Presentation by India

The TRIPS Agreement recognizes public heath concerns and provides flexibilities to address these concerns. Yet there appear to be significant impediments to taking full advantage of such flexibilities. In this context, the Doha Declaration on TRIPS Agreement and Public Health was a landmark when it said that " ***We affirm that the (TRIPS) Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."*** The Declaration gave sound guidance for interpretation by clarifying the right to grant compulsory licences and the freedom to determine the grounds. The concerns of Members with insufficient or no manufacturing capacities were sought to be addressed by the Decision of August 30, 2003 – "paragraph 6 system"

The coming together of developing countries at Doha paid dividends. Public health concerns raised at Doha were addressed – the clarifications and Para 6 system was intended to facilitate taking advantage of flexibilities. Has it really happened?? Five years – one instance. Only yesterday (Sept 24, 2008) the Canadian company Apotex Ltd shipped to Rwanda its first consignment of seven million tablets of the drug Apo Tri Avir which may save the lives of 21,000 people.

India had negotiated the Doha declaration on public health and the Aug 30 Decision with a great deal of expectations. Frankly, the results leave us a bit disappointed.

Public Health concerns addressed in Indian Patent Amd Act 2005, while being TRIPS Compliant

In fulfillment of its WTO commitments, India replaced the Patent Act 1970 (eif 1972) with the Indian Patent (Amd) Act in 2005. The 1970 Act– served us well as a industrial policy instrument to encourage industrialization and promote self reliance. It is also credited with addressing public health concerns and growth of a strong generics industry.

Public health concerns in a country of over a billion people with 600 million living under $ 2 a day needs no elaboration. The 2005 Patent Law effectively balances and calibrates Intellectual Property Protection with public health, national security and public interest concerns. It contains several public health safeguards, which I will list:

- Availability of products at reasonable price is ensured through the provision of **compulsory licence** (Section 84).
- Compulsory licence can be issued to deal with circumstances of national emergency, extreme urgency or public non-commercial use (Section 92).
- **Parallel import** can be allowed to ensure availability of patented drugs at reasonable prices through parallel imports (Section 107 A). Parallel import need not be only from a person authorised by the patentee.
- With a view to make available patented drugs through Government dispensaries, hospitals, etc. the Government can import patented drugs without the consent of the patent holder (Section 47).
- For public purpose the Government can compulsorily acquire patent rights. Compensation may be determined by mutual agreement between the Government and patent holder and failing which by High Court (Section 102).
- Patent can be **revoked on the ground of non-working** or the patented invention not being available to the public at reasonably affordable price (Section 85).
- Patent can be **revoked by the Government in public interest** if it is prejudicial to the public or exercised in mischievous manner (Section 66).
- No rights accrue to a patent holder for mailbox applications for the period prior to the date of grant of patent (Section 11 A).
- Manufacturing of products by enterprises having made substantial investment to continue on payment of reasonable royalty, even if patent is granted on a mailbox application (Section 11 A).
- **Bolar Provision:** Those interested in manufacturing generic version of patented product on expiry of the patent can make necessary preparations for production even during the validity of the patent (Section 107). This provision facilitates availability of generic

version of the patented product at competitive prices immediately on expiry of the patent.

- **No Ever-greening:** No patent is allowed for a new use of a known drug or substance (Section 3[d]): This provision is unique to Indian law and one of the most important safeguards included to protect public health. It is a *bonafide* provision to combat the problem of ever greening. (Ever greening is a technique companies use to stagger patent applications so as to extend market monopoly and prevent entry of generic drugs.
  - Mere discovery of a new form/ use/ property/ process etc. of a known substance which does not result in **enhanced efficacy** is not patentable.
  - Salts, esters, ethers, polymorphs, etc. of known substance are to be considered to be the same substance until these differ significantly in properties with regard to efficacy.
- **Export of medicines to other countries**

  To use the Para 6 system, India has already adopted the implementing legislation. For export of medicines to countries w/o adequate production facilities, Section 92A has been introduced in the law for obtaining CL for manufacturing and exporting the pharmaceutical products from India, in accordance with the August 2003 Decision.
- **Production and export of medicines for treatment of AIDS**

  The 12 main ARVs (Anti-Retro Viral Drugs) for treatment of Aids (namely, Zidovudine, Lamivudine, Stavudine, Nevirapine, Nelfinavir, Abacavir, Efavirenz, Didanosine, Saquinavir, Lopinavir, Ritonavir, Indinavir) are all pre-1995 molecules, and these will always be off-patent in India, and so it would be possible for Indian companies to keep manufacturing and exporting these medicines to those countries which require such drugs.

Access to affordable medicines in India;

- Availability of essential medicines at affordable prices is a major challenge. Several public policy instruments to ensure availability:
  - Drug Price Control Regime for essential drugs

- Access to public medical facilities and health programmes
- National Aids Control Organisation (NACO) – ensures free supply of AIDS drugs to 150,000 patients through its 187 centres.

- We also note differential pricing by MNCs for as compared to developed country markets. Perhaps, economies of scale have a role to play in price determination.
- 97% drugs are pre 1995 molecules – off patent, and will continue to be so.
- The presence of a robust Generic industry

Use of Compulsory Licenses in India

No responsible government can give up the flexibility in matters of public health. Especially so for a country of a billion people with public health challenges including infant mortality, TB, malaria, AIDS, jaundice and rising coronary and pulmonary diseases.

While CL has been used in recent years by several developing countries, **India has never used CL post TRIPS i.e.since 1995** . However, it has been used it 9 times about 30 years ago. The Government was considering using it in case of Avian Influenza when 100,000 doses were required. The situation was addressed by negotiating with Roche and some generic manufacturers.

Contribution of existence of provision for CL

- Salutary effect of CL against high prices of essential drugs

Why Para 6 flexibilities used only once since 2003 (by Rwanda - Canada)

- Reasons by MSF regarding difficulties of the Para 6 system including arduous notification requirements for importing and exporting countries leading to inordinate delays
- Pressure from patent holders and symbolic 'CSR' activity by free distribution of limited number of doses
- generic medicines available outside patent system
- legislative changes in exporting countries are either recent or not yet completed
- meant to address situation where non-predominant limit proves restrictive

- solutions at times have come through voluntary licences and reduction of prices offered by patent owners