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From the Director's Desk

Dr. Surajit Mitra

The Doha Round of negotiations embodies several concerns for developing countries. Since launch of Doha in 2001, many developmental issues have surfaced in WTO negotiations. One of the most significant and intricate one has been the interface between Trade Related Intellectual Property Rights (TRIPS)and the objective of universal and equitable access to public health. Overriding importance of this subject could be gauged from the fact that there was a separate Ministerial Declaration on TRIPS and Public Health at the time of announcement of Doha.

The TRIPS Agreement for the first time in 1995 set down minimum standards and universally applicable benchmarks on intellectual property (IP) to be administered on all WTO member countries. While certain relaxation in implementation was given to developing countries and least developed countries as they were in nascent state of IP development, within years of operation of the Agreement, it was felt that the avowed intent of universally equitable and affordable access to health could be severely compromised unless concessions were made by amending the TRIPS Agreement.

On 6 December 2005, the TRIPS Agreement was amended to incorporate specific safeguard measure to ensure that public health concerns were not compromised keeping in view the issue of affordability and accessibility for a large section of people who live in developing countries. These amendments are yet to come into force as two-third members of the WTO have not yet ratified them as required under the WTO provision. The deadline to amend has been postponed to 31st December 2013 by the General Council.

The significant part of the current debate relating to TRIPS compliance by developing countries in general, and India in particular, has focused on the establishment of a product patent regime. It has been contended seriously on the one hand that a product patent regime would encourage innovation and foreign direct investment in a developing country, while on the other hand it would severely undermine the capability and growth of the domestic generic drug manufacturing industries. Such a regime would not only make public health more expensive, but also push it out of the reach of the large sections of the poor, living in developing countries.

TRIPS, Public Health and CBD

Issues and Concerns

Manisha Shridhar*

The issue of TRIPs and public health is gaining momentum in current Doha Round of negotiations. Various concerns of the developing and LDCs have been highlighted in several multilateral meetings. Developing countries argue, current regime of product patent regime would vigorously affect their accessibility and affordability to medicine and affect the capability of their domestic pharmaceutical industry. The article makes an attempt to analyze the issue in detail in the context of the developments taken place in the areas of TRIPS, CBD and public health sharing. It suggests certain measures keeping in view the prospect and debate surrounding the issue of TRIPS.

1. UN Decade for Biodiversity and Nagoya Protocol

THE United Nations (UN) has declared 2011-2020 the UN Decade on Biodiversity, with a view to contributing to the implementation of the Strategic Plan for Biodiversity 2011-2020. By the launch of a major international agreement at Nagoya, Japan on 30 October 2010, the tenth Conference of Parties (COP) to the Convention on Biological Diversity (CBD)[1] adopted an international protocol on Access and Benefit Sharing (ABS). This agreement sets ground rules for improving access to, and the equitable sharing of, the world's genetic resources.

UN Secretary-General Ban Ki-moon has stated that the landmark treaty was a positive step in efforts to achieve the Millennium Development Goals, (the global action plan to achieve the eight anti-poverty goals including women's and children's health and other initiatives against poverty, hunger and disease by their 2015 target date).[2]

The Convention on Biological Diversity (CBD) is a key agreement adopted during the historic Earth Summit held in Rio de Janeiro in 1992. This is the first comprehensive global agreement which addresses all aspects of biodiversity. The CBD seeks

- conservation of biological diversity,
- sustainable use of its components,
- fair and equitable sharing of the benefits arising out of the utilization of genetic resources by appropriate transfer of relevant technologies[3] (Article 15 of the Convention).

CBD recognizes that states have sovereign rights over their biological resources, and are responsible for conserving biological diversity.[4] The states will also endeavour to create conditions to facilitate access to genetic resources. The provision in respect of intellectual property rights (IPRs) states that in the case of technology subject to patents and IPRs, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.

The Nagoya Protocol will be invoked in outlining benefits – for example, from when a plant's genetics are turned into a commercial product, such as medicine – will be shared with countries and communities who conserved and managed that resource. It also lays out rules on how substances and compounds derived from genetic

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resources will be dealt with, besides the issue of pathogens, including how developed countries could obtain a flu virus in emergency situations to develop a vaccine to counter a possible epidemic.

In Nagoya, governments also adopted a new strategic plan, including targets for addressing biodiversity loss to be met by 2020.[5]

2. IPRs, Nagoya Protocol and Aichi Targets

The common IPRs are patents, copyrights, trademarks, geographical indications used to identify products and undisclosed information such as trade secrets. IPRs are the rights given to a person over the use of his/her creation for a certain period of time to allow the creator to benefit from his creation.

The Nagoya Protocol affirms that IPRs play an important role in the fair and equitable sharing of benefits arising from the use of genetic resources, their derivatives and associated traditional knowledge. Nagoya affirms that these rights need to be supportive of and not run counter to the three objectives of the Convention. This also provides that nothing in this Protocol shall be interpreted as affecting the granting, or the exercise of intellectual property rights and reiterates that Member states will establish clear rules and procedures for requiring and establishing mutually agreed terms and legal and institutional development/framework. They will also provide for joint ownership of relevant IPRs and the terms shall be set out in writing and include:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing.

The management of IPR issues in Nagoya Protocol need to be in line with Aichi biodiversity targets (named after Aichi prefecture in Japan whose capital is Nagoya) that aim to achieve the following goals:

A : Address the underlying causes of biodiversity loss by mainstreaming biodiversity across government and society,

B : Reduce the direct pressures on biodiversity and promote sustainable use,

C : Improve the status of biodiversity by safeguarding ecosystems, species and genetic diversity,

D : Enhance the benefits to all from biodiversity and ecosystem services,

E : Enhance implementation through participatory planning, knowledge management and capacity building.

These goals must be achieved in a manner that promotes the interests of the local communities, permits equitable exploitation of natural resources under the overall arching umbrella of conservation of biodiversity. In the context of fair and equitable sharing of benefits arising out of the utilization of genetic resources by appropriate transfer of relevant technologies the most important IPR is a patent.

3. IPRs, CBD, TRIPS and UPOV in Benefit Sharing

The current debate on the issues of biodiversity and intellectual property is propelled by three international conventions: the CBD, Trade Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO)[6] and the International Convention for the Protection of New Varieties of Plants (UPOV).[7] The Member states signed the CBD in 1992 when the Dunkel draft, the forerunner of the World Trade Organization and the TRIPS was under consideration. On the one hand they sought the protection and enforcement of intellectual property under the IPRs agreement of the WTO, while on the other the CBD emphasized the equitable sharing of biological resources by nations.

The CBD calls for the determination of the access to genetic resources by national legislation, emphasizing that prior, informed consent (PIC) is necessary. PIC is necessary to enable the local communities to participate in exploitation of their resource. It is also envisaged that this would motivate these communities to better preserve their natural resources and lead to measures supporting conservation. There is an urgent need for the biodiversity to be preserved and prevent its loss by overexploitation and by adoption of monoculture production. Indeed, in view of the

germplasm being held world over in the gene banks, the access provisions seem to have been invoked quite late by the resource rich developing world. However, the benefits of *in situ* conservation are tangible and more favourable than the *ex situ* measures. The latter would remain secondary to preserving biodiversity.

There is a genuine concern in the developing world that the obligations to conform to the patent regime under the TRIPS make products and technology very expensive. While this has major repercussions for the pharmaceutical industry, the agriculture and the farming community has serious concerns on food security where patented seeds and other farm inputs will impact their livelihood. A major apprehension is that these seeds and other farm inputs are frequently derivatives of genetic resources from the resource rich developing world. While these developing countries are providing the genetic material, they have little say in technology transfer and are unable to reap the benefits of technology emanating from their resource.

The TRIPS Agreement seeks the protection of IPRs in international trade. TRIPS made it mandatory for the developing countries to bring their national legislations in line with the international conventions for intellectual property in copyrights, trademarks, geographical indications, industrial designs, patents and trade secrets. TRIPS is also unique in that it called for an extensive revision of national legislation.

Of all forms of intellectual property, it is the operation of the patents in TRIPS in Art 27 which is closely linked to fair and equitable sharing of the benefits arising out of the utilization of genetic resources by appropriate transfer of relevant technologies. Art 27 of the TRIPS Agreement, read together with Art 7 and Art 8 of the Agreement, calls for the protection and enforcement of intellectual property in a manner contributing to the transfer and dissemination of technology to the mutual advantage of producers and users of such technology conducive to social and economic welfare. In 2001, Doha Declaration and Para. 19 affirmed that the TRIPS Council should also look at the relationship between the TRIPS Agreement and CBD and protection of traditional knowledge and folklore.

While certain exceptions to patents (plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes) are recognized, it is mandated that the countries *shall* provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.[8] Therefore, while plants and animals other than micro-organisms, and other biological processes are excluded, it is clear that to bring their domestic legislations in line with international commitments it is essential for the Member states to provide some form of protection to plant varieties. There is no flexibility regarding the fact that protection is to be given, however, the method of such protection is left to the discretion of countries who may adopt their own unique system.

To comply with this provision, India enacted the Plant Variety Protection and Farmers Rights Act (PVPFA), 2001, (a *sui generis* legislation) rather than acceding to the UPOV Convention. PVPFA provides for 'benefit sharing' in relation to a plant variety. Plant variety refers to the essence of plant breeding and the discovery or the creation of genetic variation in a plant species where its selection with desirable traits that can be inherited in a stable manner. The developing countries, that are genetically rich, lack appropriate technologies for harnessing their resources. For determining the amount of the "benefit sharing" on plant varieties, the issues considered are

(a) the extant and nature of the use of genetic material of the claimant in the development of the variety relating to which the 'benefit sharing' has been claimed.

(b) the commercial utility and demand in the market of the variety relating to which the 'benefit sharing' has been claimed.[9] This obligation does not extend to the protection of animal varieties.

There is, thus, a need to address the obligations on IPR and the objectives of fair and equitable sharing of the benefits arising out of the utilization of genetic resources desired under the CBD in a concerted manner with PVPFA and other relevant legislations in order to maximize outcomes for

developers of IPR and genetically rich resource provider communities.

4. CBD and Access & Benefit Sharing (ABS): Indian Position

India has taken a number of CBD measures related to biodiversity conservation and combat biopiracy. India was one of the first few countries in the world to enact a national legislation, the Biological Diversity Act in 2002, which contains provisions for ABS. A National Biodiversity Authority has also been set up in Chennai. This provides an opportunity to India to realize benefits for its people from the use of its varied biodiversity.

Also, India has created a database of traditional knowledge – called the Traditional Knowledge Digital Library (TKDL) – managed by the Council of Scientific and Industrial Research (CSIR). The TKDL is a computerized database of documented information available in published texts of Indian systems of medicine. The objective of the TKDL is to make documented information easily accessible to patent examiners to prevent grant of patents on non-original inventions. So far over 2 lakh formulations of Ayurveda, Siddha, Unani and Yoga have been documented into the TKDL on 34 million pages of information, over a period of 8 years at an estimated cost of ₹ 7 crore. About 2,000 patents related to the Indian System of Medicine are granted every year in the US Patent & Trademark Office (USPTO), the European Patent Office (EPO) and other overseas patent offices. To address this issue, India is signing agreements with other patent offices for access to the TKDL database. An important next step is to set up a People's Register of Biodiversity, so that traditional knowledge passed down through the oral tradition can also be documented and protected.[10]

While a number of steps have been taken, in view of the interdependence of the various treaty provisions in CBD and TRIPS, a concerted approach to regulations for fair and equitable sharing of benefits from utilization of genetic resources is necessary.

5. Commercialization of IP, ABS and PIC

For any invention, a patent application is filed as soon as the requirements of novelty, inventive step and industrial application are met. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources by appropriate transfer of relevant technologies principle is brought forth to play when the benefits arise due to commercialization. The time lag from the time a patent is obtained and the possible commercialization of the patent varies from industry to industry.

Pharmaceutical R&D falls into three main stages. The *discovery*—the basic research in life sciences by which a lead is found, including the acquisition of materials for screening—and *development*—the most challenging aspect is the process of taking the candidate through all the required stages of pre-clinical and clinical research and regulatory process (which includes chemical improvements to a drug molecule and animal and clinical studies) and *delivery* – making available the new products through health systems.[11] It takes roughly 10-15 years for a compound to make its way through discovery and development into commercialization, and roughly one in 10,000 compounds screened are commercialized.[12]

New crop ornamental varieties are also research intensive. The identification and evaluation of agronomically important traits from exotic germplasm, for example, can take 5-10 years or longer and a further 10 years may be required to develop an improved variety that is acceptable to the farmer.[13]

On the other hand, in the biotechnology industry it is not uncommon for the development cycle for an industrial or technical product – such as enzymes for biofuels and detergents—to take no more than 1-2 years from when a lead enzyme is identified. Food and feed products take longer, given more involved approval procedures and requirements for toxicology and their development could take 2-3 years.[14]

ABS is an important issue for the pharmaceutical industry, biotechnology (health care and agriculture) industry, seed, crop protection and horticulture industry. ABS issue was recently fueled by the actions of Indonesia, which has had more human

cases of avian flu than any other country, and in early 2007 stopped sending samples of the H5N1 virus to the World Health Organization (WHO) on the grounds that it required a more equitable system of access to vaccines for developing countries.[15] Partnerships around the sourcing of raw materials for the pharmaceutical industry are also a potential benefit in that sector. For example, Novartis has worked with the Shanghai Institute of Materia Medica, other scientists and the government of China on sourcing *Artemisia annua* for production of Coartem, an anti-malarial therapy developed from traditional Chinese medicine.[16]

In recent years, industry has responded to negotiations for an international ABS Regime, and proposed requirements for "disclosure of origin" on patent applications, with concerns of the impact this may have on industry R&D. One example of the pharmaceutical industry's increased interest in ABS is reflected in the recent development by the International Federation of Pharmaceutical Manufacturers and Associations of guidelines for their members on "Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization" (IFPMA, 2006). These guidelines support the objectives of the CBD, and lay out the elements of "industry best practice" including obtaining PIC, reaching mutually agreed terms incorporated into a "formal contractual benefit-sharing agreement", and avoiding negative impacts on traditional use when commercializing genetic resources. In return, they request governments to assign national focal points, enact ABS legislation, enter into good faith negotiations, and agree on dispute resolution—in sum, to provide legal certainty over material accessed.

In this regard the Union for Ethical Biotrade has introduced a Biotrade Verification Framework for Native Natural Ingredients which includes important principles relating to ABS, such as the need to ensure the PIC of those providing access; the recognition and promotion of traditional knowledge and fair compensation for its use; the fair and equitable sharing of benefits derived from biodiversity use; and the introduction of systems of traceability (Union for Ethical BioTrade, 2007). Such initiatives reflect an increased convergence around ABS amongst sectors using genetic resources and those using raw materials as commodities. Prior Informed Consent (PIC) poses a number of difficulties for companies. In many cases, such as Astra Zeneca in Queensland and Novozymes and Diversa in Kenya, companies work through local partner institutions that take responsibility for all permits, approvals and liaisons with local governments and communities.

While CBD gives legal authority to national governments to grant PIC, in practice companies or research institutions require consent from a range of parties, including collaborating institutions, communities, land owners/stewards, governments, and others. In the International Cooperative Biodiversity Groups (ICBG) program, it is seen a number of constraints and complexities contribute to the time it takes to conclude an ABS agreement: national governments without focal points and clear procedures; the requirements of legal staff involved in complex negotiations; the time required to get sign off from senior and busy management in companies; community outreach and consultation, and the need to follow traditional decision-making practices and timelines; and university or research institution policy deliberations.

Many in the seed, crop protection and plant biotechnology sectors have commented on the difficulties of operating in the absence of clear-cut rules or knowledge of the value of the material. Some countries, such as Brazil and India, are regularly avoided by companies, since it takes 1-3 years to get a permit, and researchers fear the hostility that meets their research, and the "national regulatory labyrinths". As strategy to avoid such complexities, the trade association Phytotrade Africa focuses on countries with whom it has an established relationship, and avoids conducting research on samples from countries such as South Africa, where the regulatory framework is perceived to be unclear and where relationships with the relevant authorities and stakeholders have not yet been established.[17]

The relationship between IPRs and benefit sharing varies considerably among sectors but is especially complex in the seed sector, where conflicting views exist as to the most effective intellectual property environment for plant varieties and associated benefit-sharing mechanisms. In this sector material is typically either protected by plant breeder's rights (PBRs)

(in the EU and elsewhere) or plant patents (in the US). Unlike other sectors, where patents protect genetic material from unauthorized use, PBRs include a breeders' exemption which involves new material being made freely available for others to use. If PBRs exist some feel that no further financial benefit-sharing is required since free availability of the improved material is a significant benefit. Under a plant patent system, however, additional payments would be required since these patents place constraints on the free availability of breeding material. A flexible regulatory framework would encourage research and commercialization where the original germplasm would be subject to different IPR systems.[18]

There is a need, therefore, to guard against establishing procedures under PIC that take future research and industry away from the country. There are numerous types of agreements and contrary to what is often imagined, bio-prospecting partnerships rarely involve a single framework agreement, and more often utilize an inter-locking web of agreements between the various involved parties. The legal and regulatory framework must respond to such flexibility to cater to the interests of the stakeholders.

6. ABS and Exploitation of Resources and Strategic Framework in Nagoya Protocol

Given the vast number of issues involved in fair and equitable sharing of the benefits arising out of the utilization of genetic resources by appropriate transfer of relevant technologies and IPR, it is important to recognize the significance of these in perspective of each of the different types of activities in the pharmaceutical industry, biotechnology (health care and agriculture) industry, seed, crop protection and horticulture industry.

The consequences of PIC are not uniform across all industry groups. The implications due to the nature of the industry, vast gestation periods of 8-12 years for results in pharmaceuticals on the one hand and shorter, 1-2 years development period for biotechnology, make the canvas for PIC very large and complicated. Another challenge for ABS in biodiversity is the need to determine the source or countries of origin for certain natural products. In the horticulture sector for instance, germplasm acquisition via the "cowboy approach" is still prevalent with many plant collectors working outside of government approval systems to supply nurseries and horticultural firms.[19] This is a key difference between the horticultural and, for example, the pharmaceutical industry. This sector will thus require a different regulatory approach to ABS from pharmaceuticals.

PIC serves two main purposes: one is for benefits to the local community including monetary value of the products and may come in the form of royalties and the second is motivating the suppliers of biodiversity towards conservation of this resource. The regulatory regime must address both these issues in order to create a favourable environment to gainfully and sustainably exploit resources.

Appropriate regulatory systems need to be designed for pharmaceutical industry, biotechnology (health care and agriculture) industry, seed, crop protection and horticulture industry to address ABS. Weak and non-functioning regulatory systems will act as a deterrent to ABS. Development of national ABS measures has proven difficult for many countries due to a number of factors, including lack of technical expertise, budgetary constraints, weak government structures and political support, local social conflicts, and conflicts over ownership of genetic resources.[20] The cost and time required developing partnerships within complex and evolving regulatory frameworks are significant, and many companies report a retraction of collections into fewer countries with more straightforward procedures. National ABS mechanisms, therefore, must address variations across sectors.

A question is when the information on the source of raw material significant for ABS. The information obtained in a patent application is worthless if not commercialized by the patent. Evidence suggests that despite renewed interest in natural products, most large companies are not expanding their in-house natural products programs, but are licensing in, or forming partnerships, with small companies and universities that generate interesting leads from natural products discovery research.[21]

At a time when natural product discovery programs are being outsourced by the large pharmaceutical companies and is increasingly undertaken by smaller companies, academic and government research institutes, which license compounds to large pharmaceutical companies for development, it is critical to simplify legal and regulatory processes. Small companies are by nature resource constrained and will not have the wherewithal to resolve complicated regulatory processes. Therefore, we must devise mechanisms that encourage, simplify and aid small industry for research and commercialization in the first instance, and encourage easy ABS for local communities. It may be worthwhile to examine various ABS possibilities and suggest an array of choices for industry and local communities to encourage this process. This is important as the communities may not be interested in exclusivity of resource rights but rather in using the benefits collectively.[22] Hence, clear, simplified regulatory systems for different sectors will aid conservation, commercialization and translate benefits to local populations.

For certain industry sectors, e.g. pharmaceuticals, vaccines, etc, we may borrow from ancillary rules of international trade under the World Trade Organization, e.g. Rules of Origin for ascertaining the origin of a biological material. Rules of Origin are the criteria needed to determine the national source of a product. This will enable determination for fair and equitable sharing of the benefits arising out of the utilization of genetic resources. Rules of Origin are derived from the fact that duties and restrictions in several cases depend upon the source of imports.[23] For instance, the US requires certain mandatory country of origin labeling (COOL) provisions in the Agricultural Marketing Act of 1946 as amended by the 2008 Farm Bill and implemented through an Interim Final Rule of 28 July 2008. These rules include the obligation to inform consumers at the retail level of the country of origin in respect of certain commodities. The emergence of anti-dumping law as one of most important trade policy instruments during the 1980s and 1990s has largely been responsible for the growing attention to the use of Rules of Origin as commercial policy instruments which could influence the interaction between the internationalization of production and its location.[24] Suitably developed, these rules of origin determinants could be adapted for the relevant industries for ABS under CBD for the benefit of the communities and pharmaceutical industry, biotechnology (health care and agriculture) industry, seed, crop protection and horticulture industry.

7. Way Forward

The Aichi biodiversity goals of Nagoya Protocol must be achieved in a manner that promotes the interests of the local communities and permits equitable exploitation of natural resources under the overall arching umbrella of conservation of biodiversity. This needs to be taken up where the relevant provisions of IPRs, CBD, TRIPS and PVPFA are considered together for a concerted approach and to maximize benefits. The ABS mechanisms established must be done in a manner that guard against establishing procedures under PIC that take future research and industry away from the country. The legal and regulatory framework must cater to the interests of all stakeholders.

The countries are presently engaged in developing an overarching framework on biodiversity to translate Nagoya goals into national and international action plans. It would be appropriate that India addresses these issues in a concerted manner and takes a lead in developing suitable regulatory frameworks for maximizing outcomes under this mechanism.

NOTES

[1] Convention on Biological Diversity http://www.biodiv.org/conv/

[2] http://www.cbd.int/doc/notifications/2010/ntf-2010-201-cop10-en.pdf

[3] Art 1 Convention on Biological Diversity (CBD).

[4] Art 3 CBD.

[5] http://www.un.org/apps/news/story.asp?NewsID=36618&Cr=biodiversity&Cr1

[6] World Trade Organization Final Act, Annex I C 519 http://www.wto.org

[7] International Convention for the Protection of New Varieties of Plants. http://www.upov.int

[8] Art 27.3 Section 5 Patents Annex IC Agreement on Trade Related Aspects of Intellectual Property Rights.

[9] Art 26, The Protection of Plant Varieties and Farmers' Rights Act, 2001.

[10] http://pib.nic.in/release/rel_print_page1. asp?relid =56597

[11] Commission on Intellectual Property Rights, Innovation and Public Health; WHO.

[12] ten Kate, K. and Laird, S. (1999), *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, London: Earthscan.

[13] Smith, S. and Grace, J. (2007) *Access and benefit sharing of plant genetic resources for food and agriculture*.

[14] CBD Technical Series No. 38; *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors*.

[15] McNeil, D.G. (2007) Indonesia may sell, not give, bird flu virus to scientists, *The New York Times*, 7 February 2007.

[16] CBD Technical Seriers No. 38; Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors p. 25.

[17] *Ibid*, p. 25.

[18] *Ibid*, p. 34.

[19] *Ibid*, p. 117.

[20] UNEP/CBD/WG-ABS/3/2, 2004.

[21] CBD Technical Seriers No. 38; Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors, p. 104.

[22] Wynberg, Rachel, 2008, "Access and benefit-sharing agreements in the commercial development of Hoodia" in: Laird, Sarah and Rachel Wynberg, 2008, *Access and benefit sharing in practice: Trends in partnerships across sectors*, Convention on Biological Diversity Technical Series No. 38.

[23] http://www.wto.org/english/tratop_e/roi_e/roi_info_e.htm

[24] http://assets.cambridge.org/97805218/51909/copyright/9780521851909_copyright_info.pdf

EU-India Free Trade Negotiations Threatening Access to Medicines

INDIAN firms are major global producers of relatively affordable generic medicines. Access to such drugs make the difference between life and death for billions of people in the Global South. *The Economist* noted recently that 'America should not use trade deals to swaddle drug makers in excessive patent protections'. Nor should the European Union (EU) impose obstacles to the supply of generic drugs by Indian firms beyond those already mandated by the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

Free trade negotiations between the EU and India (reported to be close to completion) constitute a clear threat to the role of India as the 'pharmacy of the developing world'. From Independence in 1947 until the 1970s, India relied on imports of highly priced medicines as a result of the patent regime inherited from the British. In 1970, the Indian Parliament changed the patent regime and till 2005 product patents were not issued on medicines in India. The Indian government in this period also put in place industrial policy measures in support of local industry. The result was a strong and vibrant generic industry producing safe, effective and affordable generic medicines.

The case of anti-retrovirals (ARVs) provides the most dramatic illustration of the global impact of Indian drug firms. In 2001 an Indian company, Cipla, introduced first-line triple combination AIDS medicines at $350 per person per year, a stunning offer at the time. The then GlaxoSmithKline CEO Jean-Pierre Garnier described Cipla as price-undercutting "pirates". Other Indian firms followed Cipla's model and today 80 per cent of the 8 million people living with HIV who are on treatment in developing countries are on Indian made generics. As a result of competition from and between Indian generic producers, the price for first-line AIDS medicines has come down from as much as US$15,000 in 2000 to less than US$120 per person per year for the current preferred first-line triple combination in 2012.

The TRIPS Agreement mandates minimum intellectual property rights (IPRs), including 20-year patent protection for products and processes in "all fields of technology" including medicines. With associated policy practices, rules, and trade agreements, TRIPS sustains a global regime of private monopoly rights which is widely recognized as impeding access to essential medicines in the Global South. While TRIPS is not the only obstacle to public health, product patents complicate and delay the production and market entry of lower cost generic drugs.

In the sphere of global politics, a coalition of public health advocates, non-governmental organizations and governments, such those of India, Thailand, South Africa and Brazil, has sought to limit the impact of IPRs on access to medicines. The Declaration on the TRIPS Agreement and Public Health- the Doha Agreement - is the major achievement of this campaign. Adopted at the fourth WTO ministerial conference in Doha in 2001, the Declaration confirmed and extended the right of WTO members to utilize a range of "flexibilities" available under TRIPS, which make possible the circumvention of patent rights to meet pressing population health needs. It is fair to say that several policies that challenge the norms, rules and basic political economy of the global IPR regime have attained legitimacy as a result of the widespread acceptance of human rights and public goods discourses to the field of health.

Many of these policies and 'flexibilities' were included in India's new TRIPS-compliant patent regime by the Indian Parliament in 2005. Health advocates, patient groups and the Indian government have effectively used these safeguards to ensure that only truly innovative medicines receive patents in India and where patented medicines are exorbitantly priced, generic production can be sanctioned to ensure access and affordability. This was evidenced by India's first compulsory license issued in March this year on Bayer's cancer medicine sorefanib tosylate that Bayer was importing and selling in India for $5,000 per person per month. The generic equivalents cost between $120 and $160.

But in the same period of limited public health gains the governments of the North have pursued, with increasing vigour, bilateral and regional free trade agreements (FTAs). Many of these include so-called TRIPS-plus provisions (not required under TRIPS) which have the effect of entrenching and extending IPR protection and thus delaying the market entry of cheaper generic drugs.

Till recently, the European Union (EU) did not feature among the aggressive developed nations pursuing TRIPS-plus measures. But FTA negotiations with India, which started in 2007, raise serious concerns. Leaked negotiating texts of the IP and Investment Chapters show that the European Commission (EC), in a stark departure from its traditional model of trade negotiations, has demanded ambitious TRIPS-plus measures. After 11 rounds of negotiations, talks are now being held in smaller groups instead of full rounds of negotiation. Both sides are aiming to conclude the deal by the end of this year or in early 2013.

There are three distinct areas of concern: Intellectual Property provisions, the Investment provisions and the Regulatory Standards provisions. The leaked chapters show that the EC has demanded longer patent terms, data exclusivity and TRIPS-plus IP enforcement measures from the Indian government.

A key area is the EC push for aggressive IP enforcement, widely considered the latest front in the IP battle between the North and the South. Best reflected in the secretly negotiated ACTA which was recently rejected by the European Parliament, IP enforcement entails measures that significantly alter how IP holders like multinational pharmaceutical companies can use public resources, public money and public authorities to enforce their private rights.

Referred to as anti-counterfeiting measures, the rhetoric around IP enforcement uses the different meanings of counterfeit (i.e. fake in GOVERNMENT GAZETTE OCTOBER 2012 97 EU - India Trade Relations everyday parlance and trademark violation under the TRIPS Agreement) to argue that such measures are required to ensure that patients have access to safe and good quality medicines. However, the safety and quality of medicines requires investment in drug regulatory frameworks, not IP enforcement. In fact, there is increasing evidence that aggressive IP enforcement hampers access to medicines. The clearest impact of this has been seen in 2008 and 2009 when generic medicines on their way from India to Africa and Latin America were seized at European ports.

Several IP enforcement provisions that were in the now rejected ACTA appear to still feature in the EU-India FTA negotiations. These provisions empower patent holding companies to seek measures against generics producers that are not limited to damages. The freezing of bank accounts, the seizure of properties and documents and several other harsh penalties are proposed as measures to strengthen the arsenal of patent holders.

Other provisions would drag the whole supply and distribution chain into potential litigation, creating a strong disincentive for chemists to stock generic medicines, truckers to transport them or even those building machines for generic companies to continue working with the generic industry and could pose a serious threat to the work of humanitarian organizations.

In 2011, the EC received a mandate from the European Council to include an "investment" chapter in EU-India FTA negotiations. The investment chapter would contain provisions designed to protect the interests of European investors in India and would be similar to provisions contained in bilateral investment treaties (BITs). These provisions would allow multinational companies to sue the Indian government in secret international arbitration over laws and policies that benefit health or the environment including for the protection of their intellectual property. For instance, Australia's tobacco control and plain

packaging laws are being challenged under such provisions on the grounds that they violate the trademarks of big tobacco companies. Resolutions passed by the European Parliament in April and May 2011 directed the EC to ensure that these investment provisions do not hamper generic production or the use of TRIPS flexibilities or other health policies.

The inclusion of regulatory standards in FTAs seems to be a relatively recent phenomenon. In February 2011, news reports suggested that the EC was demanding that India harmonize its drug regulatory standards with the standards set by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Developing countries (also known as the non-ICH countries) have argued against the adoption of ICH standards as they are too burdensome and expensive not only for developing country regulators but also for companies in these countries. According to critics of the ICH standards, public health should be the first concern in non-ICH countries and higher technical standards must be justified by public health needs.

According to the EC, it is no longer demanding that the Indian government agree to longer patent terms or data exclusivity. But it appears to be still pursuing demands for TRIPS-plus IP enforcement, investment measures and regulatory harmonization. In April 2011, the Indian Prime Minister's Office issued a press release stating that nothing in the EU-India FTA would go beyond TRIPS or India's domestic law. Sources indicate that the EC has now shifted negotiation tactics to argue that several of their demands (like data exclusivity) are within the TRIPS framework or are already present in Indian law (like TRIPS-plus IP enforcement).

In February 2012, the 11th EU-India Summit was held in Delhi. According to news reports, both India and the EC stuck to their stands on various contentious issues in the FTA. As the negotiation texts continue to be secret, it is difficult to ascertain the actual shift in the position of the EC. Even if the EC drops its demand for EU-style data exclusivity, it may still argue that data exclusivity is required by the TRIPS Agreement.

The European Parliament has repeatedly issued resolutions directing the European Commission to ensure that access to medicines not be affected by the FTA. In May 2011, the European Parliament specifically asked the EC not to demand data exclusivity of the Indian government and recognized the importance of the use of TRIPS flexibilities by India.

Several of the health safeguards included in the Indian patent regime are at risk of being overturned or undermined by TRIPS-plus provisions demanded in the negotiation for an FTA with the EU. If accepted, these demands would have an impact not only in India but on patients across the developing world. The EU's FTA negotiations have drawn concern from UN agencies and international organizations such as UNITAID, the Global Fund on AIDS, TB and Malaria, Oxfam, MSF and many others. As recommended by the UN Special Rapporteur on the Right to Health, "developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health". Several other developing countries (such as Thailand) are engaged in FTA negotiations with the EU and reports indicate that the EC is demanding TRIPS-plus measures of these countries as well. If so, the global protests sparked by India's FTA negotiations will only intensify and the already weakened position of European countries as the promoters and defenders of human rights is likely to be further eroded.

Courtesy: Kajal Bhardwaj and Hans Löfgren (http://donttradeourlivesaway.wordpress.com/about-2/, 28 September 2012)

Strong Medicine for Poor Countries

AS curtains on the six-year-long legal tussle with Swiss drug giant Novartis AG finally came down earlier this month, the Indian government did not waste a second in hailing the Indian patent law which it said was in "full conformity" with intellectual property rules under the World Trade Organization (WTO), which is referred to as the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, ironically, it was India that had severe objections to the agreement and had accused it of being tilted towards the developed world when it became a signatory to the deal in 1995. Later, in 2005, India

amended its patent law to act in accordance with the TRIPS Agreement and moved to a regime of product patents. Till then, the country recognized only process patents. In other words, Indian pharmaceutical companies were free to make any medicine in the world so long as they used an unpatented process to do that - even that provision was loosely monitored.

The recent judgment by India's Supreme Court to not grant patent for Novartis' blockbuster cancer medicine Glivec was not only seen as the victory of India's patent law, specifically Section 3(d) which mandates the need for a substantive innovation while deciding on a case for grant of a fresh patent, but it also firmly asserted India's adherence to global IPR norms under the TRIPS deal. Section 3(d) of the Indian Patents Act, the constitutionality of which was challenged in the Glivec case, provides a patenting standard which is fully within the standards laid down in TRIPS. On its part, Novartis had alleged that Section 3(d) violated TRIPS in the Madras High Court but did not appeal against the rejection of this argument by the High Court.

(*Business Standard*, 27 April 2013)

EU-India Trade Deal Branded 'Nail in Coffin' for Access to Medicines

AN upcoming trade deal between the EU and India represents "another nail in the coffin" of access to affordable medicines in developing countries, it has been claimed.

The EU-India free trade agreement (FTA) negotiations are expected to conclude in a matter of weeks, if not days.

But some leading NGOs say that "many provisions" which they claim are harmful to access to medicines still remain in the agreement.

These provisions, it is claimed, would impact on access to affordable medicines for millions throughout the developing world and could have legal and financial consequences for treatment providers.

In a bid to highlight their concerns, groups such as Médecins Sans Frontières who rely on over 80 per cent of generic medicines from India to treat nearly a quarter of a million people with HIV, staged an angry protest outside Parliament.

Dozens of "zombies" dressed in suits and gowns - among them Swedish MEP Carl Schlyter - danced to the Michael Jackson song, 'Thriller', to highlight the "harmful" intellectual property provisions they claim the European Commission is pressing for.

As the mid-April deadline to conclude negotiations for the EU-India trade agreement approaches, other MEPs and civil society groups from across Europe also joined in the protest.

Oliver Moldenhauer, Médecins Sans Frontières access campaign coordinator in Germany, told this website there is growing concern that the provisions the Commission is "pressuring" India to accept as part of the FTA will "choke off a vital lifeline for millions of people".

He said, "The intellectual property provisions the Commission is pressuring India to accept in the free trade agreement would also impact on the EU and its member states via any global health programmes they fund.

"For example, the Commission and the EU countries together make up over half of the contributions to the global fund to fight AIDS, TB and malaria in the 10 years to 2011."

He said that EU Trade Commissioner Karel de Gucht's "perusal of these harmful policies could end up shooting the Commission and member states in the foot, since a rise in the cost of medicines would mean less value for donors' money".

India - known as "the pharmacy of the developing world" - is the source for more than 80 per cent of the HIV medicines used in developing countries.

But Mr. Moldenhauer said the pressure is now becoming "intense", as the April deadline to conclude negotiations and sign the agreement is imminent.

He added, "The EU is pressuring India to include harmful intellectual property provisions that could block the export of generic medicines - a lifeline for millions across the developing world.

"The FTA provisions could also draw in third parties, including suppliers of active pharmaceutical ingredients used to produce generic medicines and

treatment providers, potentially subjecting them to heavy fines.

"Other measures could see the Indian government secretly sued by multinational companies for billions of dollars if national laws, court decisions or other actions interfere with their investments - for example, if the patent office rejects or overrides a patent on a medicine to increase access."

Further comment came from Lotti Rutter of the Stop Aids campaign, who said, "Some FTA harmful provisions are similar to ACTA, the anti-counterfeiting deal which was killed off thanks to intense public scrutiny. But now they are back: this is the issue that just never dies."

She said enforcement provisions could "potentially block" the production and export of generic medicines from India - a "lifeline" for millions of people across the developing world.

Enforcement provisions would open the door to "abusive practices" from multinational corporations, by allowing medicines to be "delayed, seized, detained and destroyed", she said.

Her concerns are shared by Katy Athersuch, of Médecins Sans Frontières, who said, "As treatment providers, we are alarmed about the impact of these measures if they go through.

"Not only will they put another nail in the coffin of access to the affordable, quality medicines [Médecins Sans Frontières] relies on to treat patients across the world, but we could be at risk of being embroiled in disputes for simply using generic medicines.

"Europe should drop all demands that threaten public health in all their trade negotiations."

(*http://www.theparliament.com*, 10 April 2013)

No Incentive to Indian Pharma to Innovate

NO one expected, when the first major clinical trial started on Glivec in 2000, that the patients would live much beyond a couple of years. Yet, 7 years later, 86 per cent of them were still alive, and 82 per cent of them had achieved a complete response to the medicine.

This breakthrough treatment for chronic myeloid leukemia is just one example of how innovation-based pharmaceutical companies continue to research and discover new therapies.

The decision by the Indian Supreme Court denying a patent to Glivec, the Novartis breakthrough medicine, discourages innovative drug discovery essential to advancing medical science for patients in need of new treatments.

The primary concern of this case was with India's growing non-recognition of intellectual property rights that sustain research and development for innovative medicines.

As a leader in both innovative and generic medicines, Novartis strongly supports the contribution of generics to improving public health once drug patents expire but generics alone do not guarantee access to medications. In India, the Novartis patient access programme for Glivec is one of the most far-reaching programmes ever conceived. We have been providing Glivec free of charge to 95 per cent of the patients prescribed the drug and the balance 5 per cent are on a very generous co-pay programme. In fact, since Novartis began the access programme for Glivec in 2002, we have provided Glivec valued at more than $1.7 billion completely free to patients in India.

The hidden harm in this decision to deny a patent to Glivec is that it offers no incentive to India's pharmaceutical companies to become innovators themselves. The immense talents in India's pharmaceutical companies should be focused on R&D of medicines that will help the people and the economy of India that go far beyond simply copying others' inventions. Without patents there will be few new medicines and without new medicines there will be no new generics.

It is time for India's own pharmaceutical companies to become creators and discoverers of medicines, and for the Indian government to protect innovation.

(*Business Standard*, 2 April 2013)

Strictest Patent Laws Will Foster Genuine Innovation

IN 2005, as the Indian Parliament debated at length the impact of complying with the WTO's TRIPS Agreement, one issue was uppermost in their minds; the impact of granting patents on access to affordable generic medicines. And, the one medicine that exemplified the concern was imatinibmesylate, sold by Novartis as Glivec. Members of Parliament cited Novartis' high costs (₹120,000 per person per month) against the generic versions (₹8-10,000 per person per month) and decided to include a critical public health safeguard, Section 3(d).

It seems fitting then that it is the legal battle on this very medicine that has finally affirmed this public health safeguard and the requirement for its "strict and narrow interpretation."

Novartis has been attempting to water down this crucial safeguard in the Indian law since 2006, after its attempt to get a patent for the beta crystalline form of imatinibmesylate was rejected at the Patent Office and again by the Intellectual Property Appellate Board on the basis of Section 3(d). After failing to have the provision struck off the law books at the Madras High Court, Novartis continued its campaign against the provision at the Supreme Court, attempting to weaken its interpretation.

Section 3(d) prohibits patents on new forms of known medicines unless there is a significant increase in efficacy. Novartis tried to argue that the physio-chemical properties of the new form of the imatinib molecule i.e. better flow properties, better thermodynamic stability and lower hygroscopicity resulted in improved efficacy. The Supreme Court has firmly rejected this contention, holding that in the case of medicines, efficacy means "therapeutic efficacy" and these properties, while they may be beneficial to some patients, do not meet this standard. The Supreme Court also held that patent applicants must prove the increase in therapeutic efficacy, based on research data in vivo in animals.

With Section 3(d) and the Supreme Court firmly behind the intent of this provision, India now has one of the strictest patent laws in the world, that will hopefully encourage genuine innovation from pharmaceutical companies and provide the right check and balance to the runaway patent systems of the West. In the words of the Supreme Court, Section 3(d) leaves "the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds."

The Supreme Court's decision is a tribute to the hard fought battles of people living with cancer, with HIV and many other diseases who have campaigned tirelessly for the right to health to be placed before the profits of pharmaceutical companies.

(*Business Standard*, 2 April 2013)

Indian Pharma Sector Fears India-European Union FTA could Imperil Local Industry

DRUGMAKERS and healthcare activists are worried that the India-European Union Free Trade Agreement (FTA), which is in the works, may contain a provision that could imperil local industry and have urged the government to keep patent infringement issues out of FTAs.

They are apprehensive that India may agree to a clause in the final agreement, stipulating that mere suspicion of patent infringement by an Indian drugmaker could lead to seizure of the company's bank accounts and immovable property. Injunctions could also be issued against intermediaries and third parties such as suppliers, drug distributors and medical procurement agencies for infringement of intellectual property rights.

It is believed that these provisions have been inserted in a draft of the agreement that is currently under negotiation. The drug industry and healthcare activists have taken up the issue with the government.

"Seizure of accounts and properties would discourage generic pharma companies even from challenging patents in legitimate cases and adversely impact medicine accessibility not only in India but across the world," said D.G. Shah, secretary general, Indian Pharma Alliance, an industry body of top domestic drugmakers.

India expects to conclude negotiations on the long-pending FTA with the European Union at a ministerial meeting with the EU trade commissioner scheduled for 14-15 April, Commerce and Industry Minister Shri Anand Sharma said recently. "The EU has sensed an opportunity in the government's anxiety to showcase its achievement by concluding the FTA," said Shri Shah.

Patent experts also feel if the government agrees to these provisions, it would go well beyond what is being offered under the Trade-Related Aspects of Intellectual Property Rights (TRIPS). The official position of the government till now has been that it would not commit to any arrangement with the EU that goes beyond TRIPS.

"Provisions on freezing bank accounts, seizing property in a suspected infringement case or holding intermediate players liable in cases of patent infringement are beyond the mandate of TRIPS," said Shamnad Basheer, an intellectual property expert. He urged the government to make the provision of the agreement public before signing the treaty, as it would have serious ramifications in areas such as public health. "The very possibility that legal proceedings could be initiated against third parties could dissuade them from working with generic producers," said Leena Menghaney of Medicins Sans Frontieres, a medical humanitarian NGO. Ms. Menghaney urged the government to keep patents out of FTA discussions. Daara Patel, secretary general, Indian Drug Manufacturers' Association, another industry body, concurs with this view. " WTO, and not FTA, is the right forum to negotiate patents. India should not cave in to pressure and include patents as part of the FTA. This could block exports and throttle the generic industry," he said.

Generic players and public health groups also fear that the border measures the EU is pushing for could lead to a repeat of the drug seizure cases of 2008-09. Legitimate generic drugs headed for other developing countries were then held up at different European ports of Netherlands and Germany in transit for infringing trademarks.

"Interruptions to medicines supplies will continue if 'civil trademark infringement' is not also excluded from FTA," said Ms. Menghaney. Unlike earlier drafts, the latest text on border measures fails to categorically mention that provisions under this section will not be applicable on transit goods, she added.

(*The Economic Times*, 27 March 2013)

Pharma MNCs are Patently Upset

MNCs are worried when life-saving drugs are cheaply available.

They are lobbying abroad to squeeze India's market access, forcing India to abandon compulsory licensing.

When all other means fail, arm-twisting is an option for the mighty. This may well be the thought behind US drug major Pfizer's recent plea to the US Government — to review "all available policy tools'' to push India to better protect intellectual property of American companies.

India's refusal to buckle under pressure from the US and EU after issuing its first compulsory licence last year to Hyderabad-based company Natco has global drug companies worried. The licence was given for selling a generic or copied version of Bayer's anti-cancer drug Nexavar.

Natco was allowed by the Indian Patent Office to sell the copied version of Nexavar at ₹8,800 for a month's treatment, compared with Bayer's version priced at ₹2.8 lakh, making treatment affordable to thousands of patients afflicted by kidney cancer.

Heartburn among MNCs

The fact that the country is now examining requests for compulsory licences — permits issued for producing copied versions of patented medicines without consent of the patent holder — for more life-saving drugs has only led to more heartburn for multinationals.

They are trying to deal with patent expiry worth an estimated $150 billion between 2010 and 2017.

India's firm stand on not allowing patents on new versions of old drugs, where changes are just cosmetic, has already created much bitterness among global pharma biggies. Pfizer recently had to bear the brunt of the country's stringent rules when its patent for cancer drug Sutent (sunitinib) was revoked by India's patent office; it was seen as being not inventive.

So, it is not surprising that Pfizer chose to urge the US Government to use pressure tactics on India.

At a Congressional hearing discussing renewal of a duty-free access scheme, of which India is a major beneficiary, Pfizer urged that pressure be brought upon India to tighten intellectual property protection.

The Generalized System of Preferences scheme, which allows certain labour-intensive products from developing countries to be imported duty-free into the US, subject to a number of conditions, is set to expire in July this year.

But can the US actually threaten India with withdrawal of duty-free benefits, if it refuses to tighten its intellectual property regime in line with the US demand?

It seems highly unlikely, as the benefits that India gets through the GSP scheme are insignificant compared with what it can achieve by issuing compulsory licences.

However, this does bring to light the limited options before the US and the EU, to make India change its intellectual property rules.

Pfizer, no doubt, has alleged that India has "routinely flouted trade rules'' to encourage its own generic industry at the cost of patent holding companies — but the million-dollar question is whether trade rules have been actually flouted. The answer to that question is a simple 'no'.

TRIPS Pact and After

The TRIPS Agreement — the multilateral pact on intellectual property under the WTO that was almost forced down India's throat in 1995 — prompted India to move to a product patent regime from a process patent regime within ten years.

India came up with a new Indian Patent Act in 2005 that was in sync with its commitment under TRIPS and tightened the patents law in the country by protecting not just the process through which a new product was created but the product itself.

This meant that other companies could not use a different method to create a similar product for which a patent had been granted during the life time of the patent.

But India and other developing countries also managed to extract some flexibilities within TRIPS. Having the authority to issue compulsory licences to generic manufacturers for producing copies of patented medicines in a situation of national emergency was one such concession.

The TRIPS & Public Health Agreement further allows countries that do not have manufacturing capacities to issue compulsory licences to drug companies in another country to manufacture generic versions of patented medicines.

Through intense negotiations India was also able to get the flexibility of not granting patents in a way that it would lead to 'ever-greening'.

So there is nothing underhand about India issuing compulsory licences for cancer drugs. Neither is it against TRIPS norms to revoke patents, if it is established that there is nothing novel about a new drug.

Yes, one needs to protect the rights of patent holding companies that spend millions of dollars on research and development every year. But isn't it exactly why the TRIPS Agreement was signed and India was made to change its laws?

Issuing a compulsory licence for a drug does not exactly pulverize the fortunes of a patent-holding pharmaceutical company, as there are rules to be followed. The Indian Patent Act lays down that such licences can be issued at least three years after the grant of the patent and the patent holder has to pay a royalty fixed by the Government.

Moreover, if a company believes that there isn't enough ground for issuing a compulsory licence, it can always approach the judiciary as many companies, including Bayer and Novartis, have already done.

NGO Watchdogs

The European Union recognizes that there is little it can do to force India to unilaterally tighten its IP regime.

That is why it is trying its best to incorporate intellectual property in the bilateral free trade agreement being negotiated, in the hope that it would place additional obligations on India.

But Non-Government Organizations (NGOs), including those in Europe, have kept a hawk-eye on the negotiations forcing India to reiterate time and again that it would not do anything that would go against the interests of the poor.

The issue of patents versus generics is not just a fight between patent holders and generic producers. It is a battle to make medicines affordable to the millions of poor.

That is one of the main reasons why the mighty pharmaceutical giants are not finding it easy to have their way.

(*http://www.thehindubusinessline.com*, 19 March 2013)

India's Health Cover Programme Takes Obamacare's Fancy

INDIA'S health insurance scheme for the poor seems to be creating buzz globally. The Brookings Institution, a think tank associated closely with the US administration, recently expressed keen interest in it and admitted to looking up to the programme for inputs for "Obamacare" - a term widely used for the US' revamped healthcare programme.

The Rashtriya Swasthya Bima Yojana (RSBY), launched in 2008 and implemented by the labour ministry, travelled all the way to Brookings' round-table discussion in Washington on 28 February. Anil Swarup, the labour welfare director-general and additional secretary in the ministry, made a presentation. "They were fascinated by the scheme and the way one state's data could travel through another via the national IT platform," he told.

In the US, states do not have interconnect technology platforms; each has its own. RSBY's single national platform enables its smart card to be portable. A beneficiary from Bihar can get treated in a Mumbai or Kochi hospital and the bills are paid in his home state by the insurance companies linked to the scheme. It is this aspect that has fascinated Brookings, Shri Swarup added.

On being asked about Brookings' role in "Obamacare" and its interest in RSBY, the think tank's fellow and the managing director of its Engelberg Centre for Health Care Reform, Kavita Patel, said: "Many of us, including myself, advise the administration. I think, RSBY will help serve as a point of reference for the health programme to understand how best to deal with secure data issues."

For payment of a small premium of ₹30 a year, RSBY offers free treatment (worth up to ₹30,000 a year) at an enrolled government or private hospital. Under the scheme, each beneficiary family is given a biometric smart card that can be used anywhere in the country. Initially limited to people below the poverty line, the programme is gradually reaching out to the general population in states like Kerala. Currently, it covers 120 million beneficiaries, with 34 million cards in use.

Brookings' Ms. Patel adds: "Another aspect of interest was (RSBY's) data infrastructure. As we bring over 30 million more US citizens under insurance next year (2014), we are still struggling with this. RSBY was able to be implemented using a secure laptop and video verification; and then the data were transmitted securely to a central location. This is an issue we are facing, to an extent. So, we were eager to hear from the people who devised the initial RSBY data infrastructure." She also lauded RSBY's outcomes, with mortality rate decreasing and screening and treatment among women increasing.

(*Business Standard*, 16 March 2013)

Great Distance Still to be Covered in Health Care Sector

THE public sector health care system of the country is "limited" and it needs to spread further, said Shri Pranab Mukherjee, President of India. India still has a "great distance" to go in ensuring proper health care systems to its teeming population.

Addressing a gathering of medical professionals and students, he said the public sector health care system of the country is "limited" and it needs to spread further.

"Despite the progress made in our health care system, we still have great distance to cover. The public sector health service in our country is limited by its reach.

"Many in our population are dependent on the private sector for delivery of health services," he said while inaugurating the golden jubilee

celebrations of the government T.D. Medical College, Alleppey (Kerala).

The medical college established in 1963 has produced over 4,200 doctors during the five decades of its existence.

Delving into the country's medical care system, Shri Mukherjee, who was on a day-long visit to the state, said it should be such that no one is "denied speciality medical treatment due to high costs".

"It is burdensome for poor people to access expensive medical treatment and many fall into the trap of poverty on account of that," he said.

The President added that the quality of health care delivery by some of the health service providers in the country leaves "much to be desired".

"We must correct this situation by expanding good quality, affordable public sector health care facilities.

"Our public expenditure on health care was 1.04 per cent of GDP during the eleventh five year plan period. This should rise to 2.5 per cent of GDP by the end of the twelfth plan period if we are to augment public health care in the country in a big way," he said.

He emphasized on the age old proverb of "health is wealth" and said the "well being of a nation is dependent on the well being of its people".

"Unless the health of the people is secured, the productive potential of the country cannot be realized to the full extent," he said.

"A sound health care system depends on the three pillars of availability, quality and affordability," the President said.

Shri Mukherjee appreciated Kerala's role in providing a huge workforce of medical professionals to the country and praised the state for being "proactive in implementing national programmes for control and eradication of diseases".

"Kerala is a big contributor to the pool of health care professionals, particularly doctors and nurses, in the country. The Kerala model of social development, where the government initiatives are matched by active civic participation, is indeed laudable," he said.

The President also stressed on the need to have more institutions which provide medical education and training to young professionals.

"There is urgent need for more institutes of learning for imparting medical education. It is gratifying to note that six AIIMS-like institutions are to be set up soon.

"It is also necessary to increase the capacity of our existing medical schools and nursing colleges and enhance the standard of education in all of them.

"I am confident that our public sector medical colleges will meet the twin challenge of greater quantity and better quality," he said.

The mechanism of health insurance must be strengthened, he said, adding that the Rashtriya Swasthya Bima Yojana that gives "beneficiaries cashless in-patient treatment should provide access to comprehensive primary, secondary and tertiary medical care."

"The benefits of this scheme should touch every one below poverty line," he said.

A sustainable model of health care with the participation of all stakeholders was the need of the hour.

"We have envisaged infant mortality rate to reduce from 44 per 1,000 live births to 25 by the end of the twelfth plan period and the maternal mortality rate to reduce from 212 per one lakh live births to 100 during this period.

"These targets are within our reach, but for that comprehensive efforts are essential," he said.

Increasing the density of medical professionals was aimed in the twelfth five-year plan.

"There were about 241 medical professionals – physicians, dentists, nurses, pharmacists and other professionals – per one lakh population in 2011-12.

"It is envisaged that this density of medical professionals will increase to 354 by the end of the twelfth five year plan period," he said.

Shri Mukherjee urged medical experts and major stakeholders in this domain to develop a technology-based "efficient health information

system for universal registration of births and deaths, nutritional surveillance and disease surveillance."

"A sound database should come handy for our policy makers to make timely interventions," he said.

On the occasion, Governor Shri H.R. Bhardwaj said it was "high time" that the health care sector is categorized as a priority one.

The President congratulated T.D. Medical College on the Golden Jubilee and wished that the institution continues to do pioneering work for medical education in the state and in the country.

(*Business Standard*, 16 March 2013)

US Trade Policy Puts Public Health at Risk

THE United States is again pushing for stricter levels of intellectual property protection in developing countries that will lock in high drug prices out of poor people's reach, warned international relief and development organization Oxfam America.

Talks resumed in Singapore during March 2013 for the Trans Pacific Partnership Agreement (TPPA), where the US is expected to insist that countries must take on strict intellectual property protection and drug pricing rules when they sign the deal. At the same time, the US will meet with World Trade Organization members in Geneva to determine whether the world's poorest countries (least developed countries, or LDCs) can avoid implementing intellectual property rules until they are able to graduate from extreme poverty.

"Between the TPPA negotiations and the meeting of the TRIPS Council, the US will seek in one week to dramatically expand intellectual property rules across most countries in Asia, Latin America and Africa, with damning public health consequences," said Stephanie Burgos, Oxfam's America's senior policy adviser. "For millions of people lacking access to medicines today, these new rules could mean that medicines will not be affordable, for themselves, their families and generations to follow."

In the past decade, the US has consistently demanded in these trade negotiations that poor countries introduce measures that will increase medicine prices. Despite opposition from many of its trading partners, the US is insisting on intellectual property provisions that introduce an expanded scope of patentability, data exclusivity, patent linkage and patent term extensions, all of which expand drug industry monopolies at the expense of public health. The US has also proposed new pharmaceutical pricing rules that would hinder the ability of governments to effectively negotiate medicine prices with big drug companies.

In Vietnam, for example, government officials, experts and civil society groups are already worried about the possible impact of the TPPA on medicine prices. Thousands more people could be pushed into poverty, forced to choose between medicines and other basic necessities, or to forego treatment altogether. Many medicines for diseases including cancer and Hepatitis B and C are already unaffordable for most people there.

The TPPA also comes at a bad time for efforts to provide universal treatment to HIV and AIDS. Up to 170,000 people living with HIV and AIDS still require basic treatment in Vietnam and thousands more will soon need new, patented anti-retroviral medicines as they will develop resistance to their current treatments. The US proposals will increase these medicine costs too – undermining the US global health efforts through PEPFAR, which currently finances more than half of the country's HIV and AIDS treatment budget. It will also undermine the Vietnamese government's future ability to sustain and expand national efforts to address HIV and AIDS, especially after 2015 when the US may stop providing foreign assistance to Vietnam to treat HIV and AIDS.

"The US is putting the interests of the drug industry above those of public health," said Ms. Burgos. "Not only do US policies fly in the face of commitments made under original World Trade Organization rules and under the Doha Declaration on TRIPS and Public Health, they also undermine the effectiveness of the US' generous aid to pay for treatment in poor countries."

As the coordinating body that oversees the implementation of the TRIPS Agreement meets in

Geneva shortly, trade negotiators must decide whether to renew a waiver issued to LDCs that previously delayed implementation of intellectual property rules for medicines until 2016, and a waiver on all other intellectual property rules until June 2013. Least developed countries are the poorest countries in the world, with approximately 80 per cent of all people in LDCs – more than 750 million people – living on less than $2 per day. But the US has been opposing this waiver, even though WTO rules clearly grant LDCs the right to request and have it granted.

"Intellectual property rules have direct and profound impacts on public health, particularly through intellectual property rules, but time and again, the US Trade Representative has insisted on far-reaching rules that expand drug industry monopolies and thus keep the prices of new medicines high," said Ms. Burgos. "Not only does this undermine the sustainability of public health-care programmes, this approach has discredited trade itself as a tool for poverty reduction. "The US government must urgently reconsider its approach on trade policy and access to medicines."

(www.oxfamamerica.org, 4 March 2013)

"Promoting Access to Medical Technologies and Innovations" – *Joint Report published by WTO, WIPO and WHO*

THE launch of a study co-edited by the WTO, WHO and World Intellectual Property Organization on the intersection between public health, intellectual property and trade drew a full attendance from a wide array of stakeholders on 5 February.

The study, titled "Promoting Access to Medical Technologies and Innovation," presents policy options involving health, trade and intellectual property, in a combination that some might have described as an oxymoron. Intellectual property and trade have, in certain circumstances, been presented as barriers to access to medicines, rather than enhancers.

The 250-page book, the result of three years of collaboration, is aimed at policymakers, international organizations, academics, researchers and non-governmental organizations.

WTO director general Pascal Lamy said the "report emphasizes that innovation and access must be seen holistically."

"Innovation without effective access offers scant public health benefit," Mr. Lamy said, adding that development of new medicines and new medical technologies need to be encouraged.

"The study points out the importance of the patent system for the pharmaceutical sector, while also identifying alternative incentive mechanisms that seek to enable much-needed new products in neglected diseases," he said.

In addition, it looks at "measures such as differential pricing as a practical way of reconciling innovation and access in medical technologies," Mr. Lamy said, adding that the study was meant to enable "an overview of how diverse policy measures can fit together coherently."

WHO in Favour of Public Interest

WHO Director General Margaret Chan called it "a big report with a noble ambition." The ambition is to "help countries promote access to medical technologies and stimulate the development of new products, especially for diseases of the poor." Every country in the world is worried about rising health care costs, she said.

In the past, trade rules and IP regime have been viewed by many people as barriers to the pursuit of public health goals, she said. Certain practices can make prices artificially high and delay the market entry of more affordable generic products, she added.

According to Ms. Chan, policy spheres in public health, intellectual property, and trade share much common ground and many social values, and all those policy spheres should operate in the public interest. International systems that govern IP rights and trade have health-specific provisions, she said, including numerous checks, balances, exemptions, exceptions and flexibilities.

The biggest achievement of the report, she said, is that it demystifies an intricate and extremely complex landscape of laws and policies and makes them accessible to the non-specialist. "It provides a

comprehensive and coherent inventory of legal instruments and policy options that you as a sovereign state can draw on to craft measures that meet national public policy objectives."

In a final comment, Ms. Chan said that an important flexibility in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) gives least developed countries transition time, extended until 1 July 2013, before obliging them to implement provisions in the agreement. She called for a possible further extension of this transition.

"I respect the sovereignty and the multilateral systems in WTO and WIPO, but from a public health perspective an extension of this transition period is worth consideration," she said.

WIPO Sees Innovation Opportunity

WIPO Director General Francis Gurry said the study represents "an expression of the basis of open innovation, namely as it is extremely unlikely that one institution has all the good ideas and all the knowledge, so the more we can collaborate, the better the result that will be produced."

The study provides an opportunity to recognize the complexity and interconnectivity in most issues and in particular of the health issue, "which emphasizes the advantages, if not the necessity, of cooperation," he said.

There are few issues in the world perhaps as sensitive as IP and health, Mr. Gurry said. The mission of IP has evolved in the course of the last 10 or 15 years, he said. IP is a mechanism that touches the whole process of the production, possession, and distribution of knowledge and culture, and within that whole process, "I believe the mission of IP is to find a balance or equilibrium point between all of those various interests and equities that surround that process," he said. "The report demonstrates the multiplicity of interests that surround that process."

In the health field, the interests are multiple and difficult to reconcile, according to Mr. Gurry. There are interests in encouraging innovation, interests in enabling intellectual assets to be diffused, and interests in enabling the social benefit of innovation to be enjoyed. Finding the point of equilibrium between these three sets of interests is an exceptionally difficult task, he said. "I don't believe that there is any one balance for eternity here," but a repeated process to find a balance, and "the report demonstrates there are multiple instruments of balance."

The heads of the three international organizations were careful to underline the fact that the report does not have a prescriptive function. "The function of the study is not to pronounce the final or authoritative word on the issues it addresses," Mr. Lamy said. The study is meant to "provide a stronger shared platform of objective information to build the capacity of policymakers and to serve as the basis for informed policy discussions," he said. "I commend the study to you as a practical resource, not as a doctrinal treatise."

"We expect it will catalyze the cross-disciplinary dialogue, pooling of resources and coordination of technical assistance that has been the hallmark of our work on public health with our colleagues in the WHO and WIPO," Mr. Lamy said.

Members of the audience who took the floor lauded the initiative. Among them was Greg Perry, executive director of the Medicines Patent Pool, who said in a release, "This report adds further weight to the idea of public-health oriented licensing as a key win for all stakeholders in the public health arena: from pharmaceutical companies, to generic companies, to – most importantly – people living with HIV."

"In light of it," he said, "the Pool invites pharmaceutical companies holding key HIV medicines patents who have not yet licensed them to the MPP to do so."

(*http://wto.org*, 14 February 2013)

WHO, WIPO, WTO Release Study on Health Innovation and Access to Medicines

FOR the first time, the three global inter-governmental bodies dealing with health, intellectual property and trade have pooled their expertise on a study of policies needed to advance medical and health technologies and to ensure they reach the people who need them.

This report "demystifies an intricate and extremely complex landscape of laws and policies and makes them accessible to the non-specialist."

The book, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, was launched on 5 February 2013, by the heads of the three bodies — WHO, World Intellectual Property Organization (WIPO) and World Trade Organization (WTO). Former Swiss President Ruth Dreifuss, who is also a former Chairperson of WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH), chaired the event.

"Public health remains a clear imperative for the international community," said Madame Dreifuss. "Promoting both medical innovation and access to the fruits of that innovation is indispensable for progress towards improved and more equitable health outcomes.

"But to achieve this result demands greater practical cooperation and dialogue within the international system — the launch of this study represents an important step forward in that direction."

This report "demystifies an intricate and extremely complex landscape of laws and policies and makes them accessible to the non-specialist," said WHO Director-General Dr Margaret Chan.

"In so doing, it sets out a comprehensive and coherent inventory of legal instruments and policy options that can be drawn on to craft measures that meet national public health objectives."

WIPO Director General Francis Gurry said: "This joint WHO-WIPO-WTO publication will enhance our shared understanding of health, trade and intellectual property and provide policymakers with a comprehensive compendium of the issues at stake.

"We look forward to our continued collaboration, in particular to show that innovation and IP are essential components of an effective health policy."

"Access to medicines requires the right mix of health policies, intellectual property rules and trade policy settings," said WTO Director-General Pascal Lamy. "And coherence is key to finding sustainable solutions. This is the spirit behind the joint study: to provide well informed, comprehensive policy choices."

Complex, Linked Issues

The book covers a broad range of complex, yet linked issues relating to public health and innovation in medical technologies, with the ultimate goal of accessibility — making medical advances available globally to all who are sick. It provides solid information for anyone concerned with these issues.

Its target audiences are: policy-makers, legislators, government officials, delegates to international organizations, non-governmental organizations, and researchers in this field.

The study reflects the debate about health that has evolved over the years, with increasing attention given to medical technologies and their invention and dissemination. Public health and innovation policies, and the rules of trade, competition and procurement, all play a part.

The policy-making focus has broadened from the basic questions of ensuring access to essential medicines, and developing treatments for neglected diseases that are available and affordable for those who are primarily affected — the poor. This is part of the right to health.

More recently, attention has turned to other aspects of how to meet this right: including the measures that are needed in order to provide incentives for medical innovations — such as medicines, vaccines and medical devices — and how to ensure equitable access to all of these vital medical technologies.

Part of the picture is the international patent system and how governments implement it domestically according to the needs of their countries. The patent system is designed to support innovation, and it offers a mechanism to ensure that these innovations are accessible to society.

The research-and-development pharmaceutical industry therefore relies heavily on exclusive patent

rights in order to recoup the investment made in research and development, as shown by the high number of applications for patents on medical technologies under WIPO's Patent Cooperation Treaty.

The secretariats of the three organizations have drawn on their experience and the data available to them to produce this study, and to support discussions on policy options and legal issues.

What the Book Covers

The book looks at the need for international cooperation, who is involved, and how to address the challenges that the sector is facing. It examines in detail the range of policy issues from health and human rights and national, regional and global regulation policies, to intellectual property, trade and tariffs, procurement, free trade agreements and other aspects of policy.

It studies a range of issues, such as: patents in the pharmaceutical sector; traditional medical knowledge; the importance of knowing what is patented and where, and how easy it is to find out; and questions of affordability and availability of medicines and market failure.

It looks in some depth at the development of medical technologies, modern research and development, ways of providing incentives for innovation, and ways of dealing with market failures, in particular with new products for treating neglected diseases. It includes comprehensive sections on trade and intellectual property rules and the flexibilities they contain for governments to meet various public health objectives.

(*http://www.who*.int, 5 February 2013)

NSIC to Set Up Three More Incubation Centres in State

NATIONAL Small Industries Corporation (NSIC), a mini-ratna Government of India enterprise, has drawn up a plan to set up three more incubation centres in Odisha. These centres would be over and above two centres that are already running in the city.

"We are planning to set up three more incubation centres in Odisha on the PPP (public private partnership) mode in 2013. These centres would be demand based and would come up in locations where we can get more number of people who can be trained," H.P. Kumar, Chairman and Managing Director of NSIC told on the sidelines of the MSME (micro, small & medium enterprises) international trade fair held in the city.

"Each of our incubation centres has the capacity to train 300 people per annum. NSIC has set up 60 centres across the country. We offer training in a simulated condition besides providing hand holding support and marketing. The training is of three months duration," he said.

Speaking at the valedictory function of the trade fair, Shri Kumar said, "We are going to build an integrated marketing complex in Bhubaneswar. It would offer all the services to the MSMEs, be it banking, insurance or convention centre."

D.K. Singh, Secretary (MSME) said, "As per preliminary figures available with us, the MSME trade fair has generated business enquiries worth ₹20 crore while sales have touched ₹2 crore. Total footfall at the fair has been 140,000. The prime objective of this fair was to catalyze the entrepreneurs in the MSM sector."

B.K. Patnaik, Chief Secretary said, "The state MSME department needs to have a permanent secretariat to cater to the needs of the entrepreneurs in the sector. The department should also have a continuous dialogue with all large industries to ensure that they promote ancillarization in a big way."

A.N. Sahay, Chairman cum Managing Director, Mahanadi Coalfields Ltd. (MCL) said, "MSME is the biggest employment generator after agriculture sector. We have 48 ancillaries that regularly supply spares and consumables to us. In this fiscal, 20 per cent of all our procurement will be from the MSMEs. This fiscal, our procurement from the MSMEs will be ₹25 crore and we are looking to ramp it up subsequently to ₹50 crore."

(*Business Standard*, 7 January 2013)

Proposed India-EU Free Trade Agreement Threatens Access to Medicines for Millions

MSF South Africa, TAC, Section27 & He-Tic Warn on Eve of Crucial Summit

AS India and the European Union prepare to meet at a New Delhi summit to finalize a Free Trade Agreement (FTA) under negotiation since 2007, Médecins Sans Frontières/Doctors Without Borders (MSF), the Treatment Action Campaign (TAC), Section 27 and He-Tic held a picket to warn that harmful provisions in the agreement could have a severely negative impact on access to medicine for people in developing countries.

The picket, which took place in front of the Indian Consulate in Johannesburg, was part of a global week of action by civil society and health activists against harmful provisions in the proposed India-EU FTA. Actions are taking place across Europe, Africa, Asia, and Latin America.

India has been called the "pharmacy of the developing world" because it produces a large number of quality affordable generic medicines. Thanks in large part to competition stemming from Indian generics, the price of first-line ARVs dropped from over ₹5,000 a month in the 1990s to less than ₹100 today. This significant price decrease has helped to facilitate the massive expansion of HIV treatment worldwide: more than 80 per cent of the HIV medicines used to treat 6.6 million people in developing countries come from Indian producers, and 90 per cent of pediatric HIV medicines are Indian-produced. MSF and other treatment providers also rely on Indian generic medicines to treat other diseases and conditions.

"The vast majority of the HIV drugs used in Southern Africa come from Indian producers or depend on India-made ingredients," said Oliver Moldenhauer, advocacy coordinator for MSF in Swaziland. "Without these low-cost, quality generic medicines, far fewer people would have access to life-saving ARVs. Europe must not be allowed to use trade rules to shut down the pharmacy of the developing world."

In trade talks setting the political framework in New Delhi the EU is pressuring India to agree to several measures in the FTA that will affect the production, registration and distribution of affordable generic medicines.

"It is a disgrace that the European Union is pressuring India to include provisions in the FTA which could restrict access to medicines and harm public health," said Nokhwezi Hoboyi, district coordinator of TAC's Ekhurhuleni branch. "India's patent law falls in line with international trade rules, but now the EU is strong-arming India into accepting provisions that go beyond those rules at the expense of the health of millions around the globe. This is unacceptable and we are here today to say that our lives are not for sale and cannot be traded away."

*(*www.msf.org.za/, 8 February 2012)

WTO, WHO, WIPO Examine Intersection of Public Health, Intellectual Property, Trade

MORE coherence is needed between public health, intellectual property (IP), and trade policies in order to advance innovation and improve access to medicines, according to a joint report released by the WTO, the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) recently.

The study, entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property, and Trade," was designed to bring together the three organizations' respective areas of expertise with the goal of better informing policy-making decisions, especially in developing countries.

Coherence is Key

In recent years, the role of the IP system in fostering medical innovation and its potential impact on medicines' availability have been the subject of extensive discussions - and controversy - at the different organizations.

"The IP system is not an isolated specialist domain, nor yet a monolithic barrier to public health; instead, IP is an element of a complex set of

policy tools required to resolve global problems," WTO Director-General Pascal Lamy explained.

Coherence between health policies, IP rules, and trade policy is therefore "key" toward ensuring that sustainable solutions are found for issues involving access to medicines and medical technologies, the WTO chief added. Along with medicines, medical technologies can also include vaccines and medical devices.

Indeed, the mission of IP is to find an equilibrium point among all interests that surround the process of knowledge production and distribution, as well as "translating intellectual assets into productive assets," WIPO Director-General Francis Gurry told the audience.

Developed countries have traditionally argued that making patent laws less stringent could hinder innovation on developing medicines and medical technologies; meanwhile, developing countries have long called for more flexibilities and exceptions to have more policy options available in this area.

The study therefore calls for appropriate and creative patent licensing strategies to ensure that drugs and medical technologies are made both affordable and available in poorer countries. While the study also points out the importance of the patent system for the pharmaceutical sector, it identifies alternative incentive mechanisms that seek to enable the development of new products for treating neglected diseases.

The organizations also list various flexibilities aimed at safeguarding the public interest that are already available in the international IP regime. In this regard, WHO Director-General Margaret Chan indicated the need to discuss ways to promote drug availability for treating non-communicable diseases - such as anti-cancer medicines - specifically mentioning the recent trend of issuing compulsory licenses to allow the production of life-saving generics. Ms. Chan stressed that generics must be brought quickly into the market, as delaying their entry "hurts public health."

She also suggested that attention should be given to the request by least developed countries (LDCs) to extend the transition period for applying the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is set to expire in July 2013.

"I fully respect the sovereignty of the multilateral systems in WTO and WIPO. From a public health perspective, an extension of the transition period is worth consideration," Ms. Chan said.

Impact of Trade Policies on Access to Medicines

The study also highlights trends in trade of health-related products, and how certain trade policies can help or hinder access to medicines. For instance, high tariffs in some countries can have negative implications for this area.

The study also considers competition and procurement policies that could be beneficial in promoting innovation and availability of medical technologies. For instance, competition policies "can serve as a corrective tool if and when IP rights hinder competition and thus constitute a potential barrier to innovation and access."

With regard to procurement policies, the study indicates that open and competitive tendering - such as what the WTO's plurilateral Government Procurement Agreement aims to ensure among its parties - is particularly important in increasing access to medical technologies at a time when governments are facing intense budget constraints.

(*http://ictsd.org*, 6 February 2013)

TRIPS and Public Health: Just Medicine

GOVERNMENT should avoid resort to compulsory licensing for guaranteeing drugs at affordable prices. Considerations of realpolitik as much as equality of treatment – the bedrock of international trade – demand that the Government reasonably address the concerns raised by multinational pharma companies over the grant of compulsory licences for local manufacture of drugs patented by them against their consent. A patent is basically a monopoly granted to an inventor, giving him the exclusive right to make commercial use of the invention for a limited time period. This limited monopoly incentivises the inventor to not just invent, but also disclose his invention publicly. Such knowledge, embodied in his patent, becomes the

basis for further research and development activity, including by others. Given the centrality of patents to this process, motivating companies to constantly innovate and bring new products into the marketplace, one needs to carefully weigh the implications of any move seen to be diluting the rights of patent-holders.

These misgivings, especially among multinationals, have mounted after the Controller of Patents issued a compulsory licence, last March, allowing the Hyderabad-based Natco Pharma to manufacture a cancer-treatment drug, patented and sold under the trade name "Nexavar" by Bayer Corporation. Subsequently, there have been reports of the Government planning to grant three more such licences for anti-cancer drug compounds patented by two other multinationals, Roche and Bristol-Myers Squibb. It has led to even the US Government intervening and seeking "reassurance" from India that the rights of patent holders would be respected. What is necessary in this case is a balanced response. Conferring an inventor the exclusive right over the production or sale of a product invented by him for a limited period is something one cannot really object to. But the Government and the public have every right to demand that this monopoly is not abused. Thus, in the event of epidemics or public health emergencies, the Government is within its rights to issue licences for manufacture of patent-protected drugs by third parties without the consent of the patent-holder. This flexibility is clearly available under the World Trade Organization's TRIPS Agreement.

Matters get more complex when it comes to diseases like cancer, which, even while widely prevalent, do not quite amount to a public health emergency warranting drastic counter-measures. But even here, it would not be unfair to expect that the patent-holder at least make the patented product sufficiently available in the local market, for which he has been granted exclusive right. Natco was given the compulsory licence to make a generic version of "Nexavar" only after the Controller of Patents concluded that Bayer was supplying the requirements of hardly 2 per cent of the country's eligible cancer patients. What the Government must avoid, however, is using the compulsory licensing route to guarantee not just availability, but even affordability of patented drugs. If Government wants to ensure the latter, it should source the necessary quantities of the drug directly from the patent-holder and pay a negotiated price, balancing the interests of both the patients and the inventor.

(*The Hindu Business Line*, 31 January 2013)

Planning Commission Suggests Cashless Universal Health Coverage by 2017

THE Planning Commission says that one of its expert groups has suggested rolling out of cashless health and portable universal health coverage (UHC) across the country by 2017.

The Commission also informed that the panel had asked for rolling out the scheme on a pilot basis in one district of every state in the first year of 12th Five-Year Plan (2012).

"Cashless and portable Universal Health Coverage (UHC) should be piloted in one district in each state and UT during the first year of the 12th plan, and gradually rolled out thereafter..."

"State governments would need to be supported by the central government in extending UHC to the entire population of the country by the end of the 12th plan," Minister of State for Planning Ashwani Kumar said quoting the recommendation of the Steering Committee on Health for 12th Plan.

The panel has also suggested that the cashless health programme should be borne by the central and state governments on a 85:15 basis, he said in a written reply in the Lok Sabha.

The panel also suggested that the central assistance should be made available to states through additional central assistance on the lines of Rashtriya Krishi Vikas Yojna after signing memorandums of understanding.

"For the states to be eligible for availing the additional central assistance for UHC, each state should ensure that the share of medical and public health in its Plan and Non-Plan budget is at least maintained at the average for the last three years," the Committee has said.

(*The Economic Times*, 28 March 2012)

Asian Governments Plan to Better Use TRIPS Flexibilities for Health

INTERNATIONAL trade rules related to intellectual property rights enshrine the notion that there may be cases where exceptions to IP rights are needed by governments such as sovereign decisions on a nation's public health. Using those flexibilities could save millions of lives but may mean taking a tough stance in free trade negotiations with bigger trading partners, concluded a meeting of Asian stakeholders recently.

More than 90 representatives of government, academia, civil society and the United Nations gathered from 29-31 May in Bangkok, Thailand at the Regional Consultation and Planning Workshop on "Use of TRIPS Flexibilities and Access to Affordable ARVs in Asia."

Participants came from Cambodia, China, India, Indonesia, Malaysia, Myanmar, the Philippines, Thailand and Viet Nam, according to a press release from the Joint United Nations Programme on HIV/AIDS (UNAIDS). It did not appear that representatives of the World Trade Organization or World Intellectual Property Organization were present. Nor, apparently, were any from the rights-holding industries.

The WTO is responsible for the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the standard on international IP protection but which also contains agreed flexibilities that were the subject of discussion in the workshop. The flexibilities were reinforced in the 2001 Doha Declaration on TRIPS and Public Health.

UNAIDS and the UN Development Programme (UNDP) launched a "joint issues brief" on the potential impact of trade agreements on public health. The brief encourages negotiating countries "to retain the benefits of TRIPS flexibilities, countries at a minimum should avoid entering into free trade agreements that contain … obligations that can impact on pharmaceutical price or availability." And if they have already signed tough IP deals, then they should try to use remaining TRIPS flexibilities.

"Countries are facing mounting challenges to produce or procure affordable HIV treatment, including cutbacks in AIDS funding and a proliferation of increasingly restrictive intellectual property measures in free trade agreements," UNAIDS said. "Each country delegation identified key areas for joint action, collaboration and support and developed a focused plan to speed up joint national action and ensure greatest impact."

Despite significant gains in the number of AIDS patients receiving treatment, more than 60 per cent of those in need of treatment in the Asian region still do not have access, UNAIDS said. The event press release claimed there is evidence that using flexibilities lowers prices on essential medicines. For instance, the annual cost of a first-line antiretroviral regimen for low-income countries dropped from more than US$10,000 per person in 2000 to below US$100 per person per year in a number of low-income countries in the region in 2010, they said.

But most countries have yet to fully use the flexibilities available in the TRIPS Agreement to sustain affordable treatment, they said.

"The sustainable future of HIV treatment programmes in Asia is of serious concern," said Steven J. Kraus, UNAIDS director for Asia and the Pacific. "Countries must use all the means at their disposal, including the TRIPS flexibilities, to increase treatment levels and to reach people most in need."

"Countries in this region should approach the TRIPS Agreement from a pro-development perspective and should use all available flexibilities and safeguards to realize universal access to HIV treatment," said Clifton Cortez, regional practice leader on HIV, health and development at the UNDP Asia-Pacific Regional Centre. "This meeting recognizes the importance of connecting key national and regional players together to pursue common goals."

The legal framework in India is key to the sustainability of treatment programmes in the region, the group said, as its industry produces "more than 85 per cent of all first generation antiretroviral drugs used to treat people living with HIV in low and middle income countries." And India is currently negotiating a free trade deal with the European Union, while other Asian countries are negotiating with the EU or with the United States through the Trans-Pacific Partnership Agreement.

The Bangkok workshop was co-organized by UNAIDS, UNDP and the Asia Pacific Network of People Living with HIV/AIDS, in partnership with the International Treatment Preparedness Coalition, Médecins Sans Frontières, TREAT Asia, United Nations Children Fund (UNICEF) and the World Health Organization.

(http://www.ip-watch.org, 1 June 2012*)*

Government Asks PSUs to Start Medical Colleges by 2014

THE Odisha government has directed three central government PSUs – Mahanadi Coalfields Ltd. (MCL), National Thermal Power Corporation (NTPC) and National Aluminium Company (Nalco) to take steps to complete construction of three medical colleges at the earliest and start admission of students from the 2014 academic year.

MCL, a subsidiary of Coal India Ltd. (CIL), proposes to set up a medical college at Talcher, NTPC at Sundergarh and Nalco at Koraput.

"The PSUs were told to complete medical college construction as early as possible and start admitting students from the 2014 academic year," said Damodar Rout, Odisha's health and family welfare minister, at a review meeting.

Similar instructions were issued to private organizations keen to set up medical colleges in the state. While Nabadiganta Educational Trust proposes to set up medical colleges at Bhubaneswar, Jharsuguda and Baripada, Blue Wheel group has plans to build a medical college at Nayagarh.

The meeting was attended by representatives of seven institutions. Shri Rout said, the Odisha government has formulated a policy to set up more hospital-cum-medical colleges through Public Private Partnership (PPP) model, which has attracted a lot of private players. As per the policy, the state government is issuing No Objection Certificates to the private players after assessing their strength and capacity and the state health department has been instructed to supervise the progress of these projects.

At present, there are three government medical colleges and four private medical colleges in the state of Odisha.

(*Business Standard*, 29 December 2012)

Multilateral Forums Should Address the Fear that Strong Pharma Patent Protection Can Affect Public Health in Developing Countries

A recent meeting of the Standing Committee on the Law of Patents in the World Intellectual Property Organization (WIPO) witnessed some sparring between the developed and developing countries over the issue of pharmaceutical patents and public health. As is the case at other multilateral platforms like the World Trade Organization, the two sides view the issue of public health differently in the context of patents.

The discussion that produced difference of opinion among members was a proposal from the Development Agenda Group (DAG) and the African Group that had been presented to the Committee in May 2011. The DAG, which consists of around 20 developing country members including India, Brazil, Egypt and Indonesia, talks for including the development agenda in WIPO discussions.

The proposal said "the patent system should be consistent with fundamental public policy priorities and in particular the promotion and protection of public health" and advocated a three-pillar approach to bringing development and public health to the core of the discussions on patents.

The three pillars elaborated in the DAG and African Group proposal included commissioning of elaborate studies by renowned independent experts; increasing information exchange among member states and experts; and providing technical assistance especially for developing and least developed countries. The proposal also called for letting the developing and least developed countries use the flexibilities available in the international trading system in their patent regimes. The proposal even talked about the use of flexibilities in WTO's TRIPS Agreement for public health in the regional and other free-trade agreements that are being negotiated by many developing and least developed countries.

The proposal specifically stated: "In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement

would need to be incorporated in the national legislation. There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards. Moreover, these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine."

The United States countered this proposal with its own proposal at the recent meeting in December. It states that "some of the public health issues facing developing and least developed countries include neglected diseases, the spread of TB, malaria and HIV/AIDS, and availability of medicines to treat these and other ailments." It further says that "none of these issues can be solved by IPR flexibilities alone and in particular cannot be solved by the wholesale use of compulsory licensing. To the contrary, the lack of effective patent protection is one factor which prevents the appropriate medicines from reaching the neediest patients in DC and LDCs". It goes on to say: "weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removes or reduces the incentive to develop new medicines, but also leads manufacturers to keep already developed medicines out of those markets. It has been shown that more goods become available in developing countries when IP rights are strengthened there. In the particular case of medicines, it has been shown that all else being equal, a new drug is more likely to be launched in a country where patent protection is strong, rather than one where such protection is lacking." It then proceeded to propose some of its ideas for addressing the issue of public health and development in the developing and least developed nations.

As expected, the developing countries pointed out that the US proposal does not reflect the opinion of the developing countries, which are seeking to balance the issue of IPR with development and public health. The developing countries particularly pointed out that the US proposal deviates from the one tabled in May and even dilutes the objective of the proposed discussions.

The issue of public health remains very crucial and delicate, and needs better handling. It is a genuine concern for the developing countries and needs to be understood by the developed countries. Confronting each other at multilateral forums may not help in bringing about the required attention that this important topic needs. The two sides would do well to sit across the table informally, to begin with, and find a solution that helps developing and least developed countries address the issue of public health while ensuring that the IPR rights of the pharmaceutical companies are not weakened.

(*Business Standard*, 22 December 2011)

Intellectual Property: TRIPS and Public Health

A decade-old WTO declaration has allowed the WTO and its partners to collaborate on helping governments target medical treatment for their poorer populations and understand their room for manoeuvre under intellectual property agreements, WTO Director-General Pascal Lamy said on 23 November 2011.

The view was shared by participants from a range of diverse organizations in the symposium on Global Health Diplomacy to mark the declaration's 10th anniversary, organized by the Geneva Graduate Institute of International and Development Studies, and held at the WTO.

Mr. Lamy was speaking in a session chaired by former Swiss President Ruth Dreifuss, who is also the former chairperson of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. Also on the podium were WHO Director-General Margaret Chan and WIPO Director-General Francis Gurry.

The November 2001 Doha ministerial declaration on TRIPS (trade-related aspects of intellectual property rights) and Public Health was a political turning point in the way public health is governed globally, Mr. Lamy said.

Before the declaration was issued, intellectual property protection (patent protection for drugs and medical products, in particular) and the WTO's TRIPS Agreement were often considered simply to be an obstacle to public health, Mr. Lamy recalled.

Now, the perception has changed: the declaration affirmed that the two are not contradictory. Mr. Lamy quoted from it: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."

An important result has been a shift in focus from the "compatibility" of trade, intellectual property and health to the more dynamic and constructive "coherence" between them, he said. It has allowed a partnership to develop between the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and WTO.

Mr. Lamy added that the main responsibility for ensuring coherence is within national governments, including how intellectual property is handled in bilateral or regional free trade agreements. If governments accept tougher standards for intellectual property protection than required in the TRIPS Agreement (known as "TRIPS-plus"), then governments are accountable to their critics not to the WTO, he said.

One area of cooperation between the three organizations has been the examination of the relationships between incentives for innovation, access to medicines and trade. WTO Intellectual Property Division Director Mr. Antony Taubman told the meeting that a forthcoming product will be a study that draws on a range of facts and figures to create a guide for policy-makers to choose among the complex options available to them to provide better health services to their poorer populations through improved access to the medical technologies and medicines that are needed.

(*http://www.wto.org*, 23 November 2011)

IIPHG to Offer Public Health Management Programme for NGO Sector

AFTER offering the one-year programme in public health management for government officials, the Indian Institute of Public Health Gandhinagar (IIPHG) is now looking to expand its purview to non-government officials as well.

IIPHG is set up under the Public Health Foundation of India (PHFI), a public-private partnership which aims to strengthen training, research and development in area of public health.

While currently the programme has around 25 candidates from the government sector, the institute is looking at increasing the seat capacity by inducting non-government candidates as well. Moreover, while the government candidates are sponsored through National Rural Health Mission (NRHM), IIPHG is looking for sponsors for funding non-government candidates.

"We are in talks with certain NGOs and other institutions for funding additional participants from the non-government sector for the programme. For each participant, we are looking for ₹2.25 lakh sponsorship and intend to induct additional 10-15 such candidates," said Dileep Mavalankar, dean - academics at IIPHG. In all, the institute intends to raise over ₹2.25 crore through NGOs and other institutions as sponsorships.

Apart from the one-year programme in public health management, IIPHG is also planning to introduce more post graduate programmes, including emergency management. With Gujarat already running the 108 emergency services successfully through EMRI, IIPHG intends to create more professionals skilled in emergency management.

Currently, IIPHG is running from a makeshift campus at the Sardar Patel Institute of Economic and Social Research campus in Ahmedabad, plans to get its own campus in next couple of years. However, the government has allotted a 50 acre land near Chiloda-Palaj road where the institute's own campus would come up.

According to Dr. Mavalankar, construction work on the new campus is expected to begin by September 2011 and is likely to be completed in one and half years. The new campus of the institute is being set up at an investment of ₹140 crore.

(*Business Standard*, 26 May 2011)

The Intellectual Property and Investment Chapters of the EU-India FTA: Implications for Health

SINCE 2007, the European Union (EU) and India have been negotiating a bilateral Free Trade Agreement (FTA). Negotiations are expected to finish by the end of 2011.

Classified as a lower middle-income developing country, and with 35 per cent of the population living on less than US$1 a day and 80 per cent living on less than US$2 a day, India is home to more poor people than the twenty-six countries of sub-Saharan Africa put together.

India is also home to a large and sophisticated generic pharmaceutical industry. Because the country produces the vast majority of quality generic medicines used in developing countries to treat diseases like HIV/AIDS, malaria, cancer, and heart disease, India is often referred to as the "pharmacy of the developing world." A 2010 study found that 80 per cent of the AIDS medicines used by donor-funded programmes were sourced from India. A report published by UNICEF in 2009 shows that India is the largest supplier to UNICEF of essential supplies for children, including life-saving products such as vaccines, essential medicines, and health commodities. In fact, the dependence of health systems and donor programmes in developing countries is such that their sustainability will depend to a large extent on India's ability to remain a major producer of affordable and quality generic medicines.

The vital role of Indian generics companies in supplying the developing world with affordable medicines can be attributed to the intellectual property (IP) policies enacted by the Indian government. First, India's 1970s Patents Act did not allow product patents on pharmaceuticals. Second, India was one of the few developing countries that made full use of the transition period allowed under the TRIPS Agreement, delaying implementation of World Trade Organization (WTO) minimum standards for IP protection until 2005. And, third, India made use of TRIPS flexibilities and incorporated key safeguards in its national patent law, thereby ensuring space for generic production once the country implemented the TRIPS Agreement in 2005.

However, India's role as pharmacy of the developing world is now under threat because of the EU-India Free Trade Agreement.

The Intellectual Property Chapter

According to publicly available negotiating texts, the EU is pushing for the introduction in the FTA intellectual property chapter of measures of IP protection that go beyond those required under TRIPS. So-called "TRIPS-plus" provisions upset the already precarious balance that exists in that agreement between public interests and the interests of IP holders. TRIPS-plus provisions in FTAs have been demonstrated to reduce the availability of generic medicines, thus raising medicines prices. The enactment of TRIPS-plus provisions in India would reduce the production, domestic sale, and export of generic medicines, thereby undermining access to affordable quality treatment for millions of people - not just in India, but across the developing world.

The following TRIPS-plus provisions have been included in past drafts of the EU-India FTA:

- Language requiring India to provide "data exclusivity," which would act like a backdoor to monopoly status by prohibiting India's medicines regulatory authority from registering generic medicines on the basis of existing clinical data, whether the medicine deserved a patent or not;
- Language requiring India to extend the length of a patent term beyond 20 years, which would keep medicines unaffordable for a longer duration.

Public outrage at the impact the FTA would have on the worldwide availability of affordable generic medicines has contributed, first, to the withdrawal of the draft provisions on patent term extension and, more recently, to a reported agreement to remove data exclusivity provisions from the FTA. While this cannot be confirmed until an updated text becomes available, the announcement is grounds for cautious optimism.

Despite this development, the following TRIPS-plus provisions still present a significant threat to

access to affordable medicines, and to health regulation more broadly:

- The introduction of TRIPS-plus IP enforcement measures, based on EU regulations. For instance, the EU is pushing for measures that would grant draconian powers to customs officials to seize and even destroy products that are in transit or intended for export, including legitimate generic medicines, at the behest of multinational pharmaceutical companies or on their own authority. Despite the documented, negative impact of the EU regulations, the EU is pushing India – where many quality generics originate - to adopt similar regulations. This would give companies the right to lodge requests with Indian customs authorities to detain, suspend the release, or destroy shipments of generic medicines on the basis of allegations of IP infringement (whether trademarks or patents) without judicial review or even notification of the patent holder.

In addition to the threat posed by IP enforcement measures in the IP chapter, other parts of the draft EU-India FTA, and notably the investment chapter, are problematic from a health perspective.

(*http://ec.europa.eu/health/eu_world/docs/ev_20110616_rd01_ en.pdf*, *Briefing Note*, May 2011)

Brazil, India to Oppose EU at WTO

INDIAN generic drug companies have been charged with violating EU's patent laws.

Brazil would join India in invoking dispute settlement proceedings against the European Union at the World Trade Organization (WTO) over Brussels' alleged violation of global trade rules by detaining on the high seas the generic drugs exported by Indian companies to other developing countries, a senior Indian trade official has said.

The two developing countries raised the issue early this year when the Dutch Customs authorities detained Indian generic drugs at the behest of leading western pharmaceutical giants. Though they charged the EU with violating WTO's core global rules concerning freedom of transit, they refrained from raising an outright trade dispute until now.

Senior trade officials from India and Brazil held talks to explore if they could raise a joint trade dispute. Given the importance of generic drugs for poor countries, the two have now decided to raise the dispute to ensure that big pharma companies are not able to raise fresh barriers.

Dutch and German Customs inspectors have stopped Indian generic drugs used to treat heart ailments, AIDS, Alzheimer's disease, and medicines used for hypertension on the ground that they violated the EU's patent laws. The repeated recourse to detaining Indian medicines was carried out at the request of companies like Sanofi-Aventis SA, Novartis AG and Eli Lilly & Co.

Despite attempts to amicably resolve the dispute, the two sides are yet to reach a blanket pact to ensure free transit for the Indian generic drugs. Consequently, Indian generic manufacturers are forced to divert shipments to avoid any legal or material challenge by the Customs authorities in the EU member countries. Besides, the Indian companies are forced to cough up high charges for directing their shipments through other routes, analysts said.

India and Brazil are expected to raise the trade dispute against the EU under Article V of GATT 1947 concerning Freedom of Transit, which says "there shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit".

Further, India will also cite violation of Article VIII of GATT 1947, which deals with fees and formalities connected with importation and exportation.

The two countries would also challenge the EU under the Doha TRIPS and Public Health Agreement and other provision of the trade-related intellectual property rights, the Indian official said.

Unconfirmed reports suggest that the Dutch Customs authorities have not released a consignment of generic drugs shipped by Cipla. Similarly, the Dutch Customs authorities have detained a 50-kg, $52,500-shipment of generic blood-thinner clopidogrel exported by a Chandigarh-based generic company, analysts said.

(*Business Standard*, 22 September 2009)

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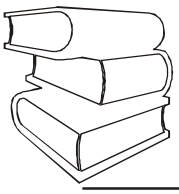

BOOKS/ARTICLES NOTES

ARTICLES

TRIPS Agreement and Public Health: An Overview of International Issues by N.S. Gopalakrishnan, *Journal of Intellectual Property Rights*, Vol. 13 September 2008, pp.395-400.

THIS paper deals with brief overview of the developments of international provisions on IPR related to public health. It discusses flexibilities before and after TRIPS Agreement and difficulties faced by developing countries in implementing TRIPS obligations and protecting public health. Also discussed are the reasons for the Doha Declaration and issues relating to implementation of Para 6 of the Declaration. It discusses the inadequacy in the compulsory licence based approach to solve public health crisis and argues for a more comprehensive approach to find a long-term solution to the public health issues.

Intellectual property protection for inventions relating to health care was one of the most debated areas in the international negotiations for IPR protection in the last three decades. The major concern was the need to facilitate access to essential medicines at affordable cost to the large sections of the population in the developing and least developed countries. Equally important was the demand to ensure adequate reward through patent system to the pharmaceutical companies mainly located in the developed countries who make considerable investment for the invention, production and marketing of essential drugs. The practice followed by many developing countries to ensure access to these medicines/drugs was to promote the growth of generic pharmaceutical industries without providing adequate patent protection for new pharmaceutical inventions. It was argued that this resulted in distortion of trade in the international market particularly in the context of globalization. One of the reasons identified for this is the lack of uniform international norms for the protection of new pharmaceutical products. The outcome was re-formulation of the then existing international norms through the TRIPS Agreement. The impression given to the world community that the provision in the TRIPS Agreement is a proper balance to ensure access of quality drugs to global population short lived when the South African Government took legislative measures to overcome the HIV/AIDS crisis. Though the WTO members found some temporary measures through the much projected Doha Declaration, it is still argued that the existing norms under the TRIPS Agreement are inadequate to provide the right balance. The implementation of the provisions of the TRIPS Agreement by various member states and the consequent disputes that arose in the last decade show that the provisions are more in favour of the owners of intellectual property to facilitate global trade. The weak manufacturing capacity coupled with low level of inventive activities is identified as the major stumbling block for many WTO members to take even the limited advantages of the TRIPS Agreement. The attempt in this paper is to examine briefly the context in which the present international norms are developed and to identify the areas in which countries, particularly, developing and least developed, need to work together to restore a balanced international norms for the protection of inventions relating to health care so that access to essential medicine at affordable cost could be a reality.

Historically, international patent norms facilitated the growth of pharmaceutical industries in many countries which lacked the capacity to invent and produce drugs.

The paper suggests that the attempt of the international community to find solution to the problem of public health care is to encourage the generic industry to produce patented drugs

through grant of compulsory licence. There are serious doubts, expressed by many, regarding efficacy of the compulsory licence to solve the public health problems. Though this could be a temporary measure in case of public health crisis, the long-term solution is to build capacity within the country to manufacture essential drugs. This means finding proper mechanism to ensure the much needed technology transfer to countries with no or insufficient manufacturing capacity. It is unfortunate to note that there is no serious effort on the part of the international community to chart out a set of enforceable binding obligation to achieve this. It is in this area, the developing and least developed countries need to join together and compel the developed countries to agree for a set of norms to ensure transfer of technology.

The "Good Old Days" of TRIPS: The US Trade Agenda and the Extension of Pharmaceutical Test Data Protection by Susan Scafidi, *Yale Journal of Health Policy, Law, and Ethics*, Vol. 4, Issue 2, http://digitalcommons.law.yale.edu/yjhple

The paper makes an attempt to deals with this issue of IPRs in detail intellectual property rights carry significant implications for world health. In 1994, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) placed pharmaceuticals among the forms of technology that constitute patentable subject matter. Over the past ten years, non-governmental organizations, governments, and international institutions have increasingly acknowledged that this mandated inclusion influences the availability of new drugs, at least within the member nations of the World Trade Organization (WTO).

The nature of this effect, however, remains open to debate. Whether pharmaceutical patents provide financial incentives that support private research and development, as the industry attests, or allow monopoly pricing and production that hinder the ability of poor nations to address health crises, such patents have become an unavoidable feature of global medicine. The TRIPS-driven harmonization of intellectual property protection across borders is likely to continue into the foreseeable future.

The paper emphasizes that original applicants should enjoy a "reasonable period" of exclusivity with respect to reliance on pharmaceutical test data to standardized periods of protection and expansive definition of what constitutes a "new" product, the mechanism of free trade agreements has allowed the United States to establish international levels of protection far beyond the original, deliberately ambiguous TRIPS consensus on trade secrets. While some countries may enjoy benefits similar to those that the United States identified in creating its own domestic protections for test data, others may not yet have reached the stage at which incentives to invest in the creation of clinical data for new drug approval outweigh the need to facilitate marketing of competing versions on an expedited basis. The serial free trade negotiation process, particularly between nations with unequal bargaining power, is an unlikely forum for development of comprehensive, balanced policies on health care. It is, however, an opportunity for the United States to advance elements of intellectual property protection that exceed worldwide norms. This apparent divide-and-conquer strategy on the part of the United States circumvents the multilateral nature of TRIPS negotiations, decreases opportunities for the flexible interpretation of TRIPS by member nations, effectively lengthens the terms of pharmaceutical patents, and threatens to create a de facto global standard that may adversely affect the development of generic pharmaceutical production capacity. Although the TRIPS regime represents a global compromise that required many nations to increase intellectual property protections only with great reluctance, recent US FTAs make TRIPS look like the good old days.

TRIPS, the Doha Declaration and Increasing Access to Medicines: Policy Options for Ghana by J.C. Cohen, M. Gyansa-Lutterodt, K. Torpey, L.C. Esmail and G. Kurokawa, *Globalization and Health*, 1: 17, 9 December 2005, http://www.globalizationandhealth.com/content/1/1/17

THE disparity in pharmaceutical access between developed and developing countries is stark. Developing countries make up approximately 80 per cent of the world's population but only represent approximately 20 per cent of global pharmaceutical consumption. Market failures, government failures and income differences account for this persisting inequity. Specifically, high drug costs, weak or

corrupt institutions, contributing to less than effective pharmaceutical purchasing and distribution systems, and the potential consequences of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement all constrain drug access. The article deals with important issues like TRIPS and Public Health which highlight core issues in a significant way.

In this paper, an attempt was made to discuss several possibilities for working within the TRIPS regime to gain better access of the population to medicines. These options include compulsory licensing, parallel importing, technology transfer, local production and voluntary differential pricing. The authors forward some favoured policy choices for Ghana. First, they encourage Ghana and its Access to Medicines (ATM) Advisory Committee to consider local production. Local manufacturing can be an effective option if human and technological capacity is scaled up. However, they emphasize that this option should only be pursued if it makes economic sense. As a start, an objective cost-benefit analysis should be done to determine whether it makes economic sense for Ghana to pursue local production. Among the alternatives available to strengthen local industry include more aggressive technology transfer.

Next, the authors encourage the use of compulsory licensing. If Ghana decides to pursue compulsory licensing, it must then address administrative and knowledge barriers. This can be achieved through obtaining support from developed countries and/or international organizations on the effective implementation of compulsory licensing. There is great potential for Ghana particularly given the Government's commitment to build up its knowledge base in this area. In September 2004, members of the Ghanaian Access to Medicines (ATM) Advisory Committee visited Canada to learn about Canada's past experience with compulsory licensing and what measures could be applied to Ghana. If, however, Ghana determines that it is more technically or economically feasible to pursue importation, Para. 6 may provide an option. Ghana will first have to establish insufficient manufacturing capacity in the pharmaceutical sector in question, and then consider what political or economic repercussions may follow. More concrete alternatives for importation include parallel importation or the voluntary tiered-pricing arrangement proposed by the European Commission. Importantly, it is critical to monitor any public policy reform to assess whether or not they are achieving attendant outcomes and adjust accordingly. This will require baseline assessments and regular review at intervals.

The opportunities presented above can only be effective in addressing access to medicines in Ghana if other existing barriers are simultaneously addressed. First and foremost, the development and implementation of an effective exemption policy for the poor without co-payments is vital. Policies can vary such as implementing a national pricing policy that control prices on the supply side by regulating actual drug costs or the demand side, through reimbursement schemes such as reference-based pricing or generic substitution policies. Furthermore, reduction of mark-ups in the public sector may generate competition and drive private sector prices down. A hard but necessary policy reform is needed in the area of national tax, tariff and mark-ups to determine what changes could facilitate more affordable prices for the population.

Is the Ghana case generalizable for other African countries? The authors express a hope that as a minimum this case adds to the debate in other African countries about public policies they should pursue to improve access to medicines. Some policies may be more applicable than others depending on economic and political realities. There is not a "one-size-fits-all" policy menu that should be applied. Governments need to make informed policy choices when it comes to improving access to medicines and assess which measures are most needed and viable for their particular country.

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DOCUMENTS

Council for Trade-Related Aspects of Intellectual Property Rights

Paragraph 6 of the Ministerial Declaration on the TRIPs Agreement and Public Health

By means of a communication dated 21 June 2002, the following text has been received from the Permanent Mission of Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela with the request that it be circulated to TRIPs Council Members.

Summary

- Paragraph 6 of the Ministerial Declaration on the TRIPs Agreement and Public Health should be read in light of the entire context of the Declaration, as well as of the flexibilities contained in the TRIPs Agreement. In this sense, WTO Members should avoid taking a narrow approach in considering expeditious solutions to the problem recognized in Paragraph 6.
- Solutions based on Paragraph 6 should not be detrimental to the fulfilment of the objective of the TRIPs Agreement of transfer of technology, which is critical to improving manufacturing capacities in the pharmaceutical sector and therefore to ensuring sustainable access to affordable medicines.
- Any WTO Member could face difficulties in making effective use of compulsory licences due to insufficient or no manufacturing capacities in the pharmaceutical sector. Therefore, the solutions envisaged by the TRIPs Council to the problem recognized in Paragraph 6 should not exclude specific categories of countries. In any event, developing countries, in particular least-developed countries, should certainly be among the main beneficiaries of possible expeditious solutions.
- Difficulties of access to public health-related products are not limited to countries with insufficient or no manufacturing capacities where these products are protected by patents. Therefore, the expeditious solutions envisaged by the TRIPs Council should also address situations where no patents exist in the countries in need of access to public health-related products, or cases where economies of scale make domestic production for a particular product impractical or too costly.
- Without prejudice to the possibility of Members seeking additional expeditious solutions to the problem identified in Paragraph 6, the TRIPs Council should recommend an authoritative interpretation of Article 30 of the TRIPs Agreement, so as to recognize the right of WTO Members to authorize third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country.

I. Introduction

1. In Paragraph 6 of the Ministerial Declaration on the TRIPs Agreement and Public Health (hereinafter referred to as "Paragraph 6"), Ministers "*recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement.*" In this sense, Ministers "*instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.*"

2. Paragraph 6 of the Ministerial Declaration on TRIPs and Public Health should be read in light of the entire context of the Ministerial Declaration on the TRIPs Agreement and Public Health. In Paragraph 4, for instance, Ministers agreed "*that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.*" Furthermore, Paragraph 5 of the Ministerial Declaration recognizes some of the existing flexibilities of the TRIPs Agreement, which must be taken into account in considering possible solutions under Paragraph 6.

3. In many situations, the problem of countries with insufficient or no manufacturing capacities identified in Paragraph 6 stems from lack of technological infrastructure and manufacturing capacities in the territory of WTO Members. Consequently, **in considering solutions to the problem recognized in Paragraph 6, Members should bear in mind the need to fulfil and operationalize the objectives and the principles of the TRIPs Agreement**. In this sense, in no way should the envisaged solutions under Paragraph 6 be detrimental to the fulfilment of the objectives of the TRIPs Agreement of transfer of technology. The development of local manufacturing capacities for public health-related products, whenever economically feasible, is critical to ensuring the development of sustainable health policies and access to affordable medicines, particularly in developing countries.[1]

II. The Problem Recognized in Paragraph 6 of the Ministerial Declaration on TRIPs and Public Health

4. Any WTO Member could face difficulties in making effective use of compulsory licences due to insufficient or no manufacturing capacities in the pharmaceutical sector. Therefore, the solution to be considered by the TRIPs Council needs not and should not be limited to a specific category of countries – although developing countries, in particular least-developed countries, might figure among its main beneficiaries. Obstacles to granting compulsory licences for the supply of the local market may result from a number of factors. The lack of adequate manufacturing facilities present within the country, for instance, may result from a failure to fulfil the objective of transfer of technology of the TRIPs Agreement. A country with insufficient or no manufacturing capacities may also lack potential licensees that are willing or capable of manufacturing locally. In some countries, capacity to manufacture public health-related products may be owned or controlled by the same companies that hold local patents, and there would be no enterprises interested in taking the role of a compulsory licence supplier. Even in cases where technology may be available, there may be no potential licensees due to lack of economies of scale or other conditions for a viable economic manufacturing. Least-developed country Members generally face particularly dire difficulties in this respect, as there may be no pharmaceutical manufacturing capacities at all in their territories. In light of the above, **each Member shall have the right to determine whether it is in a situation of insufficient or no manufacturing capacities in the pharmaceutical sector.**

5. Logically, difficulties in access to public health-related products are not limited to countries with insufficient or no manufacturing capacities where these products are protected by patents. **Therefore, the expeditious solutions envisaged by the TRIPs Council should also apply to countries where no patents exist.**

III. Expeditious Solution to the Problem: Authoritative Interpretation of Article 30 of the TRIPs Agreement

6. Within the context of the problem identified in Paragraph 6 of the Ministerial Declaration on the TRIPs Agreement and Public Health, transfer of technology to the country in need may be neither economically feasible nor expeditious enough to ensure access to affordable public health-related products. Consequently, the TRIPs Council should consider expeditious solutions under the TRIPs Agreement to ensure access to public health-related products to countries in need.

7. In this sense, the problem recognized in Paragraph 6 suggests that, among other possible solutions, a producer in a country with manufacturing capacities could be allowed to manufacture, export and sell a patented product, without the consent of the right holder, to supply the country with insufficient or no manufacturing capacities in the pharmaceutical sector.

8. As an expeditious solution envisaged in Paragraph 6 of the Ministerial Declaration on TRIPs and Public Health, **Article 30 of TRIPs[2] should be interpreted so as to recognize the right of WTO Members to authorize third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country**. Therefore, the acts of making, selling and exporting public health-related products under this circumstance could be recognized as limited exceptions to the exclusive rights conferred by a patent. An authoritative interpretation would confirm that Members may authorize local producers to manufacture, sell and export public health-related products for other countries in need of access to such products. Additionally, in line with the spirit of the "limited" exceptions in Article 30, Members may consider the possibility of establishing appropriate safeguards that would ensure legal predictability in this particular use of the provision, if such safeguards do not have the effect of undermining its practical use, or to prejudice the existing right of countries to use Article 30 of TRIPs in other circumstances.

9. **Such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner**. In the context of the proposed authoritative interpretation of Article 30, the limited exceptions address public health problems outside the territory of the Member and therefore do not conflict with the normal exploitation of the patent. Moreover, the acts of making, selling and exporting patented products by third parties without the consent of the patent owner to countries with insufficient or no manufacturing capacities do not unreasonably detract from the returns ordinarily earned by the patent owner. It should also be noted that the act of exporting is not enumerated among the exclusive rights conferred by the patent in Article 28 of TRIPs. Consequently, they do not unreasonably prejudice the legitimate interests of the patent owner.

10. An authoritative interpretation of Article 30 of TRIPs would have the major advantage of avoiding burdensome procedures related to the grant of compulsory licences in the exporting country. For the importing country, such a solution would leave the freedom to decide on the need to issue or not a compulsory licence for the importer. It would also avoid a dependency by the country in need on the grant of a compulsory licence in the export country. In addition, in situations where the authorization of the limited exceptions under Article 30 is addressed to allow exports to a country where a compulsory licence has been granted or where no patent protection exists, the current text of Article 31(f) would not necessarily amount to an obstacle, as the compulsory licence would be authorized for the supply of the domestic market of the Member authorizing such use – that is, the importing country. Therefore, the limitation of the expression "predominantly" in this context does not affect the acts of making, selling and exporting public health-related products to the country authorizing a compulsory licence to supply its domestic market.

11. Clearly, nothing in the letter and spirit of Article 30 of TRIPs prevents Members from authorizing local producers to make, sell and export public health-related products, without the consent of the patent holder, to address health needs in other countries with insufficient or no manufacturing capacities, as a limited exception under this provision. In light of the mandate to find expeditious solutions to the problem recognized in Paragraph 6, an authoritative interpretation of Article 30 confirming this legal solution would be

an important step to ensure legal certainty for all WTO Members. Moreover, in light of Paragraph 4 of the Ministerial Declaration on the TRIPs Agreement and Public Health, Article 30 of TRIPs "*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*".

12. Members should bear in mind that legal solutions based on Article 30 will be best achieved if grounded in economic solutions. In many situations, a public health problem might affect more than a single country (as in the case of – but not limited to – HIV/AIDS, tuberculosis, malaria and several tropical diseases). Therefore, in implementing such solutions, countries may consider establishing economies of scale that would reduce costs of production and thus provide more affordable prices for the beneficiary countries in situations, for instance, where domestic production in small quantities from a compulsory licence for a particularly high-priced product may be impractical or too costly.

13. Finally, it should be stressed that such an interpretation of Article 30 is not exhaustive and is without prejudice to the right of Members to allow other exceptions to the rights conferred by patent under Article 30 of TRIPs in their national legislation.

IV. Final Remarks

14. The TRIPs Council should refrain from considering narrow, burdensome, or ineffective solutions that would ultimately defeat the very purpose of the solution under Paragraph 6. A few Members have mentioned the possibility of considering the imposition of safeguards or conditions to the solution envisaged by the TRIPs Council. Such proposals should be carefully considered. In light of the importance of the possible solutions to alleviate public health problems, **it would be unacceptable to consider safeguards or conditions that in any way would limit either the flexibilities of Members under the TRIPs Agreement or the clarifications established in the Doha Ministerial Declaration on the TRIPs Agreement and Public Health**. Members particularly interested in such safeguards are encouraged to submit concrete proposals for consideration by the TRIPs Council, to the extent they actually reflect legitimate concerns and that the burden of their enforcement is placed on interested parties, such as the patent holder.

15. While an authoritative interpretation of Article 30 is the most effective solution to the problem identified in Paragraph 6, other non-exhaustive solutions could also be contemplated. Merely partial or temporary arrangements, however, such as moratoriums or waivers, would not amount to sustainable or legally predictable solutions.

16. **Other possibilities** for the problem identified in Paragraph 6 might be related, for instance, to **Article 31(f) of the TRIPs Agreement**, which establishes that compulsory licences "*shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use*". While this provision contains an in-built flexibility that allows Members to export products under a compulsory licence, the expression "*predominantly*" limits the extent of such exports. In a situation where a Member is willing to grant a compulsory licence in order to grant a local manufacturer the right to supply public health-related products for a country with insufficient or no manufacturing capacities, the imposition of this limitation could result in inefficient production, if there is not enough domestic demand where the compulsory licence has been issued (moreover, the exporting country may not wish its domestic market to be supplied under compulsory licence, yet Article 31(f) effectively requires this as a condition of supplying an export market.). In this case, the TRIPs Council could consider the possibility of an amendment of Article 31 of the TRIPs Agreement, in order to eliminate paragraph (f).

17. Another additional solution based on Article 31 of TRIPs is related to its paragraph (k)[3], under which Members are not obliged to apply the conditions set forth in paragraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. Therefore, the limitation of exports under compulsory licences based on Article 31(f) does not apply where the compulsory licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive. Members may explore the use of such provision of TRIPs as part of the expeditious solutions to the problem envisaged in Paragraph 6. In this respect, the Secretariat could provide to the TRIPs Council a

document on the current uses by Members of Article 31(k) of TRIPs in authorizing the export of products and also to elaborate on the term "or administrative process", as it relates to Article 31(k). In this study, the Secretariat could also provide the TRIPs Council with information regarding the issue of compensation to patent owners when patents are held in both exporting and importing countries, and on the exhaustion of rights in 31(k) cases.

18. Article 31-based proposals, however, raise a number of issues that might eventually impose restrictions on a solution under Paragraph 6. Those issues include, as the case may be, the need to issue compulsory licences both in the importing and the exporting countries, which is administratively burdensome. The issue of determination of remuneration is another point of concern, as the patent holder should not in any case be entitled to double remuneration, as both compulsory licences would be issued to address essentially the same problem. In this respect, it may be more reasonable to determine compensation in the country where the product is consumed, since the amount of compensation should maintain some relationship with the ability of patients to afford the product.

19. In conclusion, the proposed solution based on an authoritative interpretation of Article 30 is preferable to those based on Article 31, as the former would be administratively less burdensome, involving less steps for implementation.

20. In addition to the fulfilment of the mandate of Paragraph 6, the TRIPs Council should also consider measures under Article 66.2 of the TRIPs Agreement in order to encourage the transfer of technology to least developed countries in order to strengthen local manufacturing capacities in their territories. Therefore, developed country Members should provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base in the pharmaceutical sector. Further, in order to ensure their implementation, such incentives should be monitored under the mechanism to be established by the TRIPs Council in light of the mandate established by Paragraph 11.2 of the WTO Ministerial Decision on Implementation-Related Issues and Concerns.

NOTES

[1] In this respect, in June 2001, developing countries Members already clearly stressed the importance of fulfilling the objectives of the TRIPs Agreement: "The objective of the **promotion of technological innovation and the transfer and dissemination of technology** places the protection and enforcement of IPRs in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it **encourages the development of domestic production of pharmaceutical products**. Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs. As mentioned above, these objectives can be obtained by the normal exercise of patent rights. **Where the patent holder fails to meet the objectives of the TRIPs Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals**" ("TRIPs and Public Health - Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela", document IP/C/W/296, Paragraph 20) [emphasis in the original].

[2] Article 30 of TRIPs: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

[3] "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur."

(www.wto.org IP/C/W/355 24 June 2002)

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