INTELLECTUAL PROPERTY AND PHARMACEUTICAL MARKETS: A NODAL GOVERNANCE APPROACH

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I. INTRODUCTION

The regulated markets in pharmaceutical products are failing the world's poor people. This is a majority of the world's population. The basic problem is well known.[1] Governments regulate pharmaceutical information markets through the creation of patent systems and the establishment of regulatory agencies (patent offices) to administer those systems. The purpose behind this regulation is to correct for market failure. Without such regulation, pharmaceutical companies would not invest in the production of information. The regulated pharmaceutical markets work on the basis of consumer preferences. Consumers express those preferences by their willingness to pay for pharmaceutical information that is embodied in products. The world's poor consumers also have preferences for medicines, of course, but they do not have the ability to pay the prices that are commanded in regulated markets. As a result, they turn to unregulated markets in traditional medicines.[2] The upshot of all this is that regulated markets either fail to deliver medicines for diseases that afflict poor people (the demand as measured by preferences is not there), or the medicines that regulated markets produce for the wealthy, and which are also important for poor people's health, remain beyond poor people's reach.

As a matter of moral theory, it is not hard to find arguments that lead to the conclusion that regulated pharmaceutical markets are producing the wrong

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1. *See* Jean O. Lanjouw, *A New Global Patent Regime For Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 88-89 (2002) (noting how the developing world's lack of patent rights for drugs reduces incentive to invest in research of diseases); Hannah E. Kettler, *Using Intellectual Property Regimes to Meet Global Health R&D Needs*, 5 J. WORLD INTELL. PROP. 655, 656-59 (2002) (discussing how research and development of poverty diseases is under-developed because of poor returns for potential investors without patent rights); MÉDECINS SANS FRONTIÈRES & DRUGS FOR NEGLECTED DISEASES WORKING GROUP, FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES 16-18 (2001) (noting that company allocation of research and development funding stems not from a global health need, but from a variety of incentives, including the patent system and potential investment returns), *available at* http://www.msf.org/source/access/2001/fatal/fatalshort.pdf (last visited Sept. 7, 2004).

2. CARLOS M. CORREA, PROTECTION AND PROMOTION OF TRADITIONAL MEDICINE: IMPLICATIONS FOR PUBLIC HEALTH IN DEVELOPING COUNTRIES 6-7 (2002), *available at* http://www.southcentre.org/publications/ traditionalmedicine/traditionalmedicine.pdf (last visited Sept. 7, 2004).

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outcomes. A simple line of argument, based on a utilitarian approach, is that one must count everyone's utility when calculating the balance of happiness over suffering.[3] As Jeremy Bentham put it, "everybody to count for one, nobody for more than one."[4] Clearly, pharmaceutical markets are not counting the utilities of poor people around the world. In fact, it is hard to think of another case where so many individual utilities relating to fundamental need are routinely not counted.

The scale of the access-to-medicines problem has been brought home by the HIV/AIDS crisis. But for poor people and developing countries where the majority of poor people live, the problem has existed for a long time. This problem was there in the case of access to broad-spectrum antibiotics in the 1950s, when the price of tetracycline in many developing countries was held constant for more than ten years, at least in part allegedly due to a price cartel amongst Pfizer, Cyanamid, Bristol, Squibb, and Upjohn.[5] The problem was there in 1979 when Senator Kennedy made a speech pointing out that "'in this International Year of the Child . . . 2.6 million children will die this year from immunizable diseases because they won't have access to already-developed vaccines.'"[6] These days it has become *de rigueur* for senior western political figures to bemoan the spread of the HIV/AIDS crisis in developing countries.

Speech-making, like talk, is cheap. One might have thought that wise and rational legislators, confronted by the failure of regulated markets to reach so many people, would begin a process of critical examination of these markets that might eventually lead to serious global reform. An added reason for thinking this is that in an era when the virtues of deregulation, globalization, and free trade continue to be preached, lifting the heavy hand of patent regulation from pharmaceutical markets would carry some ideological appeal. But, as this article shows, the trend has been in exactly the opposite direction. All areas of intellectual property, including patents, are globalizing. The pharmaceutical markets of all countries are becoming more regulated by patent systems.

This article explores the question of why it is that pharmaceutical markets are moving down the path of more and more patent regulation when we might have expected states to reverse, or at least halt, this regulatory trend. This article develops an answer to this question using a theoretical approach called nodal governance. As Scott Burris observes in his article in this volume, "modes of governance structure health in the world."[7] As we shall see, a distinctive kind of nodal governance has emerged to push pharmaceutical markets in the direction

3. For more sophisticated approaches, see Brian Barry, *Humanity and Justice in Global Perspective*, *in* CONTEMPORARY POLITICAL PHILOSOPHY 525 (Robert E. Goodin & Phillip Pettit eds., 1997).

4. JOHN STUART MILL, UTILITARIANISM 105 (Roger Crisp ed., 1998) (attributing adage to Jeremy Bentham).

5. *See* JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 176-82 (1984) (discussing evidence of price fixing by the price cartel).

6. *Id.* at 246 (quoting Senator Edward Kennedy).

7. Scott Burris, *Governance, Microgovernance, and Health*, 77 TEMP. L. REV. 335, 357 (2004).

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of ever greater patent regulation.[8] Scott Burris presents this theory of nodal governance, and so this article confines itself to a summary of that topic.[9] The remaining sections of this article draw on the theories of enforcement pyramids[10] and forum shifting,[11] and show how the nodal coordination of an international enforcement pyramid offers non-state actors the possibility of securing states' compliance with emerging global standards of intellectual property rights that, in turn, constitute today's patent regulated pharmaceutical markets.[12] This case of nodal governance is a case of governance by the strong. It is at one end of the spectrum, because most states end up being the governed, rather than the governors.

The last section of this article discusses the protection of traditional knowledge ("TK") held by indigenous people.[13] There are many dimensions to TK.[14] Our interest here is in the fact that many people in the world use TK and traditional products to treat their illnesses. In developing countries, people often have no other choice of treatment. There is no doubt that TK and traditional medicine are valuable assets. Amongst other things, significant numbers of

8. See *infra* Part III for a discussion of the regulation of pharmaceutical markets through forum shifting and the global intellectual property ratchet.

9. *See* Clifford Shearing & Jennifer Wood, *Nodal Governance, Democracy, and the New "Denizens,"* 30 J.L. & SOC'Y 400, 401-06 (2003) (discussing the shift from a purely state-centered governance of security and justice to one in which the state constitutes one of many actors); Scott Burris et al., *Nodal Governance as an Approach to Regulation*, (manuscript on file with author); LES JOHNSTON & CLIFFORD SHEARING, GOVERNING SECURITY: EXPLORATIONS IN POLICING AND JUSTICE ch. 8 (2003) (discussing the pluralization of security governance). See *infra* Part II for a description of nodal governance.

10. *See* JOHN BRAITHWAITE, TO PUNISH OR PERSUADE: ENFORCEMENT OF COAL MINE SAFETY ch. 5 (1985) (describing the enforcement pyramid as an "escalating regulatory strategy from self-regulation, to enforced self-regulation, to command regulation with discretion to punish, to command regulation with nondiscretionary punishment"); IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE ch. 2 (1992) (finding that agencies employing escalating levels of penalties are most effective in maintaining regulatory compliance). See *infra* Part IV for a discussion of the usage of international enforcement pyramids in the context of intellectual property rights.

11. *See* JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION ch. 24 (2000) (discussing the role of forum-shifting strategies in international regulation). See *infra* notes 36-44 and accompanying text and diagrams for a discussion of the development of forum shifting among states to enforce intellectual property regulations.

12. See *infra* notes 45-49 and accompanying text and diagrams for an explanation of how the private sector has expanded the scope of international enforcement pyramids.

13. See *infra* Part V for a discussion of TK.

14. For overviews see CARLOS CORREA, QUAKER UNITED NATIONS OFFICE, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY 3-5 (2001), *available at* http://www.geneva.quno.info/pdf/tkmonol.pdf (last visited Sept. 7, 2004); THE CRUCIBLE II GROUP, THE INTERNATIONAL DEVELOPMENT RESEARCH CENTRE, SEEDING SOLUTIONS, vol. 1 (2000), *available at* http://web.idrc.ca/en/ev-31619-201-1-DO_TOPIC.html (last visited Sept. 7, 2004); GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 61-71 (2000); TRADING IN KNOWLEDGE chs. 16-21 (Christophe Bellmann et al. eds., 2003); WORLD INTELLECTUAL PROPERTY ORGANIZATION ("WIPO"), INTELLECTUAL PROPERTY NEEDS AND EXPECTATIONS OF TRADITIONAL KNOWLEDGE HOLDERS (2001), *available at* http://www.wipo.int/tk/en/tk/ffm/report/ final/index.html (last visited Sept. 7, 2004).

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pharmaceutical products that have been released onto the market over the years have their lineage in, and can be traced back to, traditional origins.[15] Yet, property rights protection in these assets does not match the kind of intellectual property rights protection available to companies for their compounds and processes of treatment. Probably the current level of protection for TK is suboptimal.[16] By creating a regulatory framework for the protection of TK, it is at least arguable that the world is taking steps to preserve an asset that will generate public health gains down the track. Using a nodal governance approach, this article shows how protection for TK could be improved globally. This case might be thought of as a potential example of nodal governance by the weak.

II. NODAL GOVERNANCE IN A NUTSHELL

The idea of nodal coordination derives from recent theoretical approaches that make networks and nodes the principal categories in theorizing about changes in governance.[17] Manuel Castells, for example, argues that networks have overcome their historical weaknesses in coordinating functions and in bringing resources to bear on goals by becoming information networks.[18] These networks have adaptability and superior levels of coordination and complexity management. The principal effects of information networks are changes in power relationships, where traditional centers of power are bypassed by new networks of capital, production, trade, and communication. Power must still be exercised in the networked world. Nodal governance is a theory that focuses on the role of nodes in governance and especially in the way that networks can be linked to create concentrations of power for the purposes of exercising governance. Nodes are either actors within a network or the organizational product of two or more networks which are tied together for a common purpose.

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15. Most of today's plant-based pharmaceuticals were discovered through an ethnobotanical approach, "the use of people's knowledge and experiences of the medicinal properties of plants and other genetic resources." KERRY TEN KATE & SARAH A. LAIRD, THE COMMERCIAL USE OF BIODIVERSITY: ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING 61 (1999). For a discussion of the role of natural products in the pharmaceutical industry, see *id.* at ch. 3.

16. This does not mean, however, that this protection should take the form of more intellectual property protection. *See* Paul Heald, *The Rhetoric of Biopiracy*, 11 CARDOZO J. INT'L & COMP. L. 519, 531-34 (2003) (noting that a property-rights focus is often detrimental to long-term interests of indigenous communities and advocating renewed working relationships between large companies and indigenous communities).

17. *See, e.g.*, Manuel Castells, *Materials for an Exploratory Theory of the Network Society*, 51 BRIT. J. SOC. 5, 13-14 (2000) (noting that nation-states have begun to build partnerships to retain influence within the increasingly predominant "network society"); R.A.W. RHODES, UNDERSTANDING GOVERNANCE 51-59 (1997) (describing how British governance evolved through development of interconnected networks of public-private partnerships); Shearing & Wood, *supra* note 9, at 401-03 (discussing the shift in security governance from a purely state-run system to a cooperative system between states and non-state agencies). For an analysis of networks in the context of international law, see Kal Raustiala, *The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law*, 43 VA. J. INT'L L. 1, 70-90 (2002).

18. Castells, *supra* note 17, at 14-17.

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This latter type of node (termed a "super-structural" node) does not integrate networks, but rather is a structure that brings together actors who represent networks in order to concentrate resources and technologies for the purpose of achieving a common goal.[19] Super-structural nodes are the command centers of networked governance.

In broad terms, nodal governance is an adaptive response to the problem of information that confronts governance of all kinds, but especially networked governance. Governance requires information. The dramatic proliferation of new types and new scales of networks that has been enabled by information technology means that the information that matters to governance is dispersed through a multiplicity of networks, many of which operate independently of each other. No one network, public or private, has information omniscience. The response of actors to this complexity has been to find ways to link networks to produce new structures of governance, a response that can be labeled nodal governance. These structures do not bring information omniscience to actors, but they do bring more information, and importantly, resources and technologies, which enable actors to become centers of governance. Nodes in the networked world are organizational centers in time and space from which the actions of governance flow.

III. THE OVER-REGULATION OF PHARMACEUTICAL MARKETS: FORUM SHIFTING AND THE GLOBAL INTELLECTUAL PROPERTY RATCHET

The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") that was negotiated as part of the Uruguay Round of multilateral trade negotiations (1986-1993) was probably the most important agreement on intellectual property in the twentieth century because it connected intellectual property standards to the tools of trade enforcement.[20] It was the most important so far as pharmaceutical multinationals were concerned because it meant that countries like India, which had major generic producers, had to, as a matter of domestic law, grant patents on pharmaceutical compounds.[21] The elaborate ironwork of all patenting strategies for blockbuster drugs rests on key

19. Burris et al., *supra* note 9.

20. Jerome Reichman observes that TRIPS was "a revolution in international intellectual property law." Jerome H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 442 (2000). The history of TRIPS has been well documented. *See* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 10-13 (2002) (discussing the reasoning behind the signing of TRIPS); DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 7-45 (2002) (detailing the origins of, contributors to, and reasons behind the TRIPS agreement); MICHAEL RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY 1-2 (1998) (noting TRIPS was signed in 1994 and ramifications of the agreement); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 108-20 (2003) (discussing the background of TRIPS).

21. *See* TRIPS, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, 33 I.L.M. 81 (1994) (subjecting all new inventions to patent rights, irrespective of place of invention).

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patents that protect the compound. Without such patents, generic companies may compete and the price of the compound inevitably declines.[22]

During the 1980s, the United States had set the scene for TRIPS through a series of strategic bilateral negotiations on intellectual property with countries like South Korea and Brazil. An incentive that was held out to developing countries for the successful negotiation of TRIPS was that the United States would desist from using its trade enforcement tools to obtain the standards that it wanted.[23]

After TRIPS was concluded, the United States actually intensified the level of its bilateral activity. It used its trade enforcement tools under its Trade Act of 1974 to review the intellectual property standards of more and more countries and it enforced many more bilateral agreements related to intellectual property than it had in the 1980s.[24] In effect, it had created, without anybody really noticing, a global regulatory ratchet for intellectual property. The United States was the principal architect of the global regulatory ratchet for intellectual property, with the European Union ("EU") to a lesser extent also making use of it.[25]

In short form, this ratcheting process is dependent upon:

(a) a process of forum shifting, a strategy in which the United States and EU shift the standard-setting agenda from fora in which they are encountering difficulties to those fora where they are likely to succeed;

(b) coordinated bilateral and multilateral strategies for intellectual property; and

(c) the entrenchment in agreements on intellectual property of a principle of a minimum-but-not-maximum standard of protection.

Forum shifting in international regulation is made up of three basic strategies – moving an agenda from one organization to another, leaving an organization, and pursuing agendas simultaneously in more than one organization.[26] The basic reason for forum shifting is that it increases the forum shifter's chances of victory. The rules and modes of operation of each international organization constitute the pay-offs that a state might expect to receive if it plays in that particular forum. Forum shifting is a way of constituting a new game. Facing defeat or a suboptimal result in one forum, a state may gain a better result by shifting its agenda to a new forum. In their study of global business regulation, John Braithwaite and Peter Drahos found that forum

22. For a discussion of the price effects of generic competition, see FED. TRADE COMM., GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9-11 (2002), *available at* http://www.ftc.gov/ os/2002/07/genericdrugstudy.pdf (last visited Sept. 7, 2004).

23. See, for example, the statements by Emory Simon, a member of the Office of the U.S. Trade Representative ("USTR"), in Emory Simon, *Trade-Related Aspects of Intellectual Property*, 22 VAND. J. TRANSNAT'L L. 367, 370 (1989).

24. *See* Peter Drahos, *BITs and BIPs – Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791, 792 (2001) (discussing USTR's use of Section 301 of the U.S. Trade Act in review of the adequacy of over seventy countries' intellectual property laws).

25. BRAITHWAITE & DRAHOS, *supra* note 11, at 566.

26. For a detailed explanation of this strategy and some examples, see *id.* at ch. 24.

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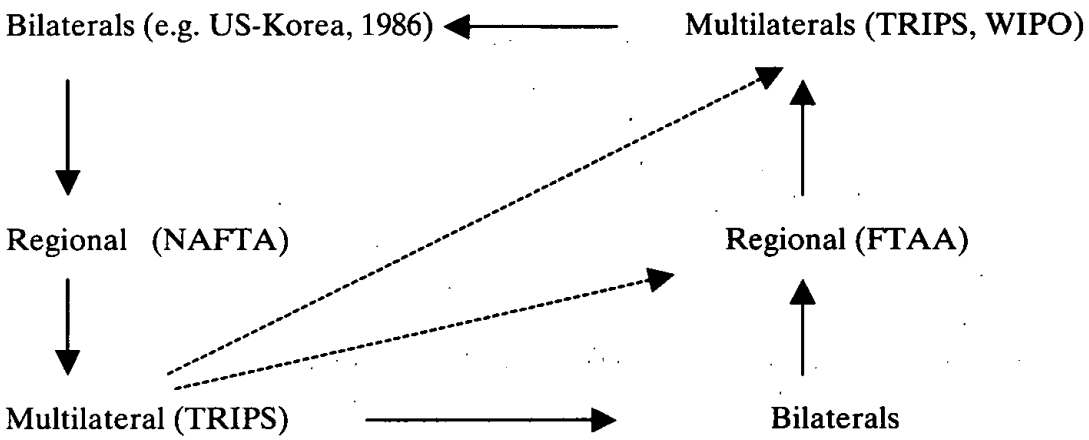
shifting had become important after the Second World War and that the United States was the main state to make use of it.[27]

The principle of minimum-but-not-maximum protection plays a vital role in the regulatory ratchet. 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 favorable treatment.[28] This means that each subsequent bilateral or multilateral agreement can establish a higher standard. The ratchet, therefore, can only travel in the direction of stronger standards.

The global ratchet for intellectual property consists of waves of bilaterals (beginning in the 1980s) followed by occasional multilateral standard-setting exercises (see Diagram 1 below). Each wave of bilateral or multilateral treaties never derogates from existing standards and very often sets new ones.

Diagram 1: The Global Intellectual Property Ratchet



The dash arrows indicate that the United States has the capacity and resources to pursue negotiations in different fora at the same time. Where the United States 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 that preceded TRIPS and that laid the foundation for TRIPS was triggered by the resistance that the

27. *Id.* at 564-65.

28. *See, e.g.*, Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, Oct. 24, 2000, art. 4, 41 I.L.M. 63 (2000) [hereinafter U.S.-Jordan FTA] (providing that the obligations to be implemented by each Party are a minimum); North American Free Trade Agreement, Jan. 1, 1994, art. 1702, 32 I.L.M. 60 (1994) [hereinafter NAFTA] (providing for the possibility of more extensive protection in the domestic law of a Party); TRIPS, *supra* note 21, at art. 1.1 (providing for the option of greater protection in domestic laws); United States-Australia Free Trade Agreement, May 18, 2004, art. 17.1.1 [hereinafter U.S.-Australia FTA] (providing for the option of greater domestic protection and enforcement of intellectual property rights), *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/ Final_Text/Section_Index.html.

United States encountered on its intellectual property agenda at the General Agreement on Tariffs and Trade ("GATT").[29] Presently, it is clear that the United States is in a bilateral phase. The Ministerial Declaration that launched the Doha round of multilateral trade negotiations in 2001 contained only a modest work program in relation to TRIPS with geographical indications being the principal item listed for negotiation.[30] Bilaterally, however, the United States has been busily negotiating free trade agreements ("FTA") with countries that it sees as being important regional models.

Table 1 provides an indication of recent activity by the United States in the negotiation of FTAs:

Table 1: The United States and Recent Free Trade Agreements and Negotiations

Passed by Congress	**Concluded, but not Passed by Congress**	**Ongoing or to Commence**
Jordan (2001)	Australia (2004)	Bahrain
Chile (2003)	Costa Rica (2004)	Bolivia
Singapore (2003)	El Salvador (2004)	Botswana
	Guatemala (2004)	Colombia
	Honduras (2004)	Dominican Republic
	Nicaragua (2004)	Ecuador
	Morocco (2004)	Lesotho
		Namibia
		Panama
		Peru
		South Africa
		Swaziland
		Thailand

The focus on FTAs, at this time, can also be explained in terms of the effective resistance that the United States has been encountering at the TRIPS Council over the last several years.[31] 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 World Trade Organization ("WTO") members agree to the Declaration on the TRIPS

29. DRAHOS & BRAITHWAITE, *supra* note 11, at 134.

30. *See* Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WTO, 4th Sess., 17-19, WT/MIN(01)/DEC/1 (Nov. 14, 2001) (providing for further negotiations on the protection of geographical indications for wine and spirits), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

31. Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 J. WORLD INTELL. PROP. 765, 780-83 (2002).

Agreement and Public Health, a declaration that the U.S. pharmaceutical industry counted as a blow against its interests and which it did its best to downplay.[32] Similarly, the review of Article 27(3)(b) that was started in 1999 has not run the way that the United States would have liked. In essence the United States wants to bring TRIPS into line with its own domestic position – "virtually anything is patentable."[33] 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.[34] Developing countries were able to resist U.S. proposals in the context of the TRIPS Council because outside of the Council they were being given assistance by civil society actors.[35] These actors were helping to provide technical expertise and through global campaigning they proved highly effective at raising questions about the origins of TRIPS and its moral legitimacy. 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 in which they could concentrate their resources. The response of the United States has been to focus on FTAs. In the FTAs that the United States has recently concluded, it has sought and in many cases obtained intellectual property standards from the relevant state which bring that state closer to the U.S. domestic position.[36]

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32. *See* Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481, 518-19 (2002) (noting the response of Pharmaceutical Research and Manufacturers of America ("PhRMA") and the reiteration of its continued commitment to TRIPS).

33. Hughes Aircraft Co. v. United States, 148 F.3d 1384, 1385 (Fed. Cir. 1998) (Clevenger, J., dissenting).

34. For an analysis of the responses to TRIPS by nongovernmental organizations and developing states, see Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 67 (2004). *See also* Boniface Guwa Chidyausiku, *Article 27.3(b) of the TRIPS Agreement: the review process and developments at national and regional levels, in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 101-04 (Christophe Bellmann et al. eds., 2003) (discussing implications for developing countries of article 27.3(b)'s patent protections for living organisms).

35. *See* Sell, *supra* note 32, at 518-19 (noting that nongovernmental organizations' involvement in this debate has shifted the political landscape in favor of developing countries); Ruth Mayne, *The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective, in* GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 244-46 (Peter Drahos & Ruth Mayne eds., 2002) (discussing the major nongovernmental contributors, including Oxfam, that helped the "pro-public health clarification" of TRIPS).

36. Under the Bipartisan Trade Promotion Authority Act of 2002, Congress has stated that one overall negotiating objective for the United States is to obtain, in bilateral and multilateral agreements, provisions that "reflect a standard of protection similar to that found in United States law." *See* 19 U.S.C. § 3802 (2004) (outlining trade negotiation objectives).

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IV. INTELLECTUAL PROPERTY OWNERS AND THEIR NODALLY COORDINATED ENFORCEMENT PYRAMID

The previous section showed how the United States has, through a strategy of forum shifting, been able to create a global intellectual property ratchet. For developing states, the costly investment in the enforcement of higher and higher intellectual property standards is to the benefit of mainly foreign intellectual property owners.[37] Assuming such states to be rational actors with limited resources, one would predict that they would enact enforcement procedures and then turn a blind eye to actual enforcement. For intellectual property owners, compliance by governments with their obligations on intellectual property, especially on enforcement, becomes of paramount importance.

This section argues that intellectual property owners have sought to achieve the goal of compliance through the creation of an international enforcement pyramid that is nodally coordinated. The theory behind enforcement pyramids is well known and summarized briefly below. We will also see that the United States' use of its trade enforcement tools follows pyramidal theory. The distinctive feature of this international enforcement pyramid is its nodal coordination by private sector actors. Nodes are specific organizational means through which the resources of multiple networks are concentrated to produce action. The crucial point about nodally coordinated pyramids is that the enforcement reach of the pyramid increases. In the case of intellectual property rights, the pyramid has real international reach and offers private sector actors a means by which to achieve the goal of secure intellectual property rights.

(i) Enforcement Pyramids

After John Braithwaite's development of the theory of the enforcement pyramid, a considerable body of scholarship has shown both theoretically and empirically how enforcement pyramids can increase compliance.[38] The key idea behind the pyramid is that punishment and persuasion should be linked in a certain sequence that begins with persuasion at the base of the pyramid and ends with the most punitive sanction at the apex of the pyramid. The assumption about human nature that lies behind this linkage sequence is that there are different actor types (e.g. rational, virtuous, irrational). The different enforcement levels of the pyramid are aimed at these different types. At the base of the pyramid are the "soft" tools of regulation such as guidelines, protocols, and educational strategies, or, in generic language, the tools of dialogue and persuasion. These soft tools assume that actors are disposed to do the "right thing" and are willing to cooperate. As one moves up the pyramid, the

37. U.N. CONFERENCE ON TRADE & DEV. ("UNCTAD"), THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES at 15, U.N. DOC. UNCTAD/ITE/1, U.N. Sales No. 96.II.D.10 (1996).

38. First put forward in BRAITHWAITE, *supra* note 10, at 142-44. *See also* AYRES & BRAITHWAITE, *supra* note 10, at 35-41 (discussing enforcement pyramids resolving game-theoretical problems in regulation); JOHN BRAITHWAITE, RESTORATIVE JUSTICE AND RESPONSIVE REGULATION ch. 2 (2002) (applying the enforcement pyramid theory to restorative justice theories).

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tools of regulation begin to assume a more coercive character until, at the top of the pyramid, there is some form of incapacitation (this depends on the area of regulation, but may involve imprisonment, suspension of trade, loss of license, and so on). Where the regulator is unsuccessful at the bottom of the pyramid, he or she can move up the pyramid to deploy more coercive tools. An enforcement pyramid gives a regulator a unified set of regulatory strategies that can be deployed against all types of actors (virtuous, rationally calculating, resistant, incompetent). As one type of strategy fails because of the type of actor involved, another is wheeled into place. Advocates of the enforcement pyramid argue that there should be a presumption in favor of starting at the base of the pyramid with dialogic and information-based strategies.[39] This is less costly, more respectful, and ultimately makes the use of coercion more legitimate, because non-coercive strategies have been given a chance to work.

The use by the United States of its trade enforcement tools in the context of trade disputes, including intellectual property, follows the shape of an enforcement pyramid (see Diagram 2 below).[40] Typically, the United States will begin an informal dialogue with a state if it believes that the state is not meeting standards of adequate and effective protection for intellectual property. Over time, the dialogue becomes more formal. If the state fails to act, it finds itself being listed for more serious attention. The various lists that are kept by the Office of the United States Trade Representative ("USTR") allow the USTR to make finely tuned escalations in deterrence.[41] It also means that states that make attempts to fix up their intellectual property problem can be taken off a list, or shifted to a less serious one. Building forgiveness and reward into the pyramid adds to its reasonableness and ultimately to its effectiveness, because those on the receiving end can see that the pyramid is not about unreasoning coercion. At the apex of the pyramid lie trade sanctions, such as the withdrawal of trade benefits or the imposition of duties on goods coming into the U.S. market.

39. *See* BRAITHWAITE, RESTORATIVE JUSTICE, *supra* note 38, at 30 (describing how dialogue and restorative regulation should be used before coercive methods for effective compliance).

40. Section 301 of the Trade Act of 1974 is the principal enforcement tool. *See* 19 U.S.C. § 2411 (1999) (outlining the Office of the U.S. Trade Representative's ("USTR") scope of authority and enforcement mechanisms for trade violations).

41. The Special 301 List is made up of Priority Foreign Countries, the Priority Watch List, and the Watch List. The USTR created these last two lists. For statutory criteria for the identification of Priority Foreign Countries, see 19 U.S.C. § 2242(b)(1) (1999) (noting criteria in selecting Priority Foreign Countries).

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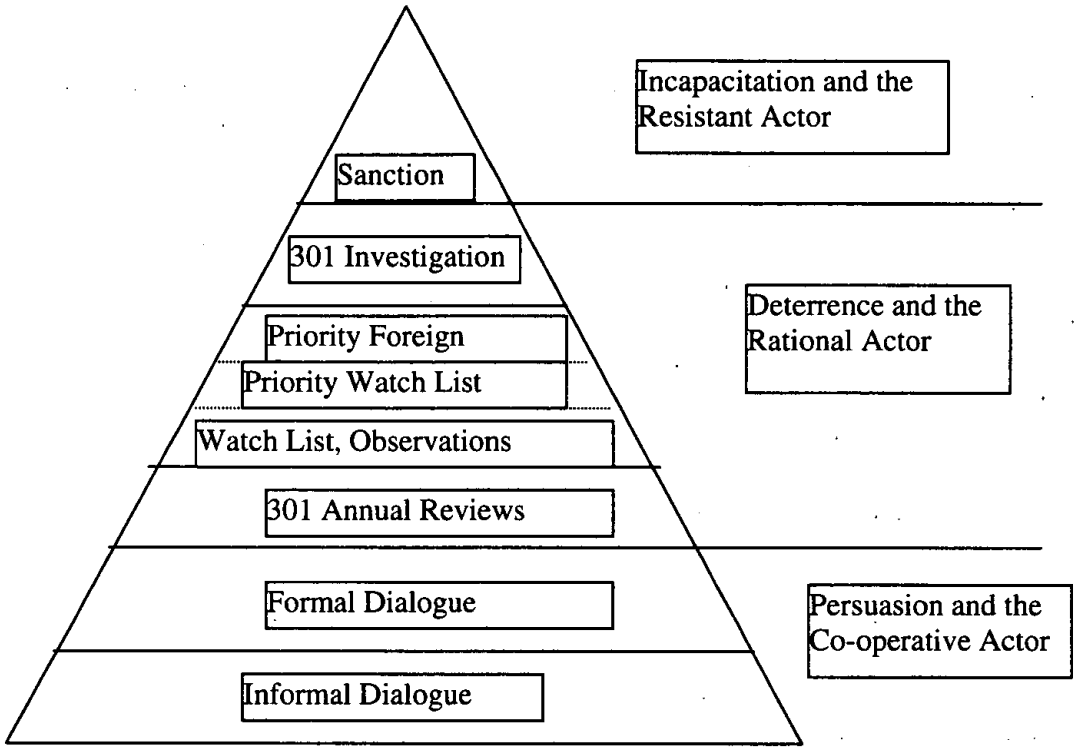
Diagram 2: U.S. Trade Enforcement Tools as an Enforcement Pyramid for Intellectual Property Rights



The ability of the USTR to wipe out the U.S. domestic market of another country across a range of products is a big stick, but it is infrequently used by the United States.[42] The theory and empirical work on enforcement pyramids shows that regulatory agencies that carry big sticks rarely use them.[43] Its simple presence combined with a belief about the inexorability of its use leads most targets of the pyramid to comply before the big stick is actually wielded. At the same time, the occasional use of the big stick projects credibility and makes the targets of enforcement in the lower reaches of the pyramid think harder about the potential costs of non-compliance. A recent statement by the current USTR, Robert Zoellick, neatly captures this pyramidal thinking:

> We resolve most problems without resorting to formal dispute proceedings, which take additional time and involve uncertain

42. *See* DRAHOS & BRAITHWAITE, *supra* note 20, at 99 (outlining the relative lack of actions brought by USTR under Section 301).

43. AYRES & BRAITHWAITE, *supra* note 10, at 40-41.

> outcomes. Most U.S. companies suggest formal dispute proceedings only as a last resort. When we determine it will be the most effective way to settle disputes, we pursue cases under the WTO, NAFTA, or our new FTAs.[44]

(ii) The nodally coordinated enforcement pyramid

Before showing how nodal coordination works for the enforcement of intellectual property rights, we need a better view of the information and coordination problems that face large corporate owners of intellectual property. At the most basic level, there has to be agreement amongst individual corporations about which standards need to be strengthened and enforced. There appear to be some areas where one would expect to find agreement, such as increasing the duration of terms of protection. But even here, there will be differences of opinion amongst companies and industry sectors. Lengthening the patent term matters to the pharmaceutical industry, but is less important to semiconductor chip manufacturers. A longer copyright term is important to publishers, but only provided it applies to works already in existence. It hardly matters to software owners. There are also fundamental questions about which parts of intellectual property (copyright, patents, trademarks) to prioritize in the global quest for stronger protection. Using the global intellectual property ratchet to set standards requires, in other words, coordination on which standards are the important ones. The ratchet also gives rise to other kinds of coordination issues. When should the United States pull back from the WTO and shift the main game to the bilaterals? Which countries should be the targets of bilaterals? Which countries should be the targets of enforcement action under the pyramid? Individual U.S. companies with different investments and intellectual property interests in different countries are likely to give different answers to these questions. Pfizer may think that India should be the priority, Microsoft may be most worried by piracy in Russia and neighboring countries, and Hollywood (in the shape of the American Motion Picture Association) may think that the real problems lie in Italy, Malaysia, and China.

The U.S. trade enforcement pyramid is characterized by fine gradations, giving the USTR many enforcement options. But running this enforcement pyramid is a highly information-intensive exercise. Where, for example, on the various levels of the pyramid does the USTR put the Ukraine from year to year? How does the USTR know, for instance, that the Ukraine is a hotbed of CD piracy? If the information comes from a company, how does the company know? If the Ukraine passes a law, how does the USTR know if it meets the U.S. test of being adequate and effective? How does the USTR know that the Ukrainian police and the courts are properly enforcing the law? Is it enough to rely on an annual report by the Ukrainian police? If not, what is a credible source of information? These kinds of questions have to be answered for the eighty or so countries that now come under annual review by the USTR for their

44. *International Trade Agenda: Hearing before the Committee on Senate Finance*, 108th Cong. 4 (Mar. 9, 2004) (statement of U.S. Trade Representative Robert B. Zoellick).

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practices on intellectual property.[45]

The way in which U.S. companies have approached these kinds of basic information and coordination problems is to create a cluster of nodes around the trade enforcement pyramid. Since only a small of number nodes are involved, the possibility of coordination amongst them becomes possible. Coordination amongst the networks that the nodes represent would create an almost intractable coordination problem because the networks have hundreds of companies as members. The International Intellectual Property Alliance ("IIPA"), for example, has a membership of over 1,100 companies and the Biotechnology Industry Organization ("BIO") has more than a 1,000 member organizations.[46] The possibility of nodal coordination has also been deepened by the fact that the nodes have overlapping membership. The Business Software Alliance ("BSA"), for example, is a key node on copyright issues and is also a member of the IIPA and the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters ("IFAC-3"), the committee that advises Congress and the President on whether trade agreements meet the goals of the United States on intellectual property. Sometimes the overlapping membership occurs at the level of the individual wearing more than one nodal hat. By way of example, Eric Smith, the President of the IIPA is also the Chairman of the IFAC-3. Diagram 3, below, shows the nodally coordinated enforcement pyramid for intellectual property. (The full cluster of nodes and their intersecting relationships are not represented for reasons of space and clarity.)

45. In the case of the Ukraine, the USTR eventually decided on the imposition of prohibitive duties. *See* Determination of Action to Increase Duties on Certain Products of Ukraine Pursuant to Section 301(b): Intellectual Property Laws and Practices of the Government of Ukraine, 67 Fed. Reg. 120 (Office of U.S. Trade Rep. Jan. 31, 2001) (notice) (imposing sanctions on certain Ukrainian imports).

46. Details of the membership of these associations are available from their respective websites, at http://www.iipa.com and http://www.bio.org (last visited July 12, 2004).

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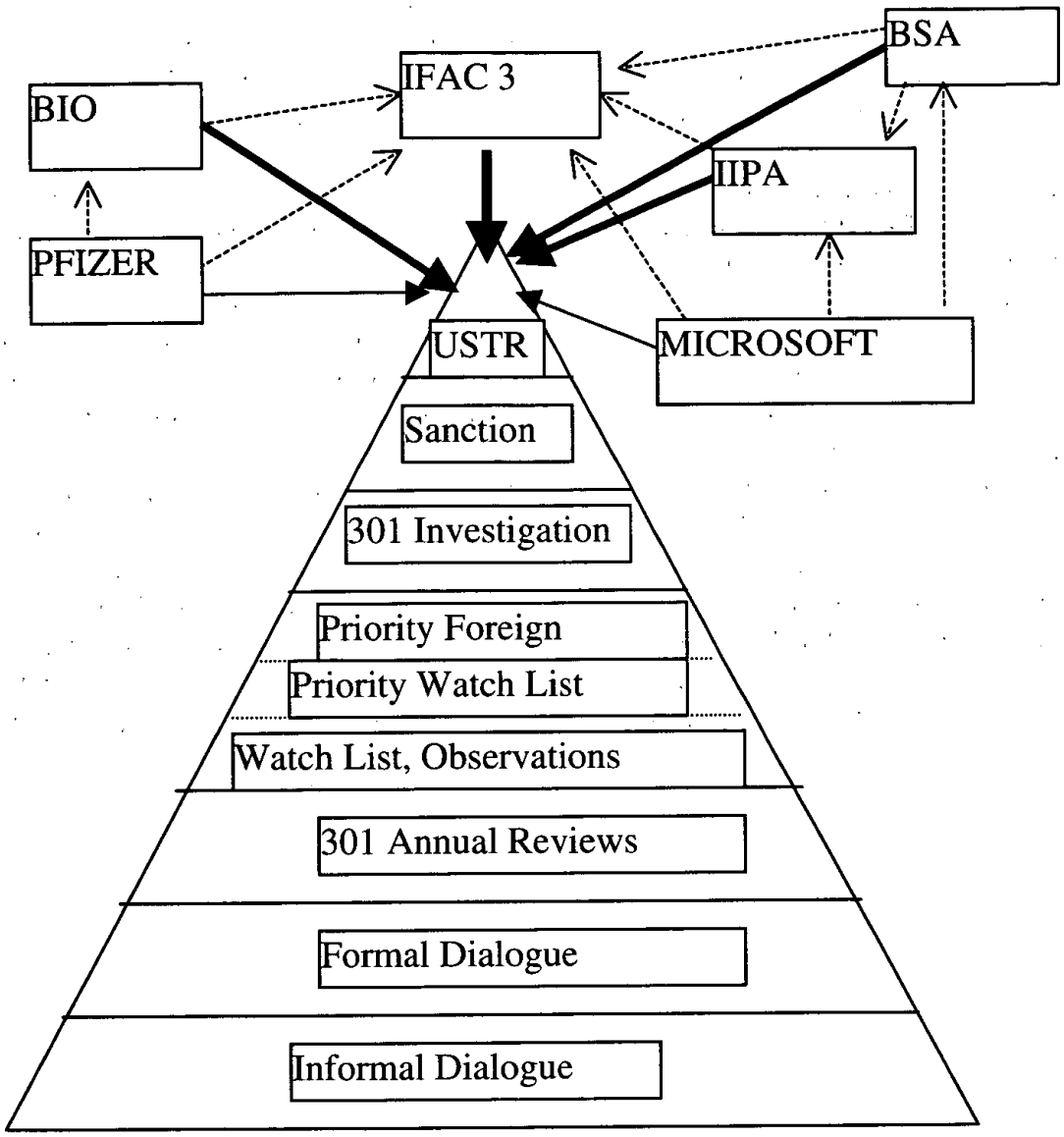
Diagram 3: Nodally Coordinated International Enforcement Pyramid for Intellectual Property Rights



In Diagram 3, the dash arrows represent membership by one node of another node (for example, Microsoft is a member of the IIPA, the BSA, and IFAC-3). The other arrows indicate that each of these nodes can work and communicate directly with the USTR if the need arises. The thicker arrows indicate that the relevant node also has an important coordinating role. IFAC-3 has the most important coordinating role in the enforcement pyramid for intellectual property. It ties together more networks than any other node and, therefore, is in the best position to deal with the problems of coordination and information that were described earlier.

IFAC-3 is a part of the private sector advisory system that advises and

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influences U.S. trade policy. This system is made up of thirty-three advisory committees that have provision for approximately 1,000 members.[47] It is a three-tiered system with the Advisory Committee on Trade Policy and Negotiations at the top, six policy advisory committees in the second tier, and twenty-six sectoral, functional, and technical advisory committees in the third tier.

In a trade negotiation, information and expert knowledge is everything. This is especially true in the case of intellectual property because the United States is typically seeking to impose complex positive standards of law on a country. This requires trade negotiators to know the gaps in that country's standards, or the way the relevant standards are interpreted in that country, from the perspective of U.S. law. Negotiators who are able to draw on expert legal knowledge will have an advantage in a negotiation. The perspective of that expertise has to come from industries that actually trade in intellectual-property-related goods and know best the legal rules they want to impose on their competitors in the other country. Every trade negotiator wants to come home with trade gains.

In the case of trade agreements that relate to intellectual property, the technical detail of these agreements is monitored by IFAC-3. IFAC-3 is made up of twenty members drawn from Industry Sector Advisory Committees and another twenty members drawn from the private sector areas, who provide the committee with a large pool of expertise in intellectual property.[48] Under its charter, IFAC-3 is to provide detailed advice on intellectual property issues in trade agreements negotiated by the USTR.[49] So, for example, in the case of the United States-Singapore FTA, IFAC-3, in the words of its report, "advised U.S. negotiators on, and reviewed draft texts of, the United States-Singapore FTA intellectual property chapter."[50] IFAC-3 is a committee that gets its hands dirty by reviewing and drafting specific agreements. Importantly, IFAC-3 reviewed the United States-Singapore FTA in the context of other multilateral and bilateral agreements and initiatives that the United States had achieved. It does this work across all U.S. trade initiatives in intellectual property, whether bilateral, regional, or multilateral. It is thus able to coordinate at a technical

47. A description can be found in The President's 2002 Annual Report on the Trade Agreement Program, *available at* http://www.ustr.gov/reports/2003.html (last visited July 12, 2004).

48. The members are: International Intellectual Property Alliance; The Gorlin Group; Pfizer, Inc.; Law Offices of Hope H. Camp, representing Eli Lilly and Company; Pharmaceutical Research and Manufacturers of America; Cowan, Leibowitz & Latman, P.C.; Anheuser-Busch Companies, Inc.; Merck & Company, Inc.; National Foreign Trade Council, Inc.; Powell, Goldstein, Frazer & Murphy, LLP, representing the Biotechnology Industry Organization; Time Warner Inc.; International Anticounterfeiting Coalition; Recording Industry Association of America; Intellectual Property Owners Association; and Levi Strauss & Company. U.S. Dep't of Comm., Int'l Trade Admin. website, *at* http://www.ita.doc.gov/td/icp/finalist23.html (last modified Nov. 17, 2003).

49. The Charter is available at http://www.ita.doc.gov/td/icp/Charter-23.html (last visited Aug. 12, 2004).

50. Industrial Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), The U.S. Singapore Free Trade Agreement (FTA): The Intellectual Property Provisions, at 3 (Feb. 28, 2003), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Singapore_FTA/asset_upload_file273_3234.pdf.

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level the work it does across these different fora, thereby ensuring that U.S. trade negotiating initiatives push intellectual property standards in the direction that U.S. industry would like. IFAC-3's technical expertise, as well as the expertise available to it from its members' corporate legal divisions, 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-3 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-3 work outside of the committee to ensure that the United States remains committed to an agenda of globalizing U.S. standards of intellectual property. So, for example, BIO, which is a member of IFAC-3, 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 summarized in a letter of January 29, 2003 to the USTR's 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."[51]

Naturally, when BIO sits on IFAC-3 it brings its advocacy position with it. A seat on IFAC-3 gives BIO the ability to provide, in cooperation with other members, technical and drafting advice to the USTR about the kinds of standards that meet the desires of the organizations that BIO represents. There are a number of incentives for the USTR to be attentive to the suggestions of IFAC-3, including the superior expertise of the committee, the fact that the negotiating mandate in the Trade Act of 2002 requires the USTR to seek protection standards comparable to U.S. domestic law, and the fact that IFAC must ultimately write a report, as it did in the case of United States-Singapore FTA, that endorses the agreement as being in the economic interests of the United States. The upshot is that the standards that members of IFAC-3 seek are very often the ones they achieve, especially in bilateral negotiations where the United States 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 should be compensatory extensions of the patent term. It has also advocated that trading partners adopt U.S. standards of data protection for pharmaceutical products. BIO also works in other ways outside of IFAC. For example, it responds to the USTR's request for public comment on which countries should be the subject of "Special 301" listing and, as a recognized international NGO in the World Intellectual Property Organization ("WIPO"), it can be active in pushing its position on patents in the WIPO Patent Agenda process.

By clustering nodes around the enforcement pyramid and nodally

51. Letter from Carl B. Feldman, President, Biotechnology Industry Organization, to U.S. Trade Representative Robert B. Zoelleck, at 1 (Jan. 29, 2003), *available at* http://www.bio.org/ip/action/20030129.pdf.

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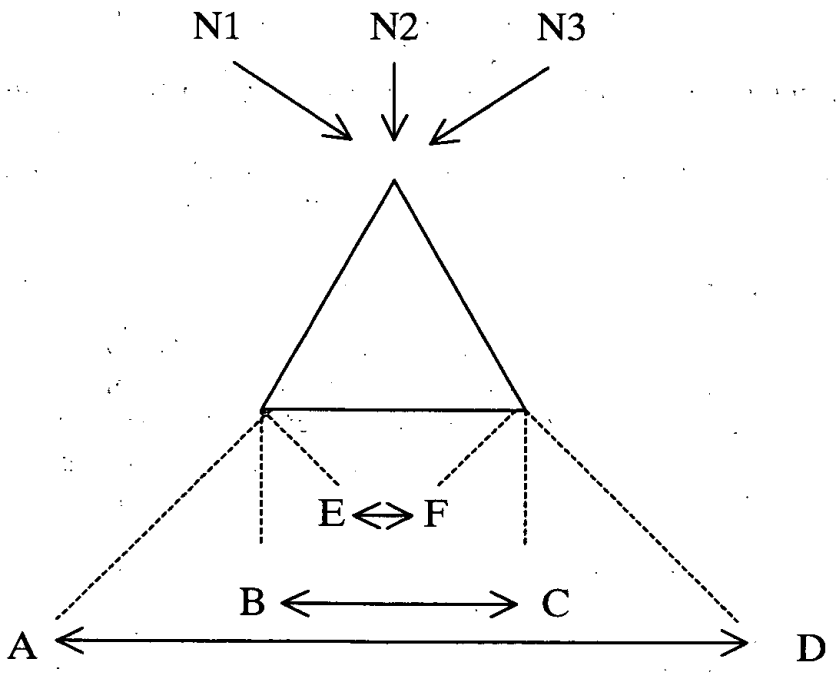
coordinating over its use, the key private sector players in the United States have found a means by which to get other governments to take their obligations on intellectual property seriously. IFAC-3 is not the only node that plays a part in creating a culture of enforcement across the globe on intellectual property. Other nodes and networks, which are linked to or are a part of IFAC-3, also provide the USTR with information about piracy and infringement and make suggestions as to the level of enforcement activity. The IIPA and the BSA each file separate 301 reports and recommendations to the USTR. But, by virtue of being part of the same compact nodal structure, they can coordinate and project consensus to the USTR on vital issues. This, in turn, enables the USTR to work out which governments are the most egregious offenders as well as those that need lighter prodding on the enforcement of intellectual property.

There is one last point to make about the relationship between nodal governance and the enforcement pyramid. By concentrating resources around the trade pyramid, corporate intellectual property owners have increased the enforcement reach of the pyramid. The enforcement reach of a pyramid is dependent upon obtaining information about non-compliance, projecting consensus about its use, and increasing the number of fora in which it can operate. The more companies and networks that feed information into the nodal structure about a country's practices on intellectual property and the more countries about which there is information, the greater the pyramid's reach. Diagram 4, below, presents a simple case of the relationship between nodes and the reach of enforcement pyramids.

Diagram 4: Nodes and the Reach of an Enforcement Pyramid



In this particular case, when Node 1 alone is providing information relevant

to the deployment of the pyramid, the enforcement reach is E-F. When Node 2 joins, the enforcement reach becomes B-C, and when Node 3 joins, it reaches A-D. It does not follow, however, that increasing the number of nodes will always lead to a commensurate increase in the enforcement reach of the pyramid. Nodal coordination that is based on the creation of supra-structural nodes, such as IFAC-3, allows large and complex networks to pool resources and to coordinate. The effect of this type of nodal coordination is to limit the number of participating actors, thereby economizing on the costs of coordination and decision-making. As each node joins the relevant nodal structure, the costs of that linkage are outweighed by the benefits. But, at some point, that will cease to be true. The information brought by new nodes will add little to information about enforcement and the costs of coordination and decision-making will rise. There is, in other words, an optimum cluster of nodes for an enforcement pyramid.

The nodal structure for intellectual property has two important contingent features. Firstly, there are a comparatively small number of nodes, but these nodes represent networks, some of which contain many members, including many of the world's largest companies. What is being nodally coordinated then are large networks that are powerful in terms of information and resources. Secondly, the enforcement reach of this pyramid is genuinely global. This has much to do with the fact that the enforcement tools of the pyramid are based on access to the U.S. market, for the time being, the most globally influential market in the world. But the nodal coordination of the pyramid itself increases its reach. For example, through the strategy of forum shifting to bilaterals that was described earlier, the United States is able to set new and higher standards of intellectual property. Importantly, each of these bilaterals comes with a set of institutional arrangements for the agreement's enforcement.[52] Through the creation of new fora and standards that are TRIPS-plus, enforcement activity under the pyramid can reach a greater number of standards in a greater number of countries. For instance, Article 6 of TRIPS says that, for the purposes of dispute settlement, nothing in TRIPS can be used to address exhaustion issues. But the United States can use FTAs to address the issue of exhaustion.

V. A TREATY ON TK – A NODAL GOVERNANCE APPROACH

Over the last ten years or so, more and more international organizations and policy networks have done work on the protection of traditional knowledge ("TK"). One of the issues that have been raised is whether there should be a treaty on TK. A number of international organizations are doing work on TK, including WIPO.[53] In 2000, the WIPO General Assembly established the

52. *See, e.g.*, U.S.-Australia FTA, Institutional Arrangements and Dispute Settlement, *supra* note 28, at ch. 21 (defining dispute resolution procedures for the US-Australia FTA).

53. For a summary of the Intergovernmental Committee's work, see WIPO Secretariat, *Overview of Activities and Outcomes of the Intergovernmental Committee*, Intergovernmental Commission on Intellectual Property & Genetic Research, Traditional Knowledge and Folklore, 5th Sess., WIPO Doc. WIPO/GRTKF/IC/5/12 (Apr. 3, 2003), *available at* http://www.wipo.int/documents/en/meetings/

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Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("Intergovernmental Committee") as a forum for the discussion of intellectual property issues related to TK. Within the Intergovernmental Committee there have been calls for WIPO to move towards the drafting of a legally binding international instrument to protect TK.[54]

In the last section, we saw how corporate intellectual property owners have used a nodal governance approach to solve their coordination and enforcement problems. These coordination and enforcement problems are even greater for indigenous groups. For example, if the treaty contained a general misappropriation norm, how would individual indigenous groups track patent applications relating to the unauthorized use of their TK? Some patent offices themselves struggle with aspects of the patent system. In 1999, the Swedish Patent and Registration Office, in commenting on the reform of the International Patent Classification ("IPC"), observed that the IPC "is too complicated and detailed for the general public or for small offices that only need to search small bodies of patent literature (or do not search at all)" and that the problems with the IPC had grown to a point "where even experts have trouble making accurate searches."[55] Even allowing for progress made since 1999, these remarks have some salience for those who would have indigenous groups tracking the use of TK through the patent system using the IPC.[56] The medical humanitarian organization Médecins Sans Frontières ("MSF"), in a report on pharmaceutical patents, observed that patent searches "on medicines . . . require technical skills in chemistry to ensure you find out exactly which patents protect which medicines."[57]

Indigenous groups will be in a much worse position than national patent offices or a well-resourced NGO like MSF to use the patent system.[58] Individual

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2003/igc/pdf/ grtkf_ic_5_12.pdf.

54. *See Chair's Conclusions: Fifth Session of the Intergovernmental Committee*, WIPO (discussing committee's concerns about protecting TK), *at* http://www.wipo.int/documents/en/meetings/2003/igc/grtkf_ic_5_conclusions.htm (last visited July 12, 2004).

55. *IPC Reform Project File*, WIPO Commission of Experts of the IPC Union, Annex 10, at 1-2, WIPO Doc. IPC/R 1/99 Rev. 1 (Oct. 26, 1999), *available at* http://www.wipo.int/classifications/ipc/en/w_groups/ reform/project/r1/r1_rev1.pdf.

56. A WIPO Taskforce on Classification of Traditional Knowledge is working on a proposal to revise the IPC to accommodate the classification of TK. The Taskforce has prepared a revision proposal in the field of medicinal preparations containing plants. The next edition of the IPC will enter into force on January 1, 2005. *See* WIPO Secretariat, *Practical Mechanisms for the Defensive Protection of Traditional Knowledge and Genetic Resources within the Patent System*, Intergovernmental Commission on Intellectual Property & Genetic Research, Traditional Knowledge and Folklore, WIPO Doc. WIPO/GRTKF/IC/5/6, at 19 (May 14, 2003) (expressing committee's desire to revise IPC concerning TK by January 1, 2005), *available at* http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_6.pdf.

57. PASCALE BOULET ET AL., DRUG PATENTS UNDER THE SPOTLIGHT 22 (2003).

58. On the problem of under-resourced patent offices in developing countries, see Mart Leesti & Tom Pengelly, *Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement*, Commission on Intellectual Property Rights, Study Paper 9 (2002), *available at* http://www.iprcommission.org/papers/word/study_papers/sp_pengelly_study.doc (last visited Sept. 7, 2004).

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indigenous groups acting alone have little chance of solving these kinds of complex information and enforcement problems. But a transparent, high profile, multilateral agency that was chartered under a treaty on TK might be able to, especially if that agency acted nodally to coordinate an international enforcement pyramid.

The various technical discussion papers produced by WIPO suggest that many of the elements of this pyramid are already in place at the national level.[59] The treaty could set out to achieve three broad goals with respect to the creation of the pyramid. The first would be to coordinate norm building at different levels of the pyramid (see Diagram 5 below). Helping indigenous groups to develop protocols that will carry information about their customary laws and practices across borders is one example of something that the treaty could prioritize. Similarly, states could commit themselves to the development of a best practice administrative procedure that required patent applicants to disclose the circumstances of acquisition of genetic materials or TK.

A second and vital goal of a treaty would be the creation of a single multilateral agency (for example, along the lines of a Global Bio-Collecting Society ("GBS"))[60] that could provide indigenous groups and developing states with the capacity to use the international enforcement pyramid (see Diagram 5 below). Without an entity that is capable of monitoring and assisting in the coordination of an enforcement action, which utilizes the available national levers within a jurisdiction, a treaty on TK is likely to be a paper tiger.

A third fundamental goal of a treaty would be the creation of a treaty review mechanism. The purpose of such a mechanism would be to commit states to a process of continuous improvement on the protection of TK. There are different approaches one might take to a treaty review mechanism, but one possibility is that states could agree on a set of performance indicators in this field. These could include reporting on the following:

- Progress on land rights issues related to TK;
- The implementation of a best practice declaration requirement for

59. For a summary of the working documents prepared for the Intergovernmental Committee, see WIPO Secretariat, *Brief Summary of Working Documents*, Intergovernmental Commission on Intellectual Property & Genetic Research, Traditional Knowledge and Folklore, WIPO Doc. WIPO/GRTKF/IC/5/INF/5 (June 25, 2003), *available at* http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_inf_5.pdf.

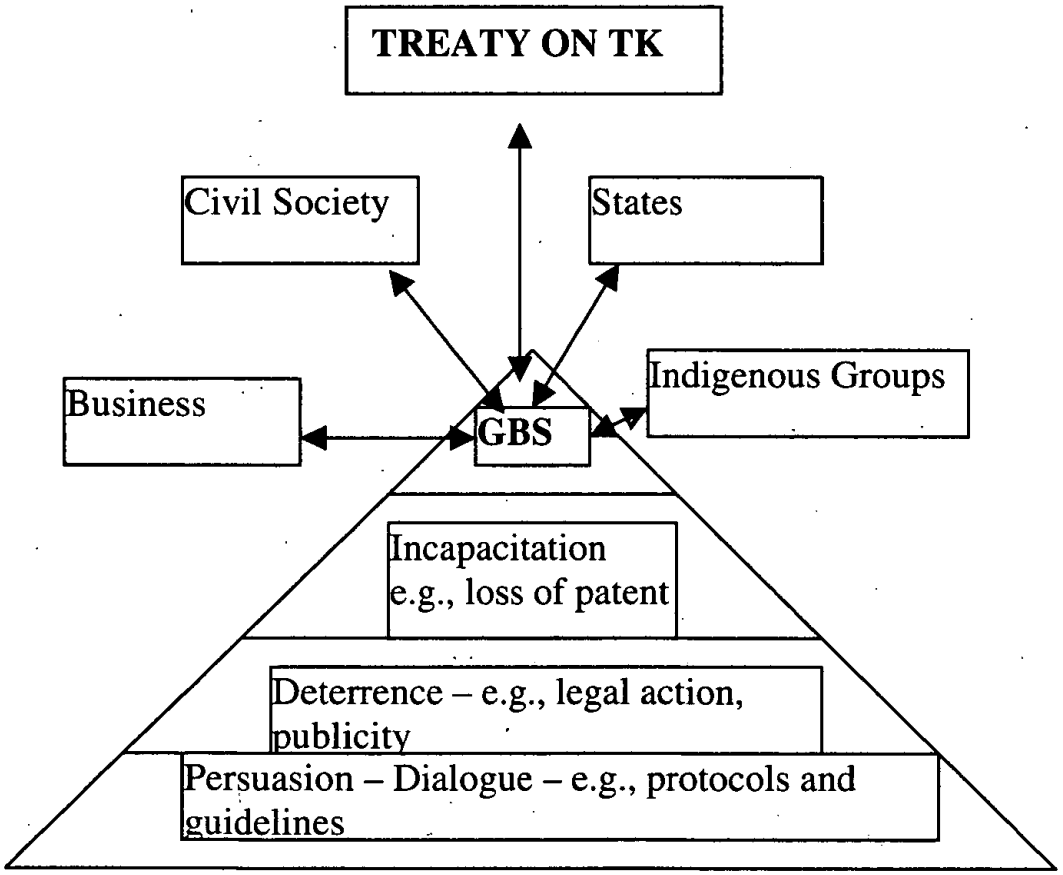
60. *See* Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, 22 EUR. INTELL. PROP. REV. 245, 245-50 (2000) (explaining need for a GBS and exploring model for such organization). The Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices observed that a "possible role for the Global Bio-Collecting Society in monitoring access to TK could be explored." *Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices: Outcome of the Expert Meeting*, UNCTAD, U.N. Doc. TD/B/COM.1/EM.13/L.1, at 5 (Nov. 9, 2000), *available at* http://r0.unctad.org/ trade_env/docs/c1em13l1.en.pdf. Support for considering the idea was also expressed in *Report of the International Seminar on Systems for the Protection and Commercialization of Traditional Knowledge*, UNCTAD, at 13 (2002), *at* http://r0.unctad.org/trade_env/test1/ meetings/delhi/Report.New%20Delhi.final.doc (last visited Sept. 7, 2004).

patents dealing with TK;

- Assistance rendered to other states on enforcement, including the number of memoranda of understanding signed with other states; and
- Assistance given to indigenous groups to develop representative commercial structures.

States could then agree, as is done in the WTO's Trade Policy Review Mechanism, that all Members would be subject to regular review.[61] A review mechanism would magnify the transparency of domestic decision-making by states on TK. The performance indicators would help to evaluate progress and might also provide a way of coordinating technical assistance to states that reported difficulties in making progress.

Diagram 5: International Enforcement Pyramid for TK[62]



61. *See* General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Trade Policy Review Mechanism, Apr. 15, 1994, Annex 3C, 33 I.L.M. 1125 (1994) (establishing periodic review as standard evaluation technique), *available at* http://www.sice.oas.org/trade/ur_round/UR28E.asp.

62. This pyramid draws upon John Braithwaite's pyramid for an integration of restorative, deterrent and incapacitative justice. *See* BRAITHWAITE, RESTORATIVE JUSTICE, *supra* note 38, at 32 & fg. 2.2 (explaining how the model of the "responsive regulatory pyramid" applies to business regulation).

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This international enforcement pyramid is different from the usual responsive regulatory pyramid in that such pyramids typically assume a single regulator. In this case, however, the GBS is not a regulator in the classical sense, but rather a nodal coordinator of other actors. The GBS may undertake enforcement action itself in certain cases, such as opposing a patent where an indigenous group is unable to do so and there is evidence of inappropriate conduct by the patent applicant. But, on other occasions, it may provide information to patent offices, indigenous groups, or civil society actors that may then in turn take appropriate action. This pyramid, in keeping with the philosophy of responsive regulation, begins with the presumption that it is best to start at the base of the pyramid with dialogue and persuasion. Other actors will often be in a better position than the GBS to begin that process of engagement. If, for example, a pharmaceutical company breaches a code of conduct it may change its behavior once the breach is brought to its attention. In some cases, the GBS may cast its shadow over the process, thereby alerting a potential offender to the possibility of an escalation up the pyramid if persuasion and dialogue do not work. The point is that, in a case where enforcement has to work across borders and accommodate a diversity of standards and values, there is no one actor that can manage all the tools of enforcement. But there does have to be an actor that can manage the many information problems that occur in this type of enforcement environment and that can coordinate a response amongst the actors best placed to utilize the next stage of the escalation in the enforcement response. In the international context in which TK is to be the subject of regulatory protection, it will be this coordination that constitutes the enforcement pyramid and, therefore, its responsive effects. Without this kind of coordination, enforcement responses will fall to the ad hoc initiatives of different actors. The result will be that sometimes the punishment will be unnecessarily severe because an excessive level of response was the first response or there is a failure of punishment because the cooperation of those actors capable of implementing a response at the top of pyramid (for example, patent offices) has not been obtained. The effect will be to create uncertainty and resentment amongst some actors who believe that they have been unfairly targeted. In such a world, trust decreases and defiance may well increase.[63]

VI. CONCLUSION

Nodal governance has been used in the last twenty years to increase the regulation of pharmaceutical markets by means of patents and other types of intellectual property. Through the vector of trade agreements, intellectual property codes are being injected into national regulatory systems around the world. An international enforcement pyramid is being nodally deployed to ensure that these codes are respected by all states. The present levels of intellectual property protection that we see throughout the world will have

63. For the reasons as to why defiance may increase, see BRAITHWAITE, RESTORATIVE JUSTICE, *supra* note 38, at ch. 4.

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effects on research in medicine, on generic producers, and, therefore, on competition in pharmaceutical markets. And this, in turn, will affect the structural capacity of these markets to serve the fundamental needs of poor people whether in the United States or Ethiopia. To date, these regulated markets have not served the health needs of the poor. More patent regulation of the kind that is being produced by means of the global intellectual property ratchet is not the answer. The nodal governance that we see occurring in the area of intellectual property is a good example of Scott Burris's general point that modes of governance do structure health in the world. A treaty for the protection of TK (nodally constituted and administered), which is important as a resource for public health, would be an example of the kind of positive dispositional approach that Scott Burris argues must be built into social systems, so that over time they function "naturally," as it were, to produce better health outcomes for people. Interestingly, the progress that has been made on the TK issue shows that our nodal world is replete with opportunities for alliances, partnerships, and forum shifting, all of which enable the weak to exercise influence over agendas that were never part of the power politics of states in other eras of governance.

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