

INDIAN CIVIL SOCIETY STATEMENT ON THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

22 April 2008

The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) is scheduled to have its next round of discussions from April 28th in Geneva. While this is supposed to be the final round of discussions, it is unclear if this meeting can conclude all discussions in this session.

Background: The IPR based R&D model is not working

The IGWG has been set up specifically to address the inability of the present intellectual property rights (IPR) based system, governed by the TRIPS agreement to address the real health needs of an overwhelming number of people in the world. In 1995 the TRIPS agreement introduced a uniform, global and higher level of patent protection. The promise that this would lead to higher levels of innovation remains a mirage. Globally, the number of New Chemical Entities (NCEs) has decreased over the past decade; of those approved for marketing, **less than 3%** constitute a significant advance over prevailing therapies. The vast majority of new products address the needs of wealthy populations in the global North, while the disease burden is largely in the global South. While the industry researches drugs for lifestyle conditions of the affluent – obesity, erectile dysfunction, baldness, etc. – conditions such as Tuberculosis, Kala Azar, Sleeping Sickness, have to make do with decade old therapies. The last drug developed specifically for Tuberculosis, was introduced some three decades back.

Clearly the IPR based model for innovation is just not working. Strong IPR protection is encouraging protectionism and harming the way science is done. Many more patents are taken out to stop others from working rather than to protect one's own research. This is premised on very high costs of development, that are sought to be recovered through high monopoly pricing of products, closing the door for research required by the global poor who do not have pockets deep enough to afford the high prices.

The importance of the IGWG negotiations for India: alternatives to IPR based R&D funding

The IGWG negotiations are of vital importance for India, as well as for developing countries. This is the first time that a global forum is engaged in discussing ways to channelise R&D into areas of concern for developing countries **and** ways to make new health products – medicines, vaccines, diagnostics – available at affordable prices. The discussions are important for India for several reasons.

First, India has the world's highest incidence of diseases such as T.B., Kala Azar, Malaria and Leprosy, and the third highest incidence of HIV/AIDS in the globe. New remedies for some of these diseases are desperately needed. Moreover, after the amendment of India's patent law, a vast majority of Indians will be denied access to patented medicines because of unaffordable monopoly prices.

Second, the outcome of the discussions can also leverage India's position as a global leader in research on health related products. While India has the best-developed capacity for research in the pharmaceutical sector in the developing world, the IPR based system prevents India from emerging as a global leader.

However, if some of the proposals under discussion in the IGWG are agreed upon, India can draw immense benefits from an alternate system of R&D that is not premised on IPR but on an open source model of R&D. This is an area of particular interest for India given that the Council for Scientific and Industrial Research in India has already initiated an open source drug discovery programme.

Caution: TRIPS plus provisions ahead!

The discussions of the IGWG, however, need to be pursued with caution because the US, Switzerland and EU have counter proposals on the table that, in fact, seek to further strengthen the TRIPS agreement by proposing several “TRIPS plus” measures, such as strong adherence to data exclusivity, and harmonization of standards that would benefit developed countries. They are also obstructing moves that would give WHO a greater role in IPR related issues, when public health is affected. It is important that Indian negotiators do not negotiate away our national concerns, which have been discussed and agreed upon by the Indian Parliament.

Government of India position unclear: need for public accountability

It is a matter of concern that the Indian Government has not discussed what positions it has been taking and shall be taking at the IGWG discussions, in any public forum in the country. The matter has not been discussed in the Indian Parliament, and neither has any explicit position been shared with other political parties or with civil society. The Government has had a few rounds of consultations in the country, but at no point has the Government made public its position. This secrecy is confounding and leads unnecessarily to suspicions regarding the real intent of the Government in these negotiations. Much of our reading of India’s role in the negotiations is based on hearsay, in the absence of an explicit position. We understand that in global negotiations countries need to retain some flexibility, but that does not mean that absolutely nothing will be made public on at least the bare non-negotiables in public interest.

India should take the lead in the creation of an alternative R&D system that de-links prices of medicines from R&D costs

It is surprising that India does not seem to have taken the lead in the process since its inception. The initial proposal for the Working Group was moved by Kenya and Brazil in 2006. Since then, a large number of developing countries have made written submissions, but there have been few issues on which our government has taken the lead. There have been occasions in the negotiations when the Indian position has been contrary to the position of many developing countries – such as its insistence that the scope of diseases under discussion be restricted. It is understood that India has, in the negotiations, been keen to follow up the proposal of a global fund that would support R&D in needed areas. While in itself a welcome idea, the precise manner in which such a fund will be governed and utilized is of prime importance; the proposed fund should not end up providing the already dominant pharmaceutical industry with still more money.

India has lead by example in placing health concerns over commercial interests in the changes to its patent law. It is thus uniquely placed to ensure that the IGWG negotiations firm up proposals that mandate such public health oriented implementation of IPR in developing countries including restrictions on patentability. The Ministry of Health and Family Welfare has stood firm on its stand against the introduction of data exclusivity recognizing the detrimental impact of yet another monopoly on the health and welfare of patients. The Ministry is now in a position to have its stand validated at an international platform.

Finally, there is no necessity for India to agree to the conclusion of the negotiations in this round itself. The negotiations have implications on research and development, drug regulation, clinical trials, pricing, competition, generic manufacture, patents, the application and interpretation of WTO rules and so on. Further it is likely that in the coming months, changes of administrations in some developed countries will likely see a change in the attitudes and approaches of these countries to the IGWG discussions. It would be prudent not to negotiate in haste, especially on issues that are contentious and on which a national consensus is needed. We trust that the Indian negotiating team shall keep this in mind while negotiating our concerns in Geneva.

In the above background some of the issues and the positions that we believe India needs be explicit in pursuing in the negotiations are:

- **Health is a fundamental human right:** The single guiding principle in the negotiations by the Indian delegation must be the universal and constitutional right to health of all persons.
- **“Alternative” R&D model the need of the hour:** India’s own experience as well as that documented from around the developing world shows that the existing system does not work. This must be fully and accurately represented in the negotiations which must stand strong on supporting an **alternative** model for R&D that **de-links prices from R&D costs**.
- **Caution on limitation of scope of diseases:** While the intention of focusing attention on certain diseases is well meaning it in effect freezes the document, requiring re-negotiations and justifications by developing countries at later stages when public health needs may change.
- **No TRIPS-plus provisions:** The negotiations must reject any and all TRIPS-plus references including the numerous references to data exclusivity/data protection in the strategy document.
- **R&D Fund to be based on open source, transfer of technology, alternative R&D models:** While a global R&D fund is welcome, it should not plough even more money back into big pharmaceutical companies. It must work on non proprietary, non IPR based principles and in developing countries.
- **Clear mandate to WHO to look at innovation and access:** The WHO’s mandate to look at issues of innovation, public health and IPR must be clear and unhindered by conditions to collaborate with the WTO and/or WIPO.
- **No harmonization of systems:** Proposals to harmonise drug regulatory and patent systems should be rejected as they are likely to import IPR based regulation from developed countries. Harmonised standards for traditional knowledge that will have a detrimental impact on small practitioners and manufacturers must also be rejected.
- **Promotion of competition and access to generic medicines:** Proposals that suggest the promotion of generic competition after “patent expiry” go against the spirit of compulsory licensing which is essential for increasing access to essential drugs.
- **Public access, accountability and transparency:** In the finalization of the strategy document and in its implementation, the involvement and representation of genuine public interest and health groups must be assured.

National Working Group on Patent Laws, Peoples Health Movement – India, All India Peoples Science Network, Knowledge Commons, All India Drug Action Network, Delhi Network of Positive People, Initiative for Health Equity and Society, Drug Action Forum – Karnataka, Lawyers Collective HIV/AIDS Unit and Center for Trade and Development.