

IGWG: BEYOND ITS MANDATE?



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The Federalist Society

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*By John S. Gardner**

At the Fifty-Ninth World Health Assembly (WHA) in 2006, issues concerning the relation between intellectual property and public health were a focus of debate and controversy. Specifically, the Assembly discussed and reacted to a report of the Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH),¹ which had been requested by the Fifty-Sixth World Health Assembly three years earlier. The CIPIH Report made a number of recommendations, which were referred to a Working Group open to all Member States of the World Health Organization with participation as appropriate from certain non-governmental organizations (NGOs).²

While the Intergovernmental Working Group (IGWG) prepares to meet in Geneva in November, its work stands at a crossroads. Most basically, it faces a choice as to whether it will confine its work and recommendations to the mandate which it was given by the Assembly last year or move in a direction far beyond that mandate—with

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¹ *Available at* <http://www.who.int/intellectualproperty/documents/thereport/en/index.html>

² WHA Resolution 59.24 (May 27, 2006). “Public health, innovation, essential health and intellectual property rights: towards a global plan of action,” *available at* www.who.int/gb/ebwha/pdf_files/WHA59REC1/e/WHA59_2006_REC1-en.pdf.

potentially severe consequences for both intellectual property rights and public health. This paper, therefore, will focus on questions concerning the extent of the mandate given to IGWG, rather than examine the proposals for their impact on public health and development more generally.

That having been said, two facts seem clear. First, weakening intellectual property rights will weaken innovation generally in the pharmaceutical industry, because innovative originator companies would likely be unable to recoup the full value of their investments and have less incentive to make those investments, even if they were able to obtain access to capital as easily as they can now. The economics which have led to the cross-subsidization that has taken place both between drugs and between different markets in drugs (for instance, HIV/AIDS patients in the West paying far more for the same AIDS drugs such as anti-retrovirals than many patients in the developing world) would be threatened. Second, even without the impetus of the CIPIH report, an increasing amount of research and development is taking place in the developing world, funded by both public and private sources. (One notable example is the Drugs for Neglected Diseases initiative, sponsored by seven organizations, most of which are in the developing world.)³ There is increasing and fruitful cooperation between Western pharmaceutical companies and these research facilities in the developing world, to the benefit of both.

³ See http://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=87&ArticleId=288&TemplateId=1.

On the question of the IGWG mandate, briefly put, the current draft working paper for the IGWG meeting shows that the group has dramatically broadened its own remit.⁴ While the WHA's mandate to the IGWG was clearly focused on diseases that disproportionately affect developing countries—and, in practice, on those for which little scientific research is currently being conducted—the IGWG's report expands this mandate to include “Type I” diseases, which under WHO's definition include those which affect both the industrialized and developing worlds.⁵ This new emphasis is included in Paragraph 6 of the Draft Strategy, Element 1 on prioritizing research and development needs, and other sections. It should be removed and the actual mandate given by the WHA Resolution should be restored, for reasons that will be discussed in this paper. The mandate itself, no less than the substance of the CIPIH recommendations, is a proper subject for discussion at the IGWG.

⁴ WORLD HEALTH ORG., INTERGOV'TAL WORKING GROUP ON PUB. HEALTH, DRAFT GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: REPORT BY THE SECRETARIAT, INNOVATION AND INTELLECTUAL PROPERTY [*hereinafter* IGWG] (2d sess.) Provisional Agenda item 3, A/PHI/IGWG/2/2 (July 31, 2007) [*hereinafter* “Draft Strategy”].

⁵ “The Commission's definitions of Type I, Type II and Type III diseases, and the specific diseases on which this draft strategy focuses, are as follows: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. The strategy will focus on the following Type I diseases, increasingly prevalent in developing countries: diabetes, cardiovascular disease and cancer. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. For the purposes of the strategy, the focus is on HIV/AIDS and tuberculosis. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. For the purposes of the strategy, the focus is on the nine neglected infectious diseases that disproportionately affect poor and marginalized populations prioritized by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis.” Draft Strategy, *supra* note 4.

The decision paragraph of Resolution 59.24, which set up the IGWG, reads as follows:

“3. [The WHA] DECIDES:

- (1) to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up 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 related to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;
- (2) [this paragraph concerns the participation of regional economic integration organizations in the IGWG]
- (3) [the IGWG shall report to the 2007 World Health Assembly]
- (4) that the working group shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board.”

This Paragraph 3(1), while referring to action “based on the recommendations of the Commission,” nevertheless is not a specific endorsement of the Commission’s work. Rather, it referred the work to governments, specifically to the IGWG, for further discussion and analysis. The paragraph further cabins the research defined as necessary to

that “related to diseases that disproportionately affect developing countries.” In WHO-speak, this means Type III diseases, not Type I diseases as well.⁶

This view is consistent with language elsewhere in the Resolution. The phrase “disproportionately affecting developing countries” appears three times in the preamble. The only occasion reference is made simply to “diseases affecting developing countries,” it is in the context of government and private efforts to “fund[] initiatives to develop new products” to fight those diseases—which is surely appropriate because both public and private efforts in the developing world have focused not only on diseases which disproportionately affect developing countries but on other types of diseases as well.⁷

Further, the most expansive language in the resolution, Paragraph 2(3) which speaks of the need “to work to ensure that progress in basic science and medicine is translated into improved, safe and affordable health products—drugs, vaccines and diagnostics—to respond to all patients’ and clients’ needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people,” is included in a

⁶ Nor would it be fair to read the Resolution as endorsing a broader mandate simply because the Resolution does not use the phrase “Type III diseases.” The Resolution uses a term which was used by many Member States during debate at the 2006 WHA [and is also included in the CIPIH study itself.]

⁷ To take but one example, consider Novartis’ continuing dispute with India over the patent on its Glivec drug for rare cancers and chronic myeloid leukemia. These are classic Type I diseases. And the private sector has been generous in assisting patients to obtain drugs for Type I diseases; in this instance, “99% of patients who are prescribed Glivec in India receive it free from Novartis.” *Available at* <http://www.novartis.com/newsroom/india-glivec-patent-case/index.shtml> .

paragraph which “urges” Member States to take action. It is neither a decision of the Assembly nor a command to Member States.

The text of the Resolution provides further support for this argument. Two consecutive clauses in the preamble to the Resolution “not[e] that intellectual property rights are an important incentive for the development of new health-care products” and “not[e], however, that this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain[.]” This clearly refers to diseases for which little research has been conducted and to those which disproportionately affect developing countries, such as AIDS or malaria. For Type I diseases, the “paying market,” primarily but certainly not exclusively in the developed world, does provide an incentive for development of new healthcare products. (In this context, it is also worth noting that both the U.S. and EU have legal and regulatory incentives for the development of products that affect rare or “orphan” conditions.) Finally, there is a general principle of international practice that the opinions and decisions of Member States in international organizations should be respected. This calls for a cautious approach in determining the exact mandate of bodies such as IGWG.

Thus, whether one examines the issue from the perspective of “neglected diseases,” such as Chagas disease or leishmaniasis as was exhaustively discussed during the 2006 WHA and side events, or from the perspective of diseases that “disproportionately affect developing countries” expounded in Paragraph 3(1) of WHA

Resolution 59.24,⁸ it is clear that the mandate of the IGWG was limited, not expansive. No mandate was given by WHO Member States to consider Type I diseases or to weaken intellectual property rights for treatments which have been developed to fight those diseases.

Similarly, the Draft Strategy references the “health needs of developing countries.” All can agree with the Draft Strategy’s Element 6.1 “encouraging governments to invest in the health-delivery infrastructure,” including the call in Element 6.1(c) to “prioritize health care in national agendas.” All observers agree that developing country health systems must be strengthened to achieve better health outcomes. But the mandate was strictly to consider *diseases* that disproportionately affect the developing world, not health systems themselves. Issues such as access to health care, the building of clinics, better record-keeping, and training and retention of healthcare workers have little to do with intellectual property rights, and should surely be discussed by the WHO, but they are not part of the mandate given to IGWG. However, discussion of these issues could lead to a positive result by avoiding the mistaken view that weakening intellectual property rights alone will lead to better health outcomes in the developing world. It will not—because it would harm innovation and because other steps necessary to strengthen health systems can lead to positive health outcomes more quickly.

⁸ HIV/AIDS, tuberculosis, and malaria are generally considered to be included in this broader definition. These are diseases for which considerable research has been done; it would be unfair to term them “neglected.”

In this context, Element 2.1 of the Draft Strategy calls for “increasing funding for research and development that focuses on the health needs of developing countries [and for] developed countries to devote a larger portion of their health research and development budgets to the health needs of developed countries.” This is already being done, as efforts such as the President’s Emergency Plan for AIDS Response (PEPFAR) and the President’s Malaria Initiative in the United States attest. Of course, broadening the IGWG mandate to include Type I diseases would have the perverse effect of reducing the amount of money available for those diseases for which little research has been done rather than focusing attention on these “neglected diseases.”

More broadly, there is a question whether IGWG is reaching not merely beyond its own mandate from the WHA but even beyond the competence of WHO. Aside from the question of the competencies of the World Intellectual Property Organization, the Draft Strategy deals with questions that are more properly the province of the World Trade Organization (WTO). For instance, the Draft Strategy calls on Member States to “assess the impact of data-exclusivity regulations [and] examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use.” These issues, which relate to Article 39 of the TRIPS agreement, are completely outside the competence of the WHO.⁹ The call to eligible Member States to make full use of the

⁹ 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. 117 (1994) [*hereinafter* TRIPS or TRIPS Agreement].

transition period (until 2016) and various waivers available under the TRIPS agreement is a matter that should be addressed by Member States (notably, their trade ministries) rather than by the WHO. Similarly, Element 6.3(d) of the Draft Strategy explicitly endorses Member States' taking the "necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export." This is a matter that should be left to Member State discretion or, at any rate, considered by the WTO. Finally, paragraph 19 under Element 6 "Improving delivery and access" declares that "[i]nternational and bilateral agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application." Monitored by whom? If the reference is to trade agreements, it is for the WTO to determine whether these agreements are compliant with the WTO Agreement and the duties of Member States of the WTO, not the WHO. However, the Draft Strategy's statement that "[t]he impact [of using flexibilities for improved access] on innovation needs to be monitored" is welcome, even if strictly the issue falls more within the competence of WIPO and WTO.

Industry Responses and Development Impact

Despite serious questions as to whether IGWG has exceeded its mandate, the CIPIH report and the Draft Strategy have notable positive aspects as well. They should be commended for their calls to explore "innovative financing mechanisms" to promote financing for increased health research and development. But the most successful of these mechanisms will likely involve the private sector. Those that seek to supplant clear patent

rights with “lump-sum prizes,” for instance, would likely have a negative effect on innovation.

Similarly, Element 3.2 of the Draft Strategy contains a call to “strengthen product regulatory capacity in developing countries.” This is a positive development. Authorities such as Ghana’s Food and Drugs Board are gaining increasing respect internationally. Regulatory authorities in the developed world such as the U.S. Food and Drug Administration (FDA) and the European Medicines Evaluation Agency stand ready to assist their international counterparts in ensuring the highest standards for safety, efficacy, and quality of drugs and in such areas of mutual interest as combating counterfeiting of drugs. Public funding for clinical trials, addressed in Element 2.3(f) of the Draft Strategy, will help bring products to market more quickly, improving access to patients who need them.

The Draft Strategy speaks of “needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries.” As written, this could encompass everything from operations research and evaluation of aid programs to fundamental genomics and proteomics. All have an impact. This is unclear at best. It is simply not accurate to imply that industry, especially industry in the developed world, has ignored issues of concern to the developing world or that weakening intellectual property rights will lead to a solution.

Many products on the WHO's list of essential medicines¹⁰ are off-patent, others are being made available in the developing world at favorable rates or through programs such as those sponsored by the William J. Clinton Foundation. Yet these efforts do not have to mean either an endorsement of compulsory licensing or an abandonment of intellectual property rights. Rather, a joint announcement of April 6, 2004 of the William J. Clinton Foundation, the Global Fund, UNICEF, and the World Bank noted that “[a]ll four organizations support strong protection of intellectual property” and further noted that “[s]ome compounds can be purchased more cheaply through procurements from patent-holding manufacturers.”¹¹ Nothing has happened in the intervening three years to change this consensus; in fact, private companies have redoubled their efforts to assist in providing medicines at affordable prices in the developing world.

The Western pharmaceutical industry is frequently vilified, yet it is clear that without the initial investments in AIDS research and development of drugs that took place in the West—the efforts of companies (among others) such as Abbott, Bristol-Myers-Squibb, GlaxoSmithKline, Pfizer, Roche, and Merck, among many others — there would be no antiretrovirals (ARVs) with which to scale up in the developing world itself.

The pharmaceutical industry has operated from the principle that progress in achieving more comprehensive health care is best advanced when governments work

¹⁰ Available at <http://www.who.int/medicines/publications/EML15.pdf>.

¹¹ See “Global Fund, World Bank, UNICEF Agreement” available at <http://www.clintonfoundation.org/040604-nr-cf-hs-ai-pr-coalition-aims-to-provide-low-cost-aids-drugs.htm>.

cooperatively with the domestic private sector, all types of civil society organizations, and international companies. There are numerous examples of industry working with governments to assist in improving health care for their people. Of the many possible examples from which to choose, this paper will highlight a few early interventions in response to the AIDS crisis, to show that the response of transnational corporations is not simply a reaction to the late WHO Director General J.W. Lee's declaration of AIDS as a "global emergency" in 2003 or to the discussions of intellectual property rights in the context of the Doha Round of the World Trade Organization.

Perhaps the best known industry initiative is the Accelerating Access Initiative (AAI). The AAI brings together states, international organizations, and pharmaceutical companies with the aim of increasing access to medication for HIV/AIDS in developing countries by making the drugs more affordable. Forty-nine countries have already reached an agreement on reduced prices for HIV treatment with the companies concerned. AAI has increased the number of people taking triple ARV therapy ten-fold in Africa since May 2000.¹²

The overall environment with respect to AIDS drugs has been one of declining prices generally, including from use of generics that do meet international standards. As long ago as 2003, GlaxoSmithKline had agreements to make Combivir® antiretroviral therapy available to non-profit organizations for as little as 65 US cents per day. In that year, the company shipped 10,000,000 tablets of preferentially-priced ARV medication,

¹² See material on the AAI at http://www.ifpma.org/Health/hiv/health_aai_hiv.aspx.

including 165 agreements in 56 countries, of which 17 agreements were with private companies who provide treatment to their uninsured employees.¹³ The company's efforts are focused on the poorest countries, while pricing negotiations take place on a case-by-case basis with middle income countries. As of last year, the company has given seven voluntary licenses for HIV medicines in Africa, accounting for 126,000,000 Combivir and Epivir tablets. The NGO Medecins sans Frontières, which has strongly supported use of generic rather than originator medicines for AIDS treatment, has noted that the average cost of generic equivalents is 64 US cents, supplied at preferential prices! Compared to the 65 US cents price given above, a one-cent difference in price seems a small price to pay for the assurance of quality supplied by the drugs' approval by a stringent regulatory authority such as the European Medicines Evaluation Agency.

Similarly, Abbott provided 11.7 million of its Determine® rapid HIV tests at no profit in 2004 alone, and its Access to HIV Care program covers 69 countries. It offers Kaletra and Norvir at a loss to the company.¹⁴ In another type of intervention, Bristol-Myers-Squibb has granted voluntary royalty-free licenses to Aspen PharmaCare in South Africa and Emcure Pharmaceuticals in India to make and sell atazanavir.

What accounts for this generosity? How can it be further encouraged? Greater transparency and accountability in the use of funds encourage donations from both the public and the private sectors; these factors are particularly important for businesses that

¹³ GSK press release, Jan. 19, 2004.

¹⁴ Available at <http://www.accesstohivcare.org>.

are used to strict accounting standards and expect no less from those to whom they provide funds.

On the governmental side, as of August 13, 2007, FDA has granted tentative approvals for the fifty-first compound available under the U.S.' PEPFAR program. "FDA's tentative approval means that, although existing patents and/or marketing exclusivity prevent the approval for sales of the product in the United States, the product meets all of FDA's manufacturing quality and clinical safety and efficacy requirements—thus helping to ensure that AIDS patients abroad who receive these medications get the same quality of medications as Americans."¹⁵ Medicines are being made available in the developing world without such fundamental and radical shifts as the Draft Strategy proposes.

Rather than a focus on state-driven R&D, public-private partnerships, including research partnerships with institutions in the developing world, are a better approach. Novartis' Institute for Tropical Diseases is one example of this type of work; the dNDI consortium mentioned above is another.

One innovative philanthropic activity has been the African Comprehensive HIV/AIDS Partnership (ACHAP),¹⁶ sponsored by the Government of Botswana, the Bill & Melinda Gates Foundation, the Merck Company Foundation, and Merck,

¹⁵ Available at <http://www.pepfar.gov/press/91018.htm>

¹⁶ Available at www.achap.org; see also Linda M. Distlerath & Guy Macdonald, *The African Comprehensive HIV/AIDS Partnerships: A New Role for Multinational Corporations in Global Health Policy*, 4 YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS 1, 147-155.

established in 2000. Half the money came from the Gates Foundation and half from Merck.¹⁷ As a leader of the project stated, “The key question we set out to answer was, ‘Could the partnership successfully introduce large-scale provision of ARV therapy in the public health system by introducing new non-traditional skill sets, providing the necessary financial resources and jointly (with government) driving the project under a results-oriented social venture capitalist operational framework?’”¹⁸ Merck contributes both in-kind donations and seconded staff to the project. The results have been dramatic: 17,000 patients have started on ART since 2002, and the program is enrolling at about 1000 per month.¹⁹ It included health systems strengthening as well, as a series of satellite clinics monitor patients’ progress.

However, partnerships in both the for-profit and philanthropic sectors can work best if they do not force abandonment of intellectual property rights. Element 1.2(a) of the Draft Strategy includes a call to “improve accessibility to compound libraries for identification of compounds with potential activity against [relevant] diseases, by means including public-private collaboration’ [and] provide technical support to developing countries in order to create libraries of new compounds.”

As written, the recommendation is confusing. Access to compound libraries, many of which include intellectual property protected by both national laws and

¹⁷ Ilavenil Ramiah & Michael R.Reich, *Public-Private Partnerships and Antiretroviral Drugs For HIV/AIDS: Lessons From Botswana*, 24 HEALTHAFFAIRS, 2, at 545.

¹⁸ ACHAP, “Rolling Out ARV Therapy in Botswana” at 2, quoting Mrs. Tsetsele Fantan, Project Leader.

¹⁹ *Id.* at 3.

international norms, should be only on a voluntary basis. Forced access could stifle new innovation and disturb the delicate balance that patent law seeks to provide. Where developing countries are tempted to deny researchers from other countries access to materials necessary for scientific research, a net reduction in innovation would also likely result. Further, from a public health perspective, it is by no means clear that the best use of often-scarce funds for health is to develop compound libraries rather than to focus on health system strengthening, training of health workers, or improving access to basic health interventions.

The concern for better health outcomes of those who drafted both the CIPIH Report and the Draft Strategy is genuine. But the danger is that several of the proposals in the Draft Strategy, if adopted, will weaken innovation. Public health can be improved, and research sponsored in the developing world, without weakening intellectual property rights as the Draft Strategy suggests. The IGWG stands at a crossroads. Even leaving aside the potential negative impact on public health, unfortunately, concerns that IGWG has exceeded the mandate given to it by the World Health Assembly provides a clear ground Member States to object to the adoption of the Draft Strategy as a basis for a report to the Executive Board and to the World Health Assembly.