Comments of the Biotechnology Industry Organization (BIO)
on

The Revised Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
(A/PHI/IGWG/2/Conf.Paper No.1 Rev.1)
of

The World Health Organization
Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

January 2008

General Comments:

The Biotechnology Industry Organization (BIO) represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and 31 other nations, including both developed and developing economies. BIO Members are involved in the research and development (R&D) of health care, agricultural, industrial and environmental biotechnology products and services. More than 80% of BIO Members are innovative small businesses. As an organization representing innovative companies active in developing new healthcare products, BIO has a keen interest in the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) and is pleased to have been named as a Concerned Entity in the process. BIO intends to continue to be actively and constructively engaged as an industry partner in assuring that effective outcomes are reached.

BIO commends the IGWG for its work on a global strategy and plan of action that, according to its mandate, will aim at "securing an enhanced and sustainable basis for needs-driven, essential health R&D relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for R&D and estimating funding needs in this area."[1] BIO Members fully support the work of the IGWG and see this as an opportunity that should not be missed to improve coordination internationally between industry, governments, and other non-governmental organizations to achieve practical results that can improve the condition of patients in the near term.

BIO is a strong proponent of successful partnerships to address concerns in this area. BIO is co-sponsoring the Partnering for Global Health Forum, along with the Bill and Melinda Gates Foundation and BIO Ventures for Global Health (BVGH), which will be held in Washington, D.C., from March 10-12, 2008. The forum is focused on accelerating the development of medicines for neglected diseases of the developing world. The forum will confront the pressing need for innovation in this area and explore new avenues for progress – through lessons learned, market incentives, innovative business models and new potential partnerships. We look forward to drawing from this experience to enrich the discussions of the IGWG. A recent study conducted for BVGH found that biotechnology companies are willing, and have the unique expertise needed, to help close the innovation gap with respect to neglected diseases.[2] The study finds that expanded research funding, new product development partnerships and other market-based collaborative efforts to harness resources in the public, private and academic sectors will help to unlock this expertise and facilitate greater participation of biotechnology industry in this effort.

However, BIO remains concerned that a significant amount of time has been spent in the IGWG meetings up to this point discussing conceptual matters relating to intellectual property standards and trade policy that are best dealt with in other *fora*. Protracted debates on these matters will only succeed in delaying outcomes in the IGWG process that are necessary to permit the

[1] World Health Assembly Resolution WHA59.24 (May 2006)
[2] Joanna Lowell et al. *Closing the Global Health Innovation Gap*. BIO Ventures for Global Health (2007), *available at* http://bvgh.org/documents/InnovationMap.pdf.

organization to make tangible progress toward its goal of promoting greater research and development efforts devoted to addressing the unmet medical needs of the developing world.

Further, BIO is seriously concerned about proposals made in the revised draft that reflect a viewpoint that protection of intellectual property rights may be inconsistent with objectives of securing an enhanced and sustainable basis for needs-driven, essential health R&D relevant to diseases that disproportionately affect developing countries or even with respect to public health more generally. While BIO appreciates concerns related to maintaining effective and affordable healthcare systems, we view an enabling environment for innovative healthcare-related industries to be an essential component of any such strategy to ensure the continued development of new and effective medicines for neglected and other diseases. A robust system for protecting intellectual property rights is critical to establishing such an environment. As illustrated by our partnership efforts, BIO Members are highly supportive partners in facing the challenges of building a sustainable R&D framework with respect to neglected diseases. A strong patent system is a key element in facilitating this partnership and achieving the mandated goals of the IGWG.

Specific Comments on Document A/PHI/IGWG/2/Conf.Paper No.1 Rev.1

The Context, The Aim, and The Principles

- A number of provisions in the Context, Aim, and Principles sections of the revised draft[3] have achieved consensus among IGWG Members and articulate the concerns underlying the process. The revised draft language maintains the acknowledgement from the previous draft of the contribution of industry in taking initiatives to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, the draft continues to downplay the impact of these initiatives by declaring simply that these initiatives are "not sufficient to surmount the challenges." BIO understands that more effort is needed and that the IGWG can play a positive role in bringing that about. It should be recognized, therefore, that current initiatives, including public-private partnerships, advance market commitments and other mechanisms, should be expanded and built upon with complementary measures, such as additional funding to scale up similar initiatives in order to continue the progress achieved to date. These initiatives can be strengthened by way of constructive policies of WHO Member State governments that facilitate the implementation of such market-based innovation models.

- For the IGWG to fulfill its purpose most effectively, its focus should remain on diseases that disproportionately affect developing countries, as noted in the terms of its mandate. In this light, the work of the IGWG should remain focused on Type II and Type III diseases. The inclusion of Type I diseases, for which there is already a significant prevalence in developed countries, threatens to divert resources from the mandated purpose of the IGWG. All references to Type I diseases should be deleted.

Element 1: Prioritizing research and development needs

[3] A/PHI/IGWG/2/Conf. Paper No. 1 Rev. 1 (December 14, 2007).

- The revised draft calls for identification of gaps in R&D on diseases that disproportionately affect developing countries, as well as appropriate assessment of those identified gaps (element 1.1). BIO views this as a sensible, fact-based approach to meeting the mandate of the IGWG. However, we continue to be concerned with references to Type I diseases, for reasons mentioned above.

- Proposed language in the revised draft calls for "leadership and commitment of governments, regional and international organizations in determining priorities" for R&D according to public health needs (e.g., element 1.2(d)). BIO agrees with the need for governments to pursue actions that provide for an enabling environment for R&D in respective countries. However, these references should not be read as endorsing government-directed or mandated R&D priorities, which have proven to be unsuccessful and may interfere with current market-based models.

- The revised draft calls for prioritizing R&D in traditional medicine (e.g., element 1.3). BIO supports increasing R&D efforts in the area of traditional medicine, as well as in other potentially under-researched fields. However, the draft strategy should not specifically mandate R&D in this one area at the potential expense of other areas, based on a decision made by the IGWG. Instead, work should be pursued in this area and prioritized in line with the gap analysis foreseen by earlier provisions.

Element 2: Promoting research and development

- BIO welcomes the consensus recognizing multiple determinants of innovation capacity in particular countries, including the political, economic and social institutions in each country. It is highly unlikely that a "one size fits all" approach will be an appropriate approach for all countries, even countries within a particular stage of economic development. BIO also is pleased with the recognition that greater investment is essential and views increased transparency mechanisms and robust protection of intellectual property rights to be elements that can facilitate this investment.

- Increased cooperation between public and private sectors is critical and BIO supports maintaining language promoting this cooperation (e.g., element 2.1(a)). Public-private partnerships (PPP's) and Venture Philanthropy models, for example, have significant potential to better leverage public and private resources for R&D. Similarly, other mechanisms, such as advance market commitments, also offer significant promise to engage industry, philanthropic and public sector mechanisms to achieve results.

- BIO remains highly skeptical of language maintained in the revised draft advocating support for "open source" methods to develop a sustainable portfolio of new products (e.g., element 2.2.(a)). As noted in previous BIO submissions, unlike other industries relying on common technology platforms, open source practices are ill-suited and do not operate to promote the development of new pharmaceutical products. Practices followed under these models eliminate the incentives that are necessary for parties to risk investing in long-term, resource-intensive research and development activities. Moreover, unlike

industries in which open source practices have become prevalent, the life sciences community rapidly and regularly publishes scientific discoveries, thereby providing access to information for researchers to draw upon to further their own research activities. Since the open-source model is neither well-suited to the long-term resource commitments of life sciences R&D efforts, nor necessary to stimulate access to scientific information, BIO believes the IGWG should not promote this model as being helpful or relevant to R&D in this field. To the extent that "open source" methods remain in the draft document, it is essential that any such recommendation remain of an entirely voluntary nature and only be considered where such an approach would be feasible and appropriate.

- Proposals to identify IP-related provisions that "might" negatively affect increased research are not an effective use of time for the IGWG (e.g., element 2.2(c)). A vetting of national, regional and international provisions would likely entail a significant diversion of resources needed instead to be addressed to the core aim of the IGWG. This type of exercise is well beyond the scope of the current mandate.

- The revised draft contains proposed language relating to access to drug leads identified through the screening of compound libraries (e.g., element 2.4(c)). In many cases, compound libraries are proprietary, and it has been recognized that they represent one of the most important elements of a company's competitive strength.[4] BIO reiterates that it is critical that any access to compound libraries be given on a voluntary basis.

- The revised draft contains proposals relating to requirements that publicly- or donor-funded medical inventions and know-how be made available through open licensing on reasonable and affordable non-discriminatory terms (e.g., element 2.4(d)) . However, such an approach may weaken incentives necessary to facilitate the application of such research to create actual new products. As noted in the next section on technology transfer, mechanisms such as permitting recipients of public research funding to retain intellectual property rights in inventions made under the publicly-funded research grants will provide greater incentives to realizing the practical value of these innovations.

- The draft revision should not maintain proposals on developing or promoting research exemptions to patent laws (e.g., element 2.5(e)). These efforts are more properly discussed in the context of the World Intellectual Property Organization (WIPO) or the World Trade Organization (WTO) and, consequently, BIO supports deleting such proposals. WHO Members may want to request that WIPO, as the UN specialized agency with expertise in intellectual property matters,[5] conduct an exchange of national experiences on the issue of research exemptions, along with other mechanisms in intellectual property laws intended to spur scientific research.

Element 3: Building and improving innovative capacity

---

[4] THE REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 41 (2006) [hereinafter CIPIH Report], *available at* http://www.who.int/intellectualproperty/report/en/index.html.

[5] *See* The Agreement Between the United Nations and the World Intellectual Property Organization, Art. 1, December 17, 1974, http://www.wipo.int/export/sites/www/treaties/en/agreement/pdf/un_wipo_agreement.pdf.

- BIO commends the WHO for recognizing the importance of building innovative capacity in developing countries, particularly through investment in tertiary education to build human resource capacities and knowledge bases (e.g., element 3.1).

- BIO supports further development of policies that will promote innovation on traditional medicine within an evidence-based framework, in accordance with national priorities and taking into account the relevant international instruments. However, the revised draft should not advocate for "protection" of traditional medicine or the broader topic of "traditional knowledge," and should not refer to the creation of an international *sui generis* protection framework for traditional knowledge (e.g., element 3.4). Work is already ongoing in other UN bodies on this issue, including the WIPO Intergovernmental Committee (IGC) on the Relationship between Genetic Resources, Traditional Knowledge and Folklore. This is a highly complex matter that is beyond the mandate of the IGWG and would divert critical resources from its mandate, while duplicating work done elsewhere.

- BIO does not support a provision directed toward developing and implementing "alternative" incentives for innovation (e.g., element 3.5) as the work of the IGWG must be complementary, and build upon, existing market-based initiatives that engage industry and other stakeholders in a manner providing pragmatic results. Further, as a fundamental matter, any determination to develop and implement any incentives should be consistent with the results of the fact-based "gap analysis" that is to be undertaken pursuant to Element 1 and not through an *a priori* determination by the IGWG.

Element 4: Transfer of technology

- The topic of technology transfer has a history of extensive debate in other international organizations such as WIPO and WTO and is better addressed in those *fora*. Additional substantive work on technology transfer mechanisms in the IGWG would likely duplicate these efforts and divert resources from achieving the goals of the IGWG. Further, some proposed language in the revised draft appears to envision a state-mandated approach to technology transfer that is not workable. BIO reiterates its strong view that any collaborative activities leading to the transfer of technology must be undertaken on a strictly voluntary basis.

- Market-based incentives, such as the Bayh-Dole Act in the United States, have enjoyed great success. Mechanisms that promote close interactions between the university and non-profit research community, and the biotechnology industry – particularly small businesses – should be further explored if work continues in this area, either in the IGWG or in other venues. The experiences in the United States under the Bayh-Dole Act, which permits universities and other research entities to retain patent rights for inventions created during research programs funded by the U.S. government, are that this simple mechanism has resulted in significant transfers of technology and has incentivized the

dramatic growth of the biotechnology industry in the United States.[6] Indeed, many new technologies in fields other than biotechnology have been developed under this policy.[7] While each country has to assess the mechanisms most well-suited to its needs, the Bayh-Dole Act model offers a proven, workable approach that would likely be adaptable in addressing matters relating to government-funded research programs with respect to neglected diseases.

- BIO does not support proposals suggesting establishment of a list of essential technologies related to research and local production of health products relevant to developing countries (e.g., element 4.1(b)). In light of the different political, economic and social situations of most countries, this would not be effective in spurring transfer of technology. Further, this type of "list" approach is emblematic of a state-directed approach to transfer of technology that is not workable and would not assist in creating the enabling environment necessary for transfer of technology to take place.

- The revised draft also contains proposed language relating to creation of patent pools and creation of guidelines or particular patenting and licensing policies to promote technology transfer (e.g., element 4.3). In the case of patent pools, the benefits for biomedical research are questionable, unlike other industries that may rely on components designed to meet a single, common specification or standard covered by hundreds or thousands of patents. Suggestions of mandatory licensing of patent rights are inconsistent with the voluntary licensing model that underlies the patent pool model, and would be counter-productive as it would discourage the innovation and sustainable R&D sought by the IGWG.

- BIO also does not support establishment of patent licensing guidelines through the IGWG (e.g., element 4.3(b)). Work on patent licensing techniques related to technology transfer or other matters would appear to be a subject directly within the expertise of WIPO. The IGWG should consider requesting that WIPO consider an exchange of practices with respect to licensing matters as it relates to technology transfer, rather than diverting IGWG resources to this area.

Element 5: Application and Management of Intellectual Property to Contribute to Innovation and Promote Public Health

- Element 5 contains numerous proposals related to intellectual property rights and the TRIPS Agreement. In light of policy debates previously in WHO and in other international organizations, such as the WTO, there is little surprise that this text remains highly bracketed and contains numerous alternative proposals. Much of this work is already ongoing in other international organizations that more appropriately deal with intellectual property and trade matters, such as WIPO and the WTO. The IGWG should focus on pragmatic means to achieve its mandate. Re-debating high-level policy

[6] CIPIH Report, *supra* note 3 at 25.

[7] See, e.g., THE BETTER WORLD REPORT PART 2: TECHNOLOGY TRANSFER WORKS: 100 INNOVATIONS FROM ACADEMIC RESEARCH TO REAL-WORLD APPLICATION. (2007), available at http://www.betterworldproject.net/documents/AUTMBWR2.pdf.

arguments, duplicated in numerous international organizations, is not an efficient use of this resource. Further, the inclusion of references to Type I diseases in this section is of particular concern as there appears to be no recognition of the existing and well-recognized benefits of the intellectual property system with respect to incentivizing the development of new medicines.

- The revised draft now contains references to the "application and management" of intellectual property rights. This language is not clear. However, this should be construed in a manner consistent with international obligations relating to intellectual property rights. As noted previously, a robust intellectual property system is a key element of any framework for sustainable R&D in neglected diseases.

- There are numerous provisions and proposals made that are indicated as not yet having been discussed by the IGWG in this section. A number of proposals indicate a desire for WHO to undertake training or other technical support measures for countries that intend to make use of flexibilities with respect to international agreements, particularly the TRIPS Agreement (e.g., various proposals in element 5.2). BIO notes that significant work is being undertaken on capacity building with respect to TRIPS implementation in WTO and WIPO. The WHO should defer to WIPO and WTO for training in implementing specific obligations under Agreements administered by those organizations, while maintaining a collaborative role on public-health related matters.

- Some proposals in the revised draft advocate specific matters, such as use of compulsory licenses or requesting that WHO formulate guidelines on specific matters in patent law or under the TRIPS Agreement (e.g., various proposals in elements 5.2 and 5.3). These proposals are well beyond the expertise of WHO and should be addressed in the appropriate forum, e.g., the TRIPS Council, if matters of interpretation of certain TRIPS Agreement provisions are raised. Further, many of these proposals appear to advocate mechanisms that may weaken the existing incentive scheme of the patent system that is crucial for the development of new medicines. These proposals should be deleted from the revised text. Instead, the IGWG should focus on proposals that complement existing incentive systems to fill gaps that are identified in the analysis to be performed under Element 1. Proposals such as adaptations of existing orphan drug schemes that are widely credited with spurring development of new products where the market is limited[8] are good examples of intellectual property management and application techniques that can achieve results.

- Some proposals inappropriately suggest that the WHO should promote or discourage certain bilateral trade agreements (e.g., element 5.2(b)). These proposals are well beyond the mandate of the IGWG and should be deleted from the draft.

- BIO agrees that consideration of complementary, but not alternative, incentive schemes for R&D may be worthwhile to explore (e.g., element 5.3(a)). In particular, market-based incentive systems, such as public-private partnerships and advance-market

[8] CIPIH Report at 86.

commitments, may be expanded upon. BIO believes that the prize fund model would not be worth exploring as many indications exist that such a system would fail. Such a model certainly should not be singled out in the text prior to any exploration of the broader topic of R&D incentive schemes. BIO strongly reiterates that any consideration of various incentive schemes must in no way undermine existing incentives.

Element 6: Improving delivery and access

- BIO lauds the inclusion of improving delivery and access as critical to address problems to access to medicines. In particular, BIO is pleased that the revised draft recognizes the need for increased investment in health-delivery infrastructure and financing of health products. It is well-recognized that the lack of access to medicines in developing countries is often not related to the price of medicine, but rather to the absence of infrastructure to deliver the health-care, including medicines, to those who need it. BIO continues to believe that more attention and resources must be focused on this critical issue.

- BIO supports the recognition in the revised draft of the need to strengthen mechanisms to regulate the quality, safety and efficacy of health products, and reiterates its support for proposals recommending the removal of tariffs and taxes on healthcare products as this unnecessarily increases prices on medicines (e.g., element 6.3(c)). The revised draft should not, however, encourage fixed pricing policies that may alter incentives for innovation, but rather should focus on market-based solutions, as described previously.

- BIO also supports proposals made to develop a strategy to combat the public health consequences of counterfeit and substandard products as sound public health policy (e.g., element 6.2(f)). A number of proposals have been made relating to the entry of generic products onto the market. BIO supports further discussion on the timely entry of generics into the market, including use of early working or "Bolar"-type exceptions, such as that found in United States law, in order to encourage the early entry of generic medicines onto the market upon expiry of patent or other intellectual property rights (e.g., element 6.3(a)). However, any such proposal must be consistent with international obligations and respect patent rights in order to maintain the critical incentives of intellectual property rights for the development of new medicines.

Element 7: Promoting Sustainable Financing Mechanisms and

- BIO supports efforts of the IGWG to reach consensus on promoting sustainable financing mechanisms, and is also pleased at the recognition of support for public-private partnerships (PPPs) and product development partnerships (PDPs) and other appropriate R&D initiatives in developing countries as a consensus matter.

Element 8: Establishing Monitoring and Reporting Systems

- BIO also supports the IGWG in its efforts to establish a sensible monitoring and reporting systems for this effort. As a recognized Concerned Entity in the process, BIO hopes that

IGWG will maintain an inclusive process that allows such Entities to provide input and remain involved with respect to further developments, including through any monitoring and reporting systems that are established. This type of inclusive process will help ensure the partnerships necessary to fulfill the aims of the global strategy and plan of action can come to fruition.