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INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES

Marshall Cavendish Academic

INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES

Confronts the hard questions head on, and provides a wealth of essential information to assist decision-makers at international and national levels.

— John Scanlon
Director, IUCN Environmental Law Centre
and Head, IUCN Environmental Law Programme

Chapter 1 ... provides an excellent account of the issues and a summary of the major themes tackled by the assembled experts. Their papers provide full and informed analyses of the current state of play and of various recommendations (including those by the authors themselves) for reform. As with the biological resources with which they are concerned, these areas of activity cannot remain static. The debate is alive and developing rapidly. Nevertheless, to all those with an interest in these matters, this volume must rank highly as an authoritative and invaluable contribution to the literature on this subject.

— from the Foreword

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Foreword

Not so long ago, biotechnology and, in particular, genetic engineering were heralded as exciting new sciences capable of solving mankind's most intractable problems. Disease was to be significantly reduced, and eventually eliminated; abundant and varied food supplies were to rescue the starving masses from their present wretched conditions; and the world would be well along the road to Valhalla.

Today, that image of biotechnology has changed. Its promise may be as great as ever, but the means of achieving these goals have become embroiled in many controversies, with intellectual property issues frequently at their centre. Access to, control over and ownership of biological resources and their products have been challenged by all kinds of interest groups: by environmentalists and others concerned with the long term protection of diminishing resources; by those concerned to protect the indigenous peoples who provide the essential traditional knowledge and materials to which our scientists add value; by developing countries who believe that their interests have been subjugated by the developed world; and by those concerned with the manifold ethical, religious, social, legal and political questions which the new technologies throw up.

The answer, as always in matters relating to intellectual property, is to find a proper balance between intellectual property rights and all these competing interests. As always, though, finding an acceptable balance is fraught with difficulty. Thus, the intellectual property/environmentalist battle features strict adherents to the TRIPS Agreement at one extreme versus beneficiaries of the Convention on Biological Diversity (and related Conventions) on the other. At first, there was little interest in addressing the critical issues affecting an appropriate relationship between these seemingly conflicting international agreements. Now, there is greater recognition that these must be addressed and some compromises made.

In December 2003, the Asia-Pacific Centre for Environmental Law (APCEL) of the Faculty of Law (National University of Singapore), the Singapore Academy of Law (SAL), the Intellectual Property Office of Singapore (IPOS) and the Intellectual Property Academy (Singapore) organised an international conference on "Intellectual Property and Biological Resources" to bring together academics, practitioners and policy makers to share their views on the controversies that the global

CHAPTER 7

Intellectual Property Engineering: The Role of the Chemical, Pharmaceutical and Biotechnology Industries

PETER DRAHOS*

7.1 INTRODUCTION

Intellectual property rights were important to chemical firms in 19th-century Europe and to US and European pharmaceutical companies in the 20th century. The relationship was one of mutual importance. Because these companies wanted intellectual property rights, especially patents, they took an interest in lobbying governments on their design. A cycle of regulatory growth was thus created. As the chemical and pharmaceutical industries took more interest in the design of intellectual property rights, the strategies of the larger companies came to be more and more based on the use of intellectual property rights and this in turn meant that the companies had a greater and greater incentive to influence their design.[1] The business model paradigm of these industries took it as axiomatic that there had to be strong intellectual property rights—the stronger the better.

In the 1980s this cycle of regulatory growth underwent something of a quantum jump. US, European and Japanese companies, including pharmaceutical and chemical companies set aside their

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differences and campaigned for the inclusion of an agreement on intellectual property rights in the Uruguay Round of Multilateral Trade Negotiations. Those negotiations produced an agreement known as the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS, in the eyes of the chemical and pharmaceutical companies that had been amongst its prime movers, was a major step in the globalisation of standards of patent, trade secret and trade mark protection, the three areas of most importance to these companies. Of major significance was the obligation on states to make available patents for products and processes without discrimination as to field of technology.[2] TRIPS was, however, far from perfect. Ultimately the handful of multinationals that had steered TRIPS through the Uruguay Round wanted an even higher set of standards. A letter from Pfizer Inc. in 1994 to the United States Trade Representative (USTR) captures this thinking quite nicely:

> Finally, GATT does not do it. Many Indians mistakenly (often very honestly) believe that if they endorse GATT they will have solved their IP and pharmaceutical patent issue. Not so, particularly if they truly want to create an environment that attracts investment and provides better medicine—legalistically agreeing to something (GATT) that brings this into play in ten years or more achieves neither of these two objectives.[3]

TRIPS did not turn out to be, as many developing countries had hoped, the end of multinational companies' plans for the globalisation of intellectual property rights. In fact, as the discussion below will show, in many ways it was only the beginning.

The remainder of this chapter is divided into four sections. The first section draws on the considerable scholarship surrounding the genesis of TRIPS and tells the story of TRIPS concentrating in particular on the role that was played by Pfizer. The second part explains how the trade regime has been used to create a global regulatory ratchet for intellectual property rights. The third section shows how US industry uses the ratchet. As a result of this ratchet, "TRIPS-plus" standards are proliferating in the national laws of many developing countries. The fourth part discusses the effects of this proliferation from the point of view of development. A conclusion then follows.

7.2 THE STORY OF TRIPS

TRIPS is one of 28 agreements that make up the Final Act of the Uruguay Round of Multilateral Trade Negotiations, the negotiations that had begun in Punta del Este in 1986 and culminated in 1994 with the signing of the Final Act and the creation of the WTO. The TRIPS Agreement requires all WTO members to adhere to minimum standards of intellectual property protection.[4] All developing countries and many developed countries had to reform their domestic intellectual property law in order to conform to the obligations in TRIPS.

On the face of it, TRIPS represents a puzzle. Why did other countries agree to TRIPS? At the time of the negotiations the US as the world's principal exporter of intellectual property, had much to gain from the globalisation of intellectual property rights via the trade regime, while the economic and social consequences for developing countries were (and are) serious. For example, TRIPS requires countries to recognise patents on pharmaceutical products and this has implications for both the cost of patented medicines, as well as the long-term fate of the generic industries in those countries.[5]

Susan Sell in her study of TRIPS points out that some 12 US corporations were primarily responsible for the lobbying that brought TRIPS into being.[6] Other studies of TRIPS have come to a similar conclusion.[7] TRIPS was not a case of simple lobbying because it required the drafting of a detailed international agreement containing US standards of intellectual property protection and then ultimately steering it through a multilateral trade negotiation involving more than one hundred states and that lasted from 1986 to 1993. The key to explaining how this was achieved lies in a small number of corporations creating ever widening circles of influence that brought more actors and networks into the cause of global intellectual property rights. The activities of Pfizer Corporation during this time illustrate how TRIPS came to be an output of private nodal governance.

Pfizer, more than most pharmaceutical corporations, had invested in developing countries and so saw the threat to international markets that generic manufacturers in countries like India posed for the R&D pharmaceutical industry. It also saw that developing countries were increasingly using their superior numbers in the World Intellectual Property Organization (WIPO) to put forward initiatives that favoured their own position as net importers of foreign technology. During the

early 1980s a small group of Washington-based policy entrepreneurs had conceived of the idea of linking the intellectual property regime to the trade regime. Pfizer executives, including the CEO Edmund Pratt, were amongst the leading proponents of this idea. Essentially their policy idea was to get an agreement on intellectual property into the General Agreement on Tariffs and Trade (GATT). Amongst other things, such an agreement would be enforceable under GATT dispute resolution procedures. It was a radical idea. States had moved cautiously in ceding sovereignty over intellectual property rights within the context of WIPO.

Pfizer executives began to use their networks in two important ways. The first way consisted of network activation. Pfizer executives used their established business networks to disseminate the idea of a trade-based approach to intellectual property. Pratt began delivering speeches at business fora like the National Foreign Trade Council and the Business Round Table outlining the links between trade, intellectual property and investment. As a CEO of a major US company, he could work the trade association scene at the highest levels. Other Pfizer senior executives also began to push the intellectual property issue within national and international trade associations.[8] Gerald Laubach, President of Pfizer Inc., was on the board of the Pharmaceutical Manufacturers Association and on the Council on Competitiveness set up by President Ronald Reagan; Lou Clemente, Pfizer's General Counsel, headed up the Intellectual Property Committee of the US Council for International Business; Bob Neimeth, Pfizer International's President was the Chair of the US side of the Business and Industry Advisory Committee to the OECD. The message about intellectual property went out along the business networks to chambers of commerce, business councils, business committees, trade associations, and peak business bodies. Progressively Pfizer executives who occupied key positions in strategic business organisations were able to enrol the support of these organisations for a trade-based approach to intellectual property. With every such enrolment, the business power behind the case for such an approach became harder and harder for governments to resist.

The second way in which Pfizer operated was through the interlinking of networks. One of the nodes that played a pivotal role in the negotiations over intellectual property was the Advisory Committee on Trade Negotiations (ACTN). ACTN had been created in 1974 by Congress under US trade law as part of a private sector advisory

committee system.[9] The purpose of this system was to ensure a concordance between official US trade objectives and US commerce. ACTN existed at the apex of this system. Pratt, with the assistance of other senior executives within Pfizer, began to put himself forward within business circles as someone who could develop US business thinking about trade and economic policy. In 1979 Pratt became a member of ACTN and in 1981 its Chairman. During the 1980s representatives from the most senior levels of big business within the US were appointed by the President to serve on the committee (Pratt was appointed by President Carter). The Committee was a purely advisory one, but with direct access to the USTR and the duty of advising him/her on US trade policy and negotiating objectives in the light of national interest. Out of this business crucible came the crucial strategic thinking on the trade-based approach to intellectual property.

With Pratt at the helm, and the CEOs of IBM and Du Pont Corporation serving, the ACTN began to develop a sweeping trade and investment agenda. John Opel, the then Chairman of IBM, headed this Task Force. During Pratt's six years of chairmanship ACTN worked closely with William E. Brock III, the USTR from 1981–1985 and Clayton K. Yeutter, the USTR from 1985–1989 helping to shape the services, investment and intellectual property trade agenda of the US.

ACTN's basic message to the US government was that it should pull every lever at its disposal in order to obtain the right result for the US on intellectual property. There were a lot of possible levers. US Executive Directors to the IMF and World Bank could ask about intellectual property when casting their votes on loans and access to bank facilities; US aid and development agencies could use their funds to help spread the IP gospel. Over time the message was heard and acted upon. Provisions protecting intellectual property as an investment activity were automatically included in the Bilateral Investment Treaty program which the US was engaged in with developing countries in the 1980s. Means of influence of a personal and powerful kind also began to operate. Shultz, the Secretary of State discussed the IP issue with then Prime Minister Lee Kuan Yew, stated Jacques Gorlin in his 1985 analysis of the trade-based approach to IP.[10] President Reagan in his message to Congress of 6 February 1986 entitled "America's Agenda for the Future" proposed that a key item was much greater protection for US intellectual property abroad.[11] This was consistent with ACTN's recommendation that the development of a US strategy for intellectual property be endorsed by

the President and Cabinet. The ground was being prepared for intellectual property to become the stuff of big picture political dealing and not just technical trade negotiation.

So far as ACTN was concerned, folding intellectual property standards into the GATT was the single best way in which to spread those standards. Realistically ACTN realised that the negotiation of a broad intellectual property agreement would be a long process. But this process would not start unless intellectual property was put on the agenda of the next trade round. For this to happen a Ministerial Conference of Contracting Parties of the GATT would have to issue a declaration containing, amongst other things, a form of words opening the way for the negotiation of an IP code. Here ACTN ran into a fundamental problem. Both Opel and Pratt had been pushing the IP agenda with the USTR, at first with William Brock and then his successor Clayton Yeutter. In 1981 Brock had formed the Quadrilateral Group (Quad) of countries, for the purpose of trying to develop a consensus for a new round of multilateral trade negotiations. In the early 1980s there were differences of view between Europe and the US on the desirability and content of a future trade round. Without the agreement of the US and Europe the prospects of a multilateral trade round getting off the ground were slim. The Quad consisted of the US, the EC, Japan and Canada. Once these countries had achieved a consensus on an agenda for a multilateral trade round, the round would most likely begin. Yeutter saw the centrality of intellectual property to the round, but the problem was, as he explained to Pratt and Opel, that when he went to meetings of the Quad there was no real support from the other Quad members to merge IP and trade.

The problem facing Pratt and Opel was clear enough. They had to convince business organisations in Quad countries to pressure their governments to include intellectual property in the next round of trade negotiations. That meant first convincing European and Japanese business that it was in their interests for intellectual property to become a priority issue in the next trade round. With a strong Quad consensus, there was a real likelihood of intellectual property making it onto the agenda for the next trade round. Without such a consensus developing countries would be able to block an initiative on intellectual property. The time frame for the consensus-building exercise was roughly six months. The Ministerial Conference to launch a new trade round was scheduled to take place at Punta del Este in Uruguay in September of 1986. The USTR had been working hard to convince the remainder of the Quad of the IP

issue, but it had to become much more than just a talking point at the Ministerial Conference.

Pratt and Opel's response was swift. In March of 1986 they created the Intellectual Property Committee (IPC).[12] The IPC was an ad hoc coalition of 13 major US corporations; Bristol-Myers, DuPont, FMC Corporation, General Electric, General Motors, Hewlett-Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer, Rockwell International and Warner Communications. It described itself as "dedicated to the negotiation of a comprehensive agreement on intellectual property in the current GATT round of multilateral trade negotiations."[13]

Europe was the key target for the IPC. Once Europe was on board Japan was likely to follow, or at least not to raise significant opposition. Canada, despite its Quad membership, was not really a player. It was the support of European and Japanese corporations that was crucial. What followed was a consensus-building exercise carried out at the highest levels of senior corporate management. CEOs of US companies belonging to the IPC would contact their counterparts in Europe and Japan and urge them to put pressure on their governments to support the inclusion of intellectual property at Punta del Este. Small but very senior and powerful business networks were activated. The IPC also sent delegations to Europe in June 1986 and Japan in August of 1986 to persuade businesses in those countries that they also had an interest in seeing the GATT become a vehicle of globally enforceable intellectual property rights. The IPC's efforts in the lead-up to Punte del Este brought it success, for both European and Japanese industry responded by putting pressure on their governments to put intellectual property on the trade agenda. Ultimately the linkages that were created between US, European and Japanese companies led to the joint release in 1988 of a suggested draft text of an agreement on intellectual property.[14]

The Ministerial Declaration on the Uruguay Round of 20 September 1986 contained a negotiating mandate on intellectual property rights.[15] In the seven years that followed, US trade negotiators with the assistance of the many networks that had been enrolled and activated in the cause of global intellectual property rights, were able to deliver a strong agreement on intellectual property in the form of TRIPS.

7.3 THE GLOBAL INTELLECTUAL PROPERTY RATCHET

During the period that TRIPS was being negotiated (1986–1993) there were suggestions that if developing countries agreed to TRIPS the US would ease off negotiating intellectual property standards bilaterally.[16] During the 1980s the US had set the scene for TRIPS through a series of strategic bilateral negotiations on intellectual property with countries like South Korea and Brazil. Provisions on intellectual property also became part of its bilateral investment treaty program during this time. One of the incentives that was held out to developing countries for the successful negotiation of TRIPS was that the US would desist from using its trade enforcement tools to obtain the standards that it wanted.

The reality turned out to be somewhat different. During the 1990s the US actually intensified the level of its bilateral activity.[17] It used its trade enforcement tools under its Trade Act to review the intellectual property standards of larger and larger number of countries and it concluded many more bilateral agreements related to intellectual property than it had in the 1980s. In effect, it had created without anybody really noticing a global regulatory ratchet for intellectual property. Moreover the ratchet only travelled in one direction—up. Thus while many areas of business regulations were experiencing deregulation during the 1980s and 1990s, intellectual property was experiencing regulation.

The US was the principal architect of the global regulatory ratchet for intellectual property, with the EU to a lesser extent also making use of it.

In short form this ratcheting process is dependent upon:

(a) a process of forum shifting[18]: a strategy in which the US and EU shift the standard-setting agenda from fora in which they are encountering difficulties to those fora where they are likely to succeed (e.g., from WIPO to the WTO to BIPs);
(b) co-ordinated bilateral and multilateral IP strategies; and
(c) the entrenchment in international agreements of a principle of minimum standards.

The principle of minimum standards plays a vital role in this strategy. Each bilateral or multilateral agreement dealing with intellectual property

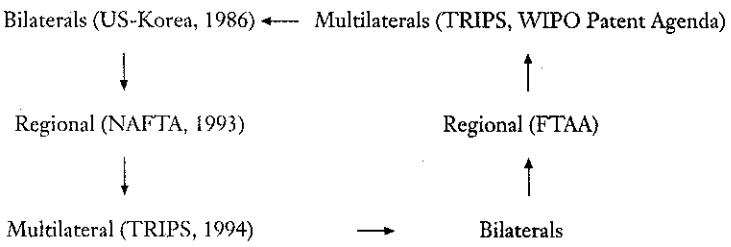
contains a provision to the effect that a party to such an agreement may implement more extensive protection than is required under the agreement or that the agreement does not derogate from other agreements providing even more favourable treatment.[19] This means that each subsequent bilateral or multilateral agreement can establish a higher standard.

Bilateral agreements are also being drafted in ways to ensure that developing countries are integrated into multilateral IP regimes with maximum speed. Developing countries are being obliged to comply with multilateral standards in conventions to which they are not a party, to ratify multilateral treaties or both. So, for example, the US-Jordan FTA requires Jordan to give effect to Articles 1–14 of the WIPO Copyright Treaty (1996) and to ratify Articles 1–22 of the International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention).[20]

The global ratchet for IP consists of waves of bilaterals (beginning in the 1980s) followed by occasional multilateral standard-setting (See Figure 7.1 below). Each wave of bilaterals or multilateral treaty never derogates from existing standards and very often sets new ones. A detailed comparison of the provisions of all of the multilateral and bilateral treaties on intellectual property is beyond the scope of this chapter. An example of the global ratchet in action can be seen by comparing the intellectual property provisions of NAFTA with TRIPS and the subsequent bilateral treaties.

Where the US or the EU are at any given moment in the cycle of ratcheting is determined essentially by how much effective resistance they are meeting in terms of their negotiating objectives. The bilateralism

FIGURE 7.1 The Global Intellectual Property Ratchet



that preceded TRIPS and that laid the foundation for TRIPS was triggered by the resistance that the US encountered on its intellectual property agenda at the GATT. Presently, it is clear that the US in particular is in a bilateral phase. The Ministerial Declaration that launched the Doha round of multilateral trade negotiations in 2001 contained only a modest work programme in relation to TRIPS with geographical indications being the principal item listed for negotiation. Bilaterally, however, the US has been busily negotiating free trade agreements (FTAs) with countries that it sees as being important regional models. The list below summarises the state of play:

1. US-Jordan (2001)
2. US-Chile (2003)
3. US-Singapore (2003)
4. US-Southern African Customs Union
5. US-Central American FTA
6. US-Morocco
7. US-Australia

The focus on FTAs at this time can also be explained in terms of the effective resistance that the US has been encountering at the TRIPS Council over the last several years. The TRIPS Council was the venue in which African states in June of 2001 launched an initiative aimed at examining the role of intellectual property rights in access to medicines. The end of 2001 saw WTO members agree to the Declaration on the TRIPS Agreement and Public Health, a Declaration that the US pharmaceutical industry counted as a blow against its interests and which it did its best to downplay.[21] Similarly, the review of Article 27(3)(b) that was started in 1999 has not run the way that the US would have liked. In essence the US wants to bring TRIPS into line with what is its own domestic position—"virtually anything is patentable".[22] Instead what eventuated during the course of the review was a very wide-ranging dialogue in the TRIPS Council that raised many issues about patents, including the need to better integrate the provisions of TRIPS with a regulatory approach towards biodiversity that states had agreed to in the context of the Convention on Biological Diversity.[23] Developing countries were able to resist US proposals in the context of the TRIPS Council because outside of the Council they were being given assistance by civil society actors.[24] These actors were helping to provide technical expertise

and through global campaigning they were instrumental in creating around TRIPS a moral atmosphere in which it was judged unfair to developing countries. This in turn expanded the art of the possible when it came to TRIPS. Moreover, it was to the advantage of both civil society and developing countries that the TRIPS Council was one highly visible forum on which they could concentrate their attentions.

This effective resistance in the TRIPS Council has led to forum shifting by the US. In the FTAs that it has recently concluded it has sought and in many cases obtained standards of intellectual property from the other state that bring that state closer to the US domestic position.[25] A good illustration of this can be found in the provisions of the US-Singapore FTA that deal with patents. Under the US-Singapore FTA the parties may only exclude those inventions from patentability that are specified in Article 27.2 and 27.3(a) of TRIPS.[26] Article 27.3(b) of TRIPS has been bypassed in other words.

TRIPS also bars its members from using its provisions to address the issue of the exhaustion of intellectual property rights. The US-Singapore FTA, however, deals with the exhaustion issue by requiring each party to give the patent owner a remedy against a third party who disturbs a contractual arrangement between a patent owner and licensee.[27] TRIPS does not specifically address the rights of generic manufacturers to make use of a patented drug prior to the patent expiring for the purposes of obtaining marketing approval of their generic product from their relevant regulatory authority. However, as Canada pointed out in the Canada–European Community pharmaceutical products case, the understanding of key players such as the US in the TRIPS negotiations was that this exception was preserved by Article 30 of TRIPS.[28] Moreover, the state practice after TRIPS came into force was also consistent with the understanding that a regulatory review exception was permitted by Article 30.[29] The scope of this Article 30 exception is, in the case of the US-Singapore FTA, limited to obtaining marketing approval including in cases where the export of the generic version is permitted. It would seem, therefore, that even if a Singaporean generic manufacturer could take advantage of an export market that was not patent-barred, it would not be able to export in commercial quantities to that market until the patent in Singapore had expired. The compulsory licensing provision of the US-Singapore FTA is, unlike TRIPS, drawn in the negative. This means that compulsory licensing is prohibited except in specified circumstances (to remedy anticompetitive acts, for public non-commercial

use, national emergency or other circumstances of extreme urgency).[30] It also contains an express restriction on the transfer of "know how", something not to be found in TRIPS. A country like Singapore that agrees to this kind of provision on compulsory licensing is clearly circumscribing the rights it would otherwise have under TRIPS to enact a wider provision. The restriction on "know how" is also important since "know how" licensing agreements frequently accompany a patent licensing arrangement and enable the licensee to make efficient use of the patent. Without access to "know how", the commercial value of access to a patent is often worth much less to a licensee.

It is also worth noting that countries by adopting this kind of provision for compulsory licensing in their patent law may be going even further than the US does. Compulsory licensing is not part of US patent law, but provisions on compulsory licensing are to be found in other parts of US law such as the Clean Air Act and the Atomic Energy Act.[31] In addition, compulsory licences are a key remedy in the context of antitrust litigation. Countries that adopt a restrictive approach to compulsory licensing as part of their patent law and do not compensate by having licensing access provisions in other parts of their law are clearly offering patent owners stronger rights than exist in US domestic law.

Another example of the way in which the US is using FTAs to bring other countries into line with its own domestic provisions is to be found in Article 16.8 of the US-Singapore FTA. This provision deals with the treatment of information by a regulatory authority that relates to the safety or efficacy of a pharmaceutical or agricultural product and is required to be submitted by that authority for the purposes of obtaining marketing approval. TRIPS deals with this situation somewhat succinctly in Article 39.3. Members are required to protect such data against "unfair commercial use" provided that it required "considerable effort" to generate, that it is undisclosed and that it is a new chemical entity. The US-Singapore FTA takes this open and flexible standard and converts it into something much more specific. Under it, Singaporean authorities cannot, in effect, rely on the information that has been submitted for the purposes of giving approval to a third party (a generic manufacturer) unless, of course, the original party submitting the information consents to such use. The period of non-reliance is five years for pharmaceutical products and 10 years for agricultural chemical products. This obligation to maintain the exclusivity of the data applies even if it has not been submitted in Singapore, but in another country and Singaporean

authorities are relying on marketing approval by a regulatory authority in that country. Further the obligation to maintain this exclusivity of data is independent of the period of patent protection in the product. These provisions essentially bring Singapore into line with US law.[32]

7.4 THE DRIVER IN THE DRIVER'S SEAT

The previous section provided examples of how FTAs are being used by the US to bring countries into line with US domestic standards of intellectual property protection. The section on TRIPS showed how TRIPS itself was the product of a highly sophisticated and co-ordinated international campaign by a group of multinationals with US multinationals in a leadership role. Lobbying understates the actual process of what occurred. It was in reality a form of private governance that might best be described as nodal governance. This process of nodal governance, which has evolved over the last 20 years within the US, has resulted in a centrally co-ordinated process of standard-setting for sectors of key importance to multinational companies—intellectual property rights, services and investment. Developing countries have had no answer to this centrally co-ordinated strategy. Whenever they are successful in mounting resistance in one forum such as the TRIPS Council, they encounter a forum-shifting response in which the US shifts the negotiating agenda from that forum to another. The global intellectual property ratchet is precisely the product of this centrally co-ordinated strategy of forum shifting.

Driving the global intellectual property ratchet is a networked private nodal governance that is formally woven into US policy and law-making at the highest levels. The Advisory Committee for Trade Policy and Negotiations, the committee that was so important in the context of TRIPS remains at the apex of a private sector advisory system that advises and influences US trade policy. This system is made up of 33 advisory committees that have provision for approximately 1,000 members.[33] It is a three-tiered system with ACTPN at the top, six policy advisory committees in the second tier and 26 sectoral, functional and technical advisory committees in the third tier. ACTPN's members include individuals drawn from the highest levels of US business. It is, as we saw in the section on TRIPS, a strategic agenda-setting committee that looks at the broad goals that the US should pursue in trade negotiations.

In the case of agreements that relate to intellectual property the technical detail of these agreements is monitored by a third tier committee, the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC). The membership of IFAC is made up of 20 members drawn from Industry Sector Advisory Committees and another 20 drawn from the private sector areas who provide the committee with technical expertise in intellectual property.[34] This technical expertise is vital to the committee's work and complements the strategic work of ACTPN. Under its charter IFAC is to provide detailed technical advice on trade agreements negotiated by the USTR.[35] In the case of the US-Singapore FTA, IFAC, in the words of its report, "advised US negotiators on, and reviewed draft texts, of the US–Singapore FTA intellectual property chapter".[36] Importantly, IFAC reviewed the US-Singapore FTA in the context of other multilateral and bilateral agreements and initiatives that the US had achieved. In other words, IFAC is a committee that gets its hands dirty by reviewing and drafting specific agreements. It does this technical work across all US trade initiatives in intellectual property, whether bilateral, regional and multilateral. It is thus able to co-ordinate at a technical level the work it does across these different fora, thereby ensuring that US trade negotiating initiatives push intellectual property standards in the direction that US industry would like. The technical expertise on IFAC, as well as the expertise available to it from the corporate legal divisions of its members means that, for example, it can evaluate a country's intellectual property standards in detail when that country seeks WTO accession and it can provide detailed assessments of the standards that USTR negotiators must bring home in a negotiation.

Formally IFAC must report to the President, the USTR and Congress when the President notifies Congress of an intention to enter into a trade agreement. This formal role, however, represents only a small part of a more complex system of private sector nodal governance. Members of IFAC work outside of the committee to ensure that the US remains committed to an agenda of globalising US standards of intellectual property. So, for example, the Biotechnology Industry Organization, which represents more than 1,100 organisations and is a member of IFAC has over the years independently lobbied the USTR on the question of intellectual property rights. Its agenda is a matter of public record and is neatly summarised in a letter of January 29, 2003 to

the USTR, Robert Zoellick: "[t]he United States' intellectual property system is the best in the world, and BIO advocates the establishment of global standards protecting intellectual property comparable to those in the United States."[37]

Naturally when BIO sits on IFAC it brings its advocacy position with it. A seat on IFAC means that BIO is able, in co-operation with the other members, to provide technical and drafting advice to the USTR as to the kind of standards that meet the desires of the organisations that BIO represents. There are a number of incentives for the USTR to be attentive to the suggestions of IFAC, including the superior technical expertise of the committee, the fact that the negotiating mandate in the Trade Act of 2002 requires the USTR to seek standards of protection comparable to US domestic law and that IFAC must ultimately write a report, as it did in the case of US-Singapore FTA, that endorses the agreement as being in the economic interests of the US. The upshot is that the standards that members of IFAC seek are very often the ones they achieve, especially in bilateral negotiations where the US almost always has superior bargaining power. So, for example, BIO has urged that where there are delays by trading partners in the granting of patents there be compensatory extensions of the patent term and it has also advocated that trading partners adopt US standards of data protection for pharmaceutical products. Articles 16.7 and 16.8 of the US-Singapore FTA implement these US domestic standards in Singapore. BIO also works in other ways outside of IFAC. It, for example, responds to the USTR's request for public comment on which countries should be the subject of "Special 301" listing and as a recognised international NGO in WIPO it can be active in pushing its position on patents in the WIPO Patent Agenda process.

To sum up: the members of IFAC become intimately involved in trade negotiations on intellectual property, not just advising but reviewing drafts and helping to decide objectives. Most importantly, they track US negotiating objectives across negotiations in different fora, thereby ensuring that these objectives are consistently pursued and pursued in a way that is most likely to bring long term success. Shifting from bilaterals to multilaterals has been at the centrepiece of US strategy for the last 20 years and has proven to be highly effective.

7.5 INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT: FUZZY VALUES, HARD RULES

The Doha Round of trade negotiations that was launched in Doha, Qatar in November 2001 has been referred to as a "development round," the idea being that this round, in apparent contrast to previous rounds, will pay some attention to the needs of developing countries. Some reference to a fairer development agenda is an almost obligatory part of speech-making for Western leaders. The policy elites that operate in the global corridors of power of institutions such as the World Bank, the IMF and WTO spend their time writing reports that symbolically utilise warm and fuzzy development values. Thus a recent World Bank report says that development is about "improving the quality of people's lives, expanding their ability to shape their own futures."[38] It is now clear that major development problems such as lack of market access for developing countries' exports, ill health and lack of education in developing countries "can be solved only with cooperation from high-income countries".[39] And in addition "[p]oor people and poor countries should have greater voice in international forums".[40] Here we have a group of fuzzy values that include co-operating with the poor, recognising their autonomy and helping to empower them. How do these values square with the detailed technical rule-making that goes on with respect to intellectual property rights in trade fora?

7.5.1 Autonomy

The value of autonomy implies at the level of rule-making for developing countries that one should set rules that do not limit the opportunities of poor countries and that leave them with some sovereign discretion over informational resources. The very concept of development, it might be argued, implies rule diversity. Yet the practice of rule-making in trade fora is about the globalisation and harmonisation of one set of intellectual property standards. The standards of intellectual property that the US is globalising are its domestic standards, standards that meet its own economic needs and fit with its cultural and philosophical traditions. Strong patent standards may make sense in the US because, amongst other things, it has 3,676 scientists and engineers in R&D per million people, but surely they make no sense in a country like Rwanda that has

only 35 per million. Around the world many people have deeply-held reservations about the patentability of plants, animals and human genetic resources, reservations that are based on a variety of ethical perspectives and traditions, including religious, indigenous and environmental ones. Yet the US has relentlessly pushed in TRIPS and subsequent bilateral agreements what the US Supreme Court has declared to be its domestic position, namely that anything under the sun is patentable.[41] It is equally relentless in seeking to impose upon the world a system of agriculture that is really a system of technology in which the farmer becomes the lessee of patented seeds, plants, fertilisers and pesticides. Fears that this technology does not meet the needs of subsistence farmers around the world, that it carries with it environmental risks that have not been properly assessed, that it cuts across farmer traditions such as the saving and exchange of seed or that it requires economies of scale that few countries can really exploit tends to be brushed aside by the US as disguised protectionism. It responds by threatening litigation in the WTO, knowing that its weight of lawyers will more than likely tilt the playing field in its favour.

Ignoring moral diversity in the definition of intellectual property rules while seeking through those rules to universalise its own cultural perceptions is a US practice to be found in other parts of intellectual property. The US was successful in excluding from TRIPS the recognition of authors' rights, those rights that are based on European philosophical traditions that recognise an indissoluble link between creators and their works (the key ones being the right to paternity and the right to integrity). Hollywood in the form of the Motion Picture Association Of America (MPA) has been opposed to these rights because they are potential interferences in its world-wide systems of production, marketing, distribution and exhibition. The right of integrity, for example, gives authors, potentially at least, some rights over how their works might be used in a film. Directors may also use the right to exercise some control over the commercial fate of their films—preventing, for example, the colourisation of a film shot in black and white.

Yet at the same time actors like the MPA invoke free speech values to argue that there should be no restrictions on the circulation of US film, television and other copyright works. Of course, there is a trade agenda because, as has been known for a long time, trade follows the film. The practical upshot of these free speech/free trade arguments is a constant pressure to remove quotas. No quota is too low to be ignored.

When Indonesia imposed a screen quota requiring its First Run theatres to show at least two Indonesian films each month for a minimum of two days, both the MPA and the International Intellectual Property Alliance raised the matter with the USTR as part of their recommendation in 1993 to list Indonesia under the 301 process. The endgame for Hollywood is no restriction on its capacity to dominate any type of screen in the world at any time and place.

7.5.2 Empowerment

Empowerment is another fuzzy value that routinely makes it into the "development-speak" of western policy elites. Whatever empowerment means, it surely does not mean transferring wealth from the poor to wealthy. Yet by imposing its own standards of intellectual property on developing country economies the US has changed the *terms of trade* of those economies. Developing states, which are net importers of intellectual property, will have to make greater payments to the US for the use of intellectual property rights than otherwise would have been the case. A study by the World Bank, for example, pointed out that the net rent transfers to the US from the patent provisions of TRIPS would be about $19 billion per year.[42] This figure only represents a beginning since it does not cover many other valuable areas of intellectual property like copyright that relates to the software, music and film industries.

7.5.3 Co-operation

Finally, we arrive at the value of co-operation, perhaps the primary value in development rights talk these days. How does this value square with the reality of technical rule-making in the international intellectual property regime? With more than 20 million dead and more than 40 million people infected by HIV, cooperation in fighting AIDS would seem to be beyond argument. Consider, however, the history of the WTO when it comes to the critical issue of defining intellectual property rights in ways that would encourage generic manufacturers to provide cheap anti-retroviral therapies for poor people in developing countries. In the WTO, negotiations follow a basic pattern in which inner circles of key players (for example, the Quad) forge a consensus that is then progressively expanded to include those in the outer circles. During the TRIPS negotiations and when the rules on patenting were being decided,

no African negotiator, the continent worst affected by AIDS, ever made it into the key inner circles of decision-making. During the negotiations, the "Green Room" process was used to discipline developing countries so that consensus decision-making could be projected to the outside world. (The Green Room refers to high-level negotiations between key players over unsettled parts of the negotiating text.) Because of the pressure of these Green Room processes, developing country negotiators began to refer to them as the "Black Room" consultations.[43]

After the signing of the TRIPS Agreement, co-operation has continued to remain elusive. In 1997 the South African government introduced a bill that gave the health minister some discretion in setting conditions to ensure the supply of affordable medicines. South Africa has the biggest HIV-infected population in Africa. The bill was signed by President Mandela on December 12, 1997. It specifically allowed the importation into South Africa of patented medicines which had been put onto another market with the consent of the patent owner. The idea was to encourage the importation of patented medicines from the cheapest market (parallel importation), a form of importation that was allowed within the European Union, amongst other places. The response of the US officials was to turn the passage of the South African bill into a trade matter. Agencies of the US government such as the USTR, the Department of Commerce and the State Department, with the assistance of officials from the European Commission, began to pressure South Africa to change the bill. One of their arguments was that the South African government, in passing the Medicines bill, would be in breach of its obligations under TRIPS. In 1998 the pressure on South Africa intensified. The USTR listed South Africa under its trade law for possible trade sanctions if it did not comply with the demands of the US pharmaceutical industry and, in February 1998, 41 pharmaceutical companies began proceedings in South African courts against the South African government, naming Nelson Mandela as first defendant. The trade dispute continued to climb up the totem pole of political importance. Senior officials from the US and the EU continued to draw attention to South Africa's obligations under TRIPS. Sir Leon Brittan, the then Vice-President of the European Commission, wrote to Thabo Mbeki, at that time the Deputy President of South Africa, drawing his attention to South Africa's obligations under TRIPS.[44] At the August 1998 US-South Africa Binational Commission meetings in Washington, Vice President Gore made the protection of US pharmaceutical patents the central issue.[45]

In March 2001, 39 pharmaceutical companies came to the Pretoria High Court armed with most of South Africa's intellectual property barristers and a barrage of arguments against the Medicines Act. TRIPS surfaced again, the line of argument being that TRIPS required that patents be "enjoyable without discrimination" as to the field of technology.[46] The South African Medicines Act was said to discriminate against pharmaceutical patents. In April of 2001 the pharmaceutical companies withdrew from the litigation because of a highly effective global public campaign by civil society.[47] It put TRIPS, patents and the price of pharmaceuticals firmly in the spotlight. With the debate threatening to spill over into the cost of drugs generally, and hard questions being asked about the patent system, it was time for the large pharmaceutical industry to withdraw to the corridors of Washington and the WTO.

At a special meeting of the TRIPS Council in June 2001, developing states pushed for the recognition of a reading of TRIPS that permitted them to deal with health crises. Ultimately this produced the Declaration on TRIPS and Public Health at a Doha WTO Ministerial in November of 2001, a Declaration that affirms the right of developing countries to protect the health of their populations. The Doha Declaration was of enormous symbolic importance to developing countries, but it did leave unsettled a practical detail. The Declaration affirmed the right of developing countries to issue compulsory licences over pharmaceutical patents, but it did not change the restrictions on the export of patented products under TRIPS. As a UNIDO study showed in 1992, most developing countries do not have a sophisticated pharmaceutical industry and so the capacity to issue domestic compulsory licences is of little practical value.[48] Today only a handful of developing countries have significant innovative capabilities in the pharmaceutical sector (Argentina, Brazil, China, India, Korea, Mexico and Thailand) and of these only India has been a major exporter. Under the TRIPS Agreement these countries face export restrictions on patented products.

During the course of 2002 and 2003 the members of the TRIPS Council worked to find a solution to the problem of export. A consensus solution was announced in August of 2003.[49] Symbolically a solution was needed to allay the concerns of western publics and more importantly to preserve the WTO as a forum in which technical rule-making on intellectual property could continue. Instead of a simple statement of principle that would permit developing country generic manufacturers

to export medicines to the countries that needed them, the solution comes in the form of six pages of provisions that set up a complex system of licensing and monitoring by states and the TRIPS Council.[50] For example, the system set up by the draft means that a generic manufacturer in an exporting country is dependent upon *both* the exporting and importing country each complying with the mandatory system of notification and conditions. The consequences of failure to comply are not spelt out. Generic manufacturers would in practical terms have to monitor the bureaucracies of two countries in relation to every act of export in relation to a single product (potentially many bureaucracies).

The detail of the provisions reveals a familiar pattern in rule-making when developed and developing countries meet at the negotiating table. Developing countries are drawn into complex juridical webs that they do not have the resources to disentangle and that ultimately do not serve them. The main pharmaceutical exporting nations (USA, UK, Japan, Germany, France and Switzerland) have indicated that they will not use the system *as importers*. This suggests that the pharmaceutical companies (including the generic affiliates of multinationals) in these countries may use the system *as exporters*. Generic manufacturers in developing countries may well face strong price competition in the export markets left to them under the system from these companies. This price competition is likely to be subsidised by the lucrative domestic markets of these companies, markets that would remain protected under the proposed system. In the long run this will simply increase the dependency of least-developed countries upon individual acts of charity or politicised development aid programmes.

The debates over AIDS, patents, TRIPS and the right to health are complex, but lying at the heart of the problem is a simple structural reality. Developing countries that are members of the WTO have to recognise patents on pharmaceutical products. The only reason that the price of patented anti-retroviral therapies have come down from US$15,000 per year to less than US$300 per year is because a few generic manufacturers like the Indian company Cipla were able to make the drugs at a price closer to marginal cost. They were able to manufacture because of their domestic patent position. However, all those developing countries with serious generic manufacturing capabilities either do or will soon have to recognise pharmaceutical patents as part of their TRIPS obligations. This will have two basic effects, one short term and the other longer term. In the short term, the capacity of these countries to export to other

developing countries will slowly dry up. In the longer term, the generic industries of the main developing country exporters will become integrated into the manufacturing and distribution strategies of US and European pharmaceutical multinationals. The effect will be to drive prices up, not down.

7.6 CONCLUSION

For some time now the US has had an historically unprecedented opportunity to use its stock of knowledge to further the development of the many poor states in the world. As measured by indicators such as number of scientific publications, number of students in higher education and number of scientists, the US has a greater volume of knowledge located within it than any other country.[51] No hegemonic power has had such a world of knowledge available for utilisation and creative use. Since knowledge has the quality of being non-rivalrous in consumption, it follows that the US would not itself lose the knowledge it utilised for development purposes (and in fact would probably add to it since the application of knowledge generally leads to more knowledge). Moreover, treating knowledge as part of a global intellectual commons would not be inconsistent with the US pursuing its own economic growth. The principle of the intellectual commons is not, as the free software movement has shown, inconsistent with the development of business models.

However, for the time being the US state and US multinationals remain committed partners in the institutional project of information feudalism, that is the project of acquiring and maintaining global power based on the ownership of knowledge assets. Patent attorneys in US corporations are able to draft patent claims that travel the institutional pathways of international treaty law arriving as domestic obligations in other states that stipulate what potential competitors may or may not do with US informational assets. This is private networked governance that draws upon public nodes of authority such as the USTR to legitimise and enforce its privately drafted property law. It is global in its reach.

At a deeper level the global intellectual property paradigm is a negative vision. The basis of competition lies in the development of skills. The acquisition of skills by newcomers disturbs roles and hierarchies. After India built a national drug industry it began exporting bulk drugs and formulations to places such as Canada. A developing country that

had acquired skills threatened those at the top of an international hierarchy of pharmaceutical production—the US, Japan, Germany, and the UK. Underneath the individualist ideology of intellectual property there lies an agenda of under-development, of maintaining an economic hierarchy in the world. Today's global intellectual property paradigm is all about protecting the knowledge and skills of the leaders of the pack.

ENDNOTES

1 For the history see Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, Ashgate, England, 2003. See also Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?*, (London: Earthscan, 2002), chap. 3.

2 See Article 27.1 of TRIPS.

3 Letter from C. L. Clemente, Senior Vice President—Corporate Affairs, Pfizer Inc. to Joseph Papovich, Deputy Assistant US Trade Representative for Intellectual Property, June 7, 1994.

4 For an analysis of its provisions see D. Gervais, *The TRIPS Agreement: Drafting History And Analysis* (London, Sweet and Maxwell, 1998).

5 See Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, London, 2002, chap .2.

6 S. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, (Cambridge: Cambridge University Press, 2003).

7 M. Ryan, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Washington DC: Brookings Institution Press, 1998); Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002); D. Matthews, *Globalising Intellectual Property Rights* (London and New York: Routledge, 2002).

8 See "Pfizer: Protecting Intellectual Property in a Global Marketplace," *Harvard Business School*, 1992, at page 8.

9 See Private Sector Advisory Committee System, USTR, 1994 Annual Report, available online: (http://www.ustr.gov/reports).

10 Jacques Gorlin, "A Trade-Based Approach for the International Copyright Protection for Computer Software", September 1, 1985, 47, fn 47.

11 See *BNA's Patent, Trademark & Copyright Journal*, 31, February 13, 1986, at page 285.

12 See Edmund Pratt, "Intellectual Property Rights and International Trade," speech to US Council for International Business, available online: (http://www.pfizer.com/pfizerinc/policy/forum).

13 IPC, "Accomplishments and Current Activities of the Intellectual Property Committee," June 14, 1988.

14 Basic Framework of GATT Provisions on Intellectual Property, Statement of Views of the European, Japanese and United States Business Communities, The Intellectual Property Committee, Keidanren (Japan), UNICE (Europe), June 1998.

15 Document MIN.DEC of 20 September 1986, reprinted in Terence P. Stewart (ed.), *The GATT Uruguay Round: A Negotiating History (1986-1992)*, vol. 3, (Deventer, Boston: Kluwer Law and Taxation Publishers, 1986), at pages 1–10.

16 See, for example, the statement by a member of the office of the USTR Emory Simon in "Remarks of Mr Emory Simon," Symposium: Trade-Related Aspects Of Intellectual Property, 22 (1989), *Vanderbilt Journal of Transnational Law*, at page 370.

17 See P. Drahos, "BITs and BIPs—Bilateralism in Intellectual Property", 4 (2001), *Journal of World Intellectual Property*, at page 791.

18 For a detailed explanation of this strategy and some examples see John Braithwaite and Peter Drahos, *Global Business Regulation* (UK: Cambridge University Press, 2000), chap. 24.

19 See, for example, Article 1702 of NAFTA, Article 1.1 of TRIPS, Article 4.1 of the US-Jordan FTA and Article X1 of the US-Nicaraguan BIT.

20 *Ibid.* See Article 4.1.

21 See Susan K. Sell, "TRIPS and the Access to Medicines Campaign" 20 (2002), *Wisconsin International Law Journal*, 481, at pages 518–519.

22 See *Hughes Aircraft Co. v. United States*, 148 F.3d 1384, 1385 (Fed. Cir. 1998).

23 For an overview and summary see Boniface Guwa Chidyausiku, "Article 27.3(b) of the TRIPS Agreement: The review process and developments at national and regional levels," in Christophe Bellmann, Graham Dutfield and Ricardo Meléndez-Ortiz (eds.) *Trading in Knowledge* (London and Sterling: Earthscan, 2003), at page 101.

24 See Susan K. Sell, "TRIPS and the Access to Medicines Campaign" 20 (2002), Wisconsin *International Law Journal*, 481; Ruth Mayne, "The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective" in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge Access and Development*, Palgrave, Macmillan, 2002, at page 244.

25 Under the Bipartisan Trade Promotion Authority Act of 2002 the Congress has stated that one overall negotiating objective for the US is to obtain in bilateral and multilateral agreements provisions that "reflect a standard of protection similar to that found in United States law". See Section 2102(b)(4)(A)(i)(II), codified as 19 USC 3802.

26 See Article 16.7.1 of the US-Singapore FTA.

27 See Article 16.7.2 of the US-Singapore FTA.

28 See WT/DS114/R 4.15.

29 Canada pointed out that Germany, Italy, Japan, Portugal, Argentina, Australia and Israel had allowed an exception to patent rights for the purposes of generic producers obtaining marketing approval.

30 The US pushed for such a compulsory licensing provision in the context of the TRIPS negotiations but was unsuccessful. See Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (New Delhi: Oxford University Press, 2001), at page 320.

31 See Donna M. Gitter, "International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption" 76 (2001), *New York University Law Review*, at pages 1623, 1681–1682.

32 See Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (New Delhi: Oxford University Press, 2001), at pages 200–201.

33 A description is to be found in The President's 2002 Annual Report on the Trade Agreement Program, available online: (http://www.ustr.gov/reports/2003.html).

34 The members are, International Intellectual Property Alliance, The Gorlin Group, Law Offices of Hope H. Camp, representing Eli Lilly and Company, Cowan, Leibowitz & Latman, P.C., Anheuser-Busch Companies, Sidley, Austin, Brown & Wood, LLP, representing Biotechnology Industry Organization, Covington and Burling representing Microsoft Corporation, Merck & Company, International Anticounterfeiting Coalition, Intellectual Property Owners Association, Pfizer, Pharmaceutical Research and Manufacturers of America, The Engineered Wood Association, Georgia-Pacific Corporation, Business Software Alliance, Lark-Holton Global Consulting, Levi Strauss & Company, Tuttle International Group, Procter & Gamble, Distilled Spirits Council of the United States, Rubber and Plastics Manufacturers Association.

35 The Charter is available online: (http://www.ita.doc.gov/td/icp/Charter-23.html).

36 See The US-Singapore Free Trade Agreement (FTA) The Intellectual Property Provisions: Report of the Industrial Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), February 28, 2003, at page 3.

37 The letter is available on BIO's website: (http://www.bio.org).

38 World Bank, *The Quality of Growth* (NY: Oxford University Press, 2000), at page xxiii.

39 *World Development Report 2000/2001: Attacking Poverty* (NY: Oxford University Press, 2001), at page 188.

40 *World Development Report 2000/2001: Attacking Poverty* (NY: Oxford University Press, 2001), 12. See also, Deepa Narayan *et al.*, *Voices of the Poor: Can Anyone Hear Us?*, World Bank, (NY: Oxford University Press, 2000), chap. 7.

41 *Diamond v. Chakrabarty* 206 USPQ 193, 200 (1980).

42 See Global Economic Prospects and the Developing Countries, World Bank, Washington DC, 2002, at page 137.

43 Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002), at page 135.

44 See Oxfam Background Briefing, "South Africa vs. the Drug Giants: A Challenge to Affordable Medicines," available online: (http://www.oxfam.org.uk/cutthecost).

45 The details of this international effort are described in "US Government Efforts To Negotiate the Repeal, Termination or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act Of 1965," United States Department of State, Washington D.C. 20520, February 5, 1999.

46 See Article 27.1.

47 See Ruth Mayne, "The Global NGO Campaign on Patents and Access to Medicines: an Oxfam Perspective" in Peter Drahos and Ruth Mayne (eds.) *Global Intellectual Property Rights: Knowledge Access and Development* (Hampshire, UK: Palgrave, Macmillan, 2002), chap. 15.

48 Robert Ballance, Janos Progany, and Helmet Forstener, *The Worlds' Pharmaceutical Industries: An International Perspective on Innovation, Competition & Policy*, UNIDO, 1992.

49 See WTO News: 2003, Press Releases, Press/350, August 30, 2003.

50 See Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W405, August 28, 2003.

51 Thomas Schott, "Global Webs of Knowledge," *American Behavioural Scientist*, 44 (2001), at pages 1740–1751.