Submission by Centre for WTO Studies, Indian Institute of Foreign Trade to the UN Secretary General's High Level Panel on Access to Medicine

A. Rationale of the Submission

Most patented medicines are priced out of reach of the patients in developing countries and LDCs[1]. This statement is borne out from the example of Sofosbuvir, a medicine developed by M/s Gilead Life Sciences for treatment of Hepatitis C, which is priced at US$84000 in the US market for a three month treatment or the case of Nexavor, a renal cancer drug, priced at Rs. 280,000 for a month's treatment in India. The predatory pricing of patented drugs and the resultant impact on access is well documented in the decision of the Indian Controller General of Patents, Designs and Trademarks in the Natco Pharma Ltd Vs Bayer Corporation (Nexavar)[2] where it was brought out that Bayer could only meet 2% of the total demand for that medicine in the country. This indicates complete policy incoherence between protection of IP, promoting access to public health and trade. It also buttresses the view, that for the patented medicines, developing countries and the LDC are not the relevant market.

It has been widely recognized that the pharmaceutical companies have high profit margins much beyond the levels seen in other industries[3] driven largely by high prices vis-a vis the cost of production. The rationale for the high prices is driven by the argument that considerable resources need to be employed by these companies on Research and Development with an average success rate of three in 10 drugs.[4] The abnormally high prices of medicines are therefore to take into account the expenditure that might have been incurred on account of disproportionately high unsuccessful attempts at developing new molecules. While one does not dispute that the originator companies are indeed in the business of developing new molecules and improved formulations for which research and development is central, it is intriguing that even

[1] Ellen F. M. 't Hoen "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond"
[2] *Natco Pharma Limited v. Bayer Corporation*, Compulsory License Application No. 1 of 2011
[3] Pharmaceutical industry gets high on fat profits by Richard Anderson Business reporter, BBC News(November 2014)
[4] ibid

then the marketing expenditures of these pharma companies considerably outweigh the expenditure incurred on research and development. According to the report filed in the BBC News, while the average spend on R&D by the Pharma companies is about 5-6% of the overall expenditure, this is much lower than the resources set aside by them for marketing purposes-making one wonder whether marketing expenses are sought to be recouped in the name of R&D by these companies.

There is extensive literature on the role of public sector research institutes in the discovery of drugs and vaccines which highlight the prominent role public sector institutes play in this sphere. Research outputs have shown that public sector institutes have a pivotal role in medicines and that their contribution is in medicines that are expected to have disproportionately higher clinical effect.[5] This is also corroborated by others who have found that both the direct and indirect impact of public sector research is important.[6]

B. Model to Address this Policy Incoherence

The model developed is based on the concept of "standard essential patents"[7]. Treatment of most diseases has a clear protocol- whether it concerns prevention through vaccines or treatment after onset of the disease. This is true for lifestyle diseases such as diabetes, hypertension, mental illnesses and cancer and also in respect of HIV or communicable diseases such as Tuberculosis, Malaria, or other vector borne diseases. The proposal is that once a protocol of treatment is decided upon, all patents that are set down as critical for the treatment of the disease should be called "standard essential patents". Such patents that are critical to implement the protocol should then be available to be manufactured by a pharmaceutical company that is prequalified by

[5] Stevens. Ashley, Jensen JJ et al "The role of Public Sector Research in the Discovery of drugs and Vaccines" The New England Journal of Medicine (2011);364:535-41

[6] Lichtenberg. F, and Sampat B, Assistant Professor in the Department of Health Policy and Management at the Mailman School of Public Health of Columbia University (2011) http://www.news-medical.net/news/20111216/Research-reveals-role-of-government-funding-in-pharmaceutical-RD.aspx

[7] Telecommunication Standardization Bureau: "Understanding patents, competition and standardization in an interconnected world" also applied in climate technologies in the US in the following way:
the Environment Protection Agency (EPA) in the US can apply to the Attorney General for a mandatory license for a patent covering a technology necessary to enable compliance with the hazardous air pollutants standards, or motor vehicle emission standards of the Clean Air Act. Under section 308 of the Clean Air Act, the United States may require the owner of the patented technology to grant the non-complying party a patent license in exchange for a reasonable royalty if the patented technology is necessary to meet the requirements in certain sections of the Clean Air Act.

WHO to do so (after due application) on payment of reasonable and non discriminatory (RAND) royalty. The royalty to be paid could be decided by the concerned companies i.e. the originator and the applicant on mutual consent or could be fixed in case of a dispute by a judicial authority. Country jurisdictions would have the freedom to decide whether interim injunctions could be applied in such cases. Much like in the case of SEPs in the telecom sector where interim injunction is not allowed in the US but allowed in Japan, countries could decide for themselves the appropriate way forward on this. Although it may be highlighted that interim injunction seriously compromises the possibility of negotiating on RAND terms and is therefore best avoided. Besides, given the impact medicines have on public health it is advisable that other means such as directing the alleged infringer to operate through a separate dedicated account for the concerned medicine could be considered.

C. Mechanism of Implementation

The mechanism of implementation could be as follows:

a. Step 1: WHO[8] sets up an expert group involving innovator companies, prominent generic companies, medical specialists to set down the protocol for treatment of major diseases whether lifestyle related or vector borne and representative group of member States. This group could deliberate upon the new proprietary technologies and the appropriate stages when these could be applied in the treatment of a disease. The committee could also discuss problems, if any, in the treatment and deliberate upon future treatment course or options.

b. Step 2: The patents that get included in the treatment protocol would be called the standard essential patents. These technologies could be used by any company other than the originator on payment of royalty on RAND terms in markets where the product is already patented. Further improvements such as fixed dose combinations, paediatric dosage forms, and sustained release molecules of the same product when developed by a company could be used by

[8] WHO has considerable experience in this area, given the vast public safety and health angle of the impact it is important that the exercise be conducted under the aegis of this body unlike SEPs in the context of telecomm where it is primarily the research based companies that have come together.

another on payment of royalty, if there is a patent on that form in the country in which it is proposed to be marketed.

c. Step 3: While royalties could be determined by the two parties to the deal, guidelines could also be drawn up by the WHO which would guide the process of fixation. Disputes if any will be resolved as per judicial decisions in the country where the generic company is incorporated or where the product is to be licensed. Interim injunctions could be avoided given the impact they are likely to have on public health matters.

D. Manner in which the Suggestion impacts Innovation, Public health, Human Rights and Trade

i) Impact on Innovation

a. The discussions in the 'expert body' comprising of originator companies, generic producers and medical experts could bring in greater synergy in developing improved drugs for treatment of specific diseases. The telecom standards body such as the ITU and ETSI[9] have helped in development of new standards in the telecomm arena and one may not be amiss in reckoning a similar impact on treatment protocol.

b. Involvement of Generic producers could help in pushing them into R&D through collaborations and cooperation. In any case licensing on non exclusive basis will unleash competition which in turn will promote innovation in product delivery, improvements in the drug such as fixed dose combinations and extension to new patient groups through paediatric dosage and sustained release forms of the molecules.

c. Payment of royalty, expansion of the markets for medicines due to competition and reduced prices will generate revenue for the innovator companies. This will

[9] European Telecommunications Standard Institute

not only extend their reach but also allow them to utilize the distribution network of the generic companies to their advantage.

d. Transfer and dissemination of technology will impact social and economic welfare and facilitate the realization of Article 7 (Objective) of the TRIPS Agreement.

ii) Impact on Access to Medicine and Public Health

a. One of the crucial reasons for the inability of people and countries to get medicines is its price. Technology transfer in a non exclusive basis will bring in competition and help to reduce the prices of medicines. Better distribution networks of the generic companies coupled with lower prices will also extend the reach to new markets. The role generic companies have played in enabling access to HIV Medicines in the world is evidence that this model can indeed work.

b. With lower prices, the mechanism will also reinforce the work of various aid giving humanitarian organizations which procure life saving drugs by enabling them to extend their services to more people and countries.

c. While safeguards in the TRIPS Agreement such as the issue of compulsory license exist, it has become increasingly difficult to take a recourse to this because of the signalling effect it has which brings with it a lot of political pressure against such measures. This makes it an unviable option if access to medicine has to be addressed in a substantive and comprehensive manner. The measure also creates inherent uncertainties and is liable to be challenged making it difficult for generic producers to use this option. We should therefore institutionalize the concept of standard essential patents in the same manner as it is done in the telecom sector to address a more important public need.

d. More significantly the model being proposed will have a profound impact on prices and access because under this, license would be given for manufacture

of the medicine with no territorial restriction on its application-as long as a country is a middle income or a low income country. The economies of scale and the competition unleashed will be precursors to reduced prices and improved access.

iii) Impact on Human Rights

The model seeks to enhance competition, create economies of scale and incentivize innovation by generic companies while addressing the need to suitably compensate innovative efforts of the originator companies through payment of royalty. The measure, as examples in the case of HIV medicines and the recent case of licensing of Sofobuvir indicate, will improve availability and affordability of life saving drugs in low income and middle income countries. It would therefore impact the Sustainable Development Goal No. 3 on promoting health for all positively. The proposal will directly impact two targets set to be achieved by 2030 - ie-

> To end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
>
> To reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being

while also impacting the others indirectly.

iv) Impact on Trade

According to the WHO, "although trade in medicines is increasing rapidly, most of it takes place between wealthy countries, with developing countries accounting for just 17% of imports and 6% of exports. It is estimated that one-third of the developing world's people are unable to receive or purchase essential medicines on a regular basis."[10]

[10] http://www.who.int/trade/glossary/story002/en/

The measure being suggested will address this and promote trade in medicine among the Developing and the Least Developed Countries.