

**Informal Interactive Hearing of the General Assembly with Non-Governmental
Organizations, Civil Society Organizations and the Private Sector
Regarding United Nations Millennium Development Goals (MDG)**

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**Responses from
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Distinguished Chair, Your excellences and Representatives,

Emerging crises especially in the context of climate change and global financial crisis, and the interdependence of crises has doubled the cost and complexity for achieving MDG at national level for developing countries. Building on what have been addressed, I would like to further comment on the issues of intellectual property rights (IPR) as a cross-cutting issue for development. IPR could have its impact on development issues in different ways, including benefit sharing for indigenous community in the context of biodiversity and traditional knowledge protection, plants variety protection and its impact on small farmers, and in the context of access to technologies and access to medicines. I would focus my comments on the issue of IPR and access to technologies and access to medicines referring to the current Draft Outcome Document.

Access to Technologies and IPR

[Re: Paragraph 42 k) and 50 s) of the Draft Outcome Document]

Paragraph 42 k) and 50 s) of the Draft Document mentioned the need for access to technology and technology transfer for mitigating and adapting climate change, and achieving food security in developing countries. However, the current text remains lacking of concrete steps for action.

Study¹ has showed that technology transfer as an obligation under Art. 66.2 of TRIPS agreement in WTO has failed to deliver. Of the 292 programs and policies reported to TRIPS Council by developed countries during 1999-2007, only 22% involve technology transfer specifically targeted to LDC WTO Members.² In the context of climate change, although Art.4.5 of United Nations Framework Convention on Climate Change (UNFCCC) has called for developed countries to assist developing countries through technology transfer, little has been done. Research has also showed that in conjunction with IPR, access and disseminates technology faces a number of limitations³, including high transaction cost of obtaining information, difficulties in negotiating and acquiring IP protected technologies, and vague definition on the subject matter covered. Such limitations could especially hinder developing countries from establishing domestic capacity of production and innovation. With reiterating the urgency of combating multiple crises and achieving sustainable development, I would like to recommend the Draft Document to:

¹ Suerie Moon, "Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to TRIPS Council (1999-2007)", Patent Law Research, China Intellectual Property Press, 2009

² *Id.*

³ John H Barton, "Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis on Solar Photovoltaic, Biofuel and Wind Technologies", International Center for Trade and Sustainable Development, 2007

- **Add stronger affirmation of access to technologies as essential element for developing countries to achieve MDG**
- **Affirm the right of developing countries to use flexibilities of IPR system, including but not limited to compulsory license and exception of patent protection, in overcoming barriers to access to technologies, especially in the context of climate change**

Access to Medicines, Health MDG and IPR

[Re: Para 45 f) and g), 48 c) and e), and 50 p) of the Draft Outcome Document]

Paragraph 45 f) and g), 48 c) and e), and 50 p) have touched upon the issue of access to medicines and medical innovation in context of achieving health related MDG. I would like to reemphasize the following echoing Third World Network's comments on Day 1 hearing:

- **The fact of patent protection and its impact on access to medicines in developing countries has been repeatedly analyzed and affirmed under a number of international forums and international agreements** including Doha Declaration on TRIPS and Public Health, Amendment on TRIPS agreement, as well as the Intergovernmental Working Group Process on Public Health, Innovation and Intellectual Property in WHO. **Therefore, such fact shall not be renegotiated and shall be affirmed by member states without controversy under the current MDG discussion.**
- In respect to the final remarks by representative of International Federation of Pharmaceutical Manufacturers Association, I would like to make some factual clarifications:

1) Medical R&D expenditures:

Acknowledging industry's effort on medical R&D, the fact shall not neglected that, according to a WHO supported research, 84.2% of the world's basic research was funded by governments and the public, 12% was funded by industry.⁴ Similarly, a case study by the US National Institutes of Health (NIH) found that 85% of the published research studies, tests and trials leading to the discovery and development of the five top-selling drugs in 1995 were conducted by taxpayer-funded scientists and foreign universities.⁵

2) Off-patent Drugs on WHO essential medicines list:

WHO list includes off-patent medicines that could enable local production by developing countries to ensure sustainable supply and affordability. Nonetheless, it is not because industry chooses not to patent those drugs, but because they are already off patent when chosen. In addition, medical need is still the aftermost consideration of essential medicines list. For diseases like HIV/AIDS, newer drugs that essential for second and third line treatment are increasingly patented in more countries as more joining WTO. Patent will still be an obstacle in scaling up the use of those newer medicines in HIV/AIDS treatment.

⁴ Monitoring Financial Flows for Health Research 2005: Behind the Global Numbers *by* Global Forum for Health Research, Page 35

⁵ National Institutes of Health, "NIH Contribution to Pharmaceutical Development," Administrative Document, February 2000.

3) “IPR is a tool for development, as emerging economies benefit from increasing patenting”? :

There are two points shall be noticed regarding this remark:

- i) Statistics showed that in many developing countries, more patents are granted to foreign applicants. Research has showed that 97% of all patents were held by rich countries.⁶ For instance, in Malaysia, out of 2242 patents granted in 2008, 2042 are for foreign applicants.⁷ In Philippines, only 29 invention patents were granted to domestic applicants out of 1785 in total in 2007.⁸

- ii) Whether domestic capacity gets boosted with broad patenting is questionable in emerging economies. Taking China as example, broad patenting on medicines has created long lasting barrier to access to HIV/AIDS medicines.

China is facing challenges of HIV/AIDS epidemic as other developing countries do. Until end of 2008, there are 700, 000 people affected by HIV/AIDS.⁹ According to government data in April 2010, HIV has become the first cause of death among communicable diseases.¹⁰ Although government launched treatment program to provide free drugs and treatment, obstacles to get sufficient access to drugs has hindered the scaling up of such program.

Case of 3TC:

Lamivudine, patent held by GlaxoSmithKline, also known as 3TC, is a drug recommended by WHO to use for 1st and 2nd line HIV/AIDS treatment, and also treat Hepatitis B in different formulation. China is the biggest supplier of Active Pharmaceutical Ingredient (raw material) of 3TC to the world, but Chinese patients have no access to generic 3TC due to patent protection. GSK introduced the drug to China in 1990 before China started granting patent on medicines, so only manufacture process of 3TC can be patented at that time. However, GSK got a number of exclusive protections on 3TC in China against the background of bilateral trade negotiation between China and US. In 2007, the main exclusive protections of 3TC expired which means in theory, Chinese company can produce 3TC by using other synthetic process. However, GSK announced publically on its website that infringement will occur if any company in China is to produce 3TC as its process patent covers ALL products of 3TC.¹¹ One deep reason that encouraged this excessive announcement is the previous Chinese patentability criteria is too broad that could over duly expend the scope of protection.

Under such circumstance, no locally produced or generically imported 3TC is available in China; although this is a drug invented in last century and has long been widely used in generic version in many other developing countries. 3TC for HIV/AIDS treatment is still relying on a donation from GSK, and Hepatitis B patients have to pay nearly 6000 RMB per year to take branded 3TC.

In 3TC case, both Chinese patients and Chinese generic manufacturers are not benefited from broad patenting. This is only one example of how over patenting could hinder domestic capacity

⁶ “Integrating Intellectual Property Rights and Development Policy”, report of the Commission on Intellectual Property Rights established by the British Government, http://www.iprcommission.org/graphic/documents/final_report.htm, Page 161

⁷ Malaysia Intellectual Property Office statistics

⁸ Philippines Intellectual Property Office statistics

⁹ Statistics of Ministry of Health of China

¹⁰ Statistic of Ministry of Health of China

¹¹ <http://www.gsk-china.com/english/html/newscentre/china-news.asp> (English version);

<http://www.gsk-china.com/asp/News/client/newconten/515200763706.htm> (Chinese version)

from growing and sustaining.

In addition to the above comments, I would also like to address a number of **missing points** in the current Draft Document:

- **Recognition of the severe burden of non-communicable diseases in public health system of developing countries, and to affirm the tension between intellectual property protection and improve access to medicines treating non-communicable diseases**

Ample of evidences have supported that the trend of burden of diseases in many developing countries, especially middle income countries, has shifted towards the non-communicable diseases. Such transition also adds additional financial and technical burden to the public health system in such countries, with access to affordable medicines stands in the core.

For instance, every year, more than 1.5 million people died from cancer in China, and the trend is still increasing. A number of cancer drugs however are only available in branded versions with expensive prices because of patent protection. One example is Gleevic, a drug treating a certain type of leukemia from Novartis Company. While the generic version in India only sold at about 1300 RMB/month because no patent on it, Chinese patients have to pay 20,000 RMB/month for patented Gleevic to extend the treatment.

- **Reaffirmation the right for developing countries to use flexibilities of IPR system to improve access to medicines and safeguard public health;**
- **Exchange of best practices of access to medicines [Re: Para 45. f] should include legal and policy exchange of using flexibilities of IPR, and such exchange should especially be encouraged in the context of South-South collaboration;**
- **No TRIPS-plus provisions will be required in any international or bilateral trade negotiation as these will adversely affect the opportunity of developing countries to apply rights abovementioned and to develop domestic capacity**
- **An effective international monitoring mechanism on Free Trade Agreement and its impact on development, especially access to medicines in developing countries, should be explored through UN mandates of implementing MDG**

Since Doha Declaration on TRIPS and Public Health launched in 2001, many progresses have been made in developing countries in terms of using TRIPS flexibilities to improve access to medicines. However, significant gaps still remain. We should not forget the political and trade pressures put on Thailand when it legally issued compulsory license on medicines in facilitating the universal access to health care with domestic capacity. We should also not forget disputes happened between India and EU over the controversial enforcement measures over generic medicines trading. New threatens are still alerting during a number of Free Trade Agreements and negotiations, including those between EU and India, Colombia and Peru, where TRIPS-plus protections on medicines are required.

Facing the urgency of fulfilling health related MDGs with boosting access to medicines on one

hand, and the above mentioned international trade and political backlashes on another, it is therefore critical that MDG discussion strongly reaffirm developing countries' right to use flexibilities of IPR in safeguarding public health and access to medicines. An international monitoring mechanism on Free Trade Agreement and its implication on access to medicines in developing countries shall be explored under UN mandates of achieving MDG.

- **Member states should deepen the discussion of alternative incentives mechanism for medical R&D and innovation as essential tool for combating lasting global health crisis and ensure sustainable development in developing countries**

The WHO report on Public Health, Innovation and Intellectual Property has concluded that “there is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor.”¹² Based on such conclusion *inter alia*, the discussion on alternative innovation mechanism is an ongoing process under the Intergovernmental Working Group in implementing the WHA resolution on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Noting that clear linkage to MDG has been speculated by WHO report, the ongoing intergovernmental working group process and discussion for alternative medical innovation incentive mechanism should be linked more closely with the achievement of health related MDG in the current negotiation and September submit. For neglected diseases mainly affecting developing countries, adequate alternative incentive mechanism for medical R&D and innovation is also essential to encourage and improve constructive involvement of private sector, and to ensure a sustainable partnership in combating global health crisis.

Finally, the experiences and lessons learned from the issue of access to medicines and intellectual property also provided a unique opportunity for developing countries to think and explore alternative development pathway, especially in terms of legal and policy mechanism that adequate for domestic capacity building. A meaningful sustainable development can only be made possible when developing countries can stand on their own feet. And only when this happens, the achievement of MDG at national level can be sustained.

Thank you!

¹² WHO, “Public Health, Innovation and Intellectual Property”, Page 85