

TRIPS Agreement and Public Health: An Overview of International Issues

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

Keywords: TRIPS, Doha Declaration, Paris Convention, Para 6, compulsory licence, IPR

Intellectual property protection for inventions relating to health care was one of the most debated areas in the international negotiations for IPR protection in the last three decades. The major concern was the need to facilitate access to essential medicines at affordable cost to the large sections of the population in the developing and least developed countries. Equally important was the demand to ensure adequate reward through patent system to the pharmaceutical companies mainly located in the developed countries who make considerable investment for the invention, production and marketing of essential drugs. The practice followed by many developing countries to ensure access to these medicines/drugs was to promote the growth of generic pharmaceutical industries without providing adequate patent protection for new pharmaceutical inventions. It was argued that this resulted in distortion of trade in the international market particularly in the context of globalization. One of the reasons identified for this is the lack of uniform international norms for the protection of new pharmaceutical products. The outcome was re-formulation of the then existing international norms through the TRIPS Agreement.

The impression given to the world community that the provision in the TRIPS Agreement is a proper balance to ensure access of quality drugs to global population short lived when the South African Government took legislative measures to overcome the HIV/AIDS crisis. Though the WTO members found some temporary measures through the much projected Doha Declaration, it is still argued that the existing norms under the TRIPS Agreement are inadequate to provide the right balance. The implementation of the provisions of the TRIPS Agreement by various member states and the consequent disputes that arose in the last decade show that the provisions are more in favour of the owners of intellectual property to facilitate global trade. The weak manufacturing capacity coupled with low level of inventive activities is identified as the major stumbling block for many WTO members to take even the limited advantages of the TRIPS Agreement. The attempt in this paper is to examine briefly the context in which the present international norms are developed and to identify the areas in which countries, particularly, developing and least developed, need to work together to restore a balanced international norms for the protection of inventions relating to health care so that access to essential medicine at affordable cost could be a reality.

Historically international patent norms facilitated the growth of pharmaceutical industries in many countries which lacked the capacity to invent and produce drugs.¹ The flexibilities available in the Paris Convention were used by many countries to build their domestic industries. Since there was no mandate

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to provide product patent, many countries who were members of the Paris Convention provided only process patent in the initial stages to augment the growth of their pharmaceutical industries. This also enabled these countries to provide access to medicines at affordable cost. Though these provisions were mainly enjoyed by the countries in the West till the middle of the last century, some of the Asian countries also used this approach to promote industrial growth in the pharmaceutical sector after the Second World War. The net result was the emergence of strong and powerful generic industries in many parts of the world, including Asia. This also enabled production and distribution of low cost medicine not only in the domestic markets of these countries but also in other developing and least developed countries. Some of these industries even started penetrating into the markets in the developed countries whose industries are mainly responsible for invention and introduction of new and improved drugs in the global market. These industrial activities emerged as a potential threat to the dominance of the powerful pharmaceutical industries in the developed countries, particularly, the US. It was argued by these industrial groups that there is a need to strengthen the international norms for the protection of new inventions to prevent distortion of international trade in pharmaceutical products in the global market. These developments compelled the governments of the developed countries to initiate negotiation for new international norms to protect the new inventions in all new fields of technologies during the Uruguay Round of GATT negotiations stated in 1986.² The need for enhanced protection of pharmaceutical products finds special mention in the submissions made by the developed countries.³ This includes product patent for new inventions in all fields of technology, extension of term of protection to 20 years considering the time taken to put the drugs into market, restrictions on compulsory licences, special protection for test data submitted for drug approval, etc. Initially the developing countries objected to the inclusion of IPR issues in the GATT negotiations and argued to confine it to the prevention of entry of infringed goods using border security measures. These countries also demanded to focus the discussion on access to technology and protection of the interest of the users of intellectual property.⁴ But during the mid-term review held in Geneva in April 1989 these countries agreed for the negotiation of 'the

provision of adequate standards and principles concerning availability, scope and use of a trade-related intellectual property rights'.⁵ This, as opined by commentators, was a compromise for greater market access for agriculture and textile products from the developing countries.⁶ It opened the door for pushing new international standards for IPR protection through the GATT framework.

During the negotiations, many strategies were used by developed countries, particularly US, to overcome strong resistance from developing countries, particularly, India, Brazil, Argentina, Thailand etc., and ensured that their proposals find place in the draft reports.⁷ The pressure tactic adopted by the US was the use of Special and Super 301 of its Trade Act against many of these countries.⁸ US also successfully concluded the North American Free Trade Agreement (NAFTA)⁹ and the Andean Pact¹⁰ with improved IPR protection, particularly for pharmaceuticals. Because of these pressures, many countries proposed amendments during the period of GATT negotiations itself, in their domestic patent law to improve protection to pharmaceutical products including pipeline protection. It was interesting to note that in the original Dunkel Draft there was no obligation on the part of countries enjoying 10 years transitional period to facilitate the change from the process patent regime to product patent system to provide pipeline protection for pharmaceutical products. The strong protest from various pharmaceutical organizations, particularly the Pharmaceutical Manufacturing Associations (PMA),¹¹ forced US to request for the change in the Dunkel Draft and to suggest pipeline provision even for countries enjoying transitional provision. Ignoring the protest from India, Canada,¹² Egypt and thirteen Latin American countries, Article 70(8) was introduced in the TRIPS to provide temporary protection for new drugs invented after entering into force of the Agreement. While it is true that these countries had the freedom to delay change from process patent regime to product patent regime for 10 years, the obligation to accept product patent application for the new inventions and to grant Exclusive Marketing Rights (EMR) on satisfaction of certain conditions during this period practically helped the inventors of new drugs to acquire protection for the new inventions during this period. This, practically, nullified the effect of the transitional provision and prevented countries with strong generic

industries from producing generics of new drugs, invented after the TRIPS Agreement. The negotiators of the developing countries appear to be unaware of this trap and were of the impression that they are bound to grant product patent only after 10 years as allowed by the transitional provision. Thus, while the developed countries enjoyed one year period for change of the law, developing countries like India were forced to amend the domestic patent law from the day in which TRIPS came into force.¹³ This is the first major blow to the continued growth of generic industries and the efforts to promote access to cheap drugs.

After the TRIPS Agreement came into force it was argued that there were enough flexibilities in the TRIPS for protecting interest of the generic industries so as to achieve the goal of providing affordable drugs. The flexibilities include freedom to determine the scope of subject matter for product patent protection,¹⁴ to determine the grounds on which compulsory licence could be issued,¹⁵ in identifying exceptions to patent,¹⁶ providing provisions for parallel import,¹⁷ and protection of test data¹⁸, etc. Countries adopted various approaches to implement the obligations and tried to protect public interest of providing access to affordable drugs. But increasingly it was realized that it is difficult to provide access to new drugs in many cases. Many developing and least developed countries could not even enjoy provisions for compulsory licence due to lack of manufacturing capabilities. This forced countries like Brazil and South Africa¹⁹ to introduce compulsory licence provisions to provide cheap medicine for HIV/AIDS victims. The reaction from US to these laws clearly reflects the limitations of the TRIPS flexibilities to provide affordable drugs.²⁰ This forced countries to bring health care issues into international attention and demand for clarification and amendment of the TRIPS provision dealing with health care. In the TRIPS Council, developing countries argued for complete freedom to introduce changes in the patent law to overcome health crisis.²¹ Though this was opposed by the developed countries they were forced to agree for a unanimous declaration on TRIPS Agreement and Public Health, using compromising words in the Doha Round of Negotiations.²²

The major achievement of the developing countries in the Doha Round was their joint effort in convincing the world community that public health is a grave issue and TRIPS provisions create problems in taking

effective measures to solve the same. This is evident from the use of the words like 'gravity of public health problems', 'other epidemics' and 'effect on prices' in the Doha Declaration on TRIPS and Public Health.²² Doha Declaration also clarified that the countries have the freedom to recognize the grounds of compulsory licence,²² freedom to determine national emergency or other circumstances of extreme urgency²² and the mechanism to facilitate parallel imports.²² The most significant contribution is the clarification on the concept of public health crisis. This is reiterated in para 5 (c) thus: "...it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency". This is clearly an improvement over the TRIPS Agreement and the use of 'other epidemics' gives more freedom to identify major local health problems and to use the provision to overcome the problem of access to essential medicines. But it is obvious that this can be enjoyed only by countries having manufacturing capacities.

The most debated issue was regarding the problem of countries with insufficient or no manufacturing capacity in using the TRIPS flexibilities, particularly provisions for compulsory licence. According to these countries, Articles 31(f) and (h) impose restrictions on importing cheap generics from other countries using compulsory licence provisions. Hence they argued for the freedom to import cheap products from generic manufacturer without any conditions. Even though many developed countries were sympathetic to their problem, the major worry was the misuse of any concession by import of drugs from generic manufacturers using compulsory licence. It was argued by the developed countries that if proper safeguards are not provided there is possibility of the same drugs entering into other countries distorting the market of the patent owner. The fear that the concessions given in the name of public health may be used by the generic manufacturers to promote trade interests forced the developed countries to refrain from allowing such concessions. Since a compromise formula could not be arrived during the negotiations, Para 6 of the Doha Declaration mandated the TRIPS Council to find expeditious solution before the end of 2002. Doha Declaration also extended period of the obligation of the least developed countries to implement the product patent regime till 2016. There is also a mandate to provide technical support to these

countries to facilitate industrial growth as per Para 7 of the Doha Declaration.

After an intricate two years of negotiations²³ the General Counsel of the WTO approved a complex set of rules to implement Para 6.²⁴ The decision contains definition for pharmaceutical products including active ingredients and diagnostic kits. It also defined eligible importing member and exporting member to ensure that only deserving countries are going to use this facility. The obligations of the exporting and eligible importing countries are elaborated to prevent misuse. This includes a detailed notification from the eligible country, indicating the requirements²⁵ and the intention to grant compulsory licence.²⁶ The exporting country is bound to indicate the conditions in the compulsory licence to ensure that the products are separately identifiable US labeling standards.²⁷ They must also ensure that only required quantity is manufactured and it reaches only eligible importing country. The exporting country is also expected to notify the details of the compulsory licence issued to the TRIPS Council²⁸ and publish it in the designated website.²⁹ The obligation to pay remuneration to the right holder is limited to the exporting country so as to prevent double payment. This is also fixed taking into consideration the economic value of the importing country.³⁰ There is also obligation on the part of the countries to prevent diversion of the trade by re-exporting the products.³¹ All the WTO members also have the obligation to take steps to prevent importing of these products into their market.³² Thus the attempt was to give a waiver to the predominant domestic supply requirement in Article 31(f) and the adequate remuneration requirement in Article 31(h) of the TRIPS Agreement. To convert this as a permanent decision and part of TRIPS obligation, Article 31bis, incorporating the provisions in the Para 6 Decision, was adopted as amendment to TRIPS Agreement³³ and is open for the acceptance of two third members of WTO.³⁴

It is evident that adequate measures are provided to prevent re-exporting of the products and distortion of the global market. Developed countries, through these provisions ensured that countries with manufacturing capabilities are not going to use public health as a shield to promote the growth of their domestic generic industries by sale of patented products in global market. The complex procedure envisaged, it is felt, would prevent many countries from using these provisions.³⁴ It is interesting to note that only one

country, Rwanda, made the notification till date as per the decision. One needs to wait and see whether public health needs of developing countries are going to be satisfied by these measures.

Conclusion

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

References

- 1 Ayyangar Rajagopala, *Report on the Revision of the Patents Law*, Government of India, 1959.
- 2 This is evident from the statements of developed countries like the US, EU, Japan. According to US, the areas include "(1) total lack of patent and copyright laws, (2) narrow scope of protection under intellectual property laws resulting in failure to protect entire categories of products or works (3) term of protection that are too short to permit an innovator time to test a product, market it and achieve an adequate return on investment and (4) misuse of compulsory licencing programmes. See statement of the United States at the meeting of 25 March 1987, MTN.GNG/NG11/W/2 (3 April 1987) at pp. 2-3. European Union identified the following: (1) inadequacy in the availability and scope of rights, (2) inadequacy in the procedures and remedies for the effective enforcement of existing rights, (3) discriminatory national rules favoring domestic economic activity over import. Japan identified the problem as (1) insufficient protection of substantive intellectual property rights, (2) excessive/discriminatory protection of intellectual property rights, (3) licensing problems in international trade, including government licencing, and unjust exercise of rights by holders, (4) restrictions on patent rights to protect domestic technologies, (5) insufficient domestic and national collaboration for enforcement including border control. Submissions from participants on trade problems

- encountered in connection with intellectual property rights, MTN.GNG/NG11/W/7 (29 May 1987), pp. 2-5. (jointly by EU, Japan and US).
- 3 Submissions from participants on trade problems encountered in connection with intellectual property rights, MTN.GNG/NG11/W/7Add.2 (5 August 1987) pp. 2-4, 7, 17.
 - 4 Intervention by Thailand, Mexico and Brazil. *The GATT Uruguay Round: A Negotiating History (1986-1994), Vol IV: The End Game (Part I)*, edited by Terence P Stewart (Kluwer Law International, The Hague), 1999, 465-482.
 - 5 Clause 4(b) of Trade Negotiations Committee Mid-Term Review of the Uruguay Round April, 1989, Geneva (MTN.TNC/11).
 - 6 Watal Jayashree, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press), 2001, Chapter 2.
 - 7 This is evident from the inclusion of patentable subject matter and exceptions in the progress report submitted by TRIPS negotiating group chairman Lars E R Annel and the inclusion of number of provisions in the Dunkel Draft in 1991.
 - 8 Use of 301 by the US on countries who were touch on the negotiation – Brazil (1987), Argentina (1988), Thailand (1990), India (1991), China (1991) Taiwan (1992) and Brazil (1993).
 - 9 Based on NAFTA Canada changed the compulsory licence provision on pharmaceutical inventions.
 - 10 Colombia, Venezuela, Bolivia, Ecuador, and Peru based on decision 313 agreed to improve protection for pharma products.
 - 11 US Pharmaceutical Manufacturers Association (PMA) protested against 10 year transition and no pipe line protection. They argued that Special 301 is better than Dunkel provisions.
 - 12 Opposition from Canadian Drug Manufactures Association (Generic industry) was against the provisions apprehending the growth of domestic industry.
 - 13 India introduced the pipeline provisions in the Patent Act through an Ordinance issued on the mid night of 31 December 1994, Gopalakrishnan N S, Patent Amendment Bill, 1995 - A Critique (1996) 3 *Supreme Court Cases* (J), 1.
 - 14 Article 27 of the TRIPS used the standards of novelty, inventive step and capable of industrial application to identify inventions for grant of patent. But since these terms are not defined the countries have the freedom to determine the level of inventive step required to satisfy patent protection. This it is felt will help countries to prevent ever greening of patents in the field of pharmaceuticals if the domestic legislation is properly structured. Various amendments introduced in the Indian Patent Act particularly Section 3(d) are considered as one of the approaches to achieve this.
 - 15 Article 31 of the TRIPS gives the freedom.
 - 16 Article 30 identified three steps to determine the limitation and exceptions to patent.
 - 17 Article 6 of the TRIPS makes it clear that ‘for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights’
 - 18 Article 39.3 deals with this, Gopalakrishnan N S and Kadavan Benoy K, *Study on Testdata Protection in India* (Eastern Book Co, Lucknow), 2005.
 - 19 South Africa’s Medicines and Related Substances Control Amendment Act No. 90 of 1997.
 - 20 www.sarpn.org.za/ContryPoveryPapers/SouthAfrica/april2002/berger/berger.pdf.
 - 21 Developing countries suggested the following wording to be introduced: ‘Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health’ (IP/C/W/312, WT/GC/W/450, 4 October 2001).
 - 22 WTO Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2 dated 20 November 2001, paras 1, 3, 5(b), 5(c), 5(d).
 - 23 Attara Amir, The Doha Declaration on the TRIPS Agreement and Public Health, access to pharmaceuticals, and options under WTO law; Sun Haochen, Reshaping the TRIPS Agreement concerning Public Health – Two critical issues’, <http://www.cid.harvard.edu/cidtradePapershaochensun.pdf>.; Correa Carlos M, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, 2002; May Ruth and Bailey Michael, ‘TRIPS and Public Health: The Next Battle’, Oxfam Briefing Paper 15, Oxfam International, 2002; Alsegard Erik, ‘Global Pharmaceutical Patents after Doha Declaration – What lies in the future’, *Script-ed*, 1(1)(2004).
 - 24 General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health WT/L/540 and Corr.1, 1 September 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm; Abbott Frederick M and Van Puymbroeck Rudolf V, Compulsory licensing for public health: A guide and model documents for implementation of the Doha Declaration Paragraph 6 Decision, World Bank, Washington D C, 2005, para 2.
 - 25 This includes the name of the produce and specific quantity and also evidence to establish insufficient on no manufacturing capacity in case of countries other than least developed countries.
 - 26 This is to inform that product patent is granted for the product and intending to issue compulsory license.
 - 27 This includes indication of the quantity necessary for the importing country, special labeling and marking, distinguishing packaging with special colour or shape of the product without affecting the price.
 - 28 The information includes the name and address of the licensee, the name of the products, quantity, name of the exporting countries, duration of the licence and address of the website in which information is given.
 - 29 Before the shipment the quantity exported and distinguishing features of the product must be given in the website of the licensee or in the WTO website.
 - 30 General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health WT/L/540 and Corr.1,1 September 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, para 3.
 - 31 General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

- WT/L/540 and Corr.1 1 September 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, para 4. In case the importing country finds it difficult to control this they are expected to take the financial and technical assistance of the developed countries on mutually agreed terms to implement this obligation.
- 32 General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health WT/L/540 and Corr.1 1 September 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, para 5.
- 33 General Council, Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/L/641, dated 8 December 2005 http://www.wto.org/english/tratop_e/trips_e/wt641_e.htm.
- 34 The last date was December 2007. Since the required number of members could not ratify and accept the amendment the date was extended till December 2009. For details see TRIPS: TRIPS and Public Health, Members accepting amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.