I. INTRODUCTION

Recent activity at major intergovernmental organizations reflects a renewed emphasis on making the international intellectual property system work to foster global health in developing countries. The World Intellectual Property Organization1 (“WIPO”) recently approved a historic “Development Agenda” – a wide-ranging set of reforms that reorients WIPO towards development and reconfigures how the organization makes policy, provides technical assistance, and is administered.2 Such an initiative may seem natural for the only inter-governmental organization (IGO) that is focused primarily on intellectual property, but such reforms are not restricted to WIPO. The World Health Organization3 (“WHO”) has launched its own development agenda of sorts – an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (“IGWG”) that is tasked with preparing “a global strategy and plan of action” aimed at “securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area.”4 Several other IGOs have implemented programs designed to help developing countries build capacity to meet their intellectual property obligations in a way that fosters public health and access to medicines in those countries.5

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4 See generally World Health Organization [WHO], www.who.int.

For example, the World Trade Organization is engaged in an ongoing process of amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)
In Part II of this Article, I describe these initiatives with particular emphasis on the proposals that have been approved or (in the case of the WHO working group) upon which Member states have reached consensus. In Part III, I compare the initiatives and examine how they might be expected to facilitate collaboration between the two IGOs. In Part IV, I pose some questions prompted by the diversity and ambition of the proposals that make up the initiatives. For example, given the institutional missions and commonly understood core competencies of the IGOs that have implemented these initiatives, how can they be expected interact, overlap, and/or conflict, and how might they be modified so that they build on each other? Can these initiatives be expected to improve access to medicines and needs-driven innovation in developing countries, particularly given the dire need in many developing countries for technical assistance with respect to intellectual property policy?

II. THE INITIATIVES

A. THE WIPO DEVELOPMENT AGENDA

The WIPO Development Agenda is the culmination of a three year process that began with an eight-page proposal submitted in August, 2004 by the delegations of Brazil and Argentina to the WIPO General Assembly.6 That proposal noted “the need to integrate the ‘development dimension’ into policy making on intellectual property protection”7 and called for, among other things: the establishment of a new subsidiary body within WIPO to examine technology transfer; a new treaty to promote access to the results of publicly funded research in developed countries; fair enforcement of IP rights; and more development-oriented technical cooperation and assistance.8

Just over three years later, the WIPO General Assembly voted to adopt forty-five recommendations made by the Provisional Committee on Proposals to make it easier for developing countries to obtain less expensive, generic versions of patented medicines. The United Nations Conference on Trade and Development, together with the International Centre for Trade and Sustainable Development, is implementing a Capacity Building Project on Intellectual Property Rights (IPRs) and Sustainable Development that conducts research designed to improve understanding of the implications of the TRIPS Agreement for developing countries and to “strengthen the analytical and negotiating capacity of developing countries so that they are better able to participate in IPR-related negotiations in an informed fashion in furtherance of their sustainable development objectives.” See Capacity Building Project on Intellectual Property Rights, www.iprsonline.org unctadictsd/description.htm. The United Nations Development Programme (“UNDP”) has launched a capacity building project designed help developing countries provide access to HIV/AIDS drugs in the context of the flexibilities and safeguards within TRIPS, through technical assistance and facilitation. See UNDP, Intellectual Property Rights, www.undp.org/poverty/intel.htm; see also Press Release, UNDP, Fostering Appropriate National Responses to Intellectual Property and Access to Medicine (Oct. 26, 2006), content.undp.org/go/newsroom/categoryID=349428&lang=en.

7 Id. at II.
8 Id. at V-VII.
Related to a WIPO Development Agenda ("PCDA") and to establish a Committee on Development and Intellectual Property to implement the recommendations.\(^9\) The PCDA's recommendations were taken from many proposals submitted by various Members over the course of four PCDA meetings.\(^10\) The recommendations are organized into five clusters, and certain proposals are to be implemented immediately.\(^11\)

Cluster A, "Technical Assistance And Capacity Building," contains 14 proposals calling for technical assistance that is "development-oriented, demand-driven and transparent," to quote from the first proposal.\(^12\) Among other things, the proposals call for increased technical assistance, more transparency in technical assistance, assistance dealing with IP-related anticompetitive practices, information sharing, capacity-building, development of an intellectual property infrastructure, and provision of advice on flexibilities contained in the TRIPS Agreement.\(^13\)

The proposals in Cluster B, "Norm-Setting, Flexibilities, Public Policy And Public Domain," comprise various institutional reforms that will govern the treaty-making process.\(^14\) The proposals appear to reflect a deep dissatisfaction on the part of developing countries with how WIPO has been run in the past, and thus include proposals: to make the norm-setting process "inclusive and member-driven," to take into account different levels of development, to consider a balance between costs and benefits, to be in line with the principle of neutrality of the WIPO Secretariat, and to be a participatory process that takes into consideration the interests and priorities of all WIPO Member States and the viewpoints of other stakeholders - including accredited IGOs and NGOs.\(^15\) Proposal 22 is particularly notable, as it suggests new procedures under which the WIPO Secretariat would consider specific development-focused issues as part of its norm-setting activity.\(^16\)

Cluster C, "Technology Transfer, Information and Communication Technologies (ICT) And Access To Knowledge," comprises nine proposals focusing on IP-related technology transfer to developing countries and the IP-related aspects of ICT for developing countries.\(^17\) This Cluster seems intended to address a perception that WIPO's technical assistance has in the past been biased towards stronger intellectual property protections and enforcement to the detriment of developing countries.\(^18\)

Cluster D, "Assessment, Evaluation and Impact Studies" proposes a "yearly review and evaluation mechanism for the assessment of all its
development-oriented activities” and also recommends conducting new studies and other assessment activities aimed at evaluating the impact of IP on development.¹⁹

Cluster E, “Institutional Matters Including Mandate and Governance,”²⁰ presents a far-reaching set of proposals designed to broaden WIPO’s mandate so that it is more development-oriented. These proposals include WIPO studies on brain drain, intensified cooperation on IP-related issues with other United Nations agencies, and enhanced measures to ensure participation of civil society groups.²¹

Cluster F, “Other Issues,” citing Article 7 of TRIPS, proposes that WIPO “approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns.”²²

The WIPO Development Agenda has been described as “an unparalleled opportunity, especially for developing countries and public interest organizations, to place at the centre of the IP debate the question of the interrelation between IP and various facets of development.”²³ Indeed, it certainly reads as an ambitious reform that would move WIPO away from its traditional, singular emphasis on the promotion and expansion of intellectual property rights towards an organization that is development-oriented from the top down.

While the Development Agenda is clearly focused on the needs of developing countries, the forty-five proposals make no mention of public health, even though the issue of access to medicine for developing countries has been a major driver of the process. For example, the issue of public health is prominently featured in the August 2004 proposal by Brazil and Argentina.²⁴ Furthermore, proposals discussing public health were introduced throughout the process.²⁵

B. THE WHO’S INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH AND INTELLECTUAL PROPERTY

The World Health Organization’s most recent effort to explore the link between intellectual property rights and public health officially began in 2003 with a short report by the Secretariat to the fifty-sixth World Health Assembly, stressing the importance of innovation and the fact that “a significant proportion of the world’s population, especially in developing

²⁰ Id. Annex A, ¶¶ 39-44.
²¹ Id.
²² Id.
²⁴ WIPO, Proposal, supra note 6.
²⁵ Note, however, that the WHO is mentioned in Proposal 40 of WIPO’s General Report, which calls for intensified cooperation on IP issues with various UN agencies. WIPO, General Report, supra note 9, at 16 (“To request WIPO to intensify its cooperation on IP related issues with United Nations agencies, according to Member States’ orientation, in particular UNCTAD, UNEP, WHO, UNIDO, UNESCO and other relevant international organizations, especially the WTO in order to strengthen the coordination for maximum efficiency in undertaking development programs”).
countries, has yet to derive much benefit from innovations that are commonplace elsewhere.\textsuperscript{26} The report points out language in TRIPS regarding public health, nutrition and technology transfer, and offers several ways in which expansive intellectual property rights can jeopardize public health in developing countries - such as through prohibitively high prices, adverse affects on innovation, and inadequate capacity to manage intellectual property systems.\textsuperscript{27}

The report suggested that “rigorous analysis of the scientific, legal, economic, ethical, and human rights aspects of intellectual property as it relates to public health, and careful monitoring of this relationship in different national contexts could prove invaluable for national and international policies and practices that ensure both innovation to respond to unmet needs and access to existing technologies for health.”\textsuperscript{28} The World Health Assembly responded by establishing a Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH”) that would:

- collect data and proposals from different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.\textsuperscript{29}

CIPIH, which comprised a diverse group representing academia, industry, and public health advocates, among other groups,\textsuperscript{30} spent the next two years conducting extensive research, holding meetings with stakeholders, hosting workshops, and commissioning studies. In April 2006, it submitted a comprehensive report addressed to the Director-General of WHO.\textsuperscript{31} The report attempts to examine public health and development not just as they relate to intellectual property rights, but in the context of “the bigger picture,”\textsuperscript{32} taking in such factors as regulation and political commitment.\textsuperscript{33} The report comprehensively examines the development and delivery of medicines in three parts: early stage research, “the long road from discovery to development,” and delivery. The report then examines how innovation can be fostered in developing countries and concludes with a chapter setting forth recommendations. CIPIH concludes, among other things, that the necessary incentives are limited or non-existent with respect to the development of

\begin{thebibliography}{9}
\bibitem{27} Id.
\bibitem{28} Id. ¶ 23.
\bibitem{31} Id.
\bibitem{32} Id. ¶ 23.
\bibitem{33} Id. For a broad overview of CIPIH’S findings, see CIPIH, Frequently Asked Questions, www.who.int/intellectualproperty/documents/thereport/questions/en/index.html (last visited Apr. 17, 2008) [hereinafter CIPIH, FAQ].
\end{thebibliography}
drugs that address health problems predominantly found in developing countries, getting drugs to patients is a major challenge in this area, and that, while much has been done to provide additional support, significant controversy remains as to the efficacy of various intellectual property tools such as recent TRIPS amendments.\textsuperscript{34}

The CIPIH report is not without controversy, and several commissioners submitted commentaries at the end of the report taking issue with a number of its conclusions.\textsuperscript{35} However, the report is notable for several reasons. Perhaps most notable—and most appropriate for a WHO-based project—it takes a holistic approach to the issue that considers not only intellectual property, but the many other factors affecting innovation, public health, and development. Thus, it devotes separate chapters to discovery, development, and delivery, examining at each stage where gaps in the process exist that fail to adequately address diseases principally affecting developing countries and offering detailed proposals for what might be done to address

\textsuperscript{34}Id. \textit{passim}. The report's conclusions are summarized by CIPIH as follows:

Intellectual property rights are a general incentive provided by governments to promote innovation in all fields. In respect of public health, they are embedded in a set of other incentives which influence the pattern of innovation. They need to be looked at as part of a bigger picture.

In particular, because of the small and uncertain market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing countries, the incentive effect of intellectual property rights may be limited or non-existent.

Because intellectual property rights may not be an effective incentive in this area, there is a need for other incentives and financial mechanisms to be put in place and for collaborative efforts between different stakeholders.

Without access to the products of innovation, there can be no public health benefits. Defining the conditions by which products can be accessed is therefore an important aspect of the report.

There has been significant progress in recent years, in particular initiatives taken by different stakeholders to promote innovation in health-care products e.g. increased funding by foundations and the formation of public-private partnerships for product development.

This momentum for change is welcome but is insufficient. More needs to be done. There are unsettled and debated issues in intellectual property for example the effectiveness of the recent amendment to TRIPS in increasing access to medicines in countries without manufacturing capacity, the impact of data exclusivity laws and the impact of intellectual property provisions in bilateral trade agreements.

And there is a need to ensure enhanced financing on a sustainable basis of innovation and access and promote synergy between the different partners. Ultimately it is a responsibility that governments must accept if these objectives are to be achieved.

It is appropriate that WHO should now take the lead in promoting a more sustainable and better-funded effort and addressing unresolved issues. WHO should accordingly develop a Global Plan of Action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.

\textsuperscript{35}For example, Professors Carlos Correa and Pakdee Pothisiri suggested, among other things, that more attention should have been paid to what they called a "drastic decline in the capacity of the pharmaceutical industry to innovate" and called for additional analysis on the negative effects of TRIPS-plus provisions in free trade agreements. CIPIH Report, \textit{supra} note 30, at 201. Trevor Jones questioned the report's connection between patents and pricing and disagreed with the report's call for further reform of the patent system, among other things. \textit{Id.} at 202.
those gaps. These proposals range from investing appropriately in health delivery infrastructure, to providing in legislation for the power to use compulsory licensing where that power might be useful as a means to promote health research, or access to cheaper medicines. It is important to note that the report stops short of proposing comprehensive reform of the international IP system; and it does not propose additional schemes for incentivizing innovation (such as innovation prizes) as alternatives to the existing intellectual property regime. Furthermore, the very breadth of the report may have distracted from its mission and led to a less-focused analysis and weaker recommendations, as Commissioner Correa argued in a comment to the report.

The report does recommend additional incentive mechanisms as a complement to the existing system. It calls for further work on a research and development treaty; recommends that WHO “now take the lead in promoting a more sustainable and better-funded effort and addressing unresolved issues;” and asks WHO to put together a Global Plan of Action that would “secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.”

In response to the Report, the World Health Assembly created the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (“IGWG”). The IGWG is tasked with creating:

- a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission; such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area.

The most recent IGWG meeting, its second, took place in November 2007, and ended with some progress but without consensus on many important issues.

At the November meeting, Drafting Groups A and B of the IGWG worked on a forty-four point draft global strategy. On some issues,
consensus was reached; others were negotiated without resolution; and still others were not discussed at all. The proposed global strategy presents eight proposed elements, which are preceded by three parts: "The context," "The aim," and "The principles."

The draft strategy opens by setting forth "The context"; the working group has reached consensus on a description of the problem in twelve paragraphs, including a statement that intellectual property rights are an important incentive for the development of new health care products but that IP rights alone do "not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain." This section also includes statements on TRIPS flexibilities and recognition that developing countries may face obstacles in implementing such flexibilities (although just what obstacles those may be remains under discussion). The drafting groups did not reach consensus, unfortunately, on some relatively basic issues, such as whether the CIPIH report "provides an effective analysis of the problems and makes recommendations that form a basis of future actions."

With respect to the second part, "The aim," the drafting groups have agreed that the aim of the global strategy is to "provide a medium-term framework based on the recommendations of the CIPIH," although consensus has not yet been reached on whether the focus will be on Type II and Type III diseases and/or the specific needs of developing countries in relation to Type I diseases.

Paragraph 14 b) of this Part provides that the Elements of the global strategy will "Promote R&D focusing on Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases." Consensus was reached on this statement, but not with respect to a critical footnote that would specify which diseases the entire draft strategy would be focused on; the footnote names HIV/AIDS and TB for Type II diseases and nine Type III diseases. Were consensus to be reached on this footnote, it would mean that the scope of the entire Global Strategy and Plan of Action would be limited to these eleven diseases and those Type I diseases that "are increasingly prevalence [sic] in developing countries . . . ." 

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48 Id.
49 Id. ¶ 7.
50 Id. ¶¶ 8, 9.
51 Id. ¶ 12.
52 Id. ¶ 6.
53 Id. ¶ 13.
54 Id. ¶ 14 b). As specified by the Commission on Macroeconomics and Health and discussed in the CIPIH Report, Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. Id. at n. 1.
55 Id. at n.1.
56 Id. at n.1.
Paragraph 14 sets forth various “elements” of the global strategy, which are designed “to promote innovation, build capacity, improve access and mobilize resources.” Of particular interest is Paragraph 14 e), stating a goal of “encourag[ing] and support[ing] the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries.” The rest of the clause is still subject to discussion as indicated by the bracketed text: “protects public health and promotes access to [health products]/[medicines] for all, as well as explore and implement, where appropriate, [innovative]/[alternative] incentive schemes for R&D [to complement the existing ones].”

The draft global strategy’s third part, “The principles,” presents twelve principles upon which the draft global strategy’s action items are based. The part begins by tying this project explicitly to WHO’s mandate as set forth in its Constitution:

The WHO Constitution states that “the objective of WHO shall be the attainment by all peoples of the highest possible level of health”. Accordingly, WHO shall play a strategic and pro-active role in contributing to pursue the agenda on “public health, innovation and intellectual property”, within its mandate and its constitutional objectives.

The principles on which consensus has been reached are relatively ambitious. The IGWG agrees, for example, that the highest attainable standard of health is a fundamental right of all people (but consensus has not yet been reached on whether to cite the International Covenant on Economic, Social and Cultural Rights). The drafting groups have also reached consensus that “Intellectual Property Rights do not and should not prevent Member States from taking measures to protect public health,” which is a fundamental principle set forth in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Other principles upon which consensus was reached include statements that “International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health,” and that IP rights, while “an important incentive in the development of new health care products, [do] not meet the

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57 Id. ¶ 14 e). This sub-paragraph corresponds with what is referred to later in the draft global strategy as Element 5.
58 Id.
60 December 14, 2007 Progress Report, supra note 47, ¶ 15.
61 Id. ¶ 16.
62 Id. ¶ 17.
63 Id. ¶ 20.
need for the development of new products to fight diseases where the potential paying market is small or uncertain.  

The drafting groups have not reached consensus on whether to address trade in this part of the draft global strategy. Potential language includes statements that “[t]he objectives of public health and the interests of trade should be appropriately balanced and coordinated,” and that “[t]he right to health takes precedence over commercial interests.”  

The first proposed element of the plan, “Prioritizing research and development needs,” contemplates a canvas of global research and the development and formulation of explicit prioritized strategies for research and development at country and regional and inter-regional levels. The drafting groups also reached consensus on prioritizing research and development in traditional medicine; but could not agree on much else with respect to this issue, including whether it would include traditional knowledge, reference international instruments, or refer to indigenous peoples and local communities.  

The preface to Element 2, “Promoting research and development,” declares that “[t]here are many determinants of innovation capacity,” and calls for substantially enhancing the range of measures to support research into Type II and III diseases and the needs of developing countries with respect to Type I diseases. This element also calls for greater investment. The proposed actions to be taken comprise: support for national health research programs and strategic research networks; upstream research and development in developing countries; enhancing links between health and biomedical research and development; and improving access to knowledge and technology relevant to meet the public health needs of developing countries through public health libraries, as well as sharing the results of government funded research, databases and compound libraries. There is some consensus on these proposed actions. There are also proposed actions on which consensus has not been reached, such as providing open licensing for publicly funded and donor-funded research in developed countries, and considering research exemptions in the national legislation of developing countries.  

It is also important to highlight that consensus has been reached on action item 2.3(c), which anticipates further discussions on a Research and Development Treaty. This is a particularly notable development because such a treaty can be seen as a prelude to future alternative or compensatory incentive systems.

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66 Id. ¶ 18.
67 Id. ¶ 27, 28.
68 Id. ¶ 28 (1.3).
69 Id. ¶ 29.
70 Id.
71 Id. ¶ 30.
72 Id.
73 Id. ¶ 30(2.4)(d).
74 Id. ¶ 30(2.4)(e).
75 Id. ¶ 30(2.3)(c) (“encourage further exploratory discussions on the utility of possible intruments [sic] or mechanisms for essential health and biomedical R&D, including inter alia, a essential health and biomedical R&D treaty”).
Element 3, "Building and improving innovative capacity," presents a plan for building innovative capacity for developing countries through actions such as: supporting investment in human resources and knowledge bases,\(^7\) developing capacity-promoting policies for innovation like improved regulatory capacity\(^7\) and mitigation of loss of health professionals through migration,\(^8\) intensifying North-South and South-South partnerships, and improving mechanisms for ethical review in R&D. There is a consensus in favor a proposal to support policies to foster innovation based on traditional medicine "within an evidence-based framework," although how such support will be achieved is yet to be determined (for example, whether through promotion and documentation of traditional knowledge and natural genetics resources or by encouraging research on chemical entities used in traditional medicine).\(^9\) The fifth paragraph in this element — on which consensus has not been reached — proposes developing and implementing incentives for innovation and includes proposed language that would call for "alternative" incentives.\(^8\)

Element 4, "Transfer of Technology," calls for a wide range of collaborative efforts aimed at building and improving technology transfer related to health innovation.\(^8\) Proposed strategies include: developing new mechanisms to facilitate transfer of technology;\(^8\) devising a list of essential technologies\(^8\) developing best practices, investment and capacity building;\(^8\) and facilitating local and regional networks.\(^8\) Sub-paragraph 4.3 appears to remain far from consensus, probably because most of the proposed actions presented therein involve possible changes in intellectual property policy.\(^8\) Proposed actions include sharing patent databases,\(^7\) examining the feasibility of patent pools of upstream and downstream technologies to promote innovation,\(^8\) consideration of complementary or alternative mechanisms to promote health innovation,\(^8\) and encouraging "patenting and licensing polices that maximize access to innovations" for products relevant to developing countries' public health needs.\(^8\)

The action items in Element 5, "Application and Management of intellectual property to contribute to innovation and promote public health," are easily the most controversial; consensus has been reached on almost none of the proposed action items.\(^9\) In fact, the drafting groups did not even
discuss many of the Element 5 proposals at the most recent meeting. Proposals involve strengthening capacity to manage and apply intellectual property "in a manner oriented to public health needs and priorities of developing countries," creating databases on health patents and traditional knowledge, and encouraging WHO to provide technical assistance to countries that intend to make use of TRIPS flexibilities.

The proposed action items in Element 6, "Improving delivery and access," concern alternative incentive mechanisms. According to the draft strategy, the proposals are based on the principle that "support for and strengthening of health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products." Proposed actions encourage greater investment in health-delivery infrastructure and financing of health products, and greater ethical review and safety mechanisms.

The drafting groups did not discuss nuts-and-bolts proposals to, among other things, strengthen the WHO pre-qualification programme and harmonize drug marketing approval processes, including by clarifying the working relationship between drug regulatory authorities and patent offices. Similarly, the drafting groups did not get to proposed action 6.3, "promoting competition and ensuring that pricing of medicines is consistent with public health," which presents a litany of proposals intended to strengthen competition and affect pricing, many of which are grounded in accepted TRIPS flexibilities. These include (among other things): allowing compulsory licensing for manufacturing countries; utilizing TRIPS flexibilities, especially for parallel importation and the research exemption; and utilizing the Bolar Exception to stimulate generic market entry. Other proposals contemplate encouraging pharmaceutical companies to adopt transparent, consistent, and equitable pricing policies, supporting

92 Id.
93 Id. ¶ 36(5.1)(b).
94 Id. ¶ 36(5.1)(c) and (f), respectively.
95 Id. ¶ 36(2.3)(f).
96 Id. ¶ 37.
97 Id. ¶ 38(6.1).
98 Id. ¶ 38(6.2).
99 Id. ¶ 39(6.2)(e).
100 Id. ¶ 39(6.2)(g). The issue of "linkage" between regulatory authorities and intellectual property has been particularly controversial, and over the last few years such provisions have been agreed upon in several bilateral trade agreements with the United States. See, e.g., Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements, Occasional Paper 14, Quaker United Nations Office (2004) (arguing that the rules set up by the Agreements are generally prohibitively complicated for individuals operating in the real world); Rafael Pastor, The Impact of Free Trade Agreements on Intellectual Property Standards in a Post-TRIPS World n.48-52, bilaterals.org, April 4, 2006, www.bilaterals.org/article.php3?id_article=4311.
102 Id. ¶ 39(6.3)(d).
103 Id. ¶ 39(6.3)(g) (first alternative).
104 Id. ¶ 39(6.3)(g) (second alternative).
105 Id. ¶ 39(6.3)(e).
production and introduction of generic medicines in developing countries, and removing or reducing tariffs and taxes on health care products.

The proposed actions in Element 7, "Promote sustainable financing mechanisms," are directed towards further funding to support a long-term research and development effort, aimed at products that meet the health needs of developing countries, and identifying gaps in financing for health products and for research and development. One particularly detailed proposal, on which consensus has not been reached, calls for an expert task force on this issue. Another proposal, again on which consensus has not been reached, calls for a global R&D fund.

Some consensus has been reached on Element 8, "Establishing monitoring and reporting systems," which calls for systems to monitor performance and progress of this strategy. The Executive Board will submit a progress report to the Health Assembly every two years, and every four years a comprehensive evaluation of the strategy will be undertaken.

Draft text not assigned to any element, and not discussed at the most recent meeting, declares that implementation of this strategy by 2015 is a "global responsibility" that rests with a range of actors including WHO's Member states, the WHO Secretariat, WIPO, WTO, national institutions, development partners, academia, pharmaceutical companies, public–private partnerships, charitable foundations and nongovernmental organizations.

The IGWG is mandated to provide its global strategy and plan of action to the 2008 World Health Assembly, and is tentatively scheduled to resume work from April 28-May 3, 2008.

Although consensus has not been reached on many of the IGWG proposals in the draft global strategy and plan of action, it can at least be said that many proposals are on the table and are slated for further discussion prior to the World Health Assembly meeting in May 2008. The major areas of controversy are, not surprisingly, centered around how the Working Group will address intellectual property and free trade agreements in Element 5, the discussion of alternative incentive mechanisms in Element 6 (specifically whether such mechanisms will be considered as a complement to the IP system or an alternative to it), and the relationship between IP and the price of medicine.

More fundamentally, there is still some disagreement as to the role that WHO should have with respect to intellectual property. As discussed infra in Part IV, the United States has on several occasions questioned WHO's technical competence to advise Member States on intellectual property matters.

106 Id. ¶ 39(6.3)(a), (h), (i), 39(6.4).
107 Id. ¶ 39(6.3)(c).
108 Id. ¶ 40-42.
109 Id. ¶ 42(7.1)(a).
110 Id. ¶ 42(7.3).
111 Id. ¶ 43-44.
112 Id. ¶ 43.
113 Id. ¶ 26.
III. THE WIPO DEVELOPMENT AGENDA AND THE WHO IGWG DRAFT GLOBAL STRATEGY AND PLAN OF ACTION: A COMPARISON

A. Common Proposals

It may seem difficult to draw parallels between the WIPO Development Agenda, which is a set of institutional reforms, and the activities of CIPIH and the IGWG, which are directed towards a global strategy and plan of action on a particular issue. From a practical standpoint, however, the actual proposals put forth in each of these initiatives have much in common, including:

- Increased funding from developed countries;116
- Development of national and regional strategies for research and development and for IP;117
- Measures to promote competition and/or deal with anticompetitive behavior;118
- Enhanced technical assistance to and capacity building for developing countries;119
- Databases and information-sharing for patents;120
- Assistance to developing countries that intend to use TRIPS flexibilities;121
- Technology transfer;122
- Proposals for studies and research;123

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117 See, e.g., WIPO Development Agenda, supra note 116, ¶ 4; December 14, 2007 Progress Report, supra note 47, ¶¶ 28(1.2), 30(2.1).
118 See, e.g., WIPO Development Agenda, supra note 116, ¶¶ 7, 23, 32; December 14, 2007 Progress Report, supra note 47, ¶¶ 36(5.3), 39(6.3).
120 See, e.g., WIPO Development Agenda, supra note 116, ¶ 8; December 14, 2007 Progress Report, supra note 47, ¶ 36.
121 See, e.g., WIPO Development Agenda, supra note 116, ¶¶ 14, 17; December 14, 2007 Progress Report, supra note 47, ¶ 36(5.2).
123 See, e.g., WIPO Development Agenda, supra note 116, ¶¶ 34, 35 (proposing studies on constraints to and impact of IP); December 14, 2007 Progress Report, supra note 47, ¶ 28(1.1) (proposing to map global R&D with a view to identifying gaps that disproportionately affect developing countries), and ¶ 42(7.1) (proposing task force to study financing mechanisms).
Regular review of progress: the Development Agenda contemplates a yearly review, while the IGWG proposes the establishment of systems to measure performance and progress;  

Measures to address the migration of healthcare professionals and other highly skilled individuals from developing countries, or brain drain;  

Multilateral mechanisms such as a treaty on research and development or an instrument for protection of genetic resources, traditional knowledge, and folklore.

B. COLLABORATION BETWEEN WIPO, WHO, AND OTHER IGOs

Both initiatives mention coordination and cooperation with other IGOs. The Development Agenda urges WIPO to “cooperate with other IGOs to provide to developing countries, including LDCs, upon request, advice on how to gain access to and make use of intellectual property related information on technology, particularly in areas of special interest to the requesting parties,” and “to request WIPO to intensify its cooperation on IP related issues with United Nations agencies, according to Member States’ orientation, in particular UNCTAD, UNEP, WHO, UNIDO, UNESCO and other relevant international organizations, especially the WTO in order to strengthen the coordination for maximum efficiency in undertaking development programs.”

Similarly, many proposals for action that involve collaboration with other IGOs have been made in the IGWG. These include the creation of a Coordination Committee among WHO, WIPO and WTO to seek solutions on the issue of public health and intellectual property, collaboration with WIPO on assistance to developing countries with respect to implementation of TRIPS flexibilities and research exemptions, and collaboration between WIPO and the WTO to monitor the impact of IP on innovation and access to health-care products. Unfortunately, the IGWG drafting groups have not yet reached consensus on even one of these proposals.

Still, the new WIPO Committee on Development and IP would do well to review closely the proposals for collaboration now under consideration in the IGWG as it develops its work-program for implementation. This is significant,

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124 WIPO Development Agenda, supra note 116, ¶ 33.
125 December 14, 2007 Progress Report, supra note 47, at Element 8: Establishing monitoring and reporting systems.
126 Id.
127 WIPO Development Agenda, supra note 116, ¶ 39.
128 December 14, 2007 Progress Report, supra note 47, ¶ 2.3(c).
129 WIPO Development Agenda, supra note 116, at 18.
130 See, e.g., id. at Proposals 30, 40; December 14, 2007 Progress Report, supra note 47, at Proposed Actions 5.1, 5.2, 2.3, 8.2.
132 Id. at Proposal 40.
133 December 14, 2007 Progress Report, supra note 47, ¶ 5.1(c).
134 Id. ¶ 5.2(a).
135 Id. ¶ 2.3(1) (to be considered within Element 5).
136 Id. ¶ 8.2(b).
if only because the IGWG proposals are more specific than the Development Agenda proposals in terms of both the subject matter contemplated and the types of activities proposed. More importantly, however, WHO's considerable expertise and resources in the area of public health can and should be utilized to help WIPO as it investigates the impact of intellectual property and implements the many proposals providing for development-oriented technical assistance.

C. ADDITIONAL INCENTIVE SCHEMES FOR RESEARCH AND DEVELOPMENT

IGWG Proposal 5.3 contemplates additional schemes for research and development in addition to the international IP system. Whether these schemes will be “explored,”137 “examined” and promoted,3 or used as alternative or complementary to the IP system, remains to be determined. IGWG Proposal 5.3 contains proposals for examining the prize fund model, advance-market commitment approaches, assessing the impact of data exclusivity and data protection regulations, dealing with anticompetitive practices, and urging strict application of patentability criteria, among other things. This is one of the most contentious proposals under discussion and, like most of Element 5, was not discussed during the last meeting. In any event, the World Health Assembly has recently expressed support for additional incentive mechanisms. In April 2007, the WHA called for discussion:

that includes a range of incentive mechanisms including also addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries.139

If this proposal is to become WHO policy at some point in the future, it could provide a useful guide for the WIPO Committee on Development and IP as it works to implement various Development Agenda proposals, particularly Cluster B, “Norm-Setting, Flexibilities, Public Policy and Public Domain.” Similarly, since the WIPO Development Agenda makes no mention of alternative or complementary incentive mechanisms, the research contemplated in Proposals 35 and 37 could draw on the IGWG's work on this issue.140

137 Id. ¶ 5.3.
138 Id.
D. Governance

The WIPO Development Agenda process explicitly contemplates significant institutional reform, but the goal of the IGWG process is to develop a global strategy and plan of action directed toward implementing the CIPIH recommendations and not institutional reform. Consequently, unlike the Development Agenda, the IGWG proposals do not recommend measures related to governance or structural change.

While the IGWG process does not contemplate governance reforms, it has been subject to some of the same criticisms as have the WIPO procedures—most notably lack of transparency and exclusion of civil society groups. At the last IGWG meeting, only a set of pre-approved experts and a very small group of "concerned public and private entities," which included both industry groups and non-profit organizations, were allowed to attend, leaving many non-governmental organizations unable to observe or participate. The WIPO Development Agenda contains various proposals that deal explicitly with the issue of civil society participation, most notably proposal 42 which provides for "enhance[d] measures that ensure wide participation of civil society at large in WIPO activities," and proposal 43, which proposes "to consider how to improve WIPO’s role in finding partners to fund and execute projects for intellectual property related assistance."

It will be interesting to observe how and whether the differences between IGWG and the Development Agenda with respect to governance-related reforms will lead to diverging outcomes in the coming years.

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141 See discussion supra Parts II.A., II.B.
142 See generally WIPO Development Agenda, supra note 116; December 14, 2007 Progress Report, supra note 47.
145 See List of Experts and Concerned Entities for the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, www.who.int/gb/phi/pdf/igwg2/listofexpert-en.pdf (last visited Apr. 26, 2008). The "concerned public and private entities" permitted to attend were: The Bill & Melinda Gates Foundation; Biotechnology Industry Organization (BIO); Directorate of Science, Technology and Industry, Organization for Economic Cooperation and Development (OECD); Drugs for Neglected Diseases Initiative (DNDI); Global Forum for Health Research; Médecins Sans Frontières (MSF); Access to Essential Medicines Campaign; and Facilité Internationale d’Achat de Médicaments (UNITEID). Id.
146 See Essential Action, supra note 144.
147 WIPO Development Agenda, supra note 116, at 31.
148 Id. at 28.
E. TECHNICAL ASSISTANCE AND CAPACITY BUILDING

Both the WIPO Development Agenda and the IGWG Draft Global Strategy and Plan of Action present numerous proposals addressed to technical assistance for developing countries. It is perhaps in this area where these initiatives present the most likely and—in the short term—possibly the most important opportunity for collaboration between WIPO and WHO.

Developing countries have a substantial need for technical expertise on IP policy matters. Many developing countries need to get into compliance with their international obligations, such as TRIPS and trading agreements with their developed country trading partners, and this process often involves amending national legislation.\footnote{See id. at 16-21.} Some nations seek to employ flexibilities built into TRIPS and other instruments; and some are negotiating new instruments and new treaties.\footnote{See Tenu AVAFIA ET AL., THE ABILITY OF SELECT SUB-SAHARA AFRICAN COUNTRIES TO UTILISE TRIPS FLEXIBILITIES AND COMPETITION LAW TO ENSURE A SUSTAINABLE SUPPLY OF ESSENTIAL MEDICINES: A STUDY OF PRODUCING AND IMPORTING COUNTRIES § 1 (2006), www.iprsonline.org/unctadictsd/docs/Trade%20and%20Competition%2030%203%2006%20final%20Edit%202._%202.pdf; William New, supra note 2; Raghavan Chakravarthi, 'No!' to 'TRIPS-plus' IP standards, Third World Network, www.twnside.org.sg/title2/twr17id.htm.} Each of these tasks requires a deep knowledge of, if not expertise in, the international IP system. These tasks also require time and resources as policymakers meet with stakeholders, gather information, and ultimately make hard decisions about how the system must be structured—all in the shadow of acute health crises.\footnote{A recent ICTSD project illustrates the challenges facing developing country governments in setting IP policy. The ICTSD recently developed a Diagnostic Toolkit to aid the assessment of needs for IP technical and financial assistance in least-developed countries. See Mart LEESTI & Tom PENGELLY, TECHNICAL AND FINANCIAL CO-OPERATION NEEDS FOR IMPLEMENTATION OF THE WTO TRIPS AGREEMENT IN SIERRA LEONE: FINAL REPORT OF NEEDS ASSESSMENT ix (2007), www.iprsonline.org/ictsd/docs/Sierra_Leone%20final%20report%20with%20logos%20November%202007.pdf. This document outlines several steps necessary merely to assess a country's priority needs for technical and financial assistance, which include assessment of: the national development context; existing IP policy and legal framework; existing arrangements for IP administration; existing arrangements for IP enforcement and regulation; and existing arrangements for promoting use of the IP system for development and promoting innovation, technology transfer, and creativity. Id.}

Many developing country governments, however, do not yet have important elements of IP administration infrastructure, such as patent examination offices, in place.\footnote{See generally Peter Drahos, Developing Countries and International Intellectual Property Standard-Setting, 5 J. WORLD INTELL. PROP. 765 (2002).} Some do not have the budget for staff to evaluate and consider IP policy, not to mention IP experts in their health and education ministries, which could advise other offices on the impact IP has on their objectives. Talented lawyers and other IP experts migrate to the developed world (in fact, one WIPO Development Agenda proposal calls for a study on “brain drain”). Countries with small populations have a small pool of experts from which to draw. These are just a few of the challenges facing IP policymakers in the developing world.\footnote{WIPO Development Agenda, supra note 116, ¶ 35.}

Hence, the consensus that technical assistance to policymakers in developing countries on IP policy issues is vitally important. Both the WIPO
Development Agenda and the IGWG Draft Global Strategy and Plan of Action present new and interesting proposals dealing with technical assistance and capacity-building.\(^{155}\)

As discussed above, Cluster A of the WIPO Development Agenda is dedicated to technical assistance and capacity building.\(^{156}\) Its 14 proposals call for increased technical assistance and capacity building and start by requiring that technical assistance be “development-oriented, demand-driven and transparent.”\(^{157}\) Among other things, the proposals call for increased technical assistance, assistance dealing with IP-related anticompetitive practices, information sharing, domestic capacity-building for protection of domestic innovation as well as scientific and technological infrastructure, development of an intellectual property infrastructure, and provision of advice on flexibilities contained in the TRIPS Agreement.\(^{158}\) Several proposals also address transparency: technical assistance staff and consultants are directed to pay particular attention to the Code of Ethics and to avoid conflicts of interest,\(^{159}\) and a database will be created to “match specific IP-related development needs with available resources.”\(^{160}\) These proposals are intended to reform WIPO technical assistance, which many perceive to have been biased towards stronger IP protection and greater enforcement.\(^{161}\)

Likewise, a number of proposals in the IGWG process deal with capacity building and technical assistance, including measures to foster upstream research and product development in developing countries,\(^{162}\) and mechanisms to build developing country capacity for R&D and health innovation.\(^{163}\) Element 5, in turn, contains numerous proposals—on which no consensus has been reached—for increased information sharing, capacity building in the application and management of intellectual property,\(^{164}\) and technical support for application of TRIPS flexibilities.\(^{165}\)

Both initiatives’ proposals relating to technical assistance and capacity building represent important changes to the administration of the international IP system and to the international public health system. With respect to the WIPO Development Agenda, WIPO can be expected to provide technical assistance that is more “development-oriented, demand-driven and transparent” than before,\(^{166}\) and presumably WIPO will be providing more technical assistance overall. In light of the IGWG Global Strategy and Plan of Action, WHO could soon be either providing IP-related technical assistance of its own, or collaborating with other IGOs on such assistance.

The WIPO Committee on Development and IP and WHO’s IGWG should study the proposals in each of these initiatives in order to collaborate actively.
as they move to implement the proposals. The rationale for this recommendation is that such collaboration presents an opportunity to take a comprehensive approach to technical assistance and capacity-building that focuses not only on the intellectual property system, but also on research and development, alternative or complementary forms of innovation incentives, drug delivery and development infrastructure, and other needs that must be considered when setting IP policy.

IV. QUESTIONS PRESENTED

In advance of the most recent IGWG meeting, the United States government sent a demarche to several Latin American governments discussing the upcoming meeting and several proposals expected to be under discussion at the meeting. Among other things, in the demarche the United States stated:

The United States believes that the WHO Secretariat goes beyond its technical competence when it seeks to advise its Member States on trade-related matters, including intellectual property. Further, the United States believes that the WHO should not set parameters by which WTO member states can negotiate their trade agreements. The United States would like to make sure you are aware of the potentially negative trade and intellectual property implications that could arise from this initiative at the WHO.167

One response to this demarche is that a core technical competency of the Secretariat of the World Health Organization is, of course, the promotion of world health.168 Furthermore, as the CIPIH report and opening provisions of the Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property make clear, there is a firm consensus that the impact of our intellectual property system on world health, positive and negative, cannot be ignored. Moreover, the drafting groups—which include the United States delegation—have reached consensus on the principles that WHO should take a “strategic and pro-active role in contributing to pursue the agenda on ‘public health, innovation and intellectual property’” and that such a role is in accordance with its constitutional mandate.169 Another response is that intellectual property, trade, and world health are indeed deeply

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168 CONST. WORLD HEALTH ORG. art. 1 (“The objective of WHO shall be the attainment by all peoples of the highest possible level of health.”), available at www.who.int/governance/eb/who_constitution_en.pdf; see also WHO website, www.who.int (last visited Apr. 27, 2008).

interrelated and bound up together; and because of this interdependence, collaboration between IGOs is all the more important.

The most obvious question at this juncture in both processes is whether these processes will lead to concrete changes with respect to governance, technical assistance, development orientation, and/or new norms, treaties, or agreements. If these processes will lead to such changes, the next question is whether such changes will be beneficial to public health. The prospects seem best for more balanced technical assistance and increased efforts towards technical assistance and capacity building. The worst case scenario is that the implementation process will amount to nothing more than a ratification of existing initiatives, studies, and programs. It seems clear, however, that both initiatives signal changes in the orientation of these two institutions. WIPO is now likely to be more development-oriented, and it is safe to say that for WHO there is no turning back from its focus on how intellectual property impacts public health.

The initiatives also raise questions about how international organizations will deal with intellectual property in the future. Do the similarities across the initiatives signal a new consistency across organizations, or do they instead mean that in the near future multiple actors with overlapping competencies and constituencies will deal with intellectual property, and what would that mean for public health?

Going forward, given the importance of public health to developing countries, the WIPO Committee for Development and IP should pay close attention to developments in the IGWG, particularly in light of the IGWG proposals' comprehensive and detailed approach to public health. Similarly, in light of the WIPO Development Agenda, the IGWG should continue to consider the drafting groups' proposals with the understanding that at least one other major IGO has recently changed its approach to focus more on how IP affects development. The IGWG should further consider how, given the goals set forth in the Draft Global Strategy, it can collaborate with WIPO and other IGOs in a way that fosters public health for developing countries, for example, by providing complementary, health-oriented technical assistance.

Developments at the IGWG and in the WIPO Committee on IP and Development continue to proceed rapidly, and this Article describes these initiatives as of February 2008. The reader is advised to visit the websites of both institutions for updates on their progress.

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