begin the creation of a living archive to save the world's biodiversity.

4. Options and the rules of the game

Historically speaking, negotiations between states on matters of intellectual property have seen divisions develop between intellectual property exporters and intellectual property importers, roughly the division between developed and developing states. Developing countries have insisted on lower levels of intellectual property protection the use of compulsory licensing and the implementation of the principle of common heritage in respect of technology. Western states have

advocated higher levels of intellectual property protection, reduced scope for compulsory licensing and a rejection of the principle of common heritage of mankind for technology. These divisions have produced crises (for example, the copyright crisis of the 1960s) and standstills (such as the breakdown in the negotiations to revise the Paris Convention) in those international fora where states met to negotiate intellectual property treaties. The U.S., because it could always be outvoted in fora such as WIPO and UNESCO by a coalition of developing countries, embarked on a strategy of forum shifting to overcome its problems. It shifted the issue of intellectual property into the negotiating stream of the General Agreement on Tariffs and Trade, now the WTO. The WTO is its preferred forum for intellectual property because it can use the size of its market, its negotiating capabilities and the multi-bargaining dimensions of the WTO to secure outcomes for intellectual property which remained beyond its reach in fora like WIPO or UNESCO. In the WTO the U.S. can also dominate the agenda setting process. In the Uruguay Round the Quad states (U.S., Europe, Canada, Japan) formed the dominant group in terms of whether or not a particular agenda item moved forward. The review which triggered a broad-ranging discussion of the relationship between intellectual property rights and the CBD was the review of Article 27(3)(b) of TRIPS which was required to begin in 1999. At present Article 27(3)(b) allows Members a certain amount of flexibility concerning the patentability of animals, plants, biological processes for their production and plant varieties.

A member may, if it wishes, exclude from patentability (or presumably restrict the patentability of):

1. plants;
2. animals;
3. biological processes for the production of plants or animals;
4. plant varieties.

If a member adopts option 4 it must protect plant varieties by an effective *sui generis* system. One can envisage a range of options for states under Article 27(3)(b) that vary from a minimalist model of patent protection in which 1, 2, 3 and 4 are all excluded and plant varieties are protected by means of a *sui generis* system, to a maximalist model in which 1, 2, 3 and 4 are all protected by patents and in addition 4 is also protected by a *sui generis* system. Irrespective of whether states adopt a minimalist or maximalist model, under Article 27(3)(b) they are obliged not to exclude from patentability micro-organisms and non-biological and microbiological processes.

Once the review of Article 27(3)(b) commenced it became clear that there were a variety of views as to what the review might encompass. Some developing countries such as India, the African Group, Thailand, Ecuador and Egypt took the view that the review was a substantive review of the provisions which could have as one

paragraph.¹⁹ Review, in effect, included the possibility of re-negotiation. Following this logic some developing countries put on the table the broad issue of the harmonisation of TRIPS and the CBD on matters relating to the use of genetic resources and protection for traditional knowledge.

From the point of view of the U.S. and E.C., the CBD was being used by developing countries to launch an attack on the patent system and TRIPS. For these two parties review came to mean, in essence, information-gathering and a study of the implementation of the provisions of 27(3)(b) by Members of TRIPS. Both the U.S. and the E.C. realised that a re-negotiation on this one article would not lead to a strengthening of it and therefore there was no gain in allowing the review to slide into a re-negotiation. The history of the U.S. on intellectual property protection to date has been to argue for ever higher, ever stronger levels of protection. Even though TRIPS gives developing countries the benefit of transitional provisions, the U.S. has pushed for accelerated national implementation by such countries. The reason for this lies in the comparative advantage the U.S. economy enjoys in the production of services and information. It is the world's first genuine information economy. The figures on licensing give a glimpse of the economic picture. The 1996 data shows that U.S. corporations had royalty and licensing receipts of \$8.3 billion from foreign unaffiliated entities. They paid out \$2.2 billion. In the case of affiliated entities receipts and payments were \$24.5 billion and \$5.7 billion respectively. In short "the U.S. has close to a 4 to 1 edge in licensing-out technology to the world."²⁰ The chemical and pharmaceutical sectors are key players in total U.S. corporate royalty income from unaffiliated entities receiving 13 per cent of the total.

The U.S. position on the Article 27(3)(b) review has been determined by U.S. business, or rather that part of U.S. business that has managed to enrol the power of key U.S. government agencies like the United States Trade Representative (USTR). The sectors of U.S. business most concerned with Article 27(3)(b) are the biotechnology industry, the pharmaceutical sector and agri-business. These industries are highly patent sensitive. Strengthening the role of the patent system internationally is high on their agenda. Patents have become a fundamental signalling device for the biotechnology sector in venture capital markets. A strong patent in strong hands is still probably the most certain route to monopoly profits. This is something which the large players in the pharmaceutical industry understand very well. There may be some internal differences between industry groups and between European and U.S. business.²¹ However, the lesson of the last trade round was that disunity on issues of intellectual property produced a weaker agreement. Article 27(3)(b) is an illustration of precisely this. One would expect, therefore, the U.S. and E.C. industries eventually to speak as the single voice of the international business community on the patent system, much as they

¹⁹ See WTO, IP/C/M/25, December 22, 1999.

²⁰ These figures and this statement come from Stephen A. Degan, "Macro View Of U.S. R&D, Licensing", (1998) 33 *Les Nouvelles*, 144, 145.

²¹ For the views of European industry see Jeroen van Wijk, "Plant patenting provision reviewed in

did in the Uruguay Round. The U.S. will continue to push for a version of Article 27(3)(b) that fits the maximalist model. This model is close to its domestic position. Irrespective of what is said by the E.C. concerning Article 27(3)(b), domestically its law is evolving in a way that is seeing the restrictions on patentability being narrowed. Like the U.S., Europe wants investment flows to be directed into its biotechnology and pharmaceutical sectors.

If both the U.S. and E.C. unite, they are likely to determine eventually the outcome of the process of review of Article 27(3)(b). One of the conclusions that Braithwaite and Drahos drew from their study of global business regulation was that "[w]hen the US and EC can agree on which direction global regulatory change should run, that is usually the direction it does run. Japan's influence is remarkably weak."²² The most likely scenario is that these two states will deal with the substantive issues raised by Article 27(3)(b) in a future MTN. In the meantime, other states have the option of attempting to set "soft" norms on this and related issues in fora such as the Conference of the Parties (COP) to the CBD and WIPO. The COP, for example, has an Expert Panel which will, amongst other things, report to an Ad Hoc Open-ended Working Group on TRIPS and biodiversity issues. The WIPO General Assembly has established a special intergovernmental committee to look at intellectual property and genetic resources, as well as traditional knowledge and folklore. The outcomes of these kinds of dialogic exercises usually take the form of guidelines or model laws. Developing states are not in the same position of influence in the WTO and nor can they be said to be likely winners from a maximalist version of Article 27(3)(b). Probably, the most practical course of action for developing states is to argue for the status quo in the case of Article 27(3)(b). Property rights, whether in intangibles or tangibles, allow governments to deal with externality problems. It is better to have more rather than less flexibility in defining property rights so far as a state is concerned. Developing states receive very little of the world's direct foreign investment (DFI). Hirst and Thompson observe that "nearly two-thirds of the world is virtually written off the map as far as any benefits from this form of investment are concerned".²³ Between 57 per cent and 72 per cent of the world population receives only 8.5 per cent of global DFI. Agreeing to stronger patent protection will not, one suspects, significantly alter the patterns of global investment flows. Moreover, agreeing to stronger and stronger patent rights is likely to have other costs for developing countries. Some have argued that TRIPS brings with it significant rises in the cost of pharmaceutical drugs.²⁴ This has implications for the health budgets and services in developing countries.

²² J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge UP, 2000), Chap. 5.

²³ P. Hirst and G. Thompson, "Globalization, foreign direct investment and international economic governance" (1994) 1 *Organization*, 277, 295.

²⁴ See B.K. Keayla, *New Patent Regime: Implications for Domestic Industry, Research & Development*

For those developing states that are also bio-diverse rich there are probably no real gains to be had from supporting a stronger patent system in respect of biotechnology patents. Exploiting bio-diverse stock in world markets is not like exploiting a comparative advantage in the growing of dates. It requires a high level of R&D capability as well as marketing and distribution systems. Developing states wishing to exploit their biodiversity through trade will probably need to develop joint ventures and strategic alliances with those transnational companies which control global distribution and marketing structures for food, agricultural and medicinal products.

One issue that has been extensively debated in the context of TRIPS and the CBD is what constitutes effective *sui generis* protection of plant varieties. This has led to a discussion of the merits of the International Convention for the Protection of New Varieties of Plants (UPOV Convention).²⁵ Adopting plant variety rights protection based on the UPOV Convention might be one way in which a developing country might begin to meet its obligations under Article 27(3)(b). An alternative might be to design its own system. The latter is perhaps the best given that such a system can be locally crafted to fit a country's specific innovation, cultural and environmental needs. Certainly, as Josep Gari's paper in this volume makes clear, it is hard to see what benefits UPOV or the patent system will bring to subsistence farmers in Amazonia.

A crucial issue for developing countries to consider is the position that they should adopt with respect to the issue of patent protection for plant varieties, since Article 27(3)(b) allows for the possibility of dual protection. One thing to bear in mind here is that patents are the strongest form of monopoly rights that exist within the intellectual property family. The genesis of the UPOV Convention lies in part in the fact that it was thought that the patent system would prove too restrictive of farming seed culture.²⁶ The strong nature of patent rights, for example, has led judges to imply licences into contracts so that purchasers of patented articles have the right to dispose of them or repair them. Patent law does recognise that in some circumstances the use of a patented invention for the purposes of experimentation does not amount to the infringement of the patent. Generally speaking, the scope of this exception has been construed very narrowly. As in most issues of patent detail much depends on the wording of the relevant patent statute. Early English cases suggested that once the experimentation was linked to commercial exploitation in some way it was likely to constitute an infringing use.²⁷ The present UK Patents Act (1977) seems more generous in the sense that the presence of a commercial purpose will not automatically lead to a negation of the exception.²⁸ In the U.S. the experimental defence to an infringement action is a creation of the

²⁵ First adopted and signed by five European countries (Belgium, France, Federal Republic of Germany, Italy and the Netherlands) on December 2, 1961.

²⁶ More generally, it lay in the failure of the patent system to adapt to the needs of plant breeders. See Noel Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (Centre For Commercial Law Studies, University of London), p. 14.

²⁷ See *Frearson v. Loe* [1878] 9 Ch. 48, 66-77; *Molins and Molins Machine Co., Ltd., v. Industrial Machine Co.*, [1938] 55 R.P.C. 31.

²⁸ First adopted and signed by five European countries (Belgium, France, Federal Republic of Germany, Italy and the Netherlands) on December 2, 1961.

courts. It "has been frequently raised but rarely sustained".²⁹ German patent law also keeps the experimental exemption within narrow bounds.³⁰ The reason why courts around the world rein in the experimental exemption relates to a simple economic argument. A liberal interpretation of the experimental exemption would allow the patentee's competitors free access to the invention, compromising the capacity of the patentee to exploit the patent. The long run effect of such an exemption would be to depress the incentive effect of the patent system.

The UPOV Convention, by contrast, does not create the same strong monopoly protection for plant varieties. Admittedly, the 1991 revision of the UPOV Convention does strengthen the position of plant breeders. However, it is important to note that even the 1991 revision enables researchers to access a plant variety for research purposes without authorisation from the breeder.³¹ For those developing states wishing to build an indigenous research capability through national biotechnology research institutes and the like, this may be significant. A cross pollination of ideas between scientists is as important as cross pollination between plants. The UPOV Convention also contains rights like farmers' privilege and breeders' exemption that are not matched by the patent system.

Unfortunately these and other issues raised by the TRIPS reviews and the CBD may well be foreclosed by bilateral agreements being negotiated by the U.S. and the E.C. TRIPS has become the object of transnational activism by the global NGO community. An alliance comprised of international NGOs and developing states such as those from the Africa Group is attempting to achieve an integration of TRIPS and the CBD. The policy proposals being put forward include proposals to extend the time for implementation of various TRIPS standards, the inclusion in the TRIPS preamble of a recital that would give force to CBD objectives and a requirement in TRIPS that applicants for patents involving genetic resources submit evidence as to the origins of these resources and the way in which they were obtained. The U.S. response has been to shift the trade negotiation game back to the bilaterals. A good example of this forum shifting strategy is the FTA between the U.S. and Jordan that was concluded on October 24, 2000. Under this agreement, Jordan is obliged to recognise patents in all fields of technology, subject only to an exclusion from patentability of an invention on the grounds of ordre public or morality (see Articles 4.17 and 4.18). This Article reduces the number of exclusions from patentability to be found in Article 27(3) of TRIPS. The U.S. Jordan FTA also requires Jordan to ratify the UPOV Convention within one year of the FTA coming into force (see Article 4.29(b)). Developing a *sui generis* option under Article 27(3)(b) which is different from UPOV is no longer a practical option for Jordan. It is also worth

observing that under the most-favoured-nation (MFN) principle to be found in TRIPS, a developing country Member of TRIPS which agrees to grant increased standards of protection to another country (for example, the U.S.) must grant those standards to other Members of TRIPS (for example, the E.C.). If both the U.S. and the E.C. continue to negotiate bilateral agreements which impose higher standards than TRIPS with other Members of TRIPS, the MFN principle will operate to globalise rapidly the new standards.³² It may also be that the U.S. Jordan FTA is the precursor to a wave of new bilateralism on intellectual property. The U.S. has announced that it is negotiating a similar agreement with Singapore and Chile. Clearly, the U.S. Jordan FTA is pregnant with implications for the aspirations of some developing countries to achieve an integration between CBD goals and TRIPS norms. By the time the U.S. and the E.C. come to the MTN table on intellectual property many of the issues currently being raised in TRIPS reviews may have been settled bilaterally. The only question will be whether to "fold" those bilaterally negotiated standards into TRIPS.

5. Conclusion

To summarise: developing states should argue for the status quo in the case of Article 27(3)(b). Increasing the role of the patent system in biotechnology should be resisted because gaining benefits from that system depends on a large industrial and organisational infrastructure. Developing states should as a matter of priority concentrate on the creation of regulatory systems under the CBD, systems that include national biodiversity documentation centres. Such centres could be used to provide evidence that many biotechnology patents currently being sought do not fulfil the criteria of inventiveness and novelty.³³

Most importantly, developing states will have to make their objectives in the TRIPS reviews part of a more co-ordinated negotiating strategy. The TRIPS reviews are nested within a broader review process and negotiating context. It is fairly clear that the 1999 TRIPS review has been little more than a trial run so far as the E.C. and the U.S. are concerned. It has presented these states with the opportunity for a pre-negotiation dialogue with developing countries on the possible linkages between TRIPS and the CBD. Developing countries for their part should not be giving too much away on intellectual property in the bilaterals. Otherwise there may not be much to deal with on the subject of intellectual property when the next MTN commences.

²⁹ R. Eisenberg, "Patents and the progress of science: exclusive rights and experimental use", (1989)

56 University of Chicago Law Review 1017.

³⁰ See Case No. XZR 99/92, Federal Supreme Court, July 11, 1995, reported in English in (1997) 28 I.L.C. 103. See also J. Pagenberg, "Comment" same volume, 111-113.

³¹ Art. 15(1)(ii) states that the breeder's right shall not extend to "acts done for experimental purposes". There is no qualification that the experimental purpose must also be for a non-commercial

³² The only qualification to this is to be found in TRIPS Agreement note 3 referred to in Article 3.

³³ Much of the traditional knowledge that relates to biodiversity exists in action and use rather than books. Patent systems around the world vary in the extent to which they recognise information that is based upon action and use for the purposes of determining novelty. In Australia and the U.S. for example, it is only acts within the jurisdiction that matter for the purposes of assessing novelty.