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# INTELLECTUAL PROPERTY

## HOW INTELLECTUAL PROPERTY BECAME CONTROVERSIAL: NGOs AND THE NEW INTERNATIONAL IP AGENDA

BY MARK F. SCHULTZ AND DAVID B. WALKER\*

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### I. Introduction

Until fairly recently, few questioned whether the nations of the world *should* promote intellectual property protection. For a long time, international discussions about intellectual property have been based on a premise that protecting intellectual property rights is beneficial to economic development and social good. This consensus arose from the understanding that intellectual property rights provide the necessary incentive to spur innovation in the arts and sciences, thus driving social and economic development. As a result, the intellectual property agenda at international organizations like the World Intellectual Property Organization (WIPO) focused on technical matters, such as establishing reciprocal intellectual property protection between nations and harmonizing intellectual property laws.

International intellectual property has become a far livelier subject in recent years with the rise of a counter-agenda far more skeptical of the value of intellectual property rights. This paper describes this counter-agenda, which it calls the “New International IP Agenda.” Proponents of the New International IP Agenda contend that even if some intellectual property rights are a good thing, more are not necessarily better. They believe that the world’s intellectual property laws have expanded to the point where they no longer strike a proper balance between the rights of intellectual property owners and the public good.<sup>1</sup> They assert that intellectual property rights may impede research and innovation, distort pharmaceutical research priorities, interfere with economic development in the developing world, and raise the cost of a host of items needed by the poorest of the poor, including pharmaceuticals, software, and educational materials. A group of developing countries led by Brazil and Argentina thus has proposed that there should be a presumption *against* increased international protection of IP rights, allowing “higher standards of protection . . . only when it is clearly necessary . . . and where the benefits outweigh the costs of protection.”<sup>2</sup>

A large number of issues fall under the New International IP Agenda, which is unified by a common thread of IP skepticism and a network of non-governmental organizations (NGOs) and activists. Attempts to expand or strengthen intellectual property rights are likely to be vigorously opposed by part or all of this network<sup>3</sup>—software patents in the European Union, patent harmonization efforts at WIPO, increased patent protection in India, and many other such efforts. Some activists propose to replace, or at least counterbalance, the current model of using IP rights to encourage the production of public goods (such as pharmaceuticals and educational materials) with government funding and “open access” or “open source” development.

Proposals include compulsory licensing of pharmaceuticals,<sup>4</sup> treaty obligations to publicly fund “open access” pharmaceutical R&D, governmental preferences for open source software, and international administration of infrastructure resources.

There may be some question as to how seriously to regard the New International IP Agenda, as radical change seems unlikely in the consensus-driven world of international organizations. Some, therefore, dismiss the revolutionary IP proposals advanced by NGOs as mere posturing to impress donors. In this view, Brazil, Argentina, and their allies in the NGO community advance radically anti-IP proposals to gain attention and improve their bargaining positions. While there is something to be said for such real politick interpretations, one ought to give credit where credit is due.

If ideas matter, then the proponents of the New International IP Agenda should be considered formidable. The NGOs pushing this agenda are well-funded, well-organized, and smart.<sup>5</sup> They are also persistent, as they have proposed to curtail intellectual property rights in one international forum after another, even where IP was not the main issue: the WTO, WIPO, UNESCO’s proposed Convention on Cultural Diversity, the U.N.’s World Summit for the Information Society, the World Health Organization, and others. Moreover, they have had some successes. As discussed below, at the urging of Brazil and Argentina, the World Intellectual Property Organization is currently considering the adoption of a “development agenda,” which would bring many of the New International IP Agenda issues before WIPO. Also, as of June 2005, patent law harmonization talks at WIPO, which would likely result in expanded patent protection in many countries, are on “indefinite hold” due to the assertion by Brazil, Argentina, and India of New International IP Agenda issues during the talks.<sup>6</sup>

Many in the U.S. who are interested in intellectual property issues remain only peripherally aware of the growing importance of international issues. While they certainly know that international harmonization efforts have brought about significant changes in U.S. intellectual property laws, many are unfamiliar with the New International IP Agenda, its strength, and the wide-ranging activities and energy of its proponents. The United States is unlikely to take on any obligations that implement the New International IP Agenda any time soon. Nevertheless, its representatives are required to defend IP rights with increasing frequency in international debates. Moreover, U.S. intellectual property owners find themselves facing a future where the questions are no longer how soon and how well other countries enforce intellectual

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property rights, but rather, whether they should or will do so at all.

This paper describes the New International IP Agenda, its major initiatives, and the key players. While a comprehensive treatment would be impossible (and rapidly out of date anyway), this paper provides an overview of some of the most important issues. It describes activities and policy proposals in three specific areas and briefly critiques the approaches advocated by New International IP Agenda proponents. The issues discussed are: (1) intellectual property and international development; (2) public health and pharmaceuticals; and (3) information infrastructure and the digital divide.

## II. International Development and Intellectual Property Law

The New International IP Agenda largely draws its impetus from concern for the developing world. One of the most contentious arguments regarding international IP policy is whether strong intellectual property protection aids developing nations. Developed nations have urged the developing world to increase protection and enforcement of intellectual property rights—a move they assert will help people of developing nations just as much as intellectual property owners in the developed world. Proponents of the New International IP Agenda express skepticism regarding the efficacy of IP rights in helping the developing world and cynicism regarding the motives of developed nations and intellectual property owners.

### *A. The New International IP Agenda's View of IP's Impact on Development*

Much of the current controversy can be traced, ironically, to one of the greatest recent successes of IP proponents—the linkage of trade liberalization to increased intellectual property protection.<sup>7</sup> The developing world has long had the weakest protection for intellectual property but the greatest desire for access to the markets of developed nations. In the last decade, the United States and other developed nations have used the incentive of access to markets to persuade developing countries to enhance and enforce intellectual property laws.<sup>8</sup> In 1994, as part of establishing the World Trade Organization (WTO), WTO members entered into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),<sup>9</sup> which established universal, relatively strong minimum standards for intellectual property protection.<sup>10</sup> The WTO has fairly significant enforcement powers, thus giving the TRIPS Agreement some real “teeth.”<sup>11</sup> The United States and the EU have also brought IP protection into bilateral trade agreements with developing nations, securing “TRIPS-Plus” agreements, with IP protection more demanding than the minimum standards of TRIPS.<sup>12</sup> This “marriage of convenience” between trade and intellectual property<sup>13</sup> has increased pressure on developing nations to increase their protection and enforcement of intellectual property rights.<sup>14</sup>

With this increased pressure on developing nations has come increased concern that TRIPS and TRIPS-plus

agreements are not in the best interests of these nations or their citizens. In 2000, the year that TRIPS obligations came into effect for developing nations,<sup>15</sup> these concerns came to a head. The U.N.’s Sub-Commission on the Promotion and Protection of Human Rights took an extremely critical look at TRIPS. In Resolution 2000/7 on Intellectual Property Rights and Human Rights, it declared that “there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement . . . and international human rights law.”<sup>16</sup> It saw negative affects across a broad range of areas: (1) technology transfer to developing countries; (2) “the right to food;” (3) “bio-piracy;” (4) “indigenous communities’ . . . control over their own genetic and natural resources and cultural values;” (5) “access to patented pharmaceuticals;” and (6) “enjoyment of the right to health.”<sup>17</sup> The Declaration called on a wide array of actors—governments, intergovernmental organizations, including WIPO, the World Health Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the United Nations Environment Programme, and NGOs to take up a critical examination of TRIPS.<sup>18</sup>

Many have accepted the Commission’s challenge to examine TRIPS and IP rights in general more skeptically. The U.N.’s human rights bureaucracy has further examined and criticized intellectual property’s effect on human rights.<sup>19</sup> Prominent among these efforts have been U.N. Human Rights Commission resolutions that view IP rights as adversely affecting access to medicine and thus exacerbating the AIDS crisis.<sup>20</sup> A number of NGOs and developing nations have also furthered this skeptical examination of intellectual property’s impact on development. Most prominent among developing nations have been Brazil and Argentina, which lead a group of nations known as the “Friends of Development,” which includes Bolivia, Cuba, the Dominican Republic, Ecuador, Egypt, Iran, Kenya, Sierra Leone, South Africa, Tanzania and Venezuela.<sup>21</sup>

The discussion has proceeded along two lines of argument, one philosophical and the other pragmatic. The philosophical argument frames the effect of intellectual property rights on development as a human rights issue. The pragmatic argument focuses on the tremendous and immediate needs of the developing world.

Advocates for the New International IP Agenda argue that access to health or medicine<sup>22</sup> and access to knowledge<sup>23</sup> are human rights. The reason for doing so is, in part, strategic. Human rights expert, Prof. Laurence Helfer described the long term strategy as follows:

Looking simply at treaty texts . . . there appear to be few clear-cut conflicts [between intellectual property and human rights]. . . . But treaty text alone does not tell the whole story. Human rights law is notably elastic, and contains a variety of mechanisms to develop more precise legal norms and standards over time. Advocates endorsing

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a conflictual approach to intellectual property are likely to press human rights bodies to develop specific interpretations of ambiguous rights to compete with the precise, clearly defined rules in TRIPS.<sup>24</sup>

By advocating these human rights of access, IP skeptics seek to create a conflict with intellectual property rights, which give their owners the right to control and exclude others: from medicine, in the case of pharmaceutical patents, and from knowledge, in the case of copyright. Since advocates view “human rights obligations” as having “primacy” “over economic policies and agreements,”<sup>25</sup> then it follows that intellectual property rights are secondary, to be treated as limited exceptions.<sup>26</sup>

The pragmatic argument against increased intellectual property rights in the developing world is fairly straightforward: The needs of developing countries are staggering; anything that gets in the way of alleviating those needs, including intellectual property rights, is suspect. This argument arouses sympathy—who can argue with wanting to supply a sick mother with the AIDS drugs she needs to live or a child the books she needs to learn? It also tends to bring activists on narrower issues into the network of IP skeptics, for example, medical groups with respect to patents<sup>27</sup> and librarians with respect to copyright.<sup>28</sup> A further pragmatic argument against IP in general and TRIPS in particular is that corporations in the developed world hold most IP rights, so TRIPS and other agreements offer few benefits to the people of developing nations.<sup>29</sup>

These criticisms of intellectual property’s impact on development have led to a number of initiatives, the latest and most important of which is the push for the World Intellectual Property Organization to adopt a “development agenda.” At WIPO’s Fall 2004 meeting, a group of developing countries and NGOs led by Brazil and Argentina proposed that WIPO adopt a “Development Agenda,” which would broaden WIPO’s mandate beyond its traditional focus to consider how to promote development and to ensure that the “costs do not outweigh the benefits of IP protection.”<sup>30</sup> A stated goal of Development Agenda proponents is to alter what they see as WIPO’s “pro-IP bias.” They want WIPO to adopt a presumption *against* increased IP rights, allowing “higher standards of protection . . . only when it is clearly necessary . . . and where the benefits outweigh the costs of protection.”<sup>31</sup> The General Assembly of WIPO agreed to study the proposal further in a series of meetings throughout 2005 that will result in a report to be considered at WIPO’s 2005 General Assembly meeting in September. This decision was essentially a victory for the Brazil/Argentina proposal, albeit a merely preliminary one. The question now is whether WIPO will adopt some version of a development agenda at its 2005 General Assembly meeting and what its content will be.<sup>32</sup>

By considering the Development Agenda, WIPO opens itself to a fundamental change in direction. While radical

change in a large international organization is hardly a safe bet, many opponents of strong intellectual property rights see this opening as a chance to advance proposals to change the world’s intellectual property system dramatically. A large coalition of NGOs, developing world politicians, and activists signed onto the “Geneva Declaration”<sup>33</sup> in support of the WIPO development agenda. Among other things, the Geneva Declaration asserts that “[h]umanity faces a global crisis in the governance of knowledge, technology and culture” and that the current international IP regime is “intellectually weak, ideologically rigid, and sometimes brutally unfair and inefficient” for developing countries.<sup>34</sup> A number of proposals to change the world’s IP system radically have come from supporters of the Geneva Declaration.

Among these proposals is a treaty to promote “Access to Knowledge” (often referred to as the “A2K Treaty”).<sup>35</sup> Over the past year, various NGOs and governmental representatives have advocated that an A2K Treaty as a potential goal of the Development Agenda.<sup>36</sup> The A2K Treaty proposal received a major boost in late July 2005 when Brazil proposed that it become the focus of the WIPO Development Agenda.<sup>37</sup> As of this writing, the proposal is still a draft with many open issues, but the A2K Treaty proposal clearly is consistent with the contention that access to knowledge is a fundamental human right that should trump intellectual property rights. Among other things, the draft proposes imposing an expansive version of U.S.-type fair use exceptions to copyright law; limits on legal recognition of copy protection and digital rights management technology; restrictions on the patentability of inventions arising from government-funded research; broader compulsory licensing of copyrighted material; proposals calculated to encourage open access publishing models and free/open source software; proposals for a protocol on the transfer of technology and knowledge to developing countries; and funding obligations for the public development of “knowledge goods.”<sup>38</sup> At the moment, the A2K Treaty reads more like a wish list embodying favorite proposals of IP skeptics rather than anything likely to be adopted as a treaty. Nevertheless, Brazil’s advocacy of the proposal puts it on the international policy agenda.

Recent events indicate that the controversy regarding development and intellectual property will be active for years to come. The following items show the continuing salience of the IP and development controversy:

- The WIPO Development Agenda will be discussed at least for the rest of 2005. If nothing else, Development Agenda discussions appear likely to continue in WIPO, regardless of the current disagreement as to the proper forum within WIPO.
- Brazil has once again threatened to issue compulsory licenses or even to invalidate patents entirely for AIDS drugs.<sup>39</sup>

- Intellectual property and development issues have intruded on discussions regarding the Convention on Cultural Diversity, which seeks to give countries the right to impose legislation to protect national culture, much like France's famously protectionist cultural regulations.<sup>40</sup>
- Intellectual property and development issues have also figured in discussions of the World Summit on the Information Society, which is mainly focused on digital divide issues.<sup>41</sup>
- Finally, and perhaps most dramatically, Brazil, Argentina, and India recently derailed longstanding patent harmonization talks at WIPO because of development issues. The dispute caused the U.S. Patent and Trademark Office to issue a press release publicly questioning the mission and viability of WIPO as a forum for such discussions.<sup>42</sup> While such talks likely will continue in another forum,<sup>43</sup> the controversy regarding IP and development will also be raised in other contexts and other fora.

If nothing else, the Development Agenda appears to have introduced into international IP negotiations a new element of controversy, which does not appear to be likely to abate anytime soon.

### ***B. Critique of the New International IP Agenda's Views on Economic Development***

One of the central problems with the criticisms of IP's impact on developing nations is that they focus only on barriers to obtaining products from *outside* of a developing country, ignoring the benefits that would accrue from promoting innovation *within* that country. This treats the people of the developing world as victims, forever needing help from outside corporations and more developed countries. There is no reason to believe that people in developing nations are any less inventive than people elsewhere. But innovation and creativity require a particular kind of nourishment. As development expert Robert Sherwood has explained:

If people seem to be more inventive in the United States or Europe or Japan, it is not an accident. It is not because of genes or schooling or intelligence or fate. Implementation of the intellectual property system is critical because of the habit of mind which is fostered in the population. Human ingenuity and creativity are not dispersed unevenly across the globe. Those talents are present in every country. In some, unfortunately, the enabling infrastructure of effective intellectual property protection is missing.<sup>44</sup>

Like people everywhere, people of developing nations can and do invent things. Indeed, when they immigrate to developed countries they are often among the most creative

and inventive people in their new homes. The problem in developing countries is that there is little reward for innovation. In his acclaimed book, *The Mystery of Capital*,<sup>45</sup> Hernando de Soto identified the lack of well-defined property rights as the root of many of the troubles of the developing world. Without clear, enforceable property rights, people in developing nations cannot unlock the value of the capital they hold. In developed nations, property rights and the rule of law help people to secure loans, raise investment, enter contracts, and make plans knowing that what they have today will not be taken tomorrow. Not so in much of the developing world. De Soto estimates that poor people in developing nations hold trillions and trillions of dollars worth of capital, but it remains "dead capital" because the lack of property rights prevents it from being developed.<sup>46</sup> De Soto's argument largely focuses on real property, but it applies to intellectual property with equal force. A vast amount of intellectual capital in the developing world is underdeveloped.<sup>47</sup> Not only do developing nations miss the economic benefits such innovation would bring, they miss the benefit of local knowledge being applied to solve local problems.

Intellectual property rights also help to ensure that the poor get the things they need, even if they must come from outside of their home countries. The simple, oft-repeated argument is that companies cannot afford to perform research for things like new drugs if they are not compensated.<sup>48</sup> Although simple, the argument is powerful. Somebody has to pay R&D costs. In some instances, it may be developed world consumers paying higher prices to, in effect, subsidize lower prices in the developing world.<sup>49</sup> In other instances, however, there may not be a market in the developed world sufficient to support R&D, thus preventing product development from ever happening.<sup>50</sup> Another more subtle benefit of intellectual property rights is that the commercialization of intellectual property reduces coordination problems and has positive spin-off effects.<sup>51</sup> A company with proprietary rights is more likely to set up a distribution network, educate doctors and consumers, ensure reliable distribution, hire and train local executives, technicians, and/or sales representatives, and take other such actions that benefit the local economy now and in the future.

Nevertheless, the criticisms of TRIPS and other agreements linking intellectual property to trade do have some validity. When intellectual property rights are seen solely as a trade issue, developing countries are more likely to act solely to mollify trading partners than to benefit their local economies. Without real commitment, neither the local economy nor foreign intellectual property owners are likely to benefit.<sup>52</sup>

WIPO and other institutions could do more to help developing nations implement intellectual property systems that benefit IP owners in their own countries as well as trading partners. Prof. Jerome Reichman has advocated such an approach: "at the WTO, the primary goal . . . should be to find ways in which everyone wins by implementing the TRIPS standards. When each of the developing countries comes up



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for review by the Council for TRIPS, the developed countries should approach the issues by asking, ‘how can we help you to implement these international minimum standards so that you win and we win, too?’<sup>53</sup> Reichman proposes a variety of forms of assistance in implementing IP systems that provide local benefits.<sup>54</sup> There are a number of other useful proposals for how technical assistance might greatly benefit developing countries. For example, Prof. Srividhya Ragavan contends that countries like India need to develop the flexibility and sophistication present in the patent systems of the developing world.<sup>55</sup> She describes how this lack of sophistication is causing some innovations in India to go unpatented, thus hurting investment and development.<sup>56</sup> Other creative proposals encourage least developed countries to pool resources and rely on other nations’ patentability determinations in order to give their citizens the benefit of patent protection, while reducing the cost of establishing and maintaining a patent system.<sup>57</sup> In the end, it is in the interest of developed countries to help developing countries implement IP systems that produce true domestic benefits, as such systems produce stable, lasting support for intellectual property rights.<sup>58</sup>

Finally, it must be noted that intellectual property laws may be necessary but not sufficient to spur economic growth and innovation in developing nations. Many institutions (including intellectual property rights) must be developed to support a healthy market economy. This is one of the essential insights of the new institutional economics, which examines how all of the institutions of an economy—such as customs, mores, laws, regulations, social norms, and organizations—interact to affect economic performance.<sup>59</sup> As the Nobel-winning founder of new institutional economics, Douglass North, notes, developing an economy so that it can take advantage of modern technology is a “tall order.”<sup>60</sup> Among the necessary institutions are a legal system that provides the right incentives, impartial enforcement of the law, entrepreneurial organizations, a supportive polity, and other formal and informal institutions that support entrepreneurial activity.<sup>61</sup> It is not too much to expect countries like India, Brazil, and Argentina, with sophisticated economies, advanced legal systems, and democratic political systems to take advantage of the benefits that IP protection can provide their citizens and economy. We ought to take a far more charitable view of countries whose institutions have been devastated by thuggish governments, abject poverty, war, and disease. People in such countries stand a realistic chance of benefiting from intellectual property rights only if at least some of the other institutions necessary to encourage innovation, such as freedom, security, and the rule of law, are in place.<sup>62</sup>

### III. Public Health and Pharmaceuticals

In the past several years, the most contentious international IP issues have centered on providing affordable drugs to the poor in developing countries. The establishment of TRIPS brought this issue to a head, as discussed in the previous section, by establishing minimum standards for IP protection for all WTO members. TRIPS required a substantial

change in patent policy for many developing countries, as some had not protected pharmaceutical products before (only processes) while others exempted medicines from patent protection.<sup>63</sup> These changes led many to fear that TRIPS would lead to increased drug prices and consequently less medicine in the poorest nations. Thus was born the conception of “access to health” as a human right that conflicts with intellectual property rights.<sup>64</sup> While many aspects of these concerns were addressed in the previous section in connection with development, two further issues merit specific discussion as they are among those that are driving the New International IP Agenda. The first is compulsory licensing, while the second is the funding and encouragement of R&D in medicines for the diseases of the poor.

#### A. Compulsory Licensing

“The term ‘non-voluntary’ or ‘compulsory’ licensing refers to the practice by a government to authorize itself or third parties to use the subject matter of a patent without the authorization of the right holder for reasons of public policy. In other words, the patentee is forced to tolerate, against his will, the exploitation of his invention by a third person or by the government itself.”<sup>65</sup> Current discussion of compulsory licensing is focused on pharmaceutical patents. Development activists and developing nations see the right to compel a license as an aid to ensuring affordable access to health care.

Compulsory licensing of patented inventions has a long history.<sup>66</sup> Governments have imposed compulsory licenses of patented inventions when a patent was not being “worked” (i.e., the patent owner was sitting on its rights rather than practicing the invention), as a remedy for anti-competitive behavior, and where the patent covered necessities like food or medicine.<sup>67</sup> By the early 1990s, the majority of countries had some form of compulsory licensing in their patent laws, although use was rare.<sup>68</sup>

In negotiating TRIPS, compulsory licensing became an issue largely because developing nations wanted to preserve their ability to use compulsory licensing to secure drugs inexpensively. This issue was contentious—in fact it was one of the issues that broke down an earlier attempt to revise the Paris Convention in WIPO during the 1980s, which failed after six years of discussions.<sup>69</sup> This failure caused negotiators to move their harmonization talks to GATT negotiations, ultimately resulting in TRIPS.<sup>70</sup> The parties were able to resolve some of their differences in the context of TRIPS: In the end, the prerogative of compulsory licensing remained, subject to a number of safeguards set forth in Article 31 of the TRIPS Agreement. These safeguards include a requirement that compulsory licenses be imposed on a case-by-case basis and subject to judicial review, that they be non-exclusive, that there be adequate remuneration, and that, except in the case of a national emergency, the country imposing them make “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions” for a reasonable period of time.<sup>71</sup> A detailed analysis of the compulsory licensing right under TRIPS is beyond the scope

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of this paper. It is important to note, however, that its interpretation and implementation has been the subject of much debate and dissatisfaction among developing nations and NGOs.

There was some doubt initially as to the conditions under which a country could impose a compulsory license under TRIPS. In particular, there was doubt as to what constituted a national emergency, allowing nations to forego negotiating with patent owners. There was also concern that nations without their own manufacturing capacity would not be able to take advantage of compulsory licensing. In 2001, WTO members negotiated the so-called Doha Declaration on Public Health, which clarified these issues. Article 5 states that “[e]ach member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted,” and “the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” The declaration thus reinforces the right to compulsory licensing and asserts that each nation may determine for itself when a public health emergency exists.<sup>72</sup> A further clarification in 2003 set up a process to allow countries to import generics if they were without manufacturing capacity to create their own generics under compulsory licenses. The process allows for the issuance of a waiver from TRIPS requirements, subject to a number of safeguards.<sup>73</sup>

The end result of these negotiations and clarifications regarding compulsory licensing has left proponents of the New International IP Agenda very unhappy.<sup>74</sup> Compulsory licensing is favored by activists as a solution to what they perceive as price gouging and neglect by big pharmaceutical companies.<sup>75</sup> It is rarely used,<sup>76</sup> activists would like to see it used more often.<sup>77</sup> More frequent use may, however, be impractical. TRIPS still imposes a number of safeguards, including adequate remuneration and judicial review.<sup>78</sup> Any compulsory license can be challenged in the WTO on the basis of failure to comply with these safeguards or other parts of TRIPS.<sup>79</sup> Nations that impose compulsory licenses will likely be subject to diplomatic pressure.<sup>80</sup> Finally, if a country does not have its own domestic manufacturing capacity, it must secure a foreign generic source that is willing to undersell the patent owner enough to make all the other potential difficulties worthwhile.<sup>81</sup>

### ***B. Medical Research and Development***

Perhaps partly in response to the difficulties of implementing compulsory licensing, advocates for the New International IP Agenda have turned their attention to a proposed medical R&D treaty.<sup>82</sup> The medical R&D treaty (MRD Treaty) proposes a new international framework for financing pharmaceutical research through public funding as an alternative to the patent system. The premise underlying the MRD Treaty proposal is that the current system is “designed to increase drug prices, as the sole mechanism to

increase investments in R&D.”<sup>83</sup> Proponents believe that the current system causes many ills: “problems of rationing and access to medicine; costly, misleading and excessive marketing of products; barriers to follow-on research; skewing of investment toward products that offer little or no therapeutic advance over existing treatments, and scant investment in treatments for the poor, basic research or public goods.”<sup>84</sup>

The MRD treaty is supposed to solve these problems through an obligation to fund publicly research in areas chosen by the treaty’s governing body. Member states would agree to spend a certain percentage of GDP on medical research, with the percentage based on national income.<sup>85</sup> They would appoint a committee to determine research priorities for members.<sup>86</sup> The treaty would allow for a variety of methods of funding for research, but public finance, either direct or indirect, is generally contemplated. Funding may include: “direct funding of profit or non-profit research projects, market transactions such as purchases of medicine that provide incentives for research and development, payment of royalties to patent owners, tax credits, innovation prizes, investments in competitive research intermediators, research and development obligations imposed on sellers of medicines or other alternatives that have the practical effect of either directly or indirectly financing QMRD.”<sup>87</sup> There are further provisions mandating open access to government funded research,<sup>88</sup> changes to patent and copyright law to make it more amenable to research and development,<sup>89</sup> and agreement to forego use of TRIPS enforcement procedures.<sup>90</sup>

MRD Treaty supporters believe that it would cure what they see as major distortions in the current system for encouraging innovation. Supporters assert that the recent emphasis on patent protection has not promoted new cures, but rather only higher drug prices.<sup>91</sup> They contend that the drugs needed most by people in developing countries (drugs for malaria are an oft-cited example) are not developed under the current system, because the market incentives point toward cures for diseases prevalent in the developed world.<sup>92</sup>

### ***C. Critique of Public Health Proposals***

The premise underlying the New International IP Agenda’s public health initiatives is that patent rights block access to medicine. Advocates draw this conclusion from the following observations:

- Much of the developing world lacks access to medicine;
- Even if sick people did have access, few could afford the prices charged by Western pharmaceutical companies;
- Patents give patent owners exclusive rights over manufacture, sale, and use of their inventions (i.e., the right to deny “access”);
- Patent owners use these rights to extract higher prices for their patented drugs.

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There is not much to quibble with in the facts listed above; the question is whether they present the entire picture and whether the conclusions drawn from them are accurate. Critics see (1) a lack of access and affordability to medicine, and (2) identify patents as the source of a right to deny access and extract higher prices for patented products, and thus conclude that the first is caused by the second. As they see it, patents enable pharmaceutical companies to hold out for high prices. Since they have lucrative markets elsewhere, the argument goes, pharmaceutical companies can and do choose to ignore markets (and thus people) that are too poor to offer an attractive return. Patent rights are thus seen as an obstacle to affordable medicine: Critics contend that they leave developing nations with no alternative but to pay high prices (which causes rationing) or go without (thus the lack of access for many of the poor).

These conclusions place far too much blame on patents and pharmaceutical companies for problems with access to medicine. First, some perspective is necessary. Vast numbers of people do indeed lack access to medicine and the results are tragic. In most instances, however, people lack not just patented drugs but medical care in general, as well as the other benefits of a developed market economy. As discussed below, alleviating the medical needs of the developing world is a challenging, complex problem in which patented drugs play a limited role (albeit important in specific cases). Second, one ought to consider the role of various players and factors in creating and alleviating the needs of the developing world. Are the health problems of the developing world created or exacerbated by greedy pharmaceutical companies that attempt to exploit every last bit of market power? Despite frequent vilification, evidence suggests otherwise. Although pharmaceutical companies must satisfy shareholders and ensure they have revenue to do the R&D necessary for the next drug breakthrough, they also cut prices for the developing world and engage in charitable efforts. Some governments do their best for their people under challenging conditions, while others mismanage their priorities, and still others oppress and prey upon their citizens. It is myopic to focus on and blame patents for larger problems that stem from the mismanagement and malevolence of political leaders. Third, as implied by the previous point, much of this debate comes down to a clash of visions. Many working on these issues are simply impatient with anything that they perceive as getting in the way of saving lives. But others see private corporations, capitalism, and private property rights as too arbitrary and inequitable to entrust with something as important as public health. They are deeply suspicious of the motives of private interests and their supporters. They see government led solutions as far more fair and efficient. The roots of this clash of visions are deep. This paper can do little more than point out how it affects international IP issues and critique the effectiveness of the proposals offered by proponents of the New International IP Agenda.

### 1. Patents and Access to Medicine

A vast number of people in the developing world lack access to medicine, but is it patent owners who are denying

them this access? The World Health Organization (WHO) estimates that “1.7 billion people today still have no regular access to quality essential medicines.”<sup>93</sup> WHO further notes that “in some of the lowest income countries in Africa and Asia, more than half of the population have no regular access to essential medicines.”<sup>94</sup> It would be heartless to discount the magnitude of this tragedy, but it is important to understand the causes of it. The simple logic of the syllogism “people lack access to medicine; patent rights allow the denial of access; therefore patents cause the problem of access to medicine” is lacking. Two questions are key to understanding the problem: First, how many of the drugs most needed by the developing world are covered by patents? Second, what is the importance of any other factors, besides patents, that drive up prices and impede access?

A closer look at the evidence suggests that the claim that patents are a major cause of problems with access to medicine is at least somewhat exaggerated. Most discussions of this issue look to WHO’s Model List of Essential Medicines for guidance as to which medicines are most important to human health.<sup>95</sup> A study by Prof. Amir Attaran reviewed the patent status of 319 products on the Essential Medicines list in 65 developing countries.<sup>96</sup> He found that only seventeen of the essential medicines on the list (1.4 percent) are patented in any of the 65 developing countries he studied.<sup>97</sup> Some aspects of Attaran’s work have been criticized. Many of the essential medicines that are patented are for antiretrovirals used to fight HIV, so, given the scope of the AIDS crisis, these patented drugs are needed by many millions of people.<sup>98</sup> Moreover, some of Attaran’s critics take the position that “For the African market, every dollar that can be cut off the price of [AIDS drugs] is important . . . Everything possible needs to be done. Every barrier for cheaper medicine needs to be removed.”<sup>99</sup> While these criticisms would help to rebut an assertion that patents could not possibly raise any barrier to access at all, they hardly show that patents are the major cause of problems with access to medicine.

If 98% of the drugs on WHO’s essential medicines list are off patent, and yet 1.7 billion people still do not have access to them, then patents do not appear to be the main problem.<sup>100</sup> In fact, a WHO report issued a few years ago noted that “Most of the 13 million deaths a year from infectious diseases can be prevented. Low-cost health interventions already exist to either prevent or cure the infectious diseases which take the greatest toll on human lives. And most of these interventions have been widely available for years.”<sup>101</sup>

### 2. The Role of Corporations and Governments in Access to Medicine

Millions are dying, but could be saved with low cost treatments. What is the cause of this seemingly avoidable tragedy? The WHO Report cited above provides several reasons: “Inadequate funding of health care in developing countries is one reason. Government failure to prioritize, lack of cross-sectoral collaboration and the inability of weak health service delivery systems to reach the entire population—

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particularly the most vulnerable and difficult-to-reach—are contributing factors.”

In this report, WHO thus laid the blame for lack of access to medicine on poorly funded and underdeveloped health systems. Why are health systems poorly funded and underdeveloped? One obvious cause is poverty. A poorly developed economy and tax base means that resources are not available for public health. It also means that private institutions dedicated to health (e.g., pharmacies, hospitals, clinics) or incidental to its delivery (e.g., communications, transportation) are weak or non-existent. Why some countries are poor is, of course, the subject of a vast amount of research and ideological debate far beyond the scope of this particular discussion. In any event, nobody claims that drug patents are the cause of poverty. Unless we are willing to view poverty as a permanent condition of some nations, we ought to look to short term solutions, such as aid and charity, to alleviate the challenge of drug affordability. Poverty itself ought to receive the lions’ share of attention and energy of advocates for developing nations, rather than placing blame on the system of private property rights that supports medical research and development. As the International Policy Network (IPN), a London-based free-market think tank, concluded in a recent report on access to health issues: “it is unlikely that good health will ever be sustained without long-term wealth creation that can pay for the ongoing improvements in water, sanitation, hospitals and medical research. Those who genuinely hope to improve the health of the world’s poorest people should therefore look to wealth creation as the fundamental solution to global health problems.”<sup>102</sup>

Beyond broader ideological debates about economic development, there are specific things that governments do to exacerbate the problem. A recent study found that governments impose import tariffs, value added taxes, and other fees on essential medicines.<sup>103</sup> For example, Brazil charges an import tariff of 11.7%, a VAT tax of 18%, and a state tax of 6% on imported drugs.<sup>104</sup> Note that these charges are often compounded, as taxes and fees at each level of distribution are based on a price that already includes earlier taxes and fees.<sup>105</sup> The authors of the study concluded that hidden costs raised prices an average of 68.6% in the countries studied.<sup>106</sup> Many of these costs are well within the power of governments to reduce and thus one of the first places where they should seek cost reductions.

In addition to increasing costs, some governments display questionable priorities. In the report cited above, IPN criticized a number of countries for defense budgets that exceeded public health budgets.<sup>107</sup> “For instance, the government of Pakistan spends 4.7 per cent of its GDP on defence, but a mere 1 per cent on healthcare.”<sup>108</sup> IPN found similar gaps in many other countries, the majority of which faced no significant external threats.<sup>109</sup> Similarly, India and Brazil<sup>110</sup> are aggressively funding space programs, with India planning to send an unmanned ship to the Moon by 2008.<sup>111</sup> Although sovereign nations can and should determine their

own spending priorities, they open themselves to criticism when they claim inability to meet the basic health needs of citizens but spend money on projects largely calculated to enhance their prestige.

There is another problem that is rarely raised in the polite world of international organizations and NGOs: Some governments do not have the best interests of all their citizens at heart. Recent notable examples include the complicity of the government of Sudan in genocide in Darfur<sup>112</sup> and Zimbabwean President Robert Mugabe’s destruction of the homes of over 700,000 people he deems political opponents.<sup>113</sup> Can such governments be trusted to invest in public health or to use medical aid properly? Some donors say no. The Boston Globe reported “that Zimbabwe receives \$4 in donor support for each person infected with HIV, compared to \$187 per infected person in neighboring Zambia.”<sup>114</sup> The Globe notes that “[t]he reason is simple: Donors fear the government of President Robert Mugabe would either steal some of the AIDS money or divert it for political ends.”<sup>115</sup> In some places, the problem of access to medicine has little to do with complex issues of intellectual property rights or basic economic policy, but rather starts with denial of fundamental political and human rights.

Conversely, pharmaceutical companies are hardly the greedy, heartless robber barons that appear in the one-dimensional portrayals of some critics. Pharmaceutical companies often lead the way in providing solutions to access to health problems. Since 2000, pharmaceutical companies have provided some AIDS drugs to the least developed countries at discounts of up to 90% or more.<sup>116</sup> Critics are dismissive of their efforts, contending that the deals come with too many conditions or, more commonly, that even very low prices are still too expensive in countries where per capita incomes are very low.<sup>117</sup> A common complaint has been that despite drastically lowered prices (in many cases at cost, and in a few instances, free), not many are being treated.<sup>118</sup> Pharmaceutical companies might be excused if they feel that they cannot win with some critics. Oxfam’s response to Merck and others slashing prices on AIDS drugs typifies the ideological rigidity of some critics: “Oxfam said the action by companies was undermined by their tough stance in defence of patents, which was preventing developing countries from securing the lowest-cost supply of medicines. . . . ‘As long as these kind of price cuts are not seen as a solution to this problem, then they are welcome. But if it is seen as an alternative, then it is going to be a flawed alternative.’”<sup>119</sup> Notwithstanding such antipathy, if pharmaceutical companies behave charitably where it is warranted, then it is up to private donors, developed country aid, and public health services to meet them halfway.

In some instances, pharmaceutical companies have instituted charitable programs to alleviate particular illnesses. For example, Merck’s Mectizan Donation Program has teamed with public health agencies and NGOs to combat river blindness, the second leading cause of blindness in the world.<sup>120</sup> Dr. Gilbert Burnham of Johns Hopkins University



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has described<sup>121</sup> the tremendous success of this program: “The Mectizan Donation Program is really one of the great public health success stories. It is the benchmark for all other disease prevention efforts in the developing world.”<sup>122</sup> Pfizer instituted a similar program for donating Diflucan, an antifungal medication helpful to AIDS patients.<sup>123</sup> Some activists cannot be persuaded that a pharmaceutical company could have benevolent motives and have greeted the Diflucan program with skepticism.<sup>124</sup>

### 3. A Clash of Visions: Public Funding of R&D vs. Private Property Rights

Proponents of the proposed medical R&D treaty (MRD) discussed earlier might be credited with at least offering a solution to patch a large hole in their attacks on pharmaceutical companies: If pharmaceutical companies cannot profit from their inventions, then how can they be expected to develop new medicine? MRD treaty proponents don’t expect them to do so. Instead, they expect government led development to fill this gap. Of course, those who advocate an MRD treaty do not see it as a “patch” for the hole in their argument; they see government coordination of R&D as more fair and efficient.

This is an old argument that has recurred often over the last several decades. Most relevant were debates in the late ‘80s of the relative merits of a Japanese style industrial policy versus a U.S. style private sector led technological development. Market solutions seem to have proven themselves over time, but critics are not deterred. This debate largely comes down to a clash of visions between those who advocate centralized, government solutions to societal challenges and those who advocate decentralized private solution. As Friedrich Hayek and others have advocated, decentralized solutions are more efficient and conducive to human development.<sup>125</sup> They put decision making in the hands of those who have the most knowledge and accord them freedom to do as they think is right. Still, advocates of centralized solutions insist that centralization offers economies of scale and greater democracy.

Less philosophically, there are several reasons to believe that the MRD treaty would not meet its goals. Treaty advocates hope to make R&D decision making more responsive to public needs. Government funding of health research is already common, however, and complaints about politically distorted priorities are also common. The treaty mandates a committee of 18 experts who will set research priorities. Will this committee’s decisions be any less politicized than other government efforts? Moreover, setting aside likely political rent seeking, how will a committee possess enough knowledge to best set priorities? Pharmaceutical companies strive hard to determine the needs of their customers. They conduct extensive market research, focus groups with doctors, and have a network of sales representatives who communicate directly with doctors. It is hard to conceive that any centralized process could match such a decentralized information gathering project.

Still, the proposed MRD treaty might be inefficient at worst and might even do some good (throwing money at R&D is no panacea, but it can sometimes help), but for its provisions disfavoring intellectual property rights. Most important, signatories would forego enforcing the intellectual rights of their citizens through TRIPS. This provision sets the treaty into direct opposition to the private IP system, thus necessitating the question whether centralized, government driven processes should be preferred to decentralized, private decision making. Experience advises against such experiments, but, as noted, this issue comes down to a clash of visions. Some continue to advocate centralized solutions.

## **IV. Information Infrastructure and the Digital Divide**

### *A. Introduction*

Proponents of the New International IP Agenda also have interjected themselves into international efforts to address inequities in information infrastructure between developed and developing countries and to bridge the Digital Divide.<sup>126</sup> They have promoted their agenda of IP skepticism through advocacy of a fundamental human right of “access to knowledge” as discussed above. In addition to efforts to advance a development agenda at WIPO,<sup>127</sup> they have been extremely active in the World Summit on the Information Society (WSIS). Throughout the summit, advocates of the New International IP Agenda, both national governments and NGOs, have made concerted efforts to advance an anti-IP agenda. Although the Summit has not adopted openly anti-IP positions,<sup>128</sup> substantial portions of the New International IP Agenda have been discussed and integrated into WSIS principles.

### *B. The World Summit on the Information Society*

The World Summit on the Information Society (WSIS) has become a major forum for those interested in advancing the New International IP Agenda. WSIS originated in the International Telecommunications Union (ITU) through a resolution sponsored by the government of Tunisia in 1998.<sup>129</sup> The Summit later was established by resolution of the United Nations General Assembly in 2002.<sup>130</sup> The Summit was planned to be held in two sessions, the first in Geneva in late 2003 and the second in Tunisia in 2005.

The WSIS Principles and Plan establish a broad-based development agenda<sup>131</sup> and repeat some of the human rights arguments advanced by advocates of the New International IP Agenda<sup>132</sup>—namely that “everyone has the right to freedom of opinion and expression; that this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.”<sup>133</sup> More specifically, the key principles or themes of WSIS are that all stakeholders should work together to:

- improve access to information and communication infrastructure and technologies as well as to information and knowledge

- build capacity
- increase confidence and security in the use of information and communication technologies (“ICTs”)
- create an enabling environment at all levels;
- develop and widen ICT applications
- foster and respect cultural diversity
- recognize the role of the media
- address the ethical dimensions of the Information Society
- encourage international and regional cooperation<sup>134</sup>

Some of these themes have considerable resonance with advocates of the New International IP Agenda; these are the themes that will be addressed in this paper.

The WSIS defines stakeholders to include Governments, the private sector, civil society, and the United Nations and other international organizations, which each have an important role and responsibility in the development of the Information Society and, as appropriate, in decision-making processes.<sup>135</sup> More specifically, the WSIS Plan acknowledges that the private sector and civil society, in dialogue with governments, have an important consultative role to play in devising national strategies.<sup>136</sup> The WSIS thus ensures that NGOs who are skeptical of intellectual property will have a ready forum to advance the New International IP Agenda for some time to come.

In fact a large number of non-government organizations (NGOs) have been intimately involved in the Summit from the beginning. The WSIS has a formal process through which an NGO may become accredited to participate in WSIS events and preparatory committee meeting.<sup>137</sup> As of February 2005, hundreds of NGOs were accredited to participate.<sup>138</sup> In a larger sense, many NGOs with seemingly disparate charters have banded together to form the Conference of NGOs (CONGO) that works “to ensure that NGOs are present when governments discuss issues of global concern at the United Nations and to facilitate NGO discussions on such issues.”<sup>139</sup>

Perhaps most relevant of the WSIS themes to the New International IP Agenda is the access to information and knowledge, which echoes some of the human rights positions of the Agenda. This theme not only addresses removing barriers to equitable access to information but also promotes awareness and consideration of different software models. This theme closely ties development to access to information and encourages removal of barriers to equitable access to information for economic, social, political, health, cultural, educational, and scientific activities as a path to sharing and strengthening global knowledge.<sup>140</sup> They contend that a rich public domain is essential for growth of the information society. WSIS also promotes universal access with equal opportunities for all scientific knowledge and open access

initiatives for creation and publication of scientific and technical information.<sup>141</sup>

The WSIS Principles declare a commitment to turning the digital divide into a digital opportunity for all, particularly for those who risk being left behind and being further marginalized.<sup>142</sup> To overcome the digital divide, WSIS encourages more efficient use of existing approaches and mechanisms and fully exploring new ones, in order to provide financing for the development of infrastructure, equipment, capacity building and content, which are essential for participation in the Information Society.<sup>143</sup> Recognizing the potential of ICT for development, the WSIS advocates:

- 1) developing countries to increase their efforts to attract major private national and foreign investments for ICTs through the creation of a transparent, stable and predictable enabling investment environment;
- 2) developed countries and international financial organisations to be responsive to the strategies and priorities of ICTs for development, mainstream ICTs in their work programmes, and assist developing countries and countries with economies in transition to prepare and implement their national e-strategies. Based on the priorities of national development plans and implementation of the above commitments, developed countries should increase their efforts to provide more financial resources to developing countries in harnessing ICTs for development;
- 3) the private sector to contribute to the implementation of this Digital Solidarity Agenda<sup>144</sup>

To assist in bridging the Digital Divide, a Digital Solidarity Fund has been created to finance development projects that will enable excluded people and countries to enter the new era of the Information Society.<sup>145</sup> More than one hundred and twenty cities have committed to implement what is known as the “Geneva Principle.”<sup>146</sup> The Geneva Principle stipulates that public calls for bids in the field of ICT shall include a digital solidarity clause requiring the company that obtains the contract to contribute one percent of the transaction to the Digital Solidarity Fund.<sup>147</sup>

Although the WSIS Principles do not explicitly endorse a particular software model, they do promote increasing awareness among all stakeholders of the possibilities offered by different software models, including proprietary, open-source and free software, in order to increase competition, access by users, diversity of choice, and to enable all users to develop solutions which best meet their requirements.<sup>148</sup> Affordable access to software is touted as an important component of a truly inclusive Information Society.<sup>149</sup> Although the Principles do not fully endorse the government bias for one software model over another, the fact that they

promote consideration of open source and free software is some victory for advocates of the New International IP Agenda. In fact, those advocates have been instrumental in shaping the criteria for considering the various software models to include areas in which open software advocates believe they have an inherent advantage over proprietary software—namely increasing competition, access by users, diversity of choice, and affordable access. Though they have not been successful in incorporating openly anti-IP positions that likely would be rejected by some countries, including the United States, it is clear that they are shaping the discussion and having a considerable impact.

The WSIS also calls on governments to establish an enabling environment for the Information Society at the national and international level, wherein ICTs are used as an important tool for good governance.<sup>150</sup> WSIS advocates Government intervention, as appropriate, to correct market failures, to maintain fair competition, to attract investment, to enhance development of ICT infrastructure and applications, to maximize economic and social benefits, and to serve national priorities.<sup>151</sup> Not coincidentally, proponents of the New International IP Agenda advocate government intervention in favor of open source software to correct the failure of the commercial software market to maintain fair competition, to enhance development of software applications, and to maximize economic and social benefits.<sup>152</sup>

The WSIS Principles assert that both (1) intellectual property protection and (2) wide dissemination, diffusion, and sharing of knowledge are important to encourage innovation and creativity in the Information Society.<sup>153</sup> This dichotomy sets up exactly the equal footing for access to knowledge advanced by the New International IP Agenda. The WSIS Principles consider meaningful participation by all in intellectual property issues and knowledge sharing through full awareness and capacity awareness to be a fundamental part of an inclusive Information Society.<sup>154</sup> Once again the Principles ensure that NGOs and not just governments will have a seat at the table for discussions regarding the proper interplay of intellectual property protection and access to knowledge.

#### IV. Conclusion

The New International IP Agenda has brought new controversy into international IP policy discussions. This broad agenda, united by a thread of skepticism regarding intellectual property and a common network of NGOs and activists, has been asserted in many different contexts. Discussions and negotiations regarding a wide variety of topics, including international development, pharmaceuticals, software patents, the digital divide, and cultural policy, now include contentious debates regarding the morality and efficacy of intellectual property rights.

So far, the breadth and visibility of the New International IP Agenda has been more impressive than any results arising from it. Nevertheless, its proponents have put their issues on the agenda of international organizations including WIPO,

the WTO, and the U.N. They have polarized discussions regarding a wide variety of intellectual property issues, most notably stalling patent harmonization negotiations and blocking software patents in the EU.

International IP policy has entered a new age of controversy. Intellectual property owners and those who support intellectual property rights will need to better articulate their case and meet the wide ranging challenge of IP skeptics.

\* Mark Schultz is Assistant Professor of Law at Southern Illinois University School of Law. David Walker is Chief Patent Counsel, NASA Goddard Space Flight Center. The views expressed in the article are those of the authors and do not necessarily represent the views of NASA or the United States.

#### Footnotes

<sup>1</sup> See James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 9 DUKE L. & TECH. J. 0009 (2004) (“[T]he fundamental principle of balance between the public domain and the realm of property seems to have been lost. The potential costs of this loss of balance are just as worrisome as the costs of piracy that so dominate discussion in international policy making.”).

<sup>2</sup> Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document WO/GA/31/11.7 (April 6, 2005)(submission by the Group of Friends of Development to WIPO Intersessional Intergovernmental Meeting IIM/1/4-2005) [hereinafter Submission by the Group of Friends of Development to WIPO], available at [http://www.wipo.int/edocs/mdocs/mdocs/en/iim\\_1/iim\\_1\\_4.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/iim_1/iim_1_4.pdf) (last visited Aug. 2, 2005).

<sup>3</sup> Not every individual member of this international network of NGOs, academics, activists, politicians, and bureaucrats has the same concerns and opinions. In particular, many of the parts of this network are far more moderate than the whole. Individuals working on international IP issues often contend that they support the general principles of intellectual property law, professing to want only to address particular problems and/or to restore what they see as a proper balance between private ownership and the public good. On the one hand, this assertion is clearly true, especially with respect to many thoughtful academics, results-oriented development specialists, and the more pragmatic elements of the open source movement. On the other hand, there are some who laud “balance” in principle, but appear to oppose IP rights consistently in practice. These across-the-board-skeptics are not just fringe players, but rather constitute an important and serious part of the network, organizing many of the important initiatives and playing a prominent role in discussions at international organizations. The primary example is the Consumer Project on Technology (often called CPTEch), which consistently opposes IP rights. Its leaders speak frequently at international intergovernmental and non-governmental IP forums, and CPTEch plays a key organizing role by initiating treaty proposals, hosting events, issuing research, and organizing e-mail discussion lists. See CPTEch.org, *About the Consumer Project on Technology*, at <http://www.cptech.org/about.html> (last visited June 11, 2005).

<sup>4</sup> Under compulsory licensing, the government takes for itself or gives to others the right to use a patented invention, thus depriving

the patent owner of its ability to extract a royalty of its choosing. Under some compulsory licensing schemes the patent owner has some opportunity to negotiate a royalty, but its leverage is greatly reduced and thus, most likely, its payment. See *infra* note 66-69 and accompanying text.

<sup>5</sup> See *id.* As noted above, one of the key leaders of the New International IP Agenda is the U.S.-based CPTECH, which was founded by Ralph Nader and funded by George Soros, the Rockefeller Foundation, the Ford Foundation, the MacArthur Foundation and others. A perusal of CPTECH's website quickly shows the incredible breadth and sophistication of its international activities promoting skepticism of intellectual property.

<sup>6</sup> Press Release, United States Patent Office, Patent Law Harmonization Talks Stall; Brazil, Argentina, India Oppose Compromise (June 14, 2005), available at <http://www.uspto.gov/main/homepagenews/bak2005jun14.htm> (last visited June 20, 2005).

<sup>7</sup> Although the successful linkage to trade has inspired a lot of the controversy, a number of other issues have brought intellectual property to the attention of the development community in the last decade: the AIDS crisis (see Section III below), the growing importance of IP to the world economy, and concern that Western companies were appropriating indigenous knowledge and culture without compensation. The latter issue has led to proposals for rights in "traditional knowledge," whereby indigenous people would be given some measure of control over and/or compensation for pharmaceuticals, art, and entertainment made based on the knowledge of indigenous communities. While traditional knowledge has been an important topic in international forums for the past decade, it is outside of the scope of the paper. While IP skeptics are sometimes willing to make an exception for protection of traditional knowledge, they often see such information as belonging in the public domain which sometimes puts them at odds with traditional knowledge advocates. See Anupam Chander & Madhavi Sunde, *The Romance of the Public Domain*, 92 CALIF. L. REV. 1331 (2004).

<sup>8</sup> See Jagdish Bhagwati, *Comment on Services and Intellectual Property Rights*, in THE NEW GATT: IMPLICATIONS FOR THE UNITED STATES 111, 112-114 (Susan Collins & Barry Bosworth eds., 1994) (discussing reasons developing nations reluctantly accepted increased IP protection in exchange for trade liberalization).

<sup>9</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

<sup>10</sup> They were strong relative to what existed before. For details regarding the differences from prior agreements, see, e.g., J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441 (2000).

<sup>11</sup> Ralph Oman, *Berne Revision: The Continuing Drama*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 139, 144 (1993).

<sup>12</sup> See David Vivas-Eugui, *Regional and Bilateral Agreements and a Trips-Plus World: The Free Trade Area of the Americas (FTAA)* (2003), available at [http://www.geneva.quino.info/pdf/FTAA\(A4\).pdf](http://www.geneva.quino.info/pdf/FTAA(A4).pdf) (last visited Aug. 4, 2005).

<sup>13</sup> See generally R. Michael Gadbaw, *Intellectual Property and International Trade: Merger or Marriage of Convenience?*, 22 VAND.

J. TRANSNAT'L L. 223 (1989) (discussing linkage of intellectual property and trade policies).

<sup>14</sup> See Vivas-Eugui, *supra* note 14.

<sup>15</sup> TRIPS imposed a three-tiered system of implementation: Developed nations had to comply almost immediately, developing nations had five years (until January 1, 2000), and least developed nations originally had ten years. The time for least developed nations to comply with requirements regarding pharmaceutical patents was extended to 2016, and a number of waivers are also available to them, so it will be some time before they are fully obligated. See WORLD TRADE ORGANIZATION, FREQUENTLY ASKED QUESTIONS ABOUT TRIPS IN THE WTO, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm) (last visited Aug. 3, 2005).

<sup>16</sup> *Intellectual Property Rights and Human Rights*, Res. 2000/7, U.N. Sub-Comm'n. on the Promotion and Protection of Human Rights, 52nd Sess., pmb. ¶ 11, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (hereinafter Resolution 2000/7) (stating that "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights").

<sup>17</sup> See *id.* The Declaration's view of the conflict between intellectual property and human rights largely is derived from the International Covenant on Economic, Social and Cultural Rights, which recognizes the right "to enjoy the benefits of scientific progress and its applications." International Covenant on Economic, Social and Cultural Rights, adopted Dec. 16, 1966, arts. 15(1)(c), S. EXEC. DOC. D, 95-2, at 18 (1977), 993 U.N.T.S. 3, 9 (entered into force Jan. 3, 1976) [hereinafter ICESCR]. The United States has never ratified this treaty, reflecting a Cold War divide in which the USSR and socialist nations embraced ICESCR and its socialist vision of human rights. See N.D. White, *The Law of International Organisations* 232 (1996); J. Oloka-Onyango, *Reinforcing Marginalized Rights in an Age of Globalization: International Mechanisms, Non-State Actors, and the Struggle for Peoples' Rights in Africa*, 18 AM. U. INT'L L. REV. 851, 852 (2003); see also Nsongurua J. Udombana, *Articulating the Right to Democratic Governance in Africa*, 24 MICH. J. INT'L L. 1209, 1224 (2003).

<sup>18</sup> See Resolution 2000/7, *supra* note 18.

<sup>19</sup> See Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 56 (2003) (detailing several U.N. human rights initiatives related to intellectual property).

<sup>20</sup> See *Access to Medication in the Context of Pandemics such as HIV/AIDS*, Res. 2001/33, U.N. Comm'n. on Human Rights, U.N. Doc. E/CN.4/RES/2001/33 (2001) (mandating that states "adopt legislation or other measures, in accordance with applicable international law" to "safeguard access" to medicine "from any limitations by third parties"); *Id.* at ¶ 3(b); see also *Access to Medication in the Context of Pandemics such as HIV/AIDS*, Res. 2002/32, U.N. Comm'n. on Human Rights, U.N. Doc. E/CN.4/2002/2000 (2002); *Access to Medication in the Context of Pandemics such as HIV/AIDS*, Res. 2003/29, U.N. Comm'n. on Human Rights, U.N. Doc. E/CN.4/2003/L.11/Add.3 (2003).

<sup>21</sup> Submission by the Group of Friends of Development to WIPO, *supra* note 4.

<sup>22</sup> See CPTECH, HEALTH CARE AND INTELLECTUAL PROPERTY, available at <http://www.cptech.org/ip/health/> (last visited June 22, 2005) (collecting resources and advocacy on "access to health").



<sup>23</sup> See CPTECH, ACCESS TO KNOWLEDGE (A2K), available at <http://www.cptech.org/a2k/> (last visited June 22, 2005) (collecting resources and advocacy on “access to knowledge”).

<sup>24</sup> Helfer, *supra* note 21, at 57.

<sup>25</sup> Resolution 2000/7, *supra* note 18, at ¶ 3.

<sup>26</sup> See, e.g., Martin Khors, *Offsetting IPRs' Adverse Effects on Access to Knowledge*, SOUTH NORTH DEVELOPMENT MONITOR, Feb. 4, 2005, available at [http://www.choike.org/nuevo\\_eng/informes/2630.html](http://www.choike.org/nuevo_eng/informes/2630.html) (last visited June 18, 2005) (stating that Access to Knowledge treaty advocates contend “that a treaty on access to knowledge should be based on the human rights model, in which access of knowledge is acknowledged as a human right, that this right is primary, and the rights to holders of copyrights or patents are seen as secondary or exceptions, and should thus be limited and in ways that would not threaten the primary human rights.”).

<sup>27</sup> See, e.g., ELLEN ‘T HOEN, MEDECINS SANS FRONTIERES, A GUIDE TO THE POST-2005 WORLD: TRIPS, R&D AND ACCESS TO MEDICINES, (Jan. 18, 2005), available at [http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=88694E5B-0FED-434A-A21EDA1006002653&method=full\\_html](http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=88694E5B-0FED-434A-A21EDA1006002653&method=full_html) (last visited June 20, 2005).

<sup>28</sup> See, e.g., INTERNATIONAL FEDERATION OF LIBRARY ASSOCIATIONS, LIBRARY-RELATED PRINCIPLE FOR THE INTERNATIONAL DEVELOPMENT AGENDA OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (Jan. 26, 2005), available at <http://www.ifla.org/III/clm/p1/Library-RelatedPrinciples-en.html> (last visited June 20, 2005).

<sup>29</sup> See, e.g., Alan Deardorff, *Should Patent Protection Be Extended to All Developing Countries?*, in THE MULTILATERAL TRADING SYSTEM: ANALYSIS AND OPTIONS FOR CHANGE 435, 446 (Robert Stern ed., 1993) (arguing that least developed nations will be net losers under TRIPS because too little innovative activity originates in those countries); Chakravarthi Raghavan, *Patents No Longer Efficient for Biomedical Research*, THIRD WORLD NETWORK (Nov. 2002), available at <http://www.twinside.org.sg/title/twe293c.htm> (last visited June 20, 2005) (describing purported “rent seeking” behavior associated with patents and decrying “costs to the developing world of being forced to accept the global monopolies created for big pharmaceutical corporations through the WTO’s TRIPS Agreement”).

<sup>30</sup> Proposal by Argentina And Brazil for the Establishment of a Development Agenda for WIPO, 2 (Submission by Argentina and Brazil to WIPO General Assembly Meeting WO/GA/30/11-2004) (Aug. 27, 2004), available at [http://www.wipo.int/documents/en/document/govbody/wo\\_gb\\_ga/pdf/wo\\_ga\\_31\\_11.pdf](http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf) (last visited June 20, 2005).

<sup>31</sup> Submission by the Group of Friends of Development to WIPO, *supra* note 4, at 7.

<sup>32</sup> As this paper goes to press in August 2005, the Development Agenda’s future awaits further debate and decision by WIPO’s General Assembly in meetings scheduled for late September and early October 2005. See *Unfinished WIPO Development Agenda Left to General Assembly*, 2 INTELLECTUAL PROPERTY WATCH 1 (August/September 2005) available at [http://www.ip-watch.org/IP-W-August\\_Sept.2005.pdf](http://www.ip-watch.org/IP-W-August_Sept.2005.pdf). The parties participating in the Development Agenda meetings have been unable to reach agreement on most issues and have left resolution to the General Assembly. *Id.* The most intense debate over the Development Agenda at the moment is procedural. Those who embrace the Development Agenda seek ongoing meetings at WIPO devoted exclusively to pursuing the Development Agenda. See *id.* The United States and others who are skeptical of the Development Agenda seek to reduce its prominence by moving discussions to a standing committee

with other responsibilities. See *id.* Meanwhile, Brazil and others have advanced substantive proposals that call for consideration of the Access to Knowledge Treaty described below.

<sup>33</sup> OPEN SOCIETY INSTITUTE, GENEVA DECLARATION ON THE FUTURE OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (Sept. 29, 2004), available at [http://www.soros.org/initiatives/information/news/wipo\\_20040929/wipo\\_declaration.pdf](http://www.soros.org/initiatives/information/news/wipo_20040929/wipo_declaration.pdf) (last visited June 20, 2005).

<sup>34</sup> *Id.*

<sup>35</sup> See CPTECH.org, *supra* note 25 (collecting resources and advocacy on “access to knowledge”); see also *May 9, 2005 Draft Treaty on Access to Knowledge*, available at <http://www.cptech.org/a2k/consolidatedtext-may9.pdf> (May 9, 2005).

<sup>36</sup> See generally CPTECH.org, *supra* note 25.

<sup>37</sup> See *Unfinished WIPO Development Agenda Left to General Assembly*, 2 INTELLECTUAL PROPERTY WATCH 1, 4 (August/September 2005), available at [http://www.ip-watch.org/IP-W-August\\_Sept.2005.pdf](http://www.ip-watch.org/IP-W-August_Sept.2005.pdf).

<sup>38</sup> See CPTECH.org, *May 9, 2005 Draft Treaty on Access to Knowledge*, available at <http://www.cptech.org/a2k/consolidatedtext-may9.pdf> (May 9, 2005).

<sup>39</sup> *Brazil Holds Out Possibility Of Compulsory License For Aids Drugs*, FDA WEEK, June 17, 2005.

<sup>40</sup> The Convention on Cultural Diversity would allow nations to set quotas on foreign entertainment products (notwithstanding trade agreements). Some language condemning piracy upset development advocates, who attempted to replace it with language promoting access to knowledge issues. In the end, “[a]ll elements of the previous drafts that dealt with intellectual property rights and piracy were removed from the substantive clauses of the Convention. The only reference to IP is now in the preamble . . . with the exception of an additional preamble provision on the importance of the protection of indigenous knowledge, [all proposals to add IP related language] have been defeated.” Garry Neil, *Report by Garry Neil (INCD) on Final Round of UNESCO Negotiations*, MEDIA TRADE MONITOR (May 31, 2005), available at <http://www.mediatrademonitor.org/node/view/213> (last visited June 20, 2005).

<sup>41</sup> See *infra* Section V.

<sup>42</sup> See USPTO Press Release, *supra* note 8. (“The impasse . . . raises serious questions as to whether WIPO is even a viable forum for further meaningful patent discussions . . . WIPO appears to be facing a serious identity crisis, underscoring the need to consider alternative approaches for achieving harmonization so that we can realize efficiencies and better patent quality worldwide. Our users have spoken in no uncertain terms about their need for progress in this area.”).

<sup>43</sup> IP negotiations have been removed from WIPO before because of such an impasse. An attempt to revise the Paris Convention in WIPO failed after 6 years of discussions, causing negotiators to move their harmonization talks to GATT negotiations, ultimately resulting in TRIPS. See JEROME H. REICHMANN & CATHERINE HASENZAHN, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA, 12-13 (June 2003), available at [http://www.ictsd.org/pubs/ictsd\\_series/iprs/CS\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf) (last visited Aug. 3, 2005).

- <sup>44</sup> ROBERT M. SHERWOOD, *INTELLECTUAL PROPERTY AND ECONOMIC DEVELOPMENT* (ch. 9) (Westview Press 1990), *available at* <http://www.kreative.net/ipbenefits/iped/default.htm> (last visited June 20, 2005).
- <sup>45</sup> HERNANDO DE SOTO, *THE MYSTERY OF CAPITAL: WHY CAPITALISM TRIUMPHS IN THE WEST AND FAILS EVERYWHERE ELSE* (2001).
- <sup>46</sup> *See id.*
- <sup>47</sup> *See* SHERWOOD, *supra* note 46.
- <sup>48</sup> *See, e.g.*, REICHMANN & HASENZAHN, *supra* note 45, at 24.
- <sup>49</sup> There is nothing unusual about this state of affairs, as companies take advantage of patents, product differentiation, language differences, and other opportunities to engage in price discrimination among consumers in different countries, thus maximizing their overall revenue. At some level, we may also find it morally acceptable to have developed world consumers subsidize poorer consumers. *See* Thomas Cotter, *Market Fundamentalism and the TRIPS Agreement*, 22 *CARDOZO ARTS & ENT. L.J.* 307, 337 (2004) (making such a moral argument). An inability to secure a certain return (or *any* return) in some countries could, however, make a difference at the margins where a drug or other product has a smaller market and/or less price elasticity in the developed world.
- <sup>50</sup> *See* Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 *CHI. J. INT'L L.* 47, 62-63 (2002) (discussing dearth of research on "essential medicines" for diseases that plague developing world and arguing that lack of research may be attributable to lack of intellectual property protection).
- <sup>51</sup> *See generally* F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 *MINN. L. REV.* 697 (2001).
- <sup>52</sup> *See* Srividhya Ragavan, *A "Patent" Restriction On Research & Development: Infringers Or Innovators?*, 1 *J. L., Tech & Policy* 73 (2004) (stating that IP law harmonization will "suffer unless developing countries can benefit from it. Otherwise, even developing countries that amend patent legislation to become TRIPS compliant will relax implementation"); Peter K Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 *AM. U. L. REV.* 131, 207-11 (2000) (noting this dynamic at work in China and advocating local benefits from IP to as a way to promote greater IP protection).
- <sup>53</sup> Reichman, *supra* note 12, at 465.
- <sup>54</sup> *See id.*
- <sup>55</sup> *See* Ragavan, *supra* note 54.
- <sup>56</sup> *Id.*
- <sup>57</sup> *See* Robert M. Sherwood et al., *Promotion of Inventiveness in Developing Countries Through a More Advanced Patent Administration*, 39 *IDEA* 473 (1999).
- <sup>58</sup> *See* Ragavan, *supra* note 54, at 97-98 (citing example of Indian computer industry supporting IP rights once it realized that they were in their own economic interest, as well as examples of Japan, Hong Kong, Taiwan, and South Korea supporting IP rights once they produced local benefits).
- <sup>59</sup> For a primer on applying the new institutional economics to development issues, *see* FREDERIC SAUTET, MERCATUS CENTER, GEO.MASON UNIV, *THE ROLE OF INSTITUTIONS IN ENTREPRENEURSHIP: IMPLICATIONS FOR DEVELOPMENT POLICY* (2005), *available at* <http://www.mercatus.org/pdf/materials/1053.pdf> (last visited June 20, 2005).
- <sup>60</sup> Douglass C. North, *Privatization, Incentives and Economic Performance*, *ECONOMICS WORKING PAPER ARCHIVE* (Wash. U. Economics, Working Paper No. 8, 1994), *available at* <http://econwpa.wustl.edu:8089/eps/eh/papers/9411/9411002.pdf> (last visited June 20, 2005); *also published in* *THE PRIVATIZATION PROCESS: A WORLDWIDE PERSPECTIVE* (Terry L. Anderson & Peter J. Hill eds., 1996).
- <sup>61</sup> *Id.*; *see also* Sautet, *supra* note 61.
- <sup>62</sup> On the other hand, the poor institutional climate of least developed countries also often makes charitable assistance ineffective. For example, access to medicine may not be a failure of the intellectual property system so much as a failure of governments and the public health system to deliver basic health care. *See infra* nn. 104 - 127 and accompanying text.
- <sup>63</sup> *See* Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 *INT'L LAW* 835 (1996).
- <sup>64</sup> *See supra* note 26 and accompanying text.
- <sup>65</sup> REICHMANN & HASENZAHN, *supra* note 45, at 10.
- <sup>66</sup> It stretches back to the 1883 at least. *See id.* at 10-11 (describing history of compulsory licensing in various treaties and countries).
- <sup>67</sup> *Id.* at 10; *see also* Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 *IDEA* 349, 349-50 (1993).
- <sup>68</sup> Friedrich-Karl Beier, *Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law*, 30 *INT'L REV. INDUS. PROP. & COPYRIGHT L.* 251, 265-66 (1999).
- <sup>69</sup> *See* REICHMANN & HASENZAHN, *supra* note 45.
- <sup>70</sup> *See id.*
- <sup>71</sup> TRIPS Agreement, *supra* note 11, at ¶ 31.
- <sup>72</sup> Another provision gave those least developed countries that had not yet enacted pharmaceutical patent protection until 2016 to do so, with the opportunity to seek further extensions.
- <sup>73</sup> Press Release, World Trade Organization, Decision Remove Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), *available at* [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm) (last visited Aug. 4, 2005).
- <sup>74</sup> *See, e.g.*, Press Release, Health Gap Global Access Project, The Incredible Shrinking Doha Declaration (August 26, 2003), *available at* [http://www.healthgap.org/press\\_releases/03/082603\\_HGAP\\_BP\\_WTO\\_Shink\\_Doha.html](http://www.healthgap.org/press_releases/03/082603_HGAP_BP_WTO_Shink_Doha.html) (last visited June 21, 2005) (asserting that implementation of the Doha Declaration shows that "the U.S. remains more committed to maximizing profits for the most profitable industry in the world, Big Pharma, than it is to the million of lives at stake").

<sup>75</sup> See *id.*; CECILIA OH, THIRD WORLD NETWORK, TRIPS AND PHARMACEUTICALS: A CASE OF CORPORATE PROFITS OVER PUBLIC HEALTH, (2000), available at <http://www.twinside.org.sg/title/twr120a.htm> (last visited June 22, 2005) (asserting that “[o]f the 50% of the patients in developing countries who lack access to essential drugs, many die because the drugs are patented and therefore too expensive”).

<sup>76</sup> See CPTech, RECENT HEALTH-RELATED COMPULSORY LICENSES AND DISPUTES, available at <http://www.cptech.org/ip/health/cl/recent-examples.html> (last visited June 22, 2005) (collecting examples of a handful of [mostly unsuccessful] initiatives to impose compulsory licensing).

<sup>77</sup> JAMES LOVE, CPTech, CPTech STATEMENT ON WTO DEAL ON EXPORTS OF MEDICINES (Aug. 2003), available at <http://www.cptech.org/ip/wto/p6/cptech08302003.html> (last visited June 22, 2005) (“The next step for public health activists will be to be more pro-active on trade and public health, both locally and globally. Locally it is now time for countries to give effect to paragraph 4 of the Doha Declaration, and actually issue compulsory licenses to promote access to medicine for all.”).

<sup>78</sup> TRIPS Agreement, *supra* note 11, at ¶ 31.

<sup>79</sup> See Cotter, *supra* note 51, at 334.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> See CPTech, PROPOSAL FOR MEDICAL R&D TREATY, available at <http://www.cptech.org/workingdrafts/rndtreaty.html> (last visited Aug. 4, 2005).

<sup>83</sup> Letter from James Love, Director, CPTech, to World Health Organization Commission on Intellectual Property, Innovation and Health (Feb. 24, 2005), available at <http://www.cptech.org/workingdrafts/rndsignonletter.html> (last visited Aug. 4, 2005).

<sup>84</sup> *Id.*

<sup>85</sup> CPTech, MEDICAL RESEARCH AND DEVELOPMENT TREATY ¶ 4, (Feb. 7, 2005) (hereinafter MRDT), available at <http://www.cptech.org/workingdrafts/rndtreaty4.pdf> (last visited June 22, 2005).

<sup>86</sup> *Id.* at ¶ 5.

<sup>87</sup> *Id.* at ¶ 7.

<sup>88</sup> *Id.* at ¶ 13.

<sup>89</sup> *Id.* at ¶¶ 14, 15.

<sup>90</sup> *Id.* at ¶ 16.

<sup>91</sup> Andrew Jack, *WHO Members Urged to Sign Kyoto-Style Medical Treaty*, FIN. TIMES 7, February 25, 2005.

<sup>92</sup> See *id.*

<sup>93</sup> WORLD HEALTH ORGANIZATION, WHO MEDICINES STRATEGY: COUNTRIES AT THE CORE 2004 – 2007 14 (2004), available at [http://www.who.int/medicines/strategy/MedicinesStrategy2004\\_2007/MedicinesStrategy2004\\_7English.pdf](http://www.who.int/medicines/strategy/MedicinesStrategy2004_2007/MedicinesStrategy2004_7English.pdf) (last visited Aug. 4, 2005).

<sup>94</sup> *Id.* at 3. (“In developing countries, where an estimated 40 million people are infected with HIV/AIDS, life-saving antiretroviral medicines . . . are available to only 300,000 of the 5-6 million people currently in need of treatment.”).

<sup>95</sup> WORLD HEALTH ORGANIZATION ESSENTIAL DRUGS AND MEDICINES HOMEPAGE, available at <http://www.who.int/medicines> (WHO defines essential medicines as follows: “Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.”) (Note that the essential medicines concept considers cost, so it may, by definition, exclude certain more costly patented drugs. (But WHO does not directly consider patent status in creating the list.) On the other hand, it includes a number of relatively expensive antiretrovirals used against the HIV virus, presumably because they are no inexpensive substitutes, which makes them “essential.” The list is thus as authoritative a list of the most important drugs as is likely to exist.) (last visited June 22, 2005).

<sup>96</sup> Amir Attaran, *How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?* 23 HEALTH AFF. 155 (2004).

<sup>97</sup> *Id.*

<sup>98</sup> See Letter from Connie Liu, Global Health Chair, American Medical Student Association & Sanjay Basu, AIDS Program, Yale University School of Medicine, to Dr. Amir Attaran, Royal Institute of International Affairs and Idealith Research Foundation (May 11, 2004), available at <http://content.healthaffairs.org/cgi/eletters/23/3/155> (last visited June 20, 2005).

<sup>99</sup> Consumer Project on Technology, *Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral drugs in Africa* (Oct. 16, 2001), <http://www.cptech.org/ip/health/africa/dopatents/matterinafrica.html> (last visited June 22, 2005).

<sup>100</sup> As the WHO report cited previously describes, billions of people “have no regular access to quality essential medicines.” WORLD HEALTH ORGANIZATION, THE WHO REPORT ON INFECTIOUS DISEASES 1999: REMOVING OBSTACLES TO HEALTHY DEVELOPMENT (1999), available at <http://www.who.int/infectious-disease-report/pages/ch4text.html> (Not just to some medicines or to patented medicines. Rather, the problem is a total failure of the public health system.) (last visited June 22, 2005).

<sup>101</sup> *Id.*

<sup>102</sup> PHILIP STEVENS, INTERNATIONAL POLICY NETWORK, DISEASES OF POVERTY AND THE 10/90 GAP 10 (2004), available at [http://www.fightingdiseases.org/pdf/Diseases\\_of\\_Poverty\\_FINAL.pdf](http://www.fightingdiseases.org/pdf/Diseases_of_Poverty_FINAL.pdf) (last visited Aug. 4, 2005).

<sup>103</sup> Libby Levinson & Richard Laing, *The Hidden Costs of Essential Medicines*, 33 ESSENTIAL DRUGS MONITOR 20 (WHO 2003), available at [http://www.who.int/medicines/library/monitor/33/EDM33\\_20-21\\_Hidden\\_e.pdf](http://www.who.int/medicines/library/monitor/33/EDM33_20-21_Hidden_e.pdf) (last visited Aug. 4, 2005).

<sup>104</sup> *Id.* at 21.

<sup>105</sup> *Id.*

- <sup>106</sup> *Id.* A different study looked at a wider sample of countries and concluded that “the global average of these combined taxes was eighteen percent of the total price, with Malaysia having the lowest rate at 0.01 percent and India the highest at fifty-five per cent.” International Policy Network, *supra* note 104, at 9 (citing EUROPEAN COMMISSION, WORKING DOCUMENT: DEVELOPING COUNTRIES’ DUTIES AND TAXES ON ESSENTIAL MEDICINES USED IN THE TREATMENT OF THE MAJOR COMMUNICABLE DISEASES (2003), available at <http://trade-info.cec.eu.int/doclib/html/113184.htm>) (last visited Aug. 4, 2005).
- <sup>107</sup> INTERNATIONAL POLICY NETWORK, *supra* note 104, at 9 – 10.
- <sup>108</sup> *Id.* at 9.
- <sup>109</sup> *Id.* at 9 – 10.
- <sup>110</sup> Daniel Dutra, *Brazil Space Program to Get Greater Funding*, BRAZIL MAGAZINE (Jan. 28, 2005), available at <http://www.brazilmag.com/content/view/1283/49/> (last visited Aug. 4, 2005).
- <sup>111</sup> K.S. Jayaraman, *India Approves Moon Mission*, SPACE.COM, Aug. 19, 2003, available at [http://www.space.com/missionlaunches/india\\_moon\\_030819.html](http://www.space.com/missionlaunches/india_moon_030819.html) (last visited Aug. 5, 2005).
- <sup>112</sup> Glenn Kessler & Colum Lynch, *U.S. Calls Killings In Sudan Genocide*, WASH. POST, Sept. 10, 2004, at A1.
- <sup>113</sup> Warren Hoge, *Zimbabwe’s policy called ‘disastrous’: U.N. Report Blames President Mugabe for Causing 700,000 People to be Homeless*, NEW YORK TIMES, July 23, 2005, at A9.
- <sup>114</sup> John Donnelly, *In Zimbabwe, Aids Care Done On the Cheap*, BOSTON GLOBE, May 3, 2005.
- <sup>115</sup> *Id.*
- <sup>116</sup> See Michael Fleshman, *Drug Price Plunge Energizes Aids Fight*, 15 AFRICA RECOVERY 1 (June 2001), available at <http://www.un.org/ecosocdev/geninfo/afrec/vol15no1/151aids1.htm> (last visited Aug. 4, 2005).
- <sup>117</sup> See, e.g., Zadie Neufville, *HEALTH-JAMAICA: AIDS Drug Concessions Deemed Insufficient*, INTER PRESS SERVICE, Feb. 22, 2002, available at <http://www.aegis.com/news/ips/2002/Ip020216.html> (last visited Aug. 4, 2005); GUMISAI MUTUME, THIRD WORLD NETWORK, AIDS ACTIVISTS MARCH AGAINST PHARMACEUTICAL COMPANIES (March 12, 2001), available at <http://www.twinside.org.sg/title/against.htm> (last visited Aug. 4, 2005).
- <sup>118</sup> See *id.*
- <sup>119</sup> NATIONAL UNION OF PUBLIC AND GENERAL EMPLOYEES NEWS, AIDS DRUG PRICE CUTS DISTRACTS FROM REAL ISSUE: OXFAM (March 8, 2001), available at [http://www.nupge.ca/news\\_2001/news\\_ma01/n08ma01b.htm](http://www.nupge.ca/news_2001/news_ma01/n08ma01b.htm) (last visited Aug. 2, 2005).
- <sup>120</sup> Gilbert Burnham and T. Mebrahtu, *Review: The Delivery of Ivermectin (Mectizan)* 9 TROPICAL MEDICINE & INTERNATIONAL HEALTH A26 (2004), available at <http://www.blackwell-synergy.com/doi/full/10.1111/j.1365-3156.2004.01211.x> (follow “View/Print PDF article (598K)” hyperlink).
- <sup>121</sup> See *id.*
- <sup>122</sup> JOHN HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, MECTIZAN STUDIES PRESENTED AT SYMPOSIUM (May 17, 2004), available at [http://www.jhsph.edu/publichealthnews/articles/Burnham\\_Mectizan\\_event.html](http://www.jhsph.edu/publichealthnews/articles/Burnham_Mectizan_event.html) (last visited Aug. 4, 2005).
- <sup>123</sup> See DIFLUCAN PARTNERSHIP, DIFLUCAN PARTNERSHIP PROGRAMME, available at <http://www.diflucanpartnership.org/en/welcome/> (last visited June 15, 2005).
- <sup>124</sup> See, e.g., Press Release, Treatment Action Campaign, Diflucan Watch: Assessment of Pfizer’s Diflucan Donation (July 19, 2001), available at [http://www.tac.org.za/newsletter/2001/ns19\\_07\\_2001.txt](http://www.tac.org.za/newsletter/2001/ns19_07_2001.txt) (“TAC believes the donation is a greedy attempt to squeeze the maximum profits out of Diflucan in the dying days of Pfizer’s patent on the drug.”).
- <sup>125</sup> See FRIEDRICH A. HAYEK, THE FATAL CONCEIT: THE ERRORS OF SOCIALISM (University of Chicago Press 1991).
- <sup>126</sup> The Digital Divide is the phrase often used to describe the uneven distribution of the benefits of the information technology revolution between the developed and developing countries and within societies.
- <sup>127</sup> See *supra* notes 32 - 39 and accompanying text.
- <sup>128</sup> The Geneva Phase of the Summit established a Declaration of Principles (hereinafter WSIS Principles) and Plan of Action (hereinafter WSIS Plan) for the summit designed to support “An Information Society for All” (see, respectively, WORLD SUMMIT ON THE INFORMATION SOCIETY, DECLARATION OF PRINCIPLES, BUILDING THE INFORMATION SOCIETY: A GLOBAL CHALLENGE IN THE NEW MILLENNIUM, WSIS-03/GENEVA/DOC/4-E(2003), [http://www.itu.int/wsis/documents/doc\\_multi.asp?lang=en&id=1161|1160](http://www.itu.int/wsis/documents/doc_multi.asp?lang=en&id=1161|1160) (last visited Aug. 5, 2005) and WORLD SUMMIT ON THE INFORMATION SOCIETY, PLAN OF ACTION, WSIS-03/GENEVA/DOC/5-E (2003), available at [http://www.itu.int/wsis/documents/doc\\_multi.asp?lang=en&id=1161|1160](http://www.itu.int/wsis/documents/doc_multi.asp?lang=en&id=1161|1160) (last visited Aug. 5, 2005)).
- <sup>129</sup> See International Telecommunication Union Res. 73 (1998), available at <http://www.itu.int/council/wsis/R73.html> (last visited Aug. 5, 2005).
- <sup>130</sup> See G.A. Res. 56/183, U.N. Doc. A/RES/56/183 (Jan. 31, 2002), available at [http://www.itu.int/wsis/docs/background/resolutions/56\\_183\\_unga\\_2002.pdf](http://www.itu.int/wsis/docs/background/resolutions/56_183_unga_2002.pdf) (last visited Aug. 5, 2005).
- <sup>131</sup> WSIS Plan, *supra* note 130, at ¶ 4 (“The objectives of the Plan of Action are to build an inclusive Information Society; to put the potential of knowledge and ICTs at the service of development; to promote the use of information and knowledge for the achievement of internationally agreed development goals, including those contained in the Millennium Declaration; and to address new challenges of the Information Society, at the national, regional and international levels.”).
- <sup>132</sup> See Section II.A *supra*.
- <sup>133</sup> WSIS Principles, *supra* note 130, at ¶ 4.
- <sup>134</sup> WSIS Principles, *supra* note 130, at ¶ 19.
- <sup>135</sup> WSIS Principles, *supra* note 130, at ¶ 20.
- <sup>136</sup> WSIS Plan, *supra* note 130, at ¶ 3.
- <sup>137</sup> See WORLD SUMMIT ON THE INFORMATION SOCIETY, ACCREDITATION AND REGISTRATION NGOs AND CIVIL SOCIETY ENTITIES (Feb. 2005), available at <http://www.itu.int/wsis/participation/accreditation/cs.html> (last visited Aug. 5, 2005).



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<sup>138</sup> See INTERNATIONAL TELECOMMUNICATION UNION, LIST OF ACCREDITED CIVIL SOCIETY ENTITIES AND NON-GOVERNMENTAL ORGANIZATIONS FOR THE WORLD SUMMIT ON THE INFORMATION SOCIETY (Feb. 2005), *available at* <http://www.itu.int/wsis/participation/accreditation/lists/civil-society.pdf> (last visited Aug. 5, 2005). In addition, NGOs that are in a consultative status to the United Nations Economic and Social Council (ECOSOC) are not required to submit to formal accreditation, and need only submit an expression of interest to participate. For a list of NGOs in a consultative status to ECOSOC, see UNITED NATIONS, NGOs IN CONSULTATIVE STATUS WITH ECOSOC (July 25, 2005), *available at* [http://www.un.org/esa/coordination/ngo/pdf/INF\\_List.pdf](http://www.un.org/esa/coordination/ngo/pdf/INF_List.pdf) (last visited Aug. 5, 2005); see also U.N. ECON. & SOC. COUNCIL [ECOSOC] RES. 1996/31, CONSULTATIVE RELATIONSHIP BETWEEN THE UNITED NATIONS AND NON-GOVERNMENTAL ORGANIZATIONS (July 25, 1996), *available at* <http://www.un.org/documents/ecosoc/res/1996/eres1996-31.htm> (last visited Aug. 5, 2005).

<sup>139</sup> See CONFERENCE OF NON-GOVERNMENTAL ORGANIZATIONS, WHO WE ARE, *available at* <http://www.ngocongo.org/ngowhow/> (last visited Aug. 5, 2005). CONGO ostensibly does not take positions on substantive matters but does provide, through special and ad hoc NGO Committees, fora for discussion of substantive matters by its members and members of the UN Secretariat, UN delegations, and other experts. *Id.* For example, CONGO worked with the WSIS Executive Secretariat and the Tunisian hosts of the WSIS to reserve significant portions of the PREPCOM-1 conference in Tunisia for civil society meetings.

<sup>140</sup> WSIS Principles, *supra* note 130, at ¶ 25.

<sup>141</sup> WSIS Principles, *supra* note 130, at ¶¶ 26, 28.

<sup>142</sup> *Id.* at ¶ 10.

<sup>143</sup> WSIS Plan, *supra* note 130, at ¶ 27.

<sup>144</sup> *Id.*

<sup>145</sup> See DIGITAL SOLIDARITY FUND, FROM THE DIGITAL DIVIDE TO THE NEED FOR A WORLDWIDE SOLIDARITY MOVEMENT, *available at* <http://www.dsf-fsn.org/en/02-en.htm> (last visited Aug. 5, 2005).

<sup>146</sup> See DIGITAL SOLIDARITY FUND, MORE THAN ONE HUNDRED AND TWENTY CITIES COMMIT TO THE DIGITAL SOLIDARITY FUND, *available at* <http://www.dsf-fsn.org/en/15c-a04-en.htm#> (last checked July 17, 2005).

<sup>147</sup> See DIGITAL SOLIDARITY FUND, THE DIGITAL SOLIDARITY FUND AND THE “GENEVA PRINCIPLE”, *available at* <http://www.dsf-fsn.org/en/19-en.htm> (last visited Aug. 5, 2005).

<sup>148</sup> WSIS Principles, *supra* note 130, at ¶ 27.

<sup>149</sup> *Id.*

<sup>150</sup> WSIS Principles, *supra* note 130, at ¶ 38.

<sup>151</sup> *Id.* at ¶ 39.

<sup>152</sup> See *supra* Section IV.

<sup>153</sup> WSIS Principles, *supra* note 130, at ¶ 42.

<sup>154</sup> *Id.*