The Submission of the Biotechnology Industry Organization (BIO)

To the World Health Organization

Second Public Hearing on Public Health Innovation and Intellectual Property

September 2007

Section 1: Comments to the Draft Global Strategy and Plan of Action (A/PHI/IGWG/2/2)

General Comments

The Biotechnology Industry Organization ("BIO") commends the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property ("IGWG") for undertaking the task of drawing up 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 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."[1] BIO welcomes and appreciates this opportunity to offer its views on the July 2007 Draft global strategy on public health, innovation and intellectual property, and the corresponding plan of action (together, the "Draft"),[2] and looks forward to continuing its engagement as a concerned entity in the IGWG in taking on the challenges posed by diseases that disproportionately affect developing countries.

The Context

The mandate given to the IGWG was to focus on "health research and development relevant to diseases that disproportionately affect developing countries." The Draft, however, changes this mandate to include within the scope of proposed work Type I noncommunicable diseases. BIO notes that this change threatens to divert limited resources away from the challenges presented by diseases that disproportionately affect developing countries, and toward areas where health research and development is strongest, and benefits affected populations in developed and developing countries alike. The IGWG should restrict its focus to conform to the mandate it was given; namely, to focus its work on Type II and Type III diseases. Type I diseases are not and should not be part of the IGWG mandate and any mention of them should therefore be removed from the Draft.

The Draft acknowledges the contribution of industry and other sectors' initiatives yet downplays their importance. That is, it acknowledges progress achieved through "funding initiatives to develop new products against diseases affecting developing countries and to increase access to existing products" – but downplays their impact by stating simply that "these initiatives have proved inadequate to surmount the challenges. Much more must be done in relation to the scale of avoidable suffering and mortality." BIO recognizes that more must be done, but believes it should be made clear that what must be done is to scale up funding for additional similar initiatives in order to augment the progress they have achieved to date. These initiatives should be identified and strengthened by way of constructive government policies building on incentives which use or complement the market-based innovation model.

The Elements

Element 1: Prioritizing research and development needs

- The Draft calls for analysis to identify gaps in research on diseases that disproportionately affect developing countries. As noted above, the IGWG must not divert its attention and resources from diseases that disproportionately affect developing countries – that is, Type II

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[1] WHA59.24.
[2] A/PHI/IGWG/2/2.

and Type III diseases – in favor of Type I diseases, regarding which there is ample support for research and development. Type I diseases should not be included in the gap analysis.

- The Draft recommends improved accessibility to compound libraries to facilitate upstream research for diseases that disproportionately affect developing countries. It should be made clear that such access to compound libraries must remain on a strictly voluntary basis. Compulsory access would have a chilling effect on investment and public-private cooperation.

- The Draft calls for technical support to developing countries in order to create libraries of new compounds at both national and regional levels. This would enable developing countries to build capacity for research and development and organize access to libraries of new compounds.

- The Draft suggests formulating explicit prioritized strategies for research and development at the country level. It should be made clear that this exercise must not promote reliance upon state-driven research and development – which history has proven to be an unsuccessful model – and it should not include Type I diseases, as these are not properly within the scope of the IGWG's mandate.

Element 2: Promoting research and development

- The Draft suggests substantial enhancement of the range of measures to promote, coordinate and finance public and private research, and to increase investment in developed and developing countries to strengthen the research base and research capacity in developing countries. BIO supports the goal of increasing funding for research and capacity building.

- The Draft promotes cooperation between private and public sectors on research and development. BIO agrees that public-private partnerships offer a rich potential source for capacity building and ground level research and development, and that an enabling environment must be created to encourage their creation. In no event should this be understood to encompass any sort of mandatory requirements for state directed research or mandatory partnerships.

- The Draft recognizes that intellectual property management can promote research and development; however, the precise meaning of "intellectual property management" in the context of the Draft is unclear. It is critical that this phrase not be construed to encourage a weakening of existing protections of intellectual property rights ("IPRs"). BIO notes that systems for managing intellectual property rights must comply with existing international law and obligations, including those outlined in treaties administered by WIPO and the WTO. BIO urges the WHO to collaborate closely with these organizations and to defer to them for the provision of technical assistance related to issues under their respective mandates. Strong intellectual property protection, coupled with appropriate management of IPRs, helps to support an environment for innovative research and development. The converse is also true, as the incentives for innovation can easily impeded by measures that restrict availability or use of intellectual property rights.

- The Draft recommends among other mechanisms, "open source methods" to develop a sustainable portfolio of new products. BIO submits that this recommendation is

inappropriate and unworkable and should be withdrawn. Unlike in other industries relying on common technology platforms, open source practices would not promote the development of new pharmaceutical products, as they eliminate the incentives for parties to risk investing in such development.

- The Draft recommends promoting access to drug leads identified through the screening of compound libraries. BIO reiterates that it is critical that any such access be given on a voluntary basis.

- The Draft encourages developing countries to consider legislation regarding research exemptions. It is unclear that research exemptions bring products to those who need them. However, some countries already have limited statutory research exemptions, while others provide such exceptions through common law. The Draft should not encourage work on developing or promoting research exemptions, but should leave countries to determine individually what is appropriate for their domestic regimes.

- The Draft recommends further discussion of a medical research and development treaty: We believe this would be a tremendous waste of resources, and the recommendation should not be pursued. Any exercise to create a R&D treaty would undermine the work program of the IGWG, and undesirably replace a robust and successful research and development community with unproven state- and bureaucracy-driven initiatives that are neither politically feasible nor workable. Such discussions have no place in the IGWG, and its limited resources must not be squandered on them.

Element 3: Building and improving innovative capacity

- BIO commends the WHO for recognizing in this Draft the importance of building innovative capacity in developing countries, particularly through investment in tertiary education to build human resource capacities and knowledge bases. However, it is difficult to see what role the WHO as opposed to other institutions could realistically play in achieving this end.

- The Draft should name academia as a stakeholder in the actions associated with this element. Academic and research institutions play a key role in capacity building and consequently in economic development. The Draft must recognize and reflect their role.

Element 4: Transfer of technology

- BIO believes that this topic is best discussed in the appropriate international forums e.g. WTO and WIPO. BIO also strongly believes that any such collaborative activities leading to the transfer of technology must be undertaken on a strictly voluntary basis.

- The Draft suggests promoting compliance with TRIPS Article 66(2): this falls within the mandate of the WTO and the paragraph and related actions should be deleted from the Draft. Compliance with the TRIPS Agreement is regularly addressed in the WTO TRIPS Council. The WHO's duplication of this work would be inappropriate, unnecessary, and wasteful.

- The Draft proposes the use of patent pools. The benefits of patent pools in biomedical research, beyond ARV fixed dose combinations, are questionable unlike other industries which rely on components which cannot be used individually. Furthermore, other industries

employ patent pools voluntarily (i.e., the owners of patents participating in patent pools voluntarily license their patents through the pool mechanism). Suggestions of any mandatory licensing of patent rights via a patent pooling mechanism should be resisted as it would discourage innovation and R&D in medicines.

Element 5: Management of intellectual property

- The Draft appropriately recognizes that intellectual property is "a vital concept in ensuring that development of new health products continues." However, it remains unclear what is precisely meant by "management of intellectual property," and BIO reiterates that this should in no event be construed to encourage a weakening of IPRs, including by imposing limitations on use of patent or other forms of intellectual property rights by owners of those rights. Additionally, any reference the Draft makes to Type I diseases is inappropriate and should be deleted.

- The Draft promotes information sharing and capacity building in the management of intellectual property, and suggests providing support for the application of the flexibilities within the TRIPS Agreement: this work is appropriately and expertly undertaken in the WIPO and WTO respectively and resources should not be wasted duplicating this work in the WHO.

- The Draft inappropriately suggests that the WHO should promote certain bilateral trade agreements: this is well beyond the competence of the WHO and should be deleted from the Draft.

- The Draft suggests promotion of complementary incentive schemes for research and development. BIO agrees that market-based incentive schemes such as advance-market commitments should be expanded upon. BIO disagrees, however, that the prize fund model is worth exploring, as there is no evidence to suggest that such a scheme will lead to practical outcomes. Indeed, there are good reasons to suggest that it will fail. Complementary incentive schemes must in no way undermine existing incentives and IPRs.

Element 6: Improving delivery and access

- BIO is pleased that the Draft recognizes the urgent need for developing countries to invest in developing and strengthening health-delivery infrastructure. It is well recognized that the lack of access to medicines in developing countries is often not related to the price of the medicine, but rather to the absence of infrastructure to deliver the healthcare, including medicines, to those who need it. BIO believes that more attention and resources must be focused on this critical issue.

- BIO is pleased that the Draft addresses the critical need to strengthen developing countries' capacity to regulate the quality, safety and efficacy of health products, and that the Draft recommends removing tariffs and taxes on health care products.

- The Draft should not encourage fixed pricing policies, which would alter incentives for innovation. Better solutions can be found in market-based solutions, as described above.