Summary of Comments on the Elements of a Global Strategy and Plan of Action

Annex 1 Elements of a Plan of Action

#2. a. Identify gaps in current coverage of research in Type II and Type III diseases, and links to other work under way in this field
   - What about Type I?
   - This is a laudable proposal to cut on cost, what we will need then is a single platform (probably lodged/maintained by WHO), who can point to countries who is initiating/investing in certain types of diseases as far as research is concerned. We need not replicate what other countries have done. Can we include ‘support the development of sharing and inventory systems for tracking completed or on-going researches – globally, regionally, national?’

   d. Conduct research on affordable (to be defined) and technologically appropriate products to combat Type I diseases in developing countries
      - Why type I only?

#3. c. Provide support for national health-research programmes through appropriate political action and long-term funding in developing countries
   - Could also mean to support passage of an ordinance/resolution for governments to define/prioritize implementation of high stake research projects/priorities. Government to facilitate/initiate involvement of key players/partners such as academe, business-private/public sectors

   d. set up a forum, or enhance existing ones, in order to improve the coordination and sharing of information; elaborate its role and format and cost implications; coordinate stakeholders’ research and development through WHO’s endeavours
   - ensure capacity for organizing regional/global forum such that developing/less developed countries are given the chance to organize to share its expertise.

   g. consider legislation relating to the form of research exemption that might be appropriate for fostering health-related research and innovation in prevailing circumstances
      - (we can also consider a special national fund for research/development – and health research, getting a regular budget appropriation from the national research/development fund.)
#8.  b. channel more funds to research organizations in developing countries in both the public and private sector on the basis of compliance and performance
   • Yes to be tied with performance

c. continue to support public-private partnerships and research and development institutions in developing countries and assess their performances
   • (with corresponding incentives)

h. enforce donor’s contribution to health research – at least 5% of their total expenditures in health

Annex 2. Elements of a Global Strategy

#3. Meeting public health needs

• additional funding is needed for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries (resolution WHA59.24) – government to issue a law that will identify it as a national priority and hence be given due financial support

#5. Making products affordable and accessible.

• High prices of medicines contribute to inequitable access to treatment (resolution WHA59.24) (would require thorough evaluation of the different chains or modes in the drug system where it has the greatest effect in increasing drug prices.)
COMMENTS/ PROPOSALS
of the Intellectual Property Office of the Philippines (IP Philippines)

SUBJECT:
Progress to date in the Intergovernmental Group (A/PH/IGWG/1/5)
[INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH,
INNOVATION AND INTELLECTUAL PROPERTY (Agenda Item 2.3)]

I. General Comments

The IP Philippines commends the World Health Organization (WHO) in its efforts to
make medicines accessible among Members States, especially the developing and least developed
countries. We strongly support the proposed elements of a global strategy and plan of action
prepared by the Intergovernmental Working Group on Public Health, Innovation and
Intellectual Property, based on the recommendations contained in the Report of the WHO
Commission on Public Health, Innovation and Intellectual Property Rights (CIPIR), as
published in April 2006.

We are of the view that the strategy and plan of action would lead countries to take
collective action towards enhancing the affordability and accessibility of medicines. We also agree
that, among others, there is a need to deal with diseases that are predominantly affecting the
developing and least developed countries; and that it is about time that research and development
also take into account neglected and very neglected diseases.

We further agree that Member States should be equally represented in the sessions of the
Working Group to ensure a balance in terms of gender, regions and levels of development; and
to provide an equitable and inclusive approach on various issues that affect public health and
access to healthcare products and services.

II. Specific Comments

a) On the Establishment of a Guidance Document

The IP Philippines concurs with the view that developing countries should be given a
direct role in implementing the CIPIR's recommendations. We are agreeable that a guidance
document, or a Model Guideline for that matter, be considered and established to serve as
framework in assisting countries to implement the provisions of the TRIPS Agreement. We
believe that this is one way by which Member States can have a balanced, consistent and uniform
interpretation/implementation of the TRIPS flexibilities.

b) On Annex 1 (Elements of a Plan of Action)

I. Elements of a Plan of Action

The paper contains working elements for a global plan of action, including prioritizing
research and development needs, promoting research and development, building and improving
innovative capacity, transfer of technology, management of intellectual property, improving

1. HIV/AIDS, tuberculosis, malaria, and related diseases that are overwhelmingly in developing countries, such as
   rabies, encephalitis, and tuberculosis, are often termed "neglected diseases".
delivery and access, ensuring sustainable financing mechanisms, and establishing monitoring and reporting systems. The IP Philippines would like to comment as follows:

ii. Promoting R&D and Building Innovation Capacity

The IP Philippines agree that there is a need to introduce (into national legislations) provisions that seek to implement the flexibilities under the TRIPS and other international agreements. Provisions on compulsory licensing, including for export purposes, and on parallel importation, for instance, will stimulate competition and reduce prices, in particular, of pharmaceutical products. In this regard, IPRs could serve its social function by being an incentive for research and development on products that have impact on public health.

We also support, in general, moves towards exploring alternatives to drug patents as a means of encouraging the development of new, accessible and affordable drugs. We find that these alternatives could indeed promote access and affordability of drugs and/or medicines among WHO Member States and observer nations.

We are, thus, agreeable to the formulation and adoption of a global research and development treaty to fund upstream R&D for diseases that disproportionately affect developing countries. In this regard, we recommend the creation of a committee that would be tasked specifically with the drafting, formulation and policy determination on the R&D treaty. We suggest that this committee be composed of representatives and pertinent authorities from the Member States.

iii. Technology Transfer in Improving Innovation Capacity and Management of IPRs

The IP Philippines supports the proposition that technology transfer and management of IPRs should be included as core elements of the global strategy and plan of action, with separate areas of action. It should be noted, however, that while the impact of IPRs on access to medicines is currently the center of attention among Member States, it remains that other factors affect access to medicines (such as lack of funding, infrastructure and political will). As such, while the concerns on IPRs are already being addressed, these other factors should also be given appropriate focus.

We concur that Article 66.2 of the TRIPS Agreement has not been fully utilized for the benefit of least developed countries. As a matter of fact, the current trend is for R&D efforts and transfers of technology to concentrate on products that have high commercial value. In effect, the development and transfer of technology on products, particularly, healthcare products that are required to address the health needs in least developed countries are generally taken for granted. We are of the view that a global R&D treaty would help redress this concern.

With regard to free trade agreements (FTAs), we strongly agree that bilateral and/or regional FTAs should not incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries. These agreements should allow developing and least developed countries to gain the full benefits from the flexibilities that are made available in the TRIPS Agreement and recognized in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health.

iv. Improving Delivery and Access, and Establishing Monitoring and Reporting Systems

It is indeed necessary to assess the implementation of the TRIPS flexibilities by developing countries. This assessment would help determine further measures that may need to be undertaken to ensure that countries gain the full benefits that are available to them. In the same manner, it is also essential to monitor the adverse impact of the exclusive rights to pharmaceutical test data for drug registration and then come up with policies that promote accessibility and affordability of medicines.
2. IP Philippines’ Current Initiatives in Relation to the Plan of Action

The IP Philippines has already undertaken significant steps that are supportive of and are consistent with the objectives of the proposed Plan of Action as described herein below.

i. R&D and national legislation

The IP Philippines has actively joined the country’s initiative to promote access to and affordability of drugs and medicines. This initiative relates to the currently proposed amendments to the Intellectual Property Code of the Philippines (IP Code), i.e., Senate Bill 2265 which was approved by the Philippine Senate on 31 January 2007 and its House version, House Bill 6035 which was approved on second reading by the House of Representatives on 20 February 2007.

Once passed into law, the aforesaid legislation will, inter alia, promote early stage drug research and development by providing research exemption ("early working exception orSolar provision") that is appropriate for fostering health-related research and innovation. This will also entail policies that support greater competition between generics as an effective way to enhance access to drugs and/or medicines by improving affordability. This further reflects the country’s move to take advantage of the flexibilities provided for in the Agreement on the Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement).

ii. IP Education, R&D, and Technology Transfer

The IP Philippines has proposed a Memorandum of Understanding with the Commission on Higher Education (CHED) concerning the integration of IP in the curricula of universities (tertiary education) with a view of strengthening the interconnection between education and IP, and promoting IP as a tool for national development. We are also in the process of establishing an IP Institute or Training Center that is designed to develop the innovative capacity among Filipino individuals and R&D institutions while fostering technology transfer and coordination/collaboration between public and private sectors.

iii. Trade Agreements

The IP Philippines provides inputs and participates actively, as may be required, in bilateral and regional FTA negotiations, in particular, on IP provisions contained therein to ensure that such do not incorporate TRIPS plus protection which may be contrary to the country’s developmental goals.

iv. Interrelation Between National Regulatory Authority for Medicines and Intellectual Property Offices

With the view of promoting the market entry of generic drugs and/or medicines in the country, the IP Philippines, in coordination with the Bureau of Food and Drugs (BFAD), has taken the initiative to explore the possibility of establishing a database system that would provide information on drugs and/or medicines that are in the essential drugs list and are off-patent. This initiative, which is currently on its initial stage, aims to promote the market entry of generic competitors.

v. Traditional Medicines, Knowledge, Folklore, and Genetic Resources

Noting that the country possesses numerous traditional medicines, knowledge, folklore and genetic resources which have been, in fact, the subject of exploitation by biopiracy acts, the IP Philippines has coordinated with the State Intellectual Property Office of the People’s Republic of China (SIPO) on ways by which the country can come up with a database that would capture existing traditional knowledge and genetic resources, with a view of utilizing the same in
patent examination procedure and searching for the appropriate approach on how these may be subject to protection.

We have also undertaken consultations with relevant sectors and are planning to conduct further consultations that would lay the groundwork in the crafting of a national IP policy and strategy that would recognize, develop, and promote traditional medicines, among others.

c) On the Appendix to Annex 2

The paper contains a global strategy, including “Making intellectual property work for health.” The IP Philippines would like to comment as follows:

1. Global Principles

The IP Philippines agrees that high-quality research, and the generation and application of knowledge are critical for achieving the internationally agreed health-related development goals, including those contained in the United Nations Millennium Declaration.

While public health is a primary concern and is recommended by the Eastern Mediterranean Region to take precedence over rights to IP protection, the IP Philippines is of the view that Member States should find a balance between public health considerations and protection of IP. As advocated in the Doha Declaration, the TRIPS Agreement is supposed to be interpreted in a manner that ensures a proper balance between patent protection on the one hand, and the need to protect public health by promoting access to affordable medicines on the other.

The broad interpretation of the Doha Declaration should allow developing and least developed countries to enact legislation to protect the interests of the general public and provide access to essential drugs that are critical for their well-being. In this regard, we find that there are measures that can legitimately be taken to factor in this public interest component without running afoul of the provisions of the TRIPS Agreement. It remains to be seen, however, how countries would take the necessary steps at the national level to effectively implement the flexibilities of compulsory licensing and parallel importation which are clarified in the Doha Declaration and confirmed by the WTO TRIPS Council Decision of 2005.

We believe that this would ensure that equitable rights are provided to the public in terms of protecting the results of innovation and creativity, which would encourage further developments on drugs that could treat diseases and medical conditions, and in terms of safeguarding the physical condition and well-being of people. The Global Principles contained in the paper should embody this kind of balance.

2. Global Challenges

The IP Philippines supports the proposal of India to amend bullet 1 of paragraph 4 to read as follows:

“Intellectual property rights are one of the incentives for the research and development of new products, but this incentive does not meet the need for the research and development for new products to fight diseases disproportionately affecting the developing countries, which requires alternative mechanisms to meet the weaknesses.”

Further, noting that developing and least developed countries have not fully utilized the flexibilities under the TRIPS Agreement and the Doha Ministerial Declaration, and that there is a
current inclination to incorporate TRIPS plus provisions in FTAs, we also concur with India's proposal to include the following bullet points under paragraph 4:

- TRIPS flexibility under the provisions of Doha Declaration has not yet been fully utilized.
- TRIPS Plus efforts under bilateral free-trade agreements place a major limitation on access to affordable medicines for all by developing countries.


1. Expanding the Pool of Experts/Pollsters for the Sessions of the Working Group

In view of the global recognition of the relevance of IP to public health, the IP Philippines would like to suggest that IP experts from the WHO Members States, including representatives of IP Offices thereof, be invited to the forthcoming sessions of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. This would ensure that the relevant information is directly conveyed to the pertinent authorities, thus, facilitate the formulation of national policies which take into account the results of the discussions of the Working Group.

2. Issues for Consideration

The IP Philippines agrees that the Working Group should also consider and discuss, in its future sessions, issues pertaining to the exclusivity of test data related to IP, patent linkages, parallel imports, and the strict enforcement of existing TRIPS flexibilities. We are of the opinion that these issues are significant in ensuring that a balance between IP protection and public health is achieved by the Member States.