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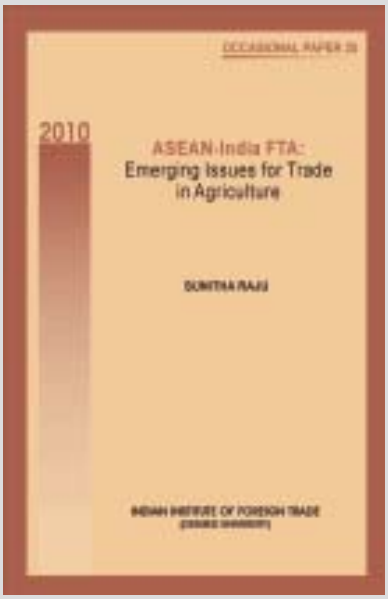

OCCASIONAL PAPER 25

ASEAN-India FTA: Emerging Issues for Trade in Agriculture

by Sunitha Raju

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In recent years, India has entered into a number of FTAs. Amongst all, ASEAN-India FTA (AIFTA) has been the most debated one. The stakeholder consultations clearly brought out the anxieties of a perceived import threat, particularly for agricultural products. Some of the sensitive sectors identified by India were spices, plantation crops, vegetable oils, rice, fish, textiles, chemicals, electronics, machinery, auto components and footwear. An assessment of the possible trade effects of the reduction or elimination of tariff across product groups is necessary for taking forward the efforts for strengthening India-ASEAN economic partnership.

This paper is a first step for examining, objectively, the import threat perception for India's agricultural products. The analysis covers both ASEAN as a group as well as individual member countries.

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TRIPs and Benefit Sharing under the CBD

Manisha Shridhar*

An international protocol on Access and Benefit Sharing (ABS) setting ground rules for improving access to and equitable sharing of world's genetic resources within Intellectual Property Rights (IPRs) framework was adopted at Nagoya, Japan on 30 October 2010. This agreement under the Convention on Biological Diversity (CBD) 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. This paper examines ABS and IPR issues under international conventions of CBD, TRIPs of the agreement on the World Trade Organization (WTO) and the International Convention for the Protection of New Varieties of Plants (UPOV) and suggests mechanisms for developing appropriate national policy strategies in time for the Rio+20 CBD Conference in 2012 at New Delhi .

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Launch of a New Treaty at Nagoya

A major international agreement was reached 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) that will set ground rules for improving access to, and the equitable sharing of, the world's genetic resources. UN Secretary-General Ban Ki-moon 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 outline how benefits – for example, 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 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]

IPRs in the Nagoya Treaty

The common IPRs are patents, copyrights, trademarks, geographical names used to identify products and undisclosed information such as trade secrets. Intellectual property rights 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 treaty affirms that intellectual property rights 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.

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 rights are those that accrue due to a patent.

The Issue of IPRs: CBD, TRIPs and UPOV

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) of the agreement on 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; especially since there is a danger of this getting lost by overexploitation and in the processes of adoption of monocultures. Indeed, in view of the germplasm being held 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 as the latter would always remain a secondary method of preserving biodiversity in nature that is in constant evolution.

There is a genuine concern in the developing world that the obligation to conform to the patent regime under the TRIPs makes 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 Article 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. Article 27 of the TRIPs Agreement, read together with Article 7 and Article 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 amended TRIPs and Paragraph 19 affirms 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 accepting provisions of 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 extent 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.

CBD and Access and 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 Systems 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.

Commercialization of IP and Challenge of ABS

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; *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 engaged, in response to negotiations for an International ABS Regime, and proposed requirements for "disclosure of origin" on patent applications, and 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 prior informed consent (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 the 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) programme, 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, bioprospecting 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.

'Rio + 20' CBD Conference at New Delhi 2012

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 (ABS) 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 in 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 is 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 programmes, 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 programmes are being outsourced by the large pharmaceutical companies and natural product discovery is increasingly undertaken by smaller companies and 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, the governments 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 commercialization and translate benefits to local population.

For certain industry sectors, e.g. pharmaceuticals, vaccines,

etc., we may borrow from ancillary rules of international trade under the World Trade Organization (WTO), e.g. Rules of Origin (ROO) for ascertaining the origin of a biological material. ROO 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. ROO 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 labelling (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 covered 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: pharmaceutical industry, biotechnology (health care and agriculture) industry, seed, crop protection and horticulture industry.

The eleventh Conference of Parties (COP) to the CBD will be held in October 2012 in New Delhi. This would mark the twentieth anniversary of the Rio Earth Summit, the "Rio + 20" CBD Conference. It would be appropriate that India addresses these issues in a concerted manner and takes a lead in developing suitable regulatory frameworks for maximizing results for ABS under the CBD.

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] Article 1 Convention on Biological Diversity (CBD).

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

[9] Article 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] 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 Series No. 38, *Access and Benefit-sharing in Practice: Trends in Partnerships Across Sectors*.

[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

Trade Related Aspects of Intellectual Property Rights (TRIPs) and Public Health: A Perspective

Archana Jatkar*

The Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement and the Doha Declaration related to public health is hailed as a watershed in international trade. This paper discusses the interaction of TRIPs Agreement in the area of public health. It is an attempt to find out if the Doha Declaration and the Paragraph 6 mechanism established by the Member countries has been able to resolve the concerns related to public health especially the problem of access to affordable medicines and in which way can the system be made more effective so as to be beneficial to the developing countries.

Introduction

THE adoption of TRIPs Agreement[1] in the framework of the GATT's Uruguay Round "marked the beginning of a new era in the international protection of intellectual property".[2] The agreement fundamentally changed the landscape of intellectual property protection by covering the most important aspects of intellectual property rights (IPRs), and by establishing minimum standards of IP protection. The Agreement's enforceability is further strengthened by applicability of binding dispute settlement mechanism contained in the WTO framework.

The TRIPs Agreement harmonizes IP protection at the global level by establishing minimum standards for intellectual property rights which have obligated all the Member countries including the developing countries to comply with the minimum standards, procedures and enforcement contained in the Agreement. This kind of harmonization has wide implications for the developing countries especially in public health issues. Given that the TRIPs Agreement provides for mandatory patent protection to all processes and products thereby depriving the developing countries of their historical capacity to refuse patent protection in order to address public health issues by way of manufacturing cheap and affordable medicines for its population.[3]

Many developing countries did not provide for product patent especially in the pharmaceutical sector which generally allowed for the production of cheap generic medicines in the local economy. Thus the availability of cheaper medicines has much to do with the manufacturing capacity of medicines in developing countries. For instance, traditionally a few countries such as India opted not to grant patent protection to pharmaceuticals products on public grounds. This eventually resulted in the development of pharmaceutical industry in India, which produces generic medicine on large scale, thereby, making the medicines available at cheaper price than its patented version. This luxury is now curbed by the existence of mandatory patent protection to all products and processes contained in the TRIPs Agreement.

Nonetheless, it is to be noted that TRIPs Agreement does provide certain flexibilities in the

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form of exception to patent protection mainly depicted under Articles 30 and 31 of the Agreement. These flexibilities are ideally suited to address the public health issue, however practically it is arguable if the existing flexibilities really allow developing countries to address public health issue. Thus the classic question whether the TRIPs Agreement does/has been able to strike a balance between public health and patent rights is still alive and has been challenged many times in the recent past.[4]

The debate between patent rights and public health also includes an underlying disagreement between developed and developing countries in regard to the nexus between IP rights and public health wherein developed countries have been arguing for narrow interpretation of flexibilities in the TRIPs Agreement and developing countries tend to take broad interpretation of the same.

Moreover, different rationales and values attached to the relationship between patent rights protection and public health is again not essentially reconciliable particularly in case of trade and human rights. Although different frameworks for right to health exists such as different United Nations declarations, the Millennium Development Goals and so on yet it is arguable that due to strong enforceability provided in the TRIPs Agreement, the patent right protection still has an edge over public health.

The nexus between patent right protection and public health can be looked at from various perspectives. However, this paper limits itself to the TRIPs Agreement and its interaction *vis-a-vis* public health in view that the TRIPs still remains the fundamental international agreement in relation to IPRs. The paper first provides an overview of relevant provisions of the TRIPs Agreement, the Doha Declaration on public health and then discusses the Paragraph 6 and its significance established by the WTO. In conclusion, a possible way forward is suggested.

TRIPs Agreement and Public Health

Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is a daunting task. While TRIPs is relatively new and countries are in different stages of the implementation process, the pressure to change had begun since the early 1990s through the US government and the multinational corporations. Because the TRIPs Agreement provided for an IPR regime which will put in place both products as well as process patents making it increasingly difficult to manufacture generic medicines.

However from the beginning, the TRIPs Agreement has recognized the nexus between IPRs and public health.[5] For instance, although the TRIPs Agreement was entered into force in the year 1996, to address the special needs of developing countries in the area of pharmaceutical patents and different levels of development, the implementation period for pharmaceutical patents as per the agreement for developing countries was ten years (which ended in 2005). The least developed countries (LDCs) are not required to provide pharmaceutical patent protection until 2016.[6]

Furthermore, Article 8 of the Agreement, which applies to all Member states, addresses the need to balance IPRs (in this context the patent rights) and public health by permitting states to "adopt measures necessary to protect public health and nutrition" as long as "such measures are consistent with the provisions of this Agreement."[7] In addition, Article 30 states that the Members may make limited exceptions to patent rights, "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent."[8] Together, these provisions are intended to provide Member states with the flexibility in drafting patent laws by taking into consideration public health. The provisions are vaguely worded, however, and require that any measures taken to protect health remain subject to the other terms of TRIPs.[9]

Article 31 specifically is an important provision in the context of public health and flexibility contained in the TRIPs Agreement. It allows governments to authorize

manufacturing of generic medicines/pharmaceuticals if good-faith negotiations with the patent holder fail.[10] The practice of government authorizing the use of patent without permission of the patent holder is called as "compulsory licensing". Compulsory licensing has ever since been controversial in terms of pharmaceutical patents and access to medicines. Negotiations over the TRIPs have focused on Article 31(f), which limits the distribution of drugs manufactured under compulsory licences, "Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[11] As Article 31 (f) imposed procedural limitation on the grant of the compulsory licences meaning it restricts the export of medicines manufactured under the compulsory licences, TRIPs did not present an effective solution for nations without the capability to manufacture drugs.[12] In other words, although the flexibility of exempting developing countries from implementation of pharmaceutical products from patenting till year 2005 was granted, yet these countries were prohibited from importing generic medicines from countries where the medicines were patented thereby not contributed much towards increase in affordability of medicines. For instance, India could obtain compulsory licence for manufacturing generic version of AIDS medicine to combat domestic epidemic but cannot export these medicines to African countries as it will be contravening the TRIPs Agreement. Due to this interpretation of Article 31 (f) countries which lacked the manufacturing capacity could not take advantage of the flexibilities built in the Agreement.

These provisions under TRIPs Agreement are sought to be operationalized by way of Member countries' national laws. Moreover, TRIPs does contain - limited flexibility, as well as some safeguards, which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs. The most important safeguards are:

(i) Compulsory licensing,

(ii) Parallel importation;[13] and

(iii) Provisions for early working (frequently referred to as "Bolar provision"[14])

The TRIPs Agreement also states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus de facto leaving countries the freedom to choose whether or not to allow parallel importation.

Doha Declaration on TRIPs and Public Health

Recognizing the ineffectiveness of Article 31 (f) and difficulties faced by developing countries in regards to public health in 2001, the WTO Members adopted a special Ministerial Declaration[15] at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for the governments to apply the principles of public health and the terms of the Agreement on TRIPs. The Declaration recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and the Member countries through the Declaration noted that "We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices".[16]

The Doha Declaration further affirmed that "the TRIPs Agreement does not and should not prevent the Members from taking measures to protect public health." The World Health Organization (WHO) commended the decision by stating that "the Doha Declaration enshrines the principles which the WHO has publicly advocated and advanced over the years, namely the re-affirmation of the right of the WTO Members to make full use of the safeguard provisions of the TRIPs Agreement in order to protect public health and enhance access to medicines for poor countries."

The Doha Declaration refers to a number of aspects of TRIPs which includes the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the

freedom to establish the regime of exhaustion of intellectual property rights.

Paragraph 6 of the Doha Declaration[17] specifically seeks to address the solution to the above question of ineffectiveness of compulsory licensing. After being influenced by the African proposals and long negotiations between the Member countries, the WTO on 30 August 2003, reached an agreement to allow a waiver of Article 31(f) for nations that need to import generic medicines.[18] The 30 August 2003 decision allows a Member state to export medicines made under the compulsory licences to any other Member state, subject to a number of conditions including notification to the TRIPs Council, remuneration to the patent holder, and safeguards to ensure that the products produced under the compulsory licences are not diverted from the "public health purposes underlying their importation."[19] Furthermore, the Agreement does not limit which the Member states can take advantage of the waiver to Article 31 (f) though many developed countries voluntarily declared that they will not use the system for importing medicines.

In December 2005 the WTO Members agreed to make the 30 August 2003 decision a permanent amendment to the TRIPs Agreement. The amendment will enter into force when two-thirds of the WTO's 150 Members ratify it.[20] In the meantime, the waiver decision remains in effect. A deadline till 1 December 2007, was set for this however the General Council extended the deadline to December 2009 and subsequently to 31 December 2011. Until then, the waiver remains in force.

It is expected that the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives and that issues such as preventing the medicines getting into the wrong hands are important.[21]

The mentioned amendment is in three parts. Five paragraphs come under Article 31 "bis" (i.e. an additional article after Article 31). The first allows pharmaceutical products made under compulsory licences to be exported to countries lacking production capacity. Other paragraphs deal with avoiding double remuneration to the patent-owner, regional trade agreements involving least-developed countries, "non-violation" and retaining all existing flexibilities under the TRIPs Agreement.

A further seven paragraphs are in a new annex to the TRIPs Agreement. These set out terms for using the system, and cover such issues as definitions, notification, avoiding the pharmaceuticals being diverted to the wrong markets, developing regional systems to allow economies of scale, and annual reviews in the TRIPs Council. Moreover, an "appendix" to the annex deals with assessing lack of manufacturing capability in the importing country. This was originally an annex to the 2003 decision. The new Article 31 "bis" and annex of the TRIPs Agreement are attached to a protocol of amendment. This in turn is attached to a General Council decision, which adopts the Protocol and opens it for members to accept it by 1 December 2007.

Is the Waiver Decision a Victory of Developing Countries towards Access to Medicine *vis-a-vis* Public Health?

During the Doha Round of negotiations, it can be argued that the developing countries were more experienced in comparison to the Uruguay Round when the TRIPs came into existence. This maturity certainly had its impact on the negotiations.[22] Doha and the development regarding the patent rights and public health can be considered as a victory of developing countries that too in a difficult situation. As Prof Abbott has mentioned, "the waiver decision was the result of a long and complex negotiation among a substantial number of interested stakeholders, many of whom had widely different perspectives regarding the optimal outcome". But with a favourable political context coupled with strong negotiation experience, developing countries finally were victorious since "both the waiver and the amendment (…) represent a formal lowering of IP protection standards imposed by the TRIPs Agreement. The traditional demanders of high standard IP protection lose something they gained in the GATT Uruguay Round".[23]

The ratification of the amendment of the TRIPs has been on the agenda for a long time if TRIPs would have been flexible enough to public health concerns of the developing countries. It is arguable that Articles 30 and 31 would have produced the same results and addressed the public health issues in theory and practice. Further, the willingness of the drafters of the Agreement can also be questioned in regards to the provision of exceptions to patent rights and to take into consideration the public health issue. Nonetheless, one thing is certain that the health crises in developing countries are worsening since the inception of TRIPs Agreement especially after the transition period for developing countries regarding pharmaceutical patents is over in 2005.

Thus Doha Declaration and the waiver decision of the TRIPs Council represent big victories for developing countries advocating and pushing for better access to medicine. While developing countries are expecting to take full advantage of these developments and to make them permanent through an amendment of the TRIPs Agreement with the proposed Article 31 *bis*, developed countries tend to counteract this evolution with external policies aiming at setting up high standards of patent protection. The so-called "TRIPs-plus" agreements may have a negative impact on TRIPs' flexibilities. As pointed out, "the most significant development in the decade since TRIPs was signed is the proliferation of "TRIPs-plus" agreements".[24] TRIPs-plus require member countries, especially developing countries, to embrace standards of intellectual property that go beyond the TRIPs.

Keeping this backdrop in mind, the crucial question, with regard to the development in the Doha Round is if the decision of the TRIPs Council and the proposed amendment will make a difference in the public health of the developing countries.

Efficacy of Paragraph 6 Mechanism and Why is it So Infrequently Used?

Although the Member countries were able to provide for the waiver decision in favour of public health and subsequently also agreed to amend the Agreement, the implementation of Paragraph 6 has practically been found cumbersome.

It is expressed by several Member countries that the procedural steps required by the TRIPs such as the patent holders be contacted to see if they will provide a voluntary licence have proved to be time taking. To cite an example, there is no assurance that the patent holders will not attempt to delay the process. Then there are other notification requirements which are to be followed by the countries to comply with the decision of August 2003. Countries wishing to use the Paragraph 6 system have to make following notifications:

(i) *Notification by importing member/s*

It is required from the Members, other than the LDCs, to notify the TRIPs Council of their intention to make use of the system as an importing country.[25] They have to announce once that they intend to make use of the system, and then they have to supply information each time they use it.

(ii) *Notification by exporting member/s*

Similarly, countries have to notify the WTO when they export

DETAILS TO BE NOTIFIED EACH TIME: PARAGRAPH 2(a) OF 2003 DECISION AND OF 2005 PROTOCOL

When an eligible importing country wants to import it has to notify certain details to the TRIPS Council each time. These details are:

- the names and expected quantities of the product(s) needed;
- confirmation that the eligible importing member in question – other than a least developed country Member – has established that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to the Decision; and
- where a pharmaceutical product is patented in the member's territory, confirmation that it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPs Agreement and the provisions of the decision.

Source: WTO webpage on TRIPs and Public Health.

pharmaceutical products manufactured under the compulsory licences under the "Paragraph 6" system. The government in the exporting country has to provide information on the conditions attached to the compulsory licence, the name and address of the licensee, the product(s) involved, the quantity or quantities to be produced under the licence, the designated importing country or countries, and the duration of the licence. This is specified in Paragraph 2(c) of both the 2003 decision and 2005 annex to the TRIPs Agreement.

These notifications have to be made available publicly by the WTO Secretariat through a dedicated page on the WTO website.

The TRIPs Council requires notification as above from countries if they intend to use the system as mentioned. Experts argue that this can be a deterrent itself, as countries often face severe political pressure when they use compulsory licences.

Given the time taking and cumbersome system so far the amendment has been used only one time. The experience of Canadian drug firm Apotex is worth analyzing in order to understand the frequent or non-utilization of Paragraph 6 mechanism. Apotex after much ado in Canada was approved the compulsory licence and in July 2007 when Rwanda was identified as Apotex's customer.[26]

Thereafter, Apotex began the process under the TRIPs. According to the TRIPs, a procedural step is required in which the patent holders must be contacted to enquire if they will provide a voluntary licence.[27] After this failed to produce a licence, Apotex applied for a compulsory licence in September 2007, which was then granted in October 2007. The company then had to undergo a review from Rwanda to obtain public tender. Finally it was granted in May 2008. The drugs were manufactured for its first delivery date in September 2008, nearly 3 years after Apotex applied to use system.

Further, the press release by Apotex after its first shipment to Rwanda stated that the "process of obtaining a licence to produce a product has to be restarted every time a new country makes a request. Also, there is no assurance that the patent holders will not attempt once again to delay the process."[28] This underlines that the current system indeed is tedious, and is required to be changed to get the quality affordable medicines (in the interest of public health) to those who have no access.

It is to be noted that the TRIPs rules require drug-by-drug, country-by-country application process. Also, it is argued that the problem with this kind of arrangement is that a generic drug industry cannot be supported by uncertainty of markets. In continuation to this, many civil society groups and some developing countries have expressed that problems in the Paragraph 6 system will become more serious as India (a key exporter of cheaper generics to the developing world) has now implemented the TRIPs Agreement.

INFORMATION TO BE PROVIDED BY LICENSEE ON ITS WEBSITE

The notification from the government also has to show the website address where the licensee is required to post the following information:

- The quantities being supplied to each destination as referred to in subparagraph 2(b)(i) of both the 2003 decision and the 2005 annex to the TRIPs Agreement. This subparagraph says that a compulsory licence issued by an exporting member under the Decision has contain the condition that only the amount necessary to meet the needs of the eligible importing member(s) may be manufactured under the licence and that all the products manufactured have to be exported to the member(s) which has notified its needs to the TRIPs Council.
- The distinguishing features of the product(s) referred to in subparagraph 2(b)(ii) of both the 2003 decision and the 2005 annex to the TRIPs Agreement. This subparagraph says that products produced under the compulsory licence have to be clearly identified as being produced under the system through specific labelling or marketing; and that suppliers should distinguish the products through special packaging, special colouring or special shaping of the products or combinations of these — provided that these distinguishing characteristics are feasible and do not have a significant impact on price.

Source: WTO webpage on TRIPs and Public Health.

There is also concern that the laws of the African Intellectual Property Organization (OAPI) are such that its 16 members may be unable to use the Paragraph 6 system. These include Benin, Burkina Faso, Cameroon, Central Africa, Chad, Congo, Cóte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger and Senegal.

In particular, a provision under the Bangui Agreement which forms the basis of OAPI's laws – says that a non-voluntary licence "cannot extend to the act of importation."

In view of the above and to precisely address these kind of questions/situations that the WTO Members agreed to subject this system to periodic review. A review of an amendment to international IP trade law that has so far failed to increase access to needed medicines for the poorest economies is now on the agenda of annual WTO review. A deeper look at existing measures opens the possibility of new solutions to the issue. These initiatives are currently under consideration.

It is difficult to say if the system under Paragraph 6 is working or not. A number of developing countries have been repeatedly pointing out that the system may not be an effective solution by citing the limited use so far and they insist in the TRIPs Council to look into real-life experiences in using the system. On the other hand, a number of developed countries counter the argument by stating that the single case does not prove anything as the system is only one of a range of options for allowing the poorer countries access to more affordable medicines.

An annual review of Paragraph 6 was recently held on 27 October 2010 in the WTO TRIPs Council, although the details of which are not yet available publicly. However, the agenda of the meeting show programme for substantive consideration of how the so-called Paragraph 6 solution to the 2001 Doha Declaration on TRIPs and Public Health is moving. The meeting is intended to result in substantial progress and recommendations.

Further, sources close to the negotiations indicate that Canada provided a comprehensive overview of its implementation of the Paragraph 6 system through Canada's Access to Medicines Regime (CAMR) programme initiative.[29] Rwanda was not present at this review; neither was Ghana, a country which has tried unsuccessfully to make use of Paragraph 6. Canada put forward some interesting conclusions while sharing its experience of using the system. It said since the adoption of the WTO 2003 waiver, there are now many more options available to importing countries and cited an example that the international environment for procurement of drugs has changed significantly with the introduction of variety of global mechanisms and alliances now offering greater choice to countries to obtain medicines. It appealed to the Council while evaluating the role, potential for broader use and effectiveness of the Waiver which further needs to be understood in the mentioned broad global context. In an interesting concluding statement it is mentioned that the Waiver was never intended to solve the issue of access to medicines on its own, but rather be a part of international strategy to combat diseases that impact the developing world.

It is also argued that the Waiver is designed to be a demand driven process by the countries in dire need, and only applies to instances where countries are seeking a generic version of patented drugs.

Way Forward

While the Doha Declaration and Paragraph 6 decision affirm important principles under the TRIPs Agreement regarding the protection of public health within international trade law, key challenges still remain. The lack of progress mentioned in implementing the TRIPs flexibilities and the ongoing discussions in the TRIPs Council to improve access to medicines, and the spread of TRIPs-plus measures through bilateral and regional trade agreements, calls for immediate and concerted efforts.

In view of the difficulties experienced in implementation of Paragraph 6 and its subsequent usage a way forward may be initiated by simplifying the content of the

Declaration especially Paragraph 6. That will help to enable the actual implementation. More fundamentally as soon as this is agreed, public health protections contained under the TRIPs may take precedence over measures in subsequent trade agreements.

It will also be useful if the large pharmaceutical markets such as India, China and so on continue to provide leadership in order to protect public health by asserting the flexibilities available in the TRIPs Agreement. They may even take proactive steps in this regard.

In order to find a rational solution to the above, it is important that in all future negotiations/discussions the text should not be restrictive. If the Agreement text is restrictive, developing and LDCs will be increasingly constrained to depend on supply from originator companies for medicines which may be expensive and unaffordable. To combat the widespread of certain diseases such as HIV/AIDS, especially in Sub Saharan Africa which has a large population afflicted with the AIDS and many more are likely to succumb, generic medicines/industry is key. Further, the TRIPs rules requiring drug-by-drug, country-by-country application process could also be considered in order to expedite the process under Paragraph 6 mechanism. It should either not have onerous conditions or unnecessary notification or must find a way to simplify the process in order to be efficacious.

The challenge of improving access to medicines is thus at cross-roads. On one hand, countries may allow the Doha Declaration to become ineffective as their vested interests are to be protected while on the other hand it has an option of adhering to public health protection under the TRIPs. The choice has to be made in favour of the TRIPs Agreement if the global community intends to resolve the issue of affordability and accessibility of medicines, a key issue in public health.

It may be useful to keep in mind that the usage of Paragraph 6 system is confined only to specific and well defined circumstances which means it keeps the burden on potential users who either have no or limited administrative resources. Hence, the system may not be the only solution to problems that are encountered in the public health sector. Nonetheless, it is like any WTO Agreement which should be subjected to periodic review, lessons should be drawn and evaluated from experiences of Canada and Rwanda so that the WTO (TRIPs Agreement in this context) can continue its effort to make the system work or find new ways, among several other efforts, to deal with new situation in enhancing access to medicines.

NOTES

[1] Trade Related Aspects of Intellectual Property Rights [hereinafter TRIPs], 4/15/1995, Annex 1C of the Agreement Establishing the World Trade Organization (WTO), available at http://www.wto.org.

[2] Lina M. Monten, The Inconsistency between Section 301 and TRIPs: Counterproductive with Respect to the Future of International Protection of Intellectual Property Rights?, 9, *Marquette Intellectual Property Law Review*, [2005], at 388.

[3] Cynthia M. Ho, A New World for the Addressing Patent Rights and Public Health, 82 *Chicago-Kent Law Review*, 1469, [2007], p. 1470. Also refer Frederick M. Abbott & Jerome H. Reichmann, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions, 10, *Journal of International Economic Law*, 921, December 2007, p. 7.

[4] Cynthia M. Ho, *op. cit.* p. 1470.

[5] Noting that the TRIPS Agreement emphasized from the beginning that it "should not prevent WTO Members from taking measure to protect public health, and that the TRIPs Agreement should be interpreted in that manner".

[6] The extension for least-developed Member states emerged from the Doha Ministerial Conference on TRIPs and Public Health in 2001.

[7] The full text of Article 8 of the TRIPs Agreement provides: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the

public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." TRIPs Agreement, Art 8.

[8] The full text of Article 30 states: "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." TRIPs Agreement, Art. 30

[9] Please see Loff and Heywood, quoting a United Nations Commissioner on Human Rights report, which stated "The various links [in TRIPs] with the subject matter of human rights—the promotion of public health, nutrition, environment and development—are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement".

[10] *See* TRIPs Agreement Article 31 ("Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected. . . .").

[11] TRIPs Agreement, Art. 31(f)

[12] *See* proposals on the compulsory licensing problem. A*lso* World Trade Organization, Press Release, *Decision Removes Final Patent Obstacle to Cheap Drug Imports,* Aug. 30, 2003 *available at* www.wto.org/english/news_e/pres03_e.htm [hereinafter "Press Release"] which discusses the effect of Article 31(f) on countries that cannot produce pharmaceuticals domestically).

[13] Article 6 of the Agreement allows each member country the freedom to incorporate the principle of international exhaustion of rights – the underlying justification for parallel imports – in its national legislation. Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product that was put on the market of the exporting country by the patent holder. The underlying concept for parallel imports is based on the principle of exhaustion of rights.

[14] Some countries permit the manufacturers of generic pharmaceuticals to use the technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of the generic product, while the patent is in force. This "Bolar" provision then allows the generic producer to market and manufacture their goods as soon as the patent expires. Bolar Provisions have been upheld as conforming to the TRIPs Agreement

[15] Declaration on TRIPs Agreement and Public Health, November, 14, 2001, dated 20 November 2001 WT/MIN(01)/DEC/2 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[16] *See* para 3 of the Doha Declaration on TRIPs and Public Health, WT/MIN(01)/DEC/2, 20 November 2001.

[17] Paragraph 6 of the Declaration states "We 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. We 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."

[18] *See* Press Release, which discusses the negotiations leading up to the agreement and its provisions.

[19] World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: Decision of the General Council of 30 August 2003, 1 Sept. 2003, WT/L/540 *available at* www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm [hereinafter "August 30 Agreement"].

[20] Until now around 31 countries, with EU being one member country, have ratified the amendment.

[21] See, WTO Press release which titled "Members OK amendment to make health flexibility permanent" Press/426, 6 December 2005.

[22] Comment of Abbott on the advantages of developing countries during the negotiations.

[23] Frederick M. Abbott & Jerome H. Reichmann, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", 10, *Journal of International Economic Law,* 921, December 2007.

[24] Cynthia M. Ho at 1495.

[25] The relevant provisions are in Paragraph 1(b) of both the 2003 decision and 2005 protocol.

[26] Canada says after the company, Apotex, received fast-track approval for its generic (TriAvir, a fixed dose combination tablet of lamivudine, 150mg + nevirapine, 200mg + zidovudine, 300mg) in June 2006, Apotex took over a year to find an interested importing country.

[27] Experts argue that this step is normally required for any compulsory licence, not only those under the Paragraph 6 system.

[28] See Press Release by Apotex "Life Saving AIDS Drug to Africa Gets Final Clearance" dated 20 Septmber 2007. Please refer http://www.apotex.com/global/about/press/20070920. asp accessed on 30 October 2010.

[29] It is believed as per the sources that Canada delivered the three interventions to the WTO TRIPs Council related to the review of the Paragraph 6 system. Please refer http://keionline.org/node/1000 for first intervention

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Now, Africa Seen Siding with India in Generics Battle

AFTER a high-pitch awareness campaign by India, leading African nations Uganda, Tanzania and Nigeria are reconsidering provisions of their proposed stringent anti-counterfeit legislations that would have hampered pharmaceutical exports to these countries.

The Centre has asked all its missions in Africa to spread awareness about Indian drugs to ensure that governments do not pass any law that could jeopardize the supply of low-cost medicines by Indian companies to these countries and also engage with civil society organizations that are working against such laws.

"We have started providing our missions in Africa all possible data to support our claim that our generic producers are genuine and instructed them to pass on the same to the departments concerned," a Commerce Department official said.

India is battling a sustained campaign by global pharma companies against Indian generics, or low-cost copies of medicines that may be under patent protection in some countries but not in India.

They have tried to equate Indian generics with spurious or low quality drugs and successfully convinced some African countries such as Kenya to pass anti-counterfeit laws banning sale of generic of a drug if it enjoys patent protection anywhere in the world.

This could really hurt India's pharma exports as most of the drugs exported by India would be labelled counterfeit under such legislation and face ban because they may be off patent in India but may still have valid intellectual property rights in other countries. Such a ban would greatly benefit multinational drug companies, allowing them to sell high-priced patented medicines in the big African markets.

India's case has been strengthened by the opposition to these legislations by the civil rights groups who have raised concern that the new law would deny cheap medicine to people.

Even Kenya, the only African country to have passed an anticounterfeit legislation, had to suspend its application after three HIV positive patients moved court on the grounds that the law made anti-AIDS medicines unaffordable.

The level of influence that multinational companies wield in Africa is evident in that a large global pharmaceutical producer offered assistance to Kenya to implement the suspended law, reports in the African media said.

"Indian missions have now been asked to work with civil society organizations who are trying to ensure that tight intellectual property norms do not hinder access to cheap medicines by the poor," the official said, adding that such organizations are heavily networked and have a power of mobilizing opinion.

A survey by India's health ministry showed that out of 24,000 samples of drugs collected from suppliers all over the country, only 11 samples were found to be sub-standard.

The report will be sent to Indian embassies in Africa to further reinforce India's position on the quality of its drugs. India exports about ₹40,000 crore worth of drugs every year.

(*The Economic Times*, 20 September 2010)

"FTAs may Close Tap on Affordable Drugs'"

India's ability to produce low-cost generics may be impacted, says UN-backed agency.

IN a rare public endorsement of a concern gaining momentum in various quarters, UNITAID has expressed concerns about the impact the Free Trade Agreements (FTAs) would have on India's capacity to make affordable medicines for domestic and overseas markets. The United Nations supported UNITAID is an international drug purchase facility.

Citing a recent study by the *Journal of the International AIDS Society*, UNITAID said Indian generic manufacturers have supplied more than 80 per cent of donor-funded AIDS medicines to developing countries in the last seven years. And it goes on to caution that the trade agreements India is currently negotiating may close the tap on affordable medicines for AIDS patients.

Grave Concerns

"The findings of this study raise grave concerns for us because UNITAID relies heavily on Indian generic manufacturers to supply quality-assured, patient-friendly, low-cost AIDS medicines in over 50 countries," said Unitaid Executive Secretary, Mr. Jorge Bermudez.

"What we need today is a more flexible approach to scale up treatment and not the opposite," it added.

India is in the process of finalizing FTAs with the European Union and Japan. In fact, the Commerce Ministry is said to be seeking Cabinet approval for the Japanese FTA, expected to be finalized during the Prime Minister Dr. Manmohan Singh's visit to Japan in later part of 2010.

In its study, the *Journal* further says, "a global trade agreement — known as Trade Related Aspects of Intellectual Property (TRIPs) — which has bound India to apply for product patents since 2005 — has already begun to curtail the country's ability to produce low-cost generic versions of newer medicines. New trade agreements being currently discussed may further reduce India's vital role as a provider of life-saving treatments."

The study comes at a time when the World Health Organization (WHO) has introduced new recommendations for people living with HIV/AIDS to begin treatment earlier and to switch to newer medicines that are more robust and less toxic, but also much more expensive, the note said.

This means, more people will need treatment today and the cost of treatment could skyrocket if new products cannot be made available at affordable generic prices. "If Indian manufacturers cannot meet these demands, a lot of the progress we have made in the last seven years will be reversed," added UNITAID's Mr. Bermudez.

AIDS Treatment

AIDS treatment has seen progress in recent years, with about four million people starting treatment between 2003 and 2008, due largely to India's ability to produce low-cost quality medicines and to healthy competition among India's producers, the study says.

For instance, the Indian generic version of the most commonly used first-line adult regimen (lamivudine/nevirapine/stavudine) dropped from $414 per person, per year in 2003 to $74 per person, per year in 2008.

Since 2006, Indian-produced generic antiretrovirals (AIDS drugs) have accounted for more than 80 per cent of the donor-funded developing country market, and comprised 87 per cent of ARV purchase volumes in 2008. In 2008, Indian-produced generics accounted for 91 per cent of paediatric ARV volumes.

By 2008, Indian generic ARVs accounted for 65 per cent of the total value ($463 million) of ARV purchases reported, while non-Indian generic and innovator ARVs accounted for 13 and 22 per cent of market value, respectively, the study says.

(*The Hindu Business Line*, 18 September 2010)

Takeover Shield for Pharma Cos in Works

THE Government of India is looking at policy options to strengthen India's thriving pharmaceutical industry to check growing instances of takeovers by foreign players.

The Commerce Department's Pharmaceuticals Exports Promotion Council (Pharmexcil) has

commissioned a study to suggest ways to enhance competitiveness of the domestic industry. The Commerce Department feels this will give confidence to the local industry to take on foreign competition and not sell out because of fear of getting swamped by the larger players.

"We are concerned about the number of takeovers of Indian pharmaceutical companies that have taken place over the last five years and want to create domestic conditions which would make such takeovers difficult," a Commerce Department official said.

The move comes close after the Department of Industrial Policy and Promotion (DIPP) initiated a public debate on whether foreign direct investment (FDI) flow into the pharmaceutical sector needs to be restricted. A restriction on FDI, in pharmceutical sector currently on 100 per cent automatic route, could discourage foreign takeover of Indian companies.

Pharmexcil has already commissioned the study to a consultant and expects it to be finalized by November-end after which it would be put up for discussion by the Commerce Department.

"The report would look at all possible ways in which the domestic industry could be made more productive and competitive through measures ranging from making raw materials available locally for manufacturers to reducing financing costs," said Shri Smitesh Shah, Chairman, Pharmexcil, and Managing Director of Calyx Chemicals and Pharmaceuticals.

Other issues such as financing of patents, warehousing and development of clusters and addressing impediments to exports will also be examined. The Commerce Department is hopeful that the suggestions would lead to concrete policies after discussions within the Government.

"We do not want to pre-judge what the study would come up with, but we will definitely push for policy initiatives that would help our industry in staying afloat," the same official said.

The ₹1 lakh crore domestic pharmaceutical industry got a jolt when the country's largest drugs producer Ranbaxy was acquired by Japanese Daiichi Sankyo for $4.6 billion in 2008. The acquisition of Piramal Healthcare's domestic business by US-based Abbot Laboratories for $3.7 billion was also a setback for the domestic industry. Other takeovers that have happened over the past years include takeover of Shanta Biotech by French company Sanofi, Dabur Pharma by German Fresenius Kabi and Matrix Lab by US-based Mylan Inc.

According to Government estimates, India exports drugs worth ₹42,000 crore annually to countries, particularly in Africa and Latin America. About ₹160,000 crore worth of drugs is sold in the domestic market.

(*The Economic Times*, 17 September 2010)

India, Brazil to Press for Dispute Settlement Panel against EU

INDIA and Brazil are expected to press ahead with a request for establishment of a WTO dispute settlement panel to adjudicate over the seizure of generic drugs on high seas by EU member countries that allegedly violated global trade rules, trade diplomats said.

The Indian drugs were on transit to Brazil and several other South American countries but the Dutch customs authorities confiscated these medicines on high seas in 2008 following complaints from some leading pharmaceutical companies.

During the consultations with the European Union (EU) in Geneva, India and Brazil sought guaranteed legal assurances from Brussels that its member states will not take recourse to seizure of generic drugs on high seas again.

The EU, however, failed to offer a firm response, sources said.

The two developing countries are now preparing ground for the next step in the WTO dispute settlement process, namely calling for the establishment of a panel to decide their complaint.

"These seizures have wide ranging implications for developing countries and they undermine the principle of universal access to medicines in poor countries and impose TRIPs obligations," India had said at the WTO when it invoked dispute settlement proceedings against the EU several months ago.

"Despite raising our concern repeatedly over the European Union's deeply flawed directive

1383 of 2003, Brussels has failed to bring its rules in compliance with the global trade rules," India said.

"The seizure of goods due to alleged patent infringements in the country of transit is a clear violation of the WTO disciplines on the freedom of transit, one of the cornerstones of the multilateral trading system," Brazil said.

In 2008, the Dutch customs authorities detained Indian generic drugs on the ground that they violated the EU's patent laws. Consequently, Indian generic manufacturers are forced to divert shipments, and cough up high charges for directing their shipments through other routes.

(*The Economic Times*, 17 September 2010)

'Free Trade Pacts may Hit Low-Cost Generic Drugs'

ACCORDING to the study conducted by UNITAID, in 2008, India-produced generics accounted for 91 per cent of paediatric anti-retroviral (ARV) volume. AIDS treatment has experienced startling progress over recent years, with about four million people starting treatment between 2003 and 2008, largely due to India's ability to produce low-cost quality medicines, said a UNITAID statement.

At the same time, the study expressed concern that the legal framework in India that facilitated such production, was changing with implementation of the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). It also expressed concern over intellectual property measures beyond TRIPs being negotiated in regional and bilateral free trade agreements (FTAs), such as the FTAs with the European Union and Japan, which could create IP obligations for India that could cause price rise and delay access to newer and better (ARV).

''Indian manufacturers of generic antiretroviral ARV medicines facilitated the rapid scale up of HIV/AIDS treatment in developing countries through provision of low-priced, quality-assured medicines,'' observed the study.

(*The Times of India*, 16 September 2010)

Pharma MNCs Take Localization Route: ICRA

THE Indian pharmaceuticals market, expected to grow to $40 billion by 2020, presents a lucrative opportunity for pharma MNCs, who are currently launching branded generics *via* product localization, a strategy that involves local branding, sourcing and pricing, says an ICRA report. Most of these companies have a two-pronged strategy for the Indian market: target the mass market *via* product localization and India-specific pricing to capture the branded generics segment and address affordability issues; and launch globally patented products in niche segments at a premium. Thus, GlaxoSmithKline (GSK), for instance, has launched branded generics like Benitec A (olmesartan in combination with amilodipine) in the cardiology segment, Meropenem in the antibiotic segment, and Calamine lotion in dermatology. Similarly, Pfizer has come out with "branded value offerings" (branded generics) like telmisartan and rabeprazole in the therapeutic segments of cardiovascular management (CVM) and gastrointestinal, respectively.

Over the last few years, the global pharma industry has been facing multiple pressures arising from increased R&D costs, the implementation of cost control measures by developed countries, issues related to pricing of patented products, and the absence of a strong product pipeline. "By 2014, the top 10 innovator companies alone would face the expiry of patents on brands that generated revenues in excess of $120 billion (2008 sales)," ICRA said. Moreover, several countries are currently implementing strong pro-generic policies with stricter norms for reimbursement of costs. Further, established drug prices are also being subjected to increasing pressure as part of the trend towards stricter pharmaceutical cost containment policies with reference pricing schemes (regulating drug reimbursement levels using a reference price cap) being extended to include therapeutic rather than merely generic reference pricing programmes.

"The growing use of generics and branded generic drugs has led to pharma companies reorganizing their strategies by focusing on the generic and branded generics business in developed

as well as developing countries for higher growth," the report says. While Novartis, through Sandoz, remains one of the multinationals most committed to generics among the leading pharma companies globally, players such as Pfizer and Sanofi Aventis also have in-house generic businesses (Greenstone and Winthrop, respectively). "It is in this context especially that the emerging markets represent exciting opportunities as they are expected to grow at a much faster rate (CAGR of 15.2% during 2006-2020) than their developed counterpart (CAGR of 2.0% during 2006-2020), given their rising health awareness and increasing spending power, among other factors," it adds.

The emerging markets are expected to reach a size of $400 billion by 2020, with India being a key market. This scenario has led to pharma MNCs reorienting their strategies and resource allocation for emerging markets. "Thus, they are now seeking to build up a significant presence in branded generics and over-the-counter drugs, launch off-patent products and adopt local pricing for patented drugs so as to attain volumes and capture market share," ICRA said.

(*The Financial Express*, 15 September 2010)

Dr. Reddy's Sued over Patent Infringement

WYETH, a wholly-owned subsidiary of US-based Pfizer Inc, has filed a suit against Hyderabad-based Dr. Reddy's Ltd at the US District Court, New Jersey, for allegedly infringing former's patent coverage in case of an anti-depressant drug, Effexor XR (Venlafaxine Hydrochloride). This drug from Wyeth's stable is a blockbuster that clocks annual revenue worth $2.75 billion in the US market alone. In the global market, the drug has sales of close to $4 billion per annum and one of the highest market share in the $11 billion-plus antidepressant pie. However, the generic opportunity for the drug is being chased by many other pharma companies, including many Indian players such as Sun Pharma, Lupin, Zydus Cadila. Also, Dr. Reddy's Abbreviated New Drug Application (ANDA) filed with US Food and Drug Administrator does not qualify as 'first to file' and is not entitled to the 180 days marketing exclusivity for the drug.

Meanwhile Israeli drug firm Teva has already started selling the drug in the US market as per a pact with Wyeth under which it legally agreed not to sell its generic version until 1 July. Sun Pharma had also filed an ANDA for the tablet form of Effexor XR (innovator Wyeth has it in capsule form) and was hoping for a non-AB rated approval (no substitutability at pharmacy level) in 2008. However, the approval for the company's product got delayed by more than one and half years because a competing firm, Osmotica, filed a citizen's petition.

Litigation has also been settled with Impax, Lupin, Anchen Pharmaceuticals and Teva Pharmaceutical Industries among others allowing these companies to introduce generics under Wyeth licence in 2011. The last of patents related to the drug would expire in 2017 even though the patent relating to Active Pharma Ingredient has already expired.

(*The Financial Express*, 14 September 2010)

Cancer Patients Appeal to PM to Reduce Drug Costs

WITH over 2.5 million people in the country affected by cancer, the Cancer Patients Aid Association (CPAA) has knocked at the door of the Prime Minister's Office, concerned over the prohibitive cost of cancer drugs.

The prices of oncology drugs, medicines used to treat cancer, are beyond the reach of patients and they seem to be outside the Government's pricing policy (the Drug Price Control Order), since they are not part of the National List of Essential Medicine (NLEM), the CPAA points out, in its letter to the PMO.

The CPAA is currently locked in a patent-related litigation with multinational drug-maker Novartis over Glivec, its blood cancer drug. And the NLEM is watered down to cover 74 medicines, in keeping with the Government's policy in the past, to "monitor" drug prices and not "control" them.

From wider insurance and a social security net for people suffering from cancer to price-control of highly-priced cancer drugs, the CPAA has urged

the Government to take steps and bring down the price of these medicines for people earning modest wages, like a daily-wage earner, whose income is less than ₹3,000 a month.

The DPCO is not being used correctly, as it covers medicines used in large quantities. Niche, highly-priced medicines that are life-saving medicines, critical to large number of patients, also need to have their prices controlled, CPAA's Shri Y.K. Sapru said.

"Unfortunately, for a drug to come under price control, the annual turnover is taken into account, not use of the drug or its importance in terms of saving life or that which is essential for extending life. The NPPA (National Pharmaceutical Pricing Authority) ought to reconsider the criteria for listing drugs as essential and must reform the policies and bring under its ambit drugs that are not only used more, but also those that are essentially life saving, and required by a huge number of people in the country suffering from diseases, such as cancer, and provide a ceiling or cap to the price that could be charged for a medicine, or provide subsidies or ensure that the Government distributes the medicines freely to the people afflicted by such diseases. The Government should also encourage social security and insurance schemes to cover costs of treatment of diseases such as cancer," the CPAA note says.

The Association has also mooted compulsory licences on patented drugs, where generic drug-makers are allowed to make medicines similar to a patented drug, under certain circumstances. "Compulsory licences can be given by the (Patent) Controller on the grounds that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonably affordable price. This option can be exercised after a period of three years from the date of grant of the patent. The Government could make use of this option to ensure that cancer drugs that are patented are provided at affordable prices to the patients," the CPAA note said, listing out several options for the Government to consider making cancer drugs affordable.

(*The Hindu Business Line*, 14 September 2010)

Healthcare Spend to be 8 per cent of GDP by 2012: FICCI

HEALTHCARE spending as a share of GDP is expected to increase to 8 per cent by 2012 from 5.5 per cent in 2009, said a report by Federation of Indian Chambers of Commerce and Industry and healthcare consultancy HOSMAC. However, public expenditure accounts for only one-fourth of the total healthcare spend in India. "India ranks 171 out of the 175 countries in the world in public healthcare spending," says the report. Private sector healthcare spending in the country is expected to reach $45 billion by 2012 at 27 per cent compounded annual growth rate.

(*The Financial Express*, 9 September 2010)

India Keen to Add Remedial Clause in Trade Agreements

WARY of third party FTAs impinging upon the country's interests, New Delhi is keen on inserting a remedial clause in all its extant and future FTAs.

India is looking to send out a stern message to its trading partners that if they enter into similar trade agreements with third parties it should not compromise the coutnry's interests.

This has been prompted by reports of constant seizures of Indian drugs by the EU Customs authorities and the subsequent formation of the Anti-Counterfeit Trade Agreement (ACTA) for the imposition of stringent norms for generic drugs over and above the ones prescribed in the WTO's TRIPs Agreement.

Currently, Korea is negotiating a trade agreement with Japan which is expected to incorporate TRIPs-plus conditions on trade especially in the context of pharmaceutical products since both the countries also form a part of the ACTA grouping.

Since India enjoys a CEPA with Korea, it fears that new standards would automatically apply to India as well thereby restricting its trade with the country.

"We do not want the TRIPS-plus conditions to be imposed on us...we are just looking to safeguard

our interests," a senior Commerce Ministry official said.

He said though initially the new clause would be only restricted to intellectual property rights (IPR) related issues, but in the future it can be used against other market access related issues as well. "If we enter into an FTA with a country expecting certain privileges in the form of market access and then that country enters into another agreement with someone else then we need to ensure that our market access is protected," an official said.

The move by India could also force its trading partners to consult New Delhi at the time of signing an agreement. "There should be clear communication from the side of our trading partners if and when they choose to shell out something extra for other countries," the official added.

Head of CII Pritam Banerjee said that the move is welcome and a step like this ought to have been taken a long back.

"India needs to safeguard its interests and that's only fair...it would be reciprocal in nature which India will have to keep in mind. But overall in the current context of global trade such safeguard mechanisms are very important," he said. Shri Banerjee said that a similar clause has been inserted in the US-Singapore FTA as well. A senior trade expert said that the attempts by India to incorporate such clauses was reflective of the growing clout of India in global trade. "Though India's share is still about 3 per cent in the global trade but because it offers a big market it is in a powerful negotiating position now," he said.

(*The Financial Express*, 4 September 2010)

Link Patented Drug Prices to Local Cost: Industry

INDIAN drug manufacturers want the price of patented drugs to be fixed based on the cost of developing and producing the medicine in the country and not in developed markets, where it costs more, to make such medicines affordable for local patients.

The drugmakers were asked to send their views on the matter following a meeting last month with the committee on price negotiations for patented drugs. The committee, formed three years ago, has made several unsuccessful attempts to arrive at a formula to lower cost of patented drugs.

"A reasonable yardstick for negotiating and fixing the price of a patented drug in India could be based on the cost of R&D, clinical trials, manufacturing, etc., if those processes are carried out in India," Shri Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA), wrote in a letter to the committee.

The chairman of small drugmakers' body SMPIC, Shri Lalit Kumar Jain, has also supported this model. Another industry body CIPI, which suggested to the Committee the Government to issue compulsory licensing, a provision that allows a non-patent holder to sell patented drugs under certain conditions, if such medicines are priced exorbitantly.

Recently, a Government arm initiated a discussion on use of compulsory licensing, tighter scrutiny for acquisition of Indian companies by global MNCs and expanding scope of price control to make patented and expensive medicines affordable for local masses.

At present, if an imported patented medicine is part of the list of 74 drugs under price control, its price is fixed based on the landed cost in India, with up to 50 per cent margin. But if a medicine is outside the list of controlled drugs, companies are free to fix the launch price, leading to high price of patented drugs. Companies are restricted from increasing the price of their brands beyond 10 per cent a year. But, they enjoy fat margins after launching the product at a high price.

India adopted a new patent regime in 2005 giving exclusive 20 years marketing rights to a patent holder. Currently, about 13 patented drugs are sold in the Indian market, mostly related to treatment of cancer, new generation HIV and Hepatatis B. Some of them cost as much as ten times of a generic or a low-cost equivalent.

One of the earlier proposals was to cap the price of patented drug at the same level as those exported to the least developed countries. But IDMA said most of those markets are forced to accept the price offered by global drugmakers as

they have no alternative sources for medicines, unlike India.

(*The Economic Times*, 28 August 2010)

Drug Seizure Row Headed for Amicable End

INDIA is "hopeful" of finding an amicable solution to the drug seizure issue with the European Union (EU), even as the two sides are fighting it out fiercely at the WTO.

"What was done to the third world countries' shipments by the Netherlands was actually a misreading of the EU notification…. The loopholes in the notification would soon be removed by amending the laws so that there's no repeat of such seizures," Commerce and Industry Minister Anand Sharma said after having a closed-door meeting with EU Trade Commissioner Karel De Gucht, as part of the 42nd Asean Economic Ministers meet.

He also said the EU trade commissioner had understood the sensibilities concerning generic drugs and their importance. "We are looking at taking forward the negotiations between India and EU for a bilateral trade and investment agreement. We have also underscored India's own ambitions of movement of natural persons under Move IV," Shri Anand Sharma added.

The problem started almost two years ago, when a generic drug shipments, on route from India to Brazil, was seized by the Dutch Customs during transit, citing violation of European patent laws. Developing nations have criticised the move as a deliberate attempt by rich nations and multinationals to diminish poor countries' access to cheap medicines.

Both sides would sit for 11 round of negotiations on the FTA, followed by a meeting between Commerce Secretary Rahul Khullar and EU Director-General for Trade David O'Sullivan.

"The EU has also recognized the fact that there is an asymmetry between India and EU when it comes to development and tariffs and it has been accepted in the negotiations. So, the level of tariff reduction would be marginally different," he said.

(*Business Standard*, 27 August 2010)

Panel on Drug Prices to Meet Industry

THE committee on price negotiation of patented drugs constituted by the Department of Pharmaceuticals (DoP), would meet industry representatives to identify possible negotiation options that can lower the cost of patent-protected and imported medicines for life-threatening illnesses in the country.

The move comes a day after yet another arm of the Government – the Department of Industrial Policy and Promotion (DIPP) – released a discussion note on compulsory licensing provisions to ensure availability of affordable medicines. Expanding the span of price control is one of the four options highlighted in the DIPP note to address the problem of exorbitant prices of patented medicines.

The price negotiation committee consists of DoP officials and has been holding meetings with various stakeholders on the issue for some time now. Officials said the committee is almost ready with its views and the final recommendation will form part of the Department's submissions to a Group of Ministers (GoM), formed to consider a draft pharmaceutical policy prepared by the Ministry of Chemicals and Fertilizers.

Both the initiatives, analysts feel, have been driven by the Government's sense of urgency to explore various options under existing laws for bringing down the cost of medicines to Indian patients.

While price negotiation will act as the primary deterrent for the high cost of patented medicines, compulsory licensing intends to take away the exclusive manufacturing rights from the patent holder for mass, low-cost manufacturing and resultant patient benefit.

The domestic drug industry has supported both moves, unlike foreign multinational drug manufacturers that remain cautious.

Indian Pharmaceutical Alliance (IPA), the select grouping of leading Indian drug makers, has welcomed the move. "We (IPA) are glad that the Government has finally woken up to the need for compulsory licensing. This will help address the public health problem," D.G. Shah, secretary general, IPA said.

Incidentally, the Prime Minister's Office had recently sought views from various ministries on an Organization of Pharmaceutical Producers of India submission that aimed at strengthening India's intellectual property norms to allow them market exclusivity for their patented medicines. Compulsory licensing, in a way, attempts to undo, what foreign drug multinationals are trying to aim for, domestic drugmakers say.

(*Business Standard*, 27 August 2010)

Bad Medicine

THE DIPP has unveiled a discussion paper on the issue of drug prices. The paper highlights the Government's concern over price escalation of certain life savings drugs for diseases like HIV and Hepatitis C in the last two or three years. In the Government's view, the root cause for the price inflation of these drugs lies in the foreign acquisition of domestic pharmaceutical firms—six Indian drug manufacturers including Ranbaxy have been acquired by multinationals since 2006. The Government believes that these multinationals have diverted drugs manufactured in India to more lucrative export markets, creating a supply shortage in India, which in turn has caused the price increase. The causation put forward by the Government needs to be considered very carefully because it can so easily lead to a revival of protectionism in the pharma sector. It is, of course, well known that even Indian companies that manufacture domestic drugs export large amounts (in volume and value) to lucrative markets in the developed countries. Given price controls and the severity of competition in the generics space in India, this is the only way to stay profitable. The Government will, therefore, have to prove that foreign manufacturers are engaging in cartelization or some other collusive activity, before they can make such a strong claim. That sort of investigation is best left to the Competition Commission of India, and the Government should wait for its investigations before making a claim of deliberate price escalation on the part of MNCs.

Fortunately, the report doesn't recommend keeping pharma MNCs out of India. Instead, it recommends compulsory licensing of key drugs, a system under which the Government can allow a third party (not the patent holder) to manufacture and market a particular drug. Compulsory licensing is permissible under international law. Article 6(b) of the Doha Declaration recognizes that the flexibilities of the TRIPs Agreement include the rights of member states to grant compulsory licences and the freedom to determine the grounds under which such licences are granted. Article 6(c) gives members the flexibility to determine what constitutes a national emergency to invoke compulsory licensing. India has never used compulsory licensing, though 52 members of the WTO including the US have. The US famously invoked compulsory licensing bypassing Bayer's patent on an anti-anthrax drug during what turned out to be a minor Anthrax scare. The key is to be able to balance the objectives of innovation and consumer interest. The Government must not resort to mindless protectionism, but should use legally permissible methods to safeguard the health interests of Indian citizens.

(*The Financial Express*, 26 August 2010)

Compulsory Licensing: A Provision that Allows Governments to Override Patent Rights

What is compulsory licensing?

Compulsory licensing is a process through which a government allows the local industry to produce drugs under patent protection without the permission of the patent holder. While the global agreement on intellectual property, the Trade Related Intellectual Property Rights (TRIPs) under the WTO, says that a patent holder will have the sole right to give permission to produce its patented products on payment of a licence fee, flexibilities have been given to countries to address public health concerns by issuing compulsory licences.

When can a government issue compulsory licences?

These could be issued to address any public health concern as considered appropriate by the issuing country. The TRIPs Agreement gives a country the freedom to decide when it wants to issue such licences and it does not necessarily have

to be an emergency. It is generally issued for producing life-saving medicines to ensure their availability at low prices.

Does compulsory licensing strip a patent holder off the right to collect licence fees on patented products or process?

Not at all. Companies that are issued compulsory licences to produce a patented product have to pay "adequate remuneration" based on the "economic value" to the patent holder, but there is no elaboration on what the value is.

Why has India not been issuing compulsory licences? Why has it suddenly woken up to the need?

While the Indian Patents Act provides for issuing of compulsory licences, the procedural guidelines and the policy framework for the same are not in place. India had been taking it easy so far, as it had a flexible patent regime till 2005, which granted protection only to processes and not the final product. This allowed other producers to manufacture generic versions using a different method.

However, ever since there was a switch-over to the more stringent product patent regime in 2005 (under which a patented product cannot be produced through any other process) to meet the country's commitments under TRIPs, the country has been facing a shortage of life-saving drugs such as anti-cancer medicines and prices of patented versions have been going up. This prompted the DIPP to float a note on compulsory licensing inviting comments on how the country should go about implementing it.

Can compulsory licences be issued for exporting to other countries?

Compulsory licences are generally issued for producing for the domestic market. However, during the Doha ministerial meet in 2001 the WTO recognized that there are countries which do not have manufacturing capacities and allowed such countries to import generic versions from other countries by issuing compulsory licences.

(*The Economic Times*, 26 August 2010)

Commerce Ministry may Step in to Check MNC Buys in Pharma

OVER the last five years, six domestic pharmaceutical operations have been acquired by multinational drug companies, a development that has raised red-flags with authorities at the Centre.

THE MAJOR DEALS

Domestic operation acquired	*Multinational company*	*Year*	*Amount (US$)*
Matrix Lab	Mylan Inc	2006	736 million
Dabur Pharma	Fresenius Kabi	2008	219 million
Ranbaxy	Daiichi Sankyo	2008	4.6 billion
Shanta Biotech	Sanofi Aventis	2009	783 million
Orchid Chemicals (injectibles business)	Hospira	2009	400 million
Piramal Healthcare (domestic formulations)	Abbott Laboratories	2010	3.72 billion

In an effort to tackle such sell-outs, the Commerce Ministry is examining the regulatory action and financial incentives required to be taken in the interest of this "vulnerable" sector, an official familiar with the development said.

The review, an internal exercise initially, will work with the Health Ministry and the Department of Pharmaceuticals, the official added.

The Ministry would take a close look at the present system of 100 per cent automatic approval for foreign investment in the sector, and see if a more guarded investment policy was required, a source familiar with the development said.

The Government also needs to notify M&A (merger and acquisition) related provisions in the Companies Act to facilitate the scrutiny of the Competition Commission on acquisitions of Indian drug companies by multinationals, points out a joint letter from a group of civil society and patient-support organizations, including the All-India Drug Action Network and Centre for Trade and Development addressed to the top-brass at different ministries, including Health, Commerce, Agriculture and Chemicals and Fertilizers (the apex Ministry for pharmaceuticals).

There are no effective legal or policy tools to address threats emerging from the acquisition of

Indian pharmaceutical companies by multinationals, the letter observed, cautioning monopolistic behaviour that would result in increase of the prices of medicines.

Ground Realities

From 2006 till date, sale of domestic drug operations (totally or in part) includes the high-profile exit of Ranbaxy's promoters when they sold their entire stake to Japanese drug-maker Daiichi-Sankyo in 2008 for close to $5 billion, and the recent sale of Piramal Healthcare's domestic formulations business to Abbott Laboratories, in May, for close to $4 billion.

Some industry-watchers say that the ground realities started becoming difficult for local drug companies, after India implemented the product patent regime in 2005. Patents ensure an innovator 20 years protection on the product, or medicine, in this case – the flip side of this being, no other company would be able to make a generically similar version of the same product during the patent-protected period. This hurt the local drug companies, which have largely been makers of generic or off-patent drugs, as innovative research required deep pockets.

(*The Hindu Business Line*, 23 August 2010)

Patently Wrong: Diluting Section 3(d) of Patents Act is a Bad Idea

IT isn't quite clear why the Prime Minister's Office decided to stir a debate on the Organization of Pharmaceutical Producers of India (OPPI)—it comprises mostly MNCs operating in India and their partners here—demand to dilute Section 3(d) of the Indian Patent Act. The Patent Act, as modified five years ago, has helped ensure India was not inundated with drugs that were just minor modifications of existing ones—something that one would expect, given the sharp slowdown in the number of new discoveries and the increased proclivity of the blockbusters-starved "innovator firms" to look for pecuniary rewards from patenting of incremental inventions and try "ever-greening". When India's lawmakers were debating 3(d) in the winter of 2004, the transnational pharma majors from the US and EU said it would violate Article 27 of the TRIPs Agreement. They were subsequently proved wrong, and even the ardent votaries of undiluted and liberal patent rights like the World Intellectual Property Organization (WIPO) have endorsed 3(d) as a legitimate, TRIPs-compliant tool.

The reason why Big Pharma dislikes Section 3(d) is that it makes it difficult to get patent rights for new (physical) forms or admixtures of previously known new chemical entities (NCEs) unless these seemingly trivial changes bring "significant improvement in the efficacy" of the product in question. If vigorously implemented, 3(d) can thwart stockpiling of separate 20-year patents for multiple attributes of a single product. According to news reports, OPPI wants the term "efficacy" to be defined and quantified. This apparently innocuous demand has the potential to undermine the utility of 3(d). It is not that the Indian patent offices haven't granted patents for deserving incremental inventions that are of real therapeutic value to the patient-consumer. True, just about 40 of the 3,500 product patents for pharmaceuticals granted since 2005 are for new crystalline forms or polymorphs of a pre-existing NCEs. However, these patents have translated into just 30-odd products in the market so far, of which a dozen are crystalline forms. This shows how important the removal/dilution of 3(d) is to the patent seekers. Indian companies, too, may get a few patents for incremental inventions if 3(d) is diluted. But this would hardly offset the adverse effect, on the consumer or the Indian industry, of a bad patent.

(*The Financial Express*, 23 August 2010)

Mid-Cap Pharma Firms to Explore LatAm Market

TO explore generic drug business opportunities in the Latin American market, around 28 mid-cap Indian pharma companies are visiting Ecuador, Uruguay, Argentina, and Peru. The delegation spearheaded by Pharma Export Council has companies including Aurochem Laboratories, Coral Laboratories, Ideal Cures, Labdhi pharmaceuticals.

This delegation is focusing on smaller but relatively unexplored markets within the Latin American region. The Latin American market is

vast, comprising of the eight major economies of the South American continent. Brazil is a leading market in this geography, followed by Mexico, Argentina, Venezuela, Colombia, Chile, Peru and Cuba. The pharmaceutical market in Latin America is pegged at about $50 billion with generic companies contributing almost 35 per cent. Indian pharma companies are already present in the larger markets of Brazil and Mexico in that region.

Dave Ramaswamy of Allied Ventures, based in Argentina, said. "Indian pharma companies are now becoming aware that the Latin American countries are pioneers in opening these markets for further investment by Indian companies in other sectors."

With its top eight markets valued at more than $30 billion in 2009, Latin America represents shining hope for an industry in flux. Infact, strong, steady growth, in the face of global financial meltdown, positive regulatory frameworks and a motivated public all translate into one of the world's leading emerging markets.

According to industry sources, because of better plans for health coverage in the region, the pharma market is bound to grow further. However, "in countries like Brazil and Colombia, you need to start with plant approvals from the respective regulatory authorities which are expensive, combined with long waits for registrations. Argentina has not opened up as a destination for Indian pharma export for finished formulations."

Besides regulatory hurdles, companies face challenges due to the geographical vastness of the region, and to fully understand the OTC market segment.

Therefore, "Government has many initiatives under Ministry of Commerce for LatAm players like incentives on the registration process. Many initiatives like buyer-seller meets, etc., are always happening. This is big focus priority area of the Indian Government and industry associations like Pharmexcil," a senior officials said.

(*The Financial Express*, 23 August 2010)

Patent Law Pits MNCs against Local Drug Firms

THE Government is examining a set of proposals by global drug manufacturers seeking changes in India's intellectual property rights (IPR) laws to reward innovation, triggering howls of protest from domestic pharmaceutical companies who said it would keep prices of many critical medicines perpetually high.

Global drug manufacturers represented by the OPPI have sought "legislative review" of the Section 3(d) of the Indian Patent Act and a redefining of the 'efficacy criteria'.

Section 3(d) of the Indian Patent Act restricts grant of patent for "incremental innovations," in many drugs unless it provides significant therapeutic advantages to existing molecules.

Several patent claims of global drug manufacturers have been rejected on grounds of this provision. Domestic drug manufacturers said the OPPI proposals would mean drugs would remain patented till perpetuity and prices of many medicines would remain high.

It would prevent the launch of cheaper generic versions of a medicine whose original patent may have expired. Generic drug refers to a cheaper copy of an original product whose patent has expired.

"The proposal moved by the PMO, if implemented, would destabilize the IPR regime by reversing. It has grave implications, not just for the domestic pharmaceutical industry but for the country as a whole," said D.G. Shah, General Secretary at Indian Pharmaceutical Alliance (IPA).

"It would seriously compromise availability and access to affordable medicines. The impact would be felt across the developing and the least developed countries as they are all dependent on India for their requirements of quality medicines at affordable prices," Shri Shah said. "Give the national industry a chance to prove their capability in R&D before succumbing to the pressures of the MNCs," he added.

(*Hindustan Times*, 22 August 2010)

India against "TRIPs-Plus" Clauses in Bilateral Trade Pacts

NEW DELHI is resisting attempts by some developed countries to have Intellectual Property Rights (IPR) enforcement provisions in bilateral trade pacts with India to their advantage. One of the things these countries are worried about is the menace of counterfeiting.

These attempts would go beyond India's commitments at the WTO's TRIPs negotiations, Commerce and Industry Ministry sources said.

Inclusion of "TRIPs-plus" provisions in Comprehensive Economic Partnership Agreements (CEPA) would restrict generics drugs exports from India and prevent Indian companies from obtaining the latest technology at affordable prices from abroad, they said.

India also disfavours CEPAs with either a positive or negative list on investments as such a list will not give the country the flexibility to limit foreign investments in sensitive sectors in a dynamic manner.

This stance could prolong the ongoing CEPA talks with Japan and the European Union and could affect future CEPAs, including the ones proposed with Canada and Australia.

On "TRIPs-plus" provisions, the sources said India has not reached a high level of IPR implementation such as Japan and the EU and therefore it now favours only a TRIPs Agreement-like IPR chapter in CEPAs.

EU, Japan, Canada, the US and some other countries are discussing an Anti-Counterfeiting Trade Agreement to set higher standards for IPR enforcement. India has already said such rules cannot be enforced as they are not WTO-recognized.

"India is an IPR consumer unlike developed nations who are IPR producers. We will think of IPR clauses that the rich countries want in bilateral pacts when we also become a major IPR producer," an official said. On investment, a negative list in CEPA would mean that barring a few "sensitive" sectors that are protected, all others are open for investment.

This is favoured by rich nations as it gives them greater scope for investment in emerging economies such as India, the sources said.

On the other hand, a positive list is more restrictive as it means investments will be permitted only in the sectors in the list. A positive list in a CEPA, say with an investment major such as Japan, will give "more comfort" to India, they said.

However, the Government is against giving any signal showing its readiness to undertake "binding commitments" on opening up sectors for investment.

"Agreeing to a list-based approach will prevent us from banning or limiting investments in some sectors at a later stage. What is a sensitive sector today can change tomorrow and vice-versa. We do not want to bind ourselves to anything now by only looking at the present," an official said.

The sources said the best would be to sign only a Bilateral Investment Protection Agreement (BIPA) with these countries to provide the needed security to investments, facilitate repatriation and expeditiously settle disputes.

(*The Hindu Business Line*, 17 August 2010)

Closure of three Public Sector Vaccine Units 'Ill-Advised'

CLOSURE of three public-sector vaccine manufacturing units in 2008 was "ill-advised" and not based on "sound reasoning", says the latest Parliamentary Standing Committee Report on Health and Family Welfare.

"While analyzing the impact of the closure of the three pubic sector vaccine producing units on the UIP (Universal Immunization Programme), it has been stated that a number of States such as Orissa, Bihar, Jharkhand, Madhya Pradesh, Assam, Punjab, West Bengal and Kerala did face shortfall of BCG, DPT, TT, OPV and Measles vaccine during 2008-09," the report says, echoing similar observations of earlier reports. Not mincing words in criticizing the decision of health authorities in 2008 and subsequent follow-up by present authorities, the Committee urged the Centre to fast-rack the revival of the three plants, against the backdrop of shortages and rising vaccine prices.

India could expose itself to "vaccine insecurity" for five years or more, the Committee cautioned, if the situation was not addressed on priority.

Cryptic Record

In January 2008, the then Drug Controller General of India had cancelled production licences of the Central Research Institute (Kasauli, Himachal Pradesh), Pasteur Institute of India (Conoor, Tamil Nadu) and Chennai's BCG Vaccine Laboratory. They were asked to suspend production for not adhering to the Good Manufacturing Practice norms.

But, there was no "explicit decision" to this effect, the Committee says, citing records that "cryptically" state, the issuance of show-cause notices for the suspension of licences was approved by the then Health Minister (Dr. Anbumani Ramadoss).

Even as it highlighted the need for a vaccine policy, and upgradation of the drug regulatory infrastructure, the Committee sought a review of the proposed ₹700 crore Integrated Vaccine Complex at Chengalpattu.

Review

"The Committee would like to emphasize once again, that there is a need for review of the ambitious project of Integrated Vaccine Complex. If all the required support of every kind, be it infrastructure, manpower, technical expertise, modern equipment and machinery is placed at the disposal of all the three units, the requirement of the proposed complex may perhaps not arise," the report points out.

(*The Hindu Business Line*, 16 August 2010)

Sun Pharma Shares Rise as Eli Lilly Loses Patent Case in US

ELI LILLY and Co has lost a patent case in the US, clearing the way for lower cost generic competition for its attention deficit disorder drug Strattera. The US District Court of New Jersey ruled Lilly's method-of-use patent for Strattera, which is set to expire in 2017, was invalid. Lilly said it plans to appeal the ruling.

This is the second victory that generic companies have had in patent litigation arena in the US in the last 15 days. Last July, Sun Pharma won a drug patent litigation in a US appeals court on Lilly's blockbuster cancer drug Gemzar.

In the case of Strattera, there are at least six generic companies in the fray, including Mumbai-based Sun Pharma, Teva and Sandoz. Last year, Lilly reported Strattera sales of $609.4 million — or about 3 per cent of total revenues.

"Assuming a launch of a generic version of Strattera in the United States, the loss of revenue will undoubtedly add to the challenges we will face during upcoming patent expirations on other key products," Lilly chief executive officer John Lechleiter said in a statement.

(*The Financial Express*, 14 August 2010)

India Warned on Moving WTO over Drug Seizures

EVEN as India considers the EU directive that allows seizure of goods-in-transit by its member countries as violative of the WTO's TRIPs Agreement, legal experts caution against the Central Government's plans to approach the dispute settlement body of WTO.

What has triggered the change of mind among the Indian experts is a recent decision of the UK High Court to refuse Nokia's plea to seize counterfeit cell phones (bearing Noika name) that had reached London's Heathrow airport from Hong Kong en route to Colombia.

Nokia wanted UK customs authorities to seize the goods under the EC Customs Regulation (Council Regulation No 1383/2003 of 22 July 2003), the rule which was invoked by EU members such as the Netherlands to seize over 15 consignments of Indian medicines that were on transit to African and South American destinations.

However, unlike Dutch customs authorities, the UK customs officials were not inclined to seize the goods in transit as their interpretation of the rule did not necessitate such an administrative action. Experts feel that any allegation of EU directive being anti-TRIPs can be countered easily by pointing the differing decisions taken by EU members.

"The Nokia ruling from the UK suggests that EC border control measures have to draw their substantive content from the laws of the specific EC member country in question. Therefore, while the Dutch authorities may interpret their law to seize Indian "in transit" generics, the UK authorities may not do so. To this extent, the assumption that EC border control measures violate the WTO norms "as such" may be misplaced. This is not to suggest that the WTO action will fail, but only to caution that it may not be as foolproof as we originally assumed it to be," said Shri Shamnad Basheer, an IP expert with the National University of Judicial Sciences, Kolkata.

Despite complaints from developing nations like India and Brazil, health NGOs and even some of the EU parliamentarians, the EU has been very consistent in maintaining that its rules are in tune with WTO obligations.

In its response, Indian mission in the EU had even informed the Central Government that "no useful purpose would be served by the Mission taking up the issue of drug seizure with the EU authorities".

(*Business Standard*, 11 August 2009)

India Protests Regional Pact on Intellectual Property Rights

INDIA has protested against the Anti Counterfeit Trade Agreement (ACTA) being negotiated by the United States, the European Union and other countries on the grounds that it will strengthen the holders of intellectual property rights (IPR) beyond reasonable measure.

During a two-day meeting of the TRIPs Council in Geneva that ended on 9 June, it urged the WTO's Council for TRIPs to initiate serious deliberations over the impact of IPR negotiations among member countries as part of regional trade agreements.

The Indian delegation was highly critical about ACTA being negotiated by countries like the US, Japan, the EU, Switzerland, Canada, Australia, New Zealand, and South Korea. According to an official who was part of the delegation, India had made it clear in the meeting that the WTO cannot remain silent on such developments.

The Indian participants said that the ACTA text "shows a general shift in the locus of enforcement which enhances the power of IPR holders beyond reasonable measure".

"ACTA option would mandate that each party provides enforcement for the full range of IPRs infringement actions 'at the border' of an importing country. This would permit IPR holders to assert infringement and demand seizure of goods before customs administrative authorities, instead of initiating their claims in domestic courts," the Indian statement said.

The draft ACTA proposed to shift the negotiated balance of the TRIPs Agreement in favour of IPR holders by shifting the enforcement forum towards customs administrative authorities and away from the civil courts, it stated.

The Indian delegation said that IPR negotiations in regional trade agreements (RTAs) and plurilateral processes like ACTA completely bypass the existing multilateral processes.

Pointing out that members can limit the benefits of further trade liberalization to partners in regional trade agreements, India stated that any TRIPs-plus protection secured by one trading partner *via* an RTA or a plurilateral agreement would automatically and unconditionally turn applicable to all other WTO members.

"Therefore, it is even more important to discuss IPR dimensions of regional and plurilateral initiatives in this Council so that they do not undermine TRIPs Agreement," the delegation clarified.

(*Business Standard*, 12 June 2010)

China, Equador Stand by India at WTO

CHINA and Equador have come out in support of India in its fight against the European Union at the WTO for "wrongful" seizure of its generic or off-patent drugs in transit to third countries.

Both have requested to be allowed to be participants in the consultations between India and the EU that is expected to begin soon as they too stand to be affected by the outcome.

"Ecuador has a substantial trade interest in these consultations as shipments of generic drugs destined for the country have been seized in transit in the territory of the European Union in 2008 and 2009," the country's representative at the WTO said it in its submission to the chairman of the dispute settlement body of the WTO.

China pointed out in its submission that since it was a significant bilateral trade partner of the EU and the Netherlands (where most of the seizures took place) and a big producing country of generic drugs, therefore it has substantial interest in these relevant consultations.

While the countries will not directly participate in the discussions India has with the EU, their presence in the consultations would add weight to India's position, a Commerce Department Official said.

"We welcome their participation in the discussions as it would give EU an idea about the kind of interest that developing countries are taking in the dispute," the official said.

Brazil, which too has sought a separate consultation with the EU on the same issue of drugs seizure, has also requested for permission to participate in India's consultations.

India requested formal consultations with the EU at the dispute settlement body of the WTO against the repeated seizures of consignments of generic drugs originating in India at ports and airports in the Netherlands on the ground of alleged infringement of patents subsisting in the Netherlands while these consignments were in transit to third country destinations. These included drugs produced by reputed Indian companies like Dr Reddy's Laboratories and Aurobindo Pharma Ltd.

While these drugs had become off-patent in India and the countries they were being supplied to, some companies held patents to these in the EU.

India said that the action went against the provisions of the WTO's intellectual property regime TRIPs, which allows India to produce generics (medicines that have become off-patent in India) which may have patent holders in other countries and sell them to developing countries on public health grounds if they do not have the capacity to produce it.

While India had tried to sort out the issue with the EU outside the WTO, it asked for formal consultations at the dispute settlement body when the EU failed to make amendments in its customs regulations after several months of dialogue. If the WTO consultations do not yield result, India will ask for setting up of a dispute settlement panel which will hear the arguments of both sides and give its judgement.

(*The Economic Times*, 14 June 2010)

India, China Move WTO on "TRIPs Plus" West Agenda

INDIA and China have decided to rake up the issue of tough intellectual property regimes being planned by certain countries that go much beyond the global agreement, TRIPs, at the WTO. The move is aimed at scuttling a draconian anti-counterfeiting trade agreement (ACTA) being negotiated by countries such as the US, Japan, the EU, Australia and South Korea which could hamper India's trade in a number of areas including pharmaceuticals and IT products.

The two countries have asked the WTO's TRIPs Council to include the issue of "TRIPs plus" enforcement trend in the agenda for its meeting in early June in order to examine the sanctity of an agreement being planned by a group of countries that goes beyond what they have agreed to under the WTO. "We cannot yet challenge the anti counterfeiting trade agreement at the WTO because it is still being formulated. But we can certainly have a discussion on where such an agreement would stand *vis-a-vis* the WTO," a Government official said.

The TRIPs Agreement was signed as part of the broader multilateral trade agreement of the WTO (erstwhile GATT) during the Uruguay Round in 1994. It forced a large number of developing countries to make sweeping changes in their domestic intellectual property regime to make it more stringent. Going beyond the TRIPs Agreement is something that is unacceptable to countries like India and China as it could render a lot of legitimate products made in such countries like generic drugs and software illegal.

The ACTA being negotiated between eleven countries (it also includes Canada, Mexico,

Switzerland, New Zealand, Morocco and Singapore), proposes to widen the scope of protection and setting up higher standards for enforcement of intellectual property rights. It would extend to import, export and in-transit goods and includes infringement of all IPRs.

While the negotiations for the agreement have been going on for more than three years, the international community got to know about it this April through media reports. "Countries like India, China and Brazil should make a lot of noise to kill the agreement before it gets implemented," an activist from an NGO campaigning for access to essential medicines said.

(*The Economic Times*, 8 June 2010)

Kenya Sees Cure in Indian Generics Now

THE Kenyan health ministry has conceded that the country should not have passed the anti-counterfeit law last year and said it would try and make changes to ensure that imports of legitimate generics were not affected.

This marks an important victory in India's sustained efforts in Africa to counter propaganda by multinational pharma companies against cheap generic drugs.

"The Kenyan health ministry has revealed at the recent WHO health assembly that the anti-counterfeit legislation passed by the country was pushed by its industry ministry and it had no clue about its ramifications," a Commerce Department official said adding that it will try to make changes to ensure that generics are not affected. The Government now plans to focus on countries such as Uganda, Nigeria, Zambia and Malawai that are planning similar anti-counterfeit legislation. Generics are copies of drugs that do not have patent protection in India, allowing any manufacturer to produce them. The competition among manu-facturers helps bring down prices substantially. India is one of the world's largest producers of generics with yearly exports of an estimated ₹30,000 crore, a sixth of which goes to Africa.

Kenya's anti-counterfeit law could render genuine generics imported from countries like India illegal if a company holding a patent to the formulation in any country files a complaint.

This could happen despite the fact that the drug is off-patent in the exporting countries. Kenya now seems to have realized that the legislation could hamper access to cheap life saving drugs for its population. The WTO's TRIPs Agreement allows exports of generics to countries with insufficient production capacities on public health grounds even if patents are held by companies in other parts of the world.

The Commerce Department had earlier written to the Kenyan Government pointing out the downsides of the anti-counterfeit legislation and had also held several meetings at the official level on the issue. Indian officials have also met Government representatives from other countries that are planning similar legislation including Uganda, Nigeria and Tanzania to sensitize them about the importance of generics for the poor.

One of the reasons behind anti-counterfeit legislation being considered in a number of African countries is an attempt by global pharma companies to create confusion between counterfeits (genuine drugs that are made in violation of patents) and fake or spurious drugs that are harmful, the official said.

Generics eat into the profits of large pharma companies holding patents to those medicines in the Western countries as they can't make inroads into poor countries that prefer to buy the cheap yet effective copies of the original drugs.

(*The Economic Times*, 3 June 2010)

India Issues Demarche to Argentina on Drug Laws

ANGRY over Argentina's insistence on denying Indian drugs access to its market, New Delhi has issued a demarche to the country asking it to relax laws.

Argentina, the third largest market in Latin America after Brazil and Mexico, is the only country in the region, which, through law, forbids Indian companies from supplying drugs. This comes at a time when Brazil is considering changes in legislation to facilitate increased supply of generics,

a move which would prove favourable for Indian players.

India's generic drug industry is incidentally one of the strongest in the world. Indian companies supply drugs to the highly-regulated markets of the US and EU, with many of them even aggressively seeking market exclusivity for their products invoking the relevant legal instruments.

Brazil has also teamed up with India to move to WTO against EU's action of seizing perfectly legitimate Indian drugs in transit. Officials say that the issue was raised earlier in the week by the delegation led by Minister of State for External Affairs, Smt. Preneet Kaur, on her visit to Argentina.

Under the Argentine presidential decree, imports are allowed from two sets of countries enlisted in separate annexures. Annexure-I contains a list of matured markets with established regulatory systems such as USA, Japan, Sweden, Switzerland, Israel and Canada, among others. The second annexure names eleven countries—Australia, Mexico, Brazil, Cuba, Finland, Hungary, Ireland, China, Luxembourg, Norway and New Zealand—from where imports are allowed if the plants of firms from these countries are approved by one of the countries included in Annexure-I. "For all other countries outside these two annexures, there is a complicated procedure which makes it virtually impossible to import from them," said a Government official. Since India is not a part of either annexure, Indian firms are unable to export to Argentina.

The fact that India exports to all matured markets included in the first annexure implies that Indian drugs meet the stringent quality standards of their regulatory framework. India also has the largest number of US Food & Drug Administration-approved laboratories outside USA. India has taken up the matter repeatedly with Argentina, batting for its inclusion. The Indian industry believes that local drug cartels are wielding their influence to prevent their entry. "If Indian players are allowed to enter the Argentine market, they could wean away a significant market share of local players by offering the same drugs at competitive prices. Also, low prices of Indian drugs could force generic players to reduce the costs of drug, thus affecting their margins and profitability significantly," said a domestic player.

Argentine pharma companies earn around $2.5 million through their exports to India. This figure includes the export from Indian drug firm Glenmark's subsidiary in Buenos Aires. Surprisingly, Argentina is significantly dependent on India for pharma raw material. Also, Indian drugs find their way to Argentina through indirect channels. For instance, vaccines supplied by the Serum Institute of India are bought by the Pan-American Health Organization in Panama and is distributed in Latin American countries, including Argentina.

India's stance is supported by independent market analysts. In a recent report, Business Monitor International noted, "Argentina has started imposing trade tariffs on imports from outside the Mercosur trade bloc, with additional regulations that will favour domestic drug firms. According to the UN Commodities Trade Statistics Database, Argentina's pharma imports touched $1.14 billion in 2008, a 109 per cent jump from 2004. The imports are projected to touch $1.25 billion in 2009 and $2.01 billion by 2014, with a Compound Annual Growth Rate of 10 per cent. Pharmaceutical imports, mainly comprising raw materials from India, witnessed a decline from $6.8 million in 2005 to $3 million in 2008. Indian pharma goods have held a declining share of Argentina's pharma imports, from 0.85 per cent in 2004 to 0.30 per cent in 2008.

(*The Financial Express*, 28 May 2010)

Patent Linkage Impermissible in India: Cipla

THE dispute between Indian drug companies and the Big Pharma over "patent linkage" has reached the domain of judiciary.

German drug major Bayer AG's attempt to introduce the concept of patent linkage into the Indian legislation is "impermissible" as it is not covered by the TRIPs Agreement to which India is a signatory, according to domestic pharma major Cipla Ltd.

Patent linkage is the term used to refer to the practice of drug quality regulators — the Drugs

Controlller General of India in India's case — denying marketing approvals for generic drugs citing existence of patents. The contrarian argument is that drug regulators should have nothing to do with patents, and they should restrict themselves to evaluating the safety and efficacy of drugs.

Opposing Bayer's plea that the concept of patent linkage is in consonance with effective enforceability of intellectual property rights, including patent rights as mandated by Part III of TRIPs, Cipla in its reply submitted before the Supreme Court said that patent linkage is a TRIPs Plus concept. Besides, the linkage is not even contemplated in either the Drugs & Cosmetics Act, 1940, or the Patents Act, 1970, it added.

According to local pharma firm, TRIPs Plus provisions are contrary to the intent and spirit of the TRIPs Agreement which in the preamble itself provides that patent rights are private in nature. Besides, various safeguards like compulsory licensing that are allowed to a nation under the TRIPs Agreement are tendered completely redundant and meaningless in nature by the TRIPs Plus provision, it said, adding that patent linkage is a policy decision and is required to be taken by the Government or Parliament and is outside the jurisdiction of the courts. The reply has come on a petition filed by Bayer seeking protection for its Nexavar even as Cipla's plea for grant of marketing approval for generic version of its kidney cancer drug, Sorafenib, is pending before the regulatory authorities.

(*The Financial Express*, 28 May 2010)

Govt. Voices Concern over M&A Deals in Pharma Sector

CONCERNED by the trend of pharmaceutical multinationals acquiring Indian drug majors, the Health Minister, Shri Ghulam Nabi Azad, has called for a meeting with Indian drug companies to find out the impact of such deals on the availability of cheap drugs.

Sources in the Health Ministry said that the concern was primarily on whether multinational drug majors, with increasing control over generic firms, will increase the price of medicines available in India.

Recently, Shri Azad had said, "I've asked for a meeting with pharma industry leaders to find out the reason. It's a worrying trend because 95 per cent of the medicines used in India are generics made. If such acquisitions continue, multinationals will gain market supremacy and people may have to pay through their nose for essential medicine."

In the past few years, some of the largest Indian drug companies have gone into the hands of foreign pharmaceutical giants. These include the recent acquisition of Piramal Healthcare by Abbott Labs and the buyout of majority share in Ranbaxy by Japanese drug major Daiichi Sankyo. Other large deals include Shantha Biotech by Sanofi-Aventis and Dabur Pharma by Fresenuis Kabi.

Concerns Unfounded

However, industry players said that the concerns are unfounded because the multinational firms who acquire Indian drug companies are themselves entering the generic space. According to Shri Ranga Iyer, Independent Pharma Consultant and former President OPPI, the evolving trend of the Indian pharma companies selling a part of their business to their global counterparts is a welcome trend as it will help to set a right balance of generic as well as innovator pharma players in India, thus helping the Indian patients in the long run.

"Since pharma R&D requires a lot of investment, this calls for a symbiotic relationship between the generic and innovator companies. India with its low-cost manufacturing facilities along with strong R&D backup from innovator companies can certainly become a global pharma hub," Shri Iyer said.

Industry analysts said that merger and acquisition has only helped the Indian pharma companies and the market. "After Daiichi Sankyo acquired Ranbaxy, the Indian drug maker has gained access to new markets and new products. The synergies between a generic firm and innovator companies are very clearly established," said a market watcher.

(*The Hindu Business Line*, 28 May 2010)

Knowledge Library Wards Off European Patents

AN electronic facility that India had set up eight years ago to pre-empt unfair patenting of the country's traditional knowledge on curative potency of various biological resources has come handy. The Traditional Knowledge Digital Library (TKDL) that came up following the turmeric patent case — which saw a US patent based on India's traditional knowledge being successfully challenged by New Delhi, forcing the US patent office to revoke it—has warded off the danger of 13 more such patenting pleas at the European Patent Office since then, official sources said. The library has also forced a steep decline in such patenting attempts across the globe.

The digital library is a unique initiative of the Government that involved documenting the database of formulations in ayurveda, unani, sidhdha, etc. It has identified 36 attempts of patent filings based on India's traditional knowledge at the European Patent Office (EPO) alone.

In two cases, the EPO has already set aside its earlier intention to grant patents after it received TKDL evidence while in 11 other cases, applicants voluntarily withdrew their four-to-five-year-old applications, said Government officials.

In the remaining 23 cases identified, the Government now expects either the EPO to reject these applications or the applicants themselves to withdraw their claims unless they are able to establish the novelty of their applications.

Further, a recent study carried out by a TKDL expert team has revealed a 44 per cent decline in filing of patent applications concerning Indian systems of medicine at the EPO.

On an average 80 such patent applications are filed at the EPO annually. Also, such applications peak during October-December in a year when an average of 25 filings are made.

However, during October-December 2009, only 14 applications were filed, indicating a decline. TKDL is a joint effort of the CSIR and the Department of AYUSH, first of its kind in the world targeted against grant of unethical patents and bio-piracy. In 2000, a TKDL expert group estimated that about 2,000 wrong patents concerning Indian systems of medicine were being granted every year at the global level, mainly because India's traditional medicine knowledge existed in languages such as Sanskrit, Hindi, Arabic, Urdu, Tamil and was neither accessible nor understood by patent examiners at the international patent offices.

India joined hands with the US and UK to help prevent misappropriation of its traditional knowledge at the United States Patent &Trademark Office (USPTO) and United Kingdom Trademark & Patent Office (UKPTO) with the signing of the TKDL (Traditional Knowledge Digital Library) Access Agreement with USPTO last November. It also has in place a similar agreement with the European Patent Office since February 2009. These agreements made TKDL database available to the patent examiners (EPO has 34 member states) of the EU and the US for establishing prior art in case of patent applications based on Indian system of medicine. On an average, it takes five to seven years to oppose a granted patent at the international level and each such effort costs a few crores for the Indian exchequers irrespective of the outcome.

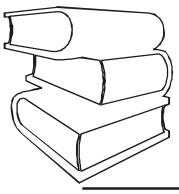
(*The Financial Express*, 1 May 2010)

TRIPs and Public Health

WITH the introduction of product patent, it was feared that because of patent monopolies in the pharmaceutical sector the prices of medicines and drugs in general, would witness an increase. However, the TRIPs Agreement under Article 31 provides for compulsory licensing procedures to make available patented medicines and drugs at affordable price. Compulsory licensing refers to the practice by a Government to authorize itself or third parties to use the subject matter of a patent without the authorization of a patent right holder. The TRIPs provisions on compulsory licensing were however seen as inadequate to address the concerns of access to medicines at affordable price, primarily because they placed several conditions to be complied with prior to their exercise.

It was this basic concern that prompted the African Group (representing countries in the African continent), supported by several

(Contd. on page 56)



BOOKS/ARTICLES NOTES

BOOKS

TRIPs and Public Health: What Should African Countries Do? by Amal Nagah Elbeshbishi, ATPC Work in Progress No. 49, *Economic Commission for Africa*, January 2007.

THE report is divided into two sections. Section I of the report presents a background about the international pharmaceutical market and the situation in Africa, the TRIPs agreement and patents on drugs, the Doha declaration on TRIPs and public health, flexibilities in the TRIPs Agreement, TRIPs Plus, and the arguments for and against the TRIPs Agreement. While mentioning about the international pharmaceutical market, the report points out about current market situation comprising non-prescription medications; generic prescription drugs; and patented prescription drugs. The report suggests the importance of the patented prescription drug in the international market and says that market is dominated by large multinationals from the developed countries, which are responsible for the development of new therapies. It states that majority of the African countries lack research, administrative resource and production capacities in modern pharmaceutical industry. However, it says that at present relatively small trade in pharmaceutical products is taking place between some African countries, which are members of regional economic groupings. It further identifies that the obstacles to the development of trade between these groupings arises from differences in the regulations of these countries relating to manufacture, import, export and distribution of pharmaceutical and health products. Under the sub-section, TRIPs Agreement and patents on drugs, the report further explains about TRIPs Agreement and different rules and regulations associated with such agreements. The sub-section mentions that the Doha Declaration on TRIPs and public health has clarified the need to interpret TRIPs from a public health perspective. The Doha Declaration also paves the way for more public health-friendly interpretation of TRIPs by explicitly recognizing that intellectual property rights are subservient to public health concerns.

The next sub-section of the report mentions about the examples of flexibility in the TRIPs Agreement, where it says that countries should use the flexibilities available in the TRIPs Agreement to interpret and implement it in a manner that furthers human development goals. It discusses two cases relevant to the use of the flexibility in the TRIPs Agreement that have arisen in the WTO so far. While first case discusses dispute between Canada and the European Communities on the so-called "Bolar" exception, the second case was a dispute brought by the US about the TRIPs consistency of the Brazilian legal framework for the grant of compulsory licences. The report explains that under the TRIPs Agreement, the governments can make limited exceptions to patent rights provided certain conditions are met. Apart from TRIPs, the report mentions about several other regional and bilateral intellectual property agreements that have troubling implications for human development. It states that many of these agreements are more stringent than the TRIPs Agreement and considerably reduce the room for manoeuvre for developing countries. Countries that have signed onto these agreements cannot take advantage of the flexibilities in the TRIPs and these agreements go beyond the TRIPs in terms of intellectual property rights (IPRs) protection. Other bilateral agreements that go beyond the TRIPs include the EU agreements with Morocco, Palestine and South Africa; and the Swiss-Vietnam treaty. Further, the report points out that the US government uses bilateral and regional free trade agreements (FTAs) to impose unnecessarily stringent intellectual property standards on

developing countries that go beyond the requirements of the WTO rules. The first section of the report also puts different arguments in favour of TRIPs Agreement by mentioning that it will help the African countries in improving the conditions for investment, encouraging the development of local industry, creating jobs, transferring technology, and enabling more goods to be produced. It also puts arguments against the TRIPs Agreement.

Section II of the report discusses the way forward for the African countries, by presenting solutions to protect these countries through the provision like compulsory licences, generic drugs, parallel imports and differential pricing. It further states that all countries are dissatisfied with certain aspects of the agreement. Each country has its own list of dissatisfactions, which is the normal outcome of any negotiations. Therefore, the report suggests that the African countries should take the advantage of the good aspects and introduce policies to minimize the adverse effects of the bad aspects of the Agreement. The report suggests solutions for the African countries, and mentions that despite a public health crisis of enormous proportions for compulsory licence for HIV/AIDS; in fact no African country has issued a compulsory licence for any medicine. The report also points out the importance of the use of generic drugs and states that the African countries under the coordination of the African Union should pool their resources and strengthen their capacity to manufacture the needed generic pharmaceutical products. It mentions that the regional trading blocs such as COMESA, SADC and ECOWAS should share the manufacturing of generic drugs based on their comparative advantages and trade among themselves. The report also suggests that the African Union should network with its members to negotiate bulk procurement of raw materials for generic production since the costs will be lower than what countries are capable of negotiating individually.

While recommending the use of parallel importation, the report suggests that for the African countries, least-developed countries and smaller economies, it can be a significant way of increasing access to medications. Moreover, in situations where the local manufacture of the product is not feasible and compulsory licences may be ineffective, parallel importation may be a relevant tool to ensure access to drugs. Finally, the report explains that the use of differential pricing can play a relevant role in providing better access to affordable medicines for the African countries and the TRIPs agreement does not stand in its way because it is not an intellectual property issue.

ARTICLES

Agenda for Hong Kong WTO Ministerial: Will Developing Nations Trip on TRIPs?
by Bharat Jhunjhunwala, *The Hindu Business Line*, 31 August 2005.

THE article in the beginning predicts that the success of the coming Hong Kong Ministerial of the WTO depends upon the resolution of the agricultural subsidies by the rich countries and loosening of the TRIPs Agreement in the area of public health as agreed at Doha. The article notes that the rich countries will concede on both the issues and Hong Kong will be brought to a successful conclusion. It further mentions that the removal of agricultural subsidies will not only benefit the rich countries but that will also save on the huge amounts they give to their farmers. The decline in the prices of imported agricultural commodities due to the intensification of competition among the supplier of developing countries will further enhance their benefits.

The article points out that the pharmaceutical companies of the rich countries will certainly lose from the loosening of the patents in the area of public health, but they will save millions in aid, by managing health epidemics in the developing countries. It says that even most vociferous opponents of the TRIPs regime only demand loosening in the area of pharmaceuticals rather than loosening of TRIPs across the board. The article takes the reference of another article titled "WTO: Shrink or Sink", which demands the removal of the TRIPs from the WTO. It also states that TRIPs Agreement promotes monopoly by transnational corporations; prevents access to essential medicines and other goods; leads to private appropriation of knowledge and life forms; undermines biodiversity; and keeps poorer countries from increasing their

levels of social and economic welfare and developing their technological capacity. The report of the Commission on Intellectual Property Rights set up by the British Government also spells out the reality of the TRIPs regime. Studies of Japan's patent system have suggested that utility models were more important than patents in stimulating productivity growth. The report also gives many more details of how the TRIPs regime has become a stumbling block to research.

Finally, the article mentions that the successful result of the Hong Kong Ministerial will hurt the developing countries. Their farmers will get lower prices for their produce; the rich countries will make savings from the reduction in aid; and the rich countries will continue to extract huge technology rents that are not justified by increased research. It suggests that the agenda of the developing countries at Hong Kong should be to take TRIPs wholly out of the WTO or, at least, reduce the period of patents to three years from present twenty years.

Pharma Sector – No Side-Effects of Patent Regime by S.D. Naik, *The Hindu Business Line*, 21 January 2005.

THE article at its outset mentions about the overall outlook of India's pharma industry in the manufacturing of the cost-effective generic drugs and says that in order to derive full benefit from the opportunities opening up; the industry needs to overcome some of the barriers. While pointing out about the new product patent regime, the article says that despite the apprehensions from some non-governmental organizations (NGOs), new product patent regime was generally welcomed by industry representatives. The article mentions that in the last two decades pharma industry has witnessed rapid growth through skilful innovations in production processes, as Indian companies have made cheap copies of patented drugs and sold them at very low prices compared to anywhere else in the world.

The article explains that the Indian pharma companies are also prepared to offer high-quality and low-cost contract services to support R&D, conduct of clinical trials, data management and manufacturing. The article states that once India demonstrates its intent to uphold intellectual property rights, many pharma MNCs will establish outsourcing arrangements with the Indian companies both in R&D and manufacturing. While Indian manufacturers have been instrumental in bringing down the cost of combination of drugs for treating HIV/AIDS victims, organizations have expressed their concern that the new patent regime may seriously compromise the accessibility and availability of life-saving medicines at affordable prices. Mentioning about the contentious issues that bother the consumers and NGOs regarding the Patents (Amendment) Ordinance, the article points out that the Ordinance does not utilize all the flexibilities provided in the TRIPs Agreement and the Doha Declaration. The article also states that after safeguards are incorporated into the Patent Act, the pharma industry can achieve new heights even in the field of new drug discoveries. Although Indian companies cannot match the world giants in the field of scale of operation, R&D budgets and new drug discoveries, but they are cost-effective manufacturers of generic drugs and will continue to flourish in this area despite the introduction of product patents. It says that the factors like a well-developed chemical industry infrastructure, strong vertical integration, abundant scientific talent, proven skills in research and manufacturing and significant cost advantages, is bound to attract a lot of business in the coming days.

Finally, the article states that the overall outlook for the industry is quite encouraging. It suggests that merger and consolidation of the smaller companies can enable them to increase their R&D expenditure. The Government also needs to address the issue of pricing regime at the earliest and except in special cases. The Government should not bring back the much-misused price control regime if it wants to encourage the industry to invest substantial amounts into R&D for new drug discoveries. The article states that the move by the ministry to bring more drugs under price control is clearly unwarranted and suggests that healthy competition is a better way to keep a check on prices.

TRIPs: India - Patent Protection for Pharmaceuticals by Ashwini R. Madgulkar, *Pharmainfo.net*, Vol. 5 Issue 2, 24 April 2007.

THE introductory section of the article presents the background of the first round of trade negotiations, agreements and commitments on market access by developed countries in sectors like

agriculture and other sectors. The article mentions about the commitments under the reform programme and explains that they should be made in an equitable way among all members, having regard to non-trade concerns, including food security and the need to protect the environment and many other issues. Mentioning about the eight rounds of multilateral trade negotiations, the article says that the Uruguay Round (the 8th round) was the first multilateral agreement dedicated to the sector. This section also provides detail of broad issues that are covered under the TRIPs Agreement.

The next section of the article is divided into three sub-sections, where it talks about different episodes of Indian Patents Act and their impact on the Indian pharmaceutical and few other sectors. Taking the first phase of post-Independence and pre-1970, the article states this period witnessed a very high cost of the drugs with low availability and high import dependency. At the same time export initiative during this phase was very less and R&D activities were practically non-existent due to lack of patent protection. The article further says that the first major transition in the patents scenario in India took place with the Indian Patents Act 1970, which serves as the basis for patent protection in India. Mentioning the importance of the Indian Patents Act 1970, it says that protected patent regime provided a safe platform to the pharmaceutical and chemical industries. The next sub-section talks about the period of 1970-95, where it mentions about the two important steps that were taken by the Government. It says that the introduction of "DPCO" to protect the consumers against high price and the introduction of process patent helped Indian pharmaceutical industry to become the second largest exporter of pharmaceuticals after China among developing countries. This period also witnessed increase in numbers of pharmaceutical applications and decrease in foreign ownerships in Indian drug industry. The third sub-section explains about the 1995-2005 period by mentioning that the provision of exclusive marketing right was introduced through the Patents (Amendment) Act, 1999 and India joined the Paris Convention and the Patent Cooperation Treaty. This section also presents a detail discussion about the Patent Amendment Act 2005, compulsory licensing and herbal preparations. Mentioning about the importance of the period of 1995-2005, the article states that the status quo has been maintained with respect to cost of the drug and it is expected to continue until MNCs and research based companies start launching their patented molecules.

The third section of the article mentions about different collaborations that are taking place in the area of joint R&D, product and process development. The article also highlights the up-gradation of facilities and infrastructure achieved by Indian pharmaceutical companies. It also presents different statistics *vis-a-vis* Indian economy and the role played by the pharmaceutical sector in its growth. This section points out that the technological capabilities of the Indian companies and institutions have attracted leading MNCs to start R&D joint ventures, commission contract research and set up R&D centres. Finally, the article states that the significant amendments in Indian intellectual property rights (IPR) since 1994 continue to impact the business dynamics in the Indian drug, pharmaceutical and healthcare industries. The article concludes by saying that the intellectual property right provides protective environment and national shelter to the sectors like pharmaceutical, where companies can innovate and rapidly diffuse their innovations into the marketplace.

TRIPs, the Doha Declaration and Paragraph 6 Decisions: What are the Remaining Steps for Protecting Access to Medicines? by Vanessa Bradford Kerry and Kelley Lee, *Globalization and Health*, Vol. 3 No. 3, 2007.

THE introductory part of the paper mentions about the WTOs Declaration on the TRIPs Agreement and Public Health (known as the Doha Declaration) of 2001. It says that the subsequent decision on the interpretation of Paragraph 6 reached in 2003, affirms the flexibilities available under the Agreement on Trade Related Property Rights (TRIPs) to member states seeking to protect public health. Despite these important clarifications, the actual implementation of these measures to improve access to medicines remains uncertain. There are also concerns that the so-called TRIPs-plus measures within many regional and bilateral trade agreements are further undermining the capacity of the poor to access affordable medicines. By reviewing the progress of the public health

protections available under the TRIPs Agreement, the paper mentions that the Doha Declaration and the Paragraph 6 decision provide clarifications on the need and available provisions, to access generic medicines.

The next section of the paper states that despite the affirmations provided by the Doha Declaration and Paragraph 6 decision, there remain a number of difficulties for LMICs (low and middle-income countries) seeking to implement them in practice. While the Doha Declaration clarifies the right of LMICs to engage in compulsory licensing and parallel importing, there remains much anxiety about its use in practice. The paper also discusses about the difficulties in the area of data exclusivity and regulatory approval, extension of patent rights, research and development gap and requirement for National Laws that remains as key challenge for the LMICs. The paper suggest that LMICs can only assert available flexibilities and enhance their purchasing power if appropriate national drug policies are in place, backed by a legislative framework concerning issues such as the use of generics, drug pricing and taxation.

The third section of the paper mentions about concern related to the spread of so-called "TRIPs-plus" measures. It says that the scope for compulsory licensing and parallel importing has been a particular focus of TRIPs-plus restrictions, which narrows the circumstances when parties are permitted to use these measures. Taking the example of negotiations under Free Trade Agreement of the Americas (FTAA), the article states that it is proposed that compulsory licensing would only be permitted when the patent on a product has expired. Further, TRIPs-plus measures increase provisions concerning data exclusivity, enabling large pharmaceutical companies to prevent or delay generic competition. It points out that these stronger protections raise concerns because they reduce the capacity of a country to issue or use compulsory licensing for unpatented drugs. Mentioning about the bilateral agreements between the US and Jordan, Chile, Australia, and proposals under the FTAA, the article says that they effectively extend the period of patent protection. While, available flexibilities under the TRIPs agreement to protect public health, face erosion by the negotiation and agreement of TRIPs-plus measures, major industrialized countries, seeking to protect the interests of transnational pharmaceutical companies, have pursued a "divide and conquer" strategy.

The fourth section of the paper reviews potential ways forward to ensure that access to medicines by the poor is secured within all trade agreements. Explaining about the report of the WHO Commission recommendation the paper identifies broad range of policy changes that are required to improve all stages of drug production and use. In relation to the Doha Declaration and Paragraph 6 decision specifically, the report call for adaptations to national legislation and institutions to allow TRIPs flexibilities to be used.

The paper suggests that LMICs with substantial pharmaceutical markets, such as India, Brazil and Thailand, can provide leadership and establish importance precedence by asserting the flexibilities available under TRIPs to protect public health. Further, LMICs and public health advocates can work collectively to resist pressures to dilute public health protections, as joint efforts and combined forces are critical to the power imbalances inherent in trade negotiations. It also suggests that "South-South" partnerships could be used to mitigate resource constraints, weaknesses in capacity and market failures.

The paper concludes by saying that the challenge of improving access to medicines for LMICs stands at a critical crossroad. It suggests that the global community should allow the Doha Declaration to become a pledge in the high politics of trade policy. It further suggests that global community should stand true to the public health protections available within the TRIPs agreement, at the time when TRIPs-plus measures are pushing the access to medicines by the poor further out of reach.

TRIPs Agreement and Public Health: An Overview of International Issues

by N.S. Gopalkrishnan, *Journal of Intellectual Property Rights*, Vol. 13, September 2008.

THE introductory section of the paper mentions the concerns of international debates and negotiations in protecting Intellectual Property Rights and facilitating access of the essential medicine at affordable cost in the developing and

least developed countries. It points out the importance of the adequate reward to the pharmaceutical companies through patent system, who have made considerable investment for the invention, production and marketing of essential drug. The paper also explains the reasons behind the re-formulation of the international norms that existed before the TRIPs Agreement. It says that while it was argued that the TRIPs Agreement will provide proper balance to the access of quality drugs, the implementation provision of TRIPs Agreement are more in favour of owners of intellectual property to facilitate the global trade.

The paper also traces the history of different conventions and negotiations that were focused on the pharmaceutical industries. It says that the Paris Convention enabled production and distribution of low cost medicine in the domestic markets of many parts of the world including other developing and least developed countries. The developments after the convention compelled the governments of developed countries to initiate the negotiation for new international norms to protect the new inventions during Uruguay Round of GATT negotiations in 1986. The paper states that initially the developing countries objected to the inclusion of IPR issues in the GATT negotiation and demanded the discussion on access to technology and protection of the interest of the users of intellectual property. The paper also mentions about the pressure tactics used by the US, which forced many countries to amend their domestic patent law in order to improve protection to pharmaceutical products including pipeline protection. It notes that original Dunkel Draft had no obligation on the part of countries enjoying 10 years transitional period to facilitate the change from process patent regime to product patent system to provide pipeline protection to the pharmaceutical products.

Mentioning about the flexibilities of the TRIPs Agreement and various approaches adopted by countries to implement the obligations, the paper states that many developing and least developed countries could not even enjoy the provisions for compulsory licence due to lack of manufacturing capabilities. Therefore countries like Brazil and South Africa introduced the compulsory licence provision to provide cheap medicine for HIV/AIDS victims, but reaction from the US reflects the limitation of the TRIPs flexibilities. The words used in the Doha Declaration on TRIPs and Public Health give more freedom to identify major local health problems and to use the provision to overcome the problem of access to essential medicines. The paper points out about the problem of countries with insufficient or no manufacturing, and says that they suffered from restriction of importing cheap generics from other countries by using compulsory licence provisions. Therefore the General Council of the WTO approved a complex set of rules to implement Para 6 decisions, which dealt with the issues related to import, export, domestic supply requirements and adequate remuneration requirements. It states that developed countries, through these provisions ensured that countries with manufacturing capabilities will not use public health as a shield to promote the growth of their domestic generic industries by sale of patented product in global market.

The paper concludes with the remark that in order to find solution to the problem of public healthcare, it is required to encourage the generic industry to produce patented drugs through compulsory licence. It mentions about the need of building capacity within the countries with no or insufficient manufacturing capacity of essential drugs through technology transfer. It suggests that the developing and least developed countries should join together and compel the developed countries to agree for a set of norms to ensure transfer of technology.

TRIPs and Affordable Healthcare: The Concept of OSDD and Patent Pool

by M.D. Nair, *Journal of Intellectual Property Rights*, Vol. 15, January 2010.

THE article in the beginning mentions about the impact of TRIPs on healthcare costs and says that even economically most advanced countries are reeling under the pressure of escalating healthcare cost. It points out that total costs of meeting healthcare needs have reached double-digit percentage of GDP in most of the developed world and has concerned governments, policy-makers, consumer groups and patients. Mentioning the reasons of the high cost of drugs, the article states that unaffordable cost of drug research in developing new drugs and strategy of large R&D

Corporations to improve the cost-effectiveness and productivity of R&D has so far not worked effectively.

While TRIPs Agreement has provisions of rewarding the innovator, the compulsion for the recovery of investment in R&D and making the drugs available at affordable cost has been greatest challenge for the R&D based pharmaceutical companies. Mentioning about safeguards and flexibilities in the TRIPs Agreement, the article also explains about Doha Declaration and different Articles that formulate the TRIPs Agreement rules and regulations. In one of such example the article says that the provision for the grant of compulsory licences under Articles 30 and 31 also emphasizes the need for ensuring availability of patented products when the patent holder is unable to meet the consumer's demand. It says that the safeguards and flexibilities in TRIPs need to be properly understood and effectively used so that the members can derive maximum benefits. Due to increasing cost of drug research companies are engaging themselves in the projects which have high market potential, neglecting the investment in the diseases that largely affect the poor population. Therefore, the article mentions about the use of Open Source Drug Discovery (OSDD) approaches and development of patent pool, which is supported by world bodies and leading pharmaceutical companies in order to encourage investment in R&D in these areas.

While explaining the OSDD approach, the article says that OSDD is basically a system of pooling global information sources, expertise, facilities and management systems. This approach helps individuals, groups and organizations to develop new drugs by offering their resource and services in an open format. The article also mentions that the Linux operating system and the Human Genome Project are the successful examples of the OSDD approach. The concept of patent pool, involves collective management of IP to expand access to needed medical technologies and products. The patent pools are also based on agreement between two or more patent owners to pool those patents which are of no direct commercial interest to them and license them to one of them or to a third party under pre-determined licensing terms for exploitation by a sponsor. It further states that the patent owners are agreeable to have a collective management of patent pool for more expeditious discovery and development of drugs. Mentioning the merit of this approach, the article points out that unlike compulsory licensing under TRIPs, patent pools are voluntary offered by the patent holder and TRIPs rules and regulations are not relevant to patent pools. The article also points out few flip sides of this approach and says that patent pools do not provide the much needed technology and know-how.

Finally, it says that though the concept is hardly two years old, many leading companies have pledged their support for the project. It suggests that once these approaches are properly implemented, drug discovery particularly for neglected diseases will get much needed support.

Doha Round and Public Health by M.D. Nair, *Journal of Intellectual Property Rights*, Vol. 14, September 2009.

THE article at its outset mentions about the background of the Doha Round and states that it provided the initiation for a new round of negotiations to address a range of complex issues. The article also points out that the mandate of the Doha Round includes not only implementation of already agreed upon terms for the proper functioning of the WTO, but also covers issues related to agriculture, services, market access for non-agricultural products, TRIPs, trade and investments, trade facilitation, anti-dumping and subsidies, regional trade agreements, dispute settlements, technology transfer, etc. It explains the importance of the Doha Round from the developing and least developed countries' perspective with regard to access to affordable healthcare, particularly to patented drugs under the TRIPs regime.

The article keeps the readers informed that the Doha declaration on "TRIPs and Public Health" attempts to protect the innovator's interests and emphasizes that TRIPs should not prevent members from acting to protect their national health problems. It affirms governments' rights to enforce the flexibilities afforded by the TRIPs in the form of compulsory licence, parallel imports and through national interventions including control on prices of drugs through appropriate legislations. The

article further mentions that as a result of several negotiations at the TRIPs Council, special provision for the implementation of their compulsory licences by the members who have no technological capability to implement them in association with other members, have now been approved by the WTO.

The article explains the case of compulsory licences for Anti HIV/AIDS drugs and says that the provision to make drugs available at affordable prices to poor patients under the TRIPs Agreement has not been effectively implemented. It also talks about the reason for the same by saying that the conditions imposed for the supply of drugs against compulsory licences granted are so cumbersome that in practice they are difficult to implement. Taking the example of supply of anti-AIDS drugs by the Canadian company to Rwanda, the article states that even with the agreed and compromised formula under the Special Safeguard Mechanisms (SSMs), there are debates and doubts for the effective utilization of these drugs in public interest. The article also mentions that India made a strong plea for a legal, procedural and practical mode of implementing the provisions under Para 6 for the sake of countries lack in technical competence to utilize effectively the compulsory licensing system.

Finally, the article takes the reference of seventh Inter-Ministerial Conference and the WIPO Conference on 'Intellectual Property and Public Policy', where issues related to health, food and environment were the focus of broader public policy debate. The article suggests that the review of the current status of implementation of Para 6 of the Doha Declaration and addressing the reasons for its failure to meet the objectives, will provide meaningful answers and solutions to the global health, food and environmental issues.

Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines
by Greg Martin, Corinna Sorenson and Thomas Faunce, *Globalization and Health*, Vol. 3 No. 4, 2007.

THE article in its background mentions about the controversies involved with the TRIPs Agreement and challenge in balancing the need for pharmaceutical companies in ensuring the access to essential medicines. It also points out that through the series of bilateral free trade agreements, the US Trade Representative (USTR) has opposed the use of flexibilities involved with TRIPs Agreement. The research and development (R&D) cost driven by market forces and patented pharmaceuticals also create a barrier in accessing the essential medicine in developing countries. Mentioning one of the broader concerns of the TRIPs Agreement, the article states that the World Health Organization (WHO) has only non-voting observer status on the principal WTO policy organ. It further says that most of the key WTO documents make no reference to international economic, social and cultural rights, such as the right to health.

The next section of the article mentions that in order to incorporate TRIPs standards and implement the changes within a stipulated time period, developing nations were informally promised greater access to developed world agricultural markets. Mentioning about the exclusive patent protection, the article says that this provision serves to protect the patent holder from another party making, selling or importing the drug during the period it is still under patent. While TRIPs Agreement upholds the right granted to a patent holder, it also considers the issues of non-discrimination, where countries cannot treat national and foreign inventions differently, nor can their respective patent laws discriminate between imports and domestic products. It also says that the TRIPs agreement prohibits countries from creating legislation that discriminates against any area of technology.

The third section of the article talks about the TRIPs and public health, where it says that in shaping their laws to conform to the TRIPs standards, countries may take measures necessary to protect public health. The article states that due to in-appropriate standards and health and development demands, developing countries can employ certain TRIPs provisions to protect public health. Doha Declaration on TRIPs and Public Health affirmed the sovereign right of countries to take measures, particularly through compulsory licensing and parallel imports, to protect public health and give it priority over intellectual property. The article also explains the process of modification of the TRIPs provisions

related to compulsory licensing. It says that it happened due to the fact that many developing countries lacked the domestic capacity or technical expertise to manufacture patented pharmaceuticals.

The fourth section of the article describes that despite the flexibilities granted by the TRIPs Agreement, effective implementation of provisions such as compulsory licensing has been adversely affected by several factors. The cost of local administrative infrastructure and bilateral and regional free trade agreements are main barriers for the implementation of the TRIPs provisions. The article also mentions that many countries have taken steps to use compulsory licensing and other flexibilities, such as government-use orders. While mentioning different cases from countries like Zimbabwe, Canada, Thailand and Brazil, the article points out that Malaysia issued a government-use order and granted a contract to a local firm to import three HIV/AIDS drugs from an Indian manufacturer for supply to government hospitals.

The fifth section of the article states about several issues and actions that are important to ensure that governments and policy-makers effectively utilize the alternatives offered by the TRIPs Agreement. While mentioning that TRIPs provisions can be used to stimulate access to generic medications, the article says that compulsory licensing should be allowed to encourage access to medications. It suggests that issues related to sufficient patent protection and remuneration should be considered to encourage the increased use of compulsory licensing and maximize competition. Further, the countries pressured into making concessions during bilateral trade negotiations should be supported in interpreting their commitments in the light of the existing Doha Declaration on TRIPs and Public Health.

Finally, the article advocates the continued monitoring of the TRIPs Agreement in order to analyze its effects and questions its relatively unclear public health impacts. It also says that understanding the TRIPs Agreement is important for creating the legal tools and public policies necessary to capitalize on the potential offered by its provisions. Therefore, it is crucial to maintain the flexibilities established by the agreement, especially with regards to developing countries, in order to achieve greater equity in accessing medicines.

A Proposal for Measuring the Degree of Public Health–Sensitivity of Patent Legislation in the Context of the WTO TRIPs Agreement by Gabriela Costa Chaves and Maria Auxiliadora Oliveira, *Bulletin of the World Health Organ*, Vol. 85 No.1, January 2007.

THE article at its outset says that since its formation the issues relating to the intellectual property rights (IPR) have acquired greater importance in the international trade environment. While the WTO Members are compelled to grant intellectual property protection in all technological fields, including patents for pharmaceutical products and processes, science-based companies consider patent protection as one of the main forms of expanding their powers of appropriation. The issues of monopoly conferred by the patent and high price of patented products has been the most important barriers to their widespread adoption, in particular hindering access to medicines in low- and middle-income countries.

The article explains about the TRIPs challenges to the countries and takes the reference of the study by one of the expert named 'Correa' and mentions his recommendations. The article also talks about his argument by stating that public health can best be protected through "health-sensitive" patent legislation incorporating all TRIPs flexibilities. It also mentions about the previous studies conducted from the public health perspective and says that they do not measure the degree of health sensitivity in legislation, nor perform country comparisons. Mentioning about their previous study on developing countries from the Latin America and the Caribbean (LAC), the authors say that the present paper proposes to advance the discussion by answering few questions. In order to answer the questions, the article develops a framework to measure health sensitivity in patent legislation which is then tested and validated. It also mentions about the materials and methods in developing the patent legislation framework and content validation. The article mentions that the framework was developed by adapting the Delphi method and help and advices were sought from graduate

professionals (lawyers, medical doctors, economists and activists), who had experience in dealing with patent legislation and access to medicines. With the help of the two types of questionnaires and selection of LAC countries, the selected legislation was analyzed by reading and identifying each legal provision included in the framework. The resulting framework of the study included flexibilities like transition period to grant patents for pharmaceuticals, exhaustion of rights and parallel imports, experimental use, the Bolar exception, compulsory licensing, the TRIPs plus provisions and health ministry's participation in the analysis of pharmaceutical industry patent claims.

The article presents the analysis of patent legislation's health-sensitivity by excluding the transition period for granting pharmaceutical patents as it expired in 2005 for all developing countries. Mentioning about the Paraguayan and Uruguayan legislation, the analysis says that Paraguay has the most health-sensitive patent legislation (83.6%) among the LAC countries in 2005. The study points out that Brazil has the second-most health-sensitive patent legislation (82.3%), while Argentina, Costa Rica and the Dominican Republic presented less health-sensitive patent legislation (81.6%), mainly because their health ministries do not have a role in the pharmaceutical patenting process. The article also presents analysis of different community and group of countries regarding the health-sensitive patent legislation.

The study points out that despite Paraguay having the most health-sensitive patent legislation, its government cannot afford to provide regular access to medicines for people with HIV. It says that Paraguay has depended on Brazilian donations since 2004 through the Brazil–Paraguay International Cooperation Programme. The civil society in countries like Brazil and India is proposing alternative ways to overcome barriers imposed on patent legislation by the TRIPs and TRIPs-plus. Finally, the study highlights the importance of this framework and says that further improvement will help in future studies by including government and organized society initiatives that minimize FTAs' negative effects on access to medicines. ●

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)

Council for TRIPs

Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health

DRAFT REPORT TO THE GENERAL COUNCIL

Please find attached a draft report to the General Council pursuant to paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health. Further updating may be needed in light of the October meeting of the Council.

1. Paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health of 30 August 2003 (the "2003 Decision") provides that the Council for TRIPs shall review annually the functioning of the System set out in the Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review is deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

2. The sixth annual review took place in October 2009 and the General Council took note of the report of the Council for TRIPs (IP/C/53) at its meeting on 17 December 2009 (WT/GC/M/124, paragraph 178). The present report covers the period since October 2009.

3. At its meeting of 8-9 June 2010, the Council for TRIPs agreed to set aside the second day of its meeting of 26-27 October for the annual review. The Annex to this report records the statements made in the review at the October meeting. The paragraphs below set out factual information regarding the implementation and use of the 2003 Decision, discussions on the operation of the System and the acceptance of the Protocol Amending the TRIPs Agreement.

1. Information on Implementation and Use of the System Established under the Decision

4. As of 30 September 2010, the following Members have formally notified the Council for TRIPs of the relevant changes to their domestic legal regime in order to implement the 2003 Decision:

- *Norway* (see explanatory note in IP/C/W/427): Amendments to the Patent Act of 15 December 1967 No.9 and to Patent Regulations of 20 December 1996 No.1162 provide the legal basis to act as an exporting Member;
- *Canada* (IP/N/1/CAN/P/5-7; see also explanatory note in IP/C/W/464): Amendments to Patent Act and Food and Drugs Act, as well as the Use of Patented Products for International Humanitarian Purposes Regulations provide the legal basis to act as an exporting Member;
- *India* (IP/N/1/IND/P/2): the Patents (Amendment) Act 2005 provides the legal basis to act as an exporting Member;
- *European Communities*[1] (IP/N/1/EEC/P/5): Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines;
- *Hong Kong, China* (IP/N/1/HKG/P/1/Add.6; see also background information in IP/N/1/HKG/17): the Patents (Amendment) Ordinance No.21 of 2007 provides the legal basis to act as exporting Member, as well as importing Member in situations of extreme urgency;
- *Switzerland* (IP/N/1/CHE/P/9 and IP/N/1/CHE/4): the consolidated version of the Federal Law on Patents for Inventions of 1 July 2008 and the Ordinance on Patents for Invention provide the legal basis to act as an exporting Member;
- *Philippines* (IP/N/1/PHL/I/10): Republic Act No. 9502 (also known as the "Universally Accessible Cheaper and Quality Medicines Act

2008") and the Implementing Rules and Regulations of Republic Act No. 9502 provide the legal basis for the grant of a special compulsory licence for the import of patented drugs and medicines, as well as for their manufacture and export; and

- *Singapore* (IP/N/1/SGP/4): the Patents (Amendment) Act 2008 provides the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency.

5. On 17 July 2007, the delegation of Rwanda submitted a notification under paragraph 2(a) of the Decision, informing the Council for TRIPs of its intention to import a pharmaceutical product from Canada under the System (IP/N/9/RWA/1). On 4 October 2007, the delegation of Canada notified the Council for TRIPs in accordance with paragraph 2(c) of the Decision that it had authorized the manufacturing and export of the pharmaceutical product concerned to meet Rwanda's needs (IP/N/10/CAN/1). No notifications have been made to the Council for TRIPs of the intention to use the System as an importer pursuant to paragraph 1(b) of the Decision.[2]

6. Detailed information on the use of the System by Canada to ship a fixed-dose combination medicine for the treatment of HIV infection to Rwanda was provided by the delegation of Canada to the Council for TRIPs at its meeting on 2 March 2010 (IP/C/M/62, paragraphs 185-195; for more details see also the Communication from the delegation of Canada, IP/C/W/526, as well as reports in earlier annual reviews IP/C/53, paragraph 6; IP/C/49, paragraph 6; and IP/C/46, paragraphs 4-5).

7. As foreseen in the 2003 Decision, the Secretariat regularly updates a page on the WTO website dedicated to this Decision, notably to ensure the public availability of notifications made pursuant to it (http://www.wto.org/English/tratop_e/public_health_e.htm).

2. Discussion on the Operation of the System Established under the Decision

8. In line with the decision taken by the Council for TRIPs at its annual review in October 2009, the Chair held a round of informal consultations on the operation of the System on 12 February 2010. The Chair reported on the outcome of those consultations under the agenda item "Other Business" at the Council's formal meeting on 2 March 2010 (IP/C/M/62, paragraphs 168-175). Subsequent discussions confirmed Members' readiness to share experiences on the use of the System and to engage in practical fact-based discussions in order to have a full understanding of its functioning (IP/C/M/62, paragraphs 176-212). Members stated their substantive positions concerning the operation and review of the System. The delegation of Canada shared its experience in using the System, including a detailed timeline of events. Some delegations expressed concern that the System had only been used once since 2003 and that it had taken some three years to deliver the medicines to Rwanda in this context. They also noted that only a limited number of Members had accepted the Protocol Amending the TRIPs Agreement (see the list of notified acceptances in Section 3 below). Other delegations noted that the limited use of the System so far was not an appropriate measure of its success. Its use in one case had demonstrated that it could work effectively and that the System could play a supportive role in the wider effort to improve access to essential medicines.

9. Various issues were suggested for further discussion, but no agreement could be reached on the appropriate format for such discussions, beyond the existing review process within the Council for TRIPs. While agreeing that annual reviews constituted a good platform for sharing experiences and evaluating the operation of the System, some delegations proposed that the reviews could be usefully complemented by a dedicated workshop to allow for an in-depth study of any potential obstacles to the System's effective and expeditious operation. In order to gather information on all aspects and concerns, the workshop should be open to all relevant stakeholders, including non-governmental organizations, pharmaceutical industry and other experts. Other delegations considered that the review process was a Member-driven process. It already offered a platform to share experiences and to examine the System's functioning, and the initial focus should be on Members reporting directly on their experience,

positive or negative, with the System. While the usefulness of the existing review process could be enhanced, including through more factual input, there was therefore no need to open a new process. Given that at the March meeting the matter was raised under the agenda item "Other Business", the Council limited itself to taking note of the statements made.

10. At the request of the delegations of Brazil, China, Cuba, Ecuador, India, Indonesia, Peru and Venezuela, an item on "Implementation of Paragraph 6 System" was put on the agenda of the Council's meeting on 8-9 June 2010. The Chair reported on the consultations he had held with interested delegations on how best to proceed with the preparations of the next annual review at the Council's meeting in October. In subsequent discussions, delegations reiterated their positions regarding the format of future work in this area (the record of the discussion will be circulated as IP/C/M/63). While no consensus could be reached on any complementary process, the Council agreed to set aside the second day of its meeting in October for the annual review to enable a special focus on the issue, with possible involvement of health experts on national delegations.

3. Decision on the Amendment to the TRIPs Agreement

11. As called for in paragraph 11 of the 2003 Decision, the General Council adopted a Protocol Amending the TRIPs Agreement, by a Decision of 6 December 2005 (WT/L/641). The Protocol is open for acceptance by Members until 31 December 2011 or such later date as may be decided by the Ministerial Conference (WT/L/785). In accordance with Article X:3 of the WTO Agreement, the Protocol will enter into force upon acceptance by two thirds of the WTO Members.

12. As of 30 September 2010, the following Members have notified their acceptance:

- United States, 17 December 2005, WT/Let/506;
- Switzerland, 13 September 2006, WT/Let/547;
- El Salvador, 19 September 2006, WT/Let/548;
- Republic of Korea, 24 January 2007, WT/Let/558;
- Norway, 5 February 2007, WT/Let/563;
- India, 26 March 2007, WT/Let/572;
- Philippines, 30 March 2007, WT/Let/573;
- Israel, 10 August 2007, WT/Let/582;
- Japan, 31 August 2007, WT/Let/592;
- Australia, 12 September 2007, WT/Let/593;
- Singapore, 28 September 2007, WT/Let/594;
- Hong Kong, China, 27 November 2007, WT/Let/606;
- China, People's Republic of, 28 November 2007, WT/Let/607;
- European Communities[3], 30 November 2007, WT/Let/608;
- Mauritius, 16 April 2008, WT/Let/619;
- Egypt, 18 April 2008, WT/Let/617;
- Mexico, 23 May 2008, WT/Let/620;
- Jordan, 6 August 2008,WT/Let/630;
- Brazil, 13 November 2008, WT/Let/636;
- Morocco, 2 December 2008, WT/Let/638;
- Albania, 28 January 2009, WT/Let/639;
- Macao, China, 16 June 2009, WT/Let/645;
- Canada, 16 June 2009, WT/Let/646;
- Bahrain, 4 August 2009, WT/Let/652;
- Colombia, 7 August 2009, WT/Let/650;
- Zambia, 10 August 2009, WT/Let/651;
- Nicaragua, 25 January 2010, WT/Let/663;
- Pakistan, 8 February 2010, WT/Let/664;
- Former Yugoslav Republic of Macedonia, 16 March 2010, WT/Let/671; and
- Mongolia, 17 September 2010, WT/Let/684.

Information on the status of acceptances of the Protocol is periodically updated in revisions of document IP/C/W/490.

NOTES

[1] On 1 December 2009, the Treaty of Lisbon amending the *Treaty on European Union and the Treaty establishing the European Community* (done at Lisbon, 13 December 2007) entered into force. On 29 November 2009, the

WTO received a Verbal Note (WT/L/779) from the Council of the European Union and the Commission of the European Communities stating that, by virtue of the *Treaty of Lisbon*, as of 1 December 2009, the European Union replaces and succeeds the European Community.

[2] Least developed country Members automatically qualify as "eligible importing Member" under the System and are therefore exempted from notifying the Council for TRIPs of their intention to use the System as importers.

[3] The text of the instrument of acceptance reads as follows:

"THE PRESIDENT OF THE COUNCIL OF THE EUROPEAN UNION,

HAVING regard to the Treaty establishing the European Community, and in particular Article 133(5) in conjunction with the first sentence of the first subparagraph of Article 300(2) and the second subparagraph of Article 300(3) thereof,

NOTIFIES by these presents the acceptance, by the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), done at Geneva on 6 December 2005,

CONFIRMS, in accordance with Article 300(7) of the Treaty establishing the European Community, that the Protocol will be binding on the Member States of the European Union.

The Secretary-General/ High Representative — The President of the Council of the European Union"

(www.wto.org JOB/IP/1 30 September 2010)

(Contd. from page 37)

developing countries including India, to raise the issue of intellectual property rights and access to medicines at the WTO's TRIPs Council meeting in June 2001. The negotiations culminated in the adoption of the Doha Declaration on TRIPs and Public Health in November 2001, which mandates that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health and that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted as well as the right to determine what constitutes a national emergency or other circumstances of extreme urgency and that each Member is free to establish its own regime for exhaustion without challenge.

One aspect of compulsory licensing under the TRIPs Agreement is that such licences can be granted only for the supply in the domestic market of the country issuing the licence. An issue that remained unresolved at the Doha conference was that of addressing problems of countries that have insufficient or no manufacturing capacity in the pharmaceutical sector. Accordingly, Doha Declaration on TRIPs and Public Health under Para 6 while recognizing this problem directed the TRIPs Council of WTO to find a solution to this problem before the end of 2002.

Various proposals were submitted in the TRIPS Council by the developing as well as developed countries. This led to the Decision in the WTO General Council meeting held on 30 August 2003 regarding grant of waivers from the obligations under Article 31(f) and 31(h) of the TRIPs Agreement (WT/L/540 dated 2nd September 2003). This Decision is aimed at easing the problem being faced by the developing countries as well as LDCs having no or insufficient manufacturing capacities in the pharmaceutical sector in using the flexibility of compulsory license. This mechanism is intended to be a temporary one which is to be followed by an appropriate amendment to the TRIPs Agreement. This Decision would enable manufacture and export of pharmaceutical products under compulsory licence to countries with limited or no manufacturing capacities in the pharmaceutical sector. The Decision is to be read along with the Chairman's Statement in this regard contained under Para 29 of WT/GC/M/82 dated 13 November 2003.

The General Council Decision instructed the TRIPs Council to initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, i.e. by June 2004. Work in this regard is going on in the TRIPs Council. As per Decision, WTO has dedicated a web-page on its website (www.wto.org) for Members to notify their intention to use the system.

(http://commerce.nic.in/trips_and_public_health.htm)

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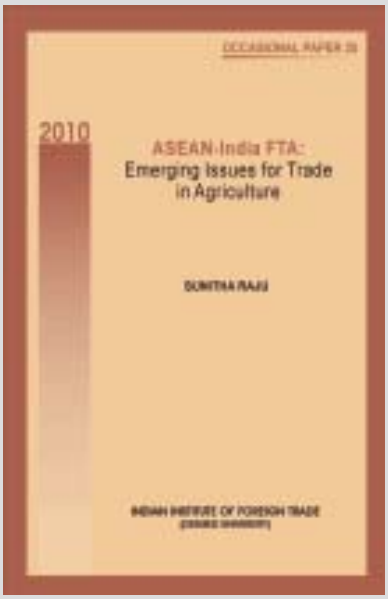

OCCASIONAL PAPER 25

ASEAN-India FTA: Emerging Issues for Trade in Agriculture

by Sunitha Raju

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In recent years, India has entered into a number of FTAs. Amongst all, ASEAN-India FTA (AIFTA) has been the most debated one. The stakeholder consultations clearly brought out the anxieties of a perceived import threat, particularly for agricultural products. Some of the sensitive sectors identified by India were spices, plantation crops, vegetable oils, rice, fish, textiles, chemicals, electronics, machinery, auto components and footwear. An assessment of the possible trade effects of the reduction or elimination of tariff across product groups is necessary for taking forward the efforts for strengthening India-ASEAN economic partnership.

This paper is a first step for examining, objectively, the import threat perception for India's agricultural products. The analysis covers both ASEAN as a group as well as individual member countries.

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