

# TRIPS Agreement and Access to Medicines

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## I. INTRODUCTION

The Agreement on Trade-Related Intellectual Property Rights (TRIPS), which came into force on the January 1, 1995, has transformed the international intellectual property system by creating a prescriptive regime for protecting intellectual property rights (IPRs). The result of the Agreement has been to bolster the international protection of patents in a way that has narrowed the scope for differentiation within national patent policies. It has been criticized for adversely impacting the attainment of social goals by sharply curtailing traditional capacity of nations in supplying of public goods, such as health care and nutrition by making medicines and other essential products expensive, and thus keeping them out of the reach of many countries.<sup>1)</sup> Public benefit is stated to lie at the heart of patent protection because high levels of patent protection are usually associated with correspondingly high levels of development.<sup>2)</sup> But the AIDS pandemic that plagued many countries in the developing world around the turn of the last century has highlighted the gaping hole in patent theory and practice.

By strengthening the international level of patent protection, TRIPS has impacted significantly the access to life saving pharmaceuticals in developing countries, especially on poor countries that have insufficient or no pharmaceutical manufacturing capacities and are afflicted with pandemics. Also, on countries that were until now dependant on the importation of life-saving drugs at low prices from countries that provided no patent protection to pharmaceuticals. In other words, TRIPS intensified the problem of access to essential medicines at affordable prices in the developing countries. According to World Health Organization (WHO), one out of three on Earth

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- 1) Lee G. Branstetter, "Do Stronger Patents Induce More Local Innovation?" in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* 309 (Keith E. Maskus & Jerome H. Reichman eds. , 2005)
- 2) See generally Richard T. Rapp & Richard P. Rozek, 'Benefits and Costs of Intellectual Property in Developing Countries' 24:5 J. World T. 75 (1990).

lacks access to essential medicines.<sup>3)</sup> Approximately 3 million people died from HIV/AIDS in 2001, 2.3 million of these deaths occurred in Sub-Saharan Africa. Nearly 1.7 million people worldwide died from tuberculosis in the same year and there had been as many as 10.2 million new cases in 2005.<sup>4)</sup> Currently 40 million people are inflicted with AIDS. About six million people in the developing world living with HIV/AIDS need access to treatment now.<sup>5)</sup> It is common knowledge that most of these deaths are preventable, that the life saving drugs do exist, and the problem lies in the inaccessibility of these drugs primarily for patients in poor countries afflicted with these diseases.

The measures taken by some of the countries afflicted with these epidemics by resorting to compulsory licenses to import generic copies of the patented drugs have met with strong opposition from developed countries and pharmaceutical companies. Seeking to increase access to essential medicines through various TRIPS-compliant regulatory mechanisms, both Thailand and South Africa suddenly found their domestic laws under attack from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the office of the US Trade Representative (USTR).<sup>6)</sup> The US trade pressure on South Africa and Thailand in 1997 galvanized criticism of TRIPS<sup>7)</sup> and laid the basis for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health<sup>8)</sup> at the WTO Ministerial Meeting in Doha in 2001.

The Declaration emphasizes the importance of public health considerations in implementing the TRIPS Agreement. It affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. The Declaration was followed by the Implementing Decision on its Paragraph 6 of 30 August 2003<sup>9)</sup>. The Declaration and Decision are

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3) WHO Bulletin (2004), p. 61, "The World Medicines Situation" WHO/EDM/PAR/2004.5

4) WHO Commission on Macroeconomics and Health. See Integrating Intellectual Property Rights and Development Policy", Report of the Commission on Intellectual Property (Sep. 2002), available at [http://www.iprcommission.org/documents/final\\_report.htm](http://www.iprcommission.org/documents/final_report.htm) at 1.

5) Of an estimated 40 million people living with HIV/AIDS globally, approximately 95% live in developing countries ("Treating 3 million by 2005: Making it happen – the WHO strategy" (World Health Organization: Geneva, 2003) at 3), see also Edwin Cameron, 'Patents and Public Health: Principle, Politics and Paradox', **Inaugural British Academy Law Lecture held at the University of Edinburgh, 19 October 2004**, available at <http://www.law.ed.ac.uk/script/newscrip/home.htm>.

6) See Susan K. Sell, 'TRIPs and the Access to Medicines Campaign' (2002) 20 Wis. Int'l L.J. 498-509 at 500.

7) Ibid.

8) Declaration on the TRIPS Agreement and Public Health, WTO Res. WT/MIN (01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001, available at [www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_TRIPs\\_e.doc](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPs_e.doc)

9) Implementation of Paragraph 6 of the Doha declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 and Corr.1, 1 Sep. 2003 available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para\\_6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para_6_e.htm)

related to national health emergencies, viz., HIV/AIDS, TB, Malaria and other epidemics. To make this decision as a part of the TRIPS Agreement, the WTO members on 6 December 2005 approved changes to the TRIPS Agreement in the form of Article 31*bis* making permanent the decision on patents and public health.<sup>10)</sup> The amendment will become part of the TRIPS, after being adopted by two-third of its members.

The adoption of the Doha Declaration, the Waiver Decision of 30 August 2003<sup>11)</sup> and the Article 31*bis* Protocol of amendment, reflects international consensus on the true balance TRIPS strikes in patent protection. Article 31*bis* has been adopted to address the problem with Article 31 (on compulsory licenses) of the TRIPS , which allows a country to issue a compulsory license that only covers drugs made—and predominantly used—within the country's borders. This is an insurmountable obstacle for many poor countries, which have no or insufficient manufacturing capacity in the pharmaceutical sector and desperately need cheap medicines to combat epidemics such as HIV/AIDS, malaria and tuberculosis.

The new rules under the Declaration and Article 31*bis* (also called Para 6 System), however, have raised few pertinent questions, viz., whether the nations with no or insufficient manufacturing capacity benefit after the system becomes operative? Will they be able to rely on imports of needed drugs from other countries? These questions are particularly significant in the context that most of developing countries have switched over to product patents from January 1, 2005, thereby reducing the scope for generics and making access to cheaper drugs more difficult. It will lead to sharp increases in prices of drugs.<sup>12)</sup> The problem of access to drugs has further been aggravated by TRIPS-plus agreements concluded by developed countries with developing countries seeking higher levels of IPR protection than that provided in the TRIPS Agreement and also imposing restriction on the importation of generics or issuance of compulsory licenses.

This article takes an account of the developments leading to the adoption of the Doha Declaration and amendment to the TRIPS (Article 31*bis*), and the TRIPS provisions on compulsory licensing. It examines the Doha Declaration, the Decision of 2003 and Article 31*bis*, followed by an account

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10) Implementation of paragraph 11 of the General Council Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [the “Decision”], WTO Doc. IP/C/41, 6 December 2005. The Decision and Article 31*bis* give effect to paragraph 6 of the Doha Declaration.

11) 2003 Decision on patents and public health, sometimes referred to as the “waiver” on public health.

12) See, J. Watal, “Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPS Agreement”, 23 *The World Economy* 733-752 (5:2000); C. Fink, *How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries*, World Bank Policy Research Paper No. 2352, World Bank, Washington DC., see also Oxfam, “Generic Competition, Price and Access to Medicines” Oxfam Briefing Paper No. 26, Oxfam, Oxford (2002). See, <http://www.oxfam.org.uk/policy/paper/26generic.html>

of the implementation by countries of the Decision/Article 31*bis*, wherein the case of India has been taken up specifically as India has remained a major supplier of generics in poor countries. As concluding remarks, it attempts to look into the viable solution to paragraph 6 problem of Doha Declaration in case the Decision and TRIPS amendment does not work.

## II. Doha Declaration – the Context

The impact of TRIPS was beginning to be felt by developing countries, particularly in Africa and other less developed countries in the late 1990s, just as the devastating effect of the HIV/AIDS pandemic deepened. Prices of life-saving medicines were no longer within the reach of the people even as they became more urgently indispensable to preserve lives. Efforts made by certain developing countries, like Thailand, Brazil and South Africa during this period, to ensure access to medicines for their people by invoking the flexibility provisions of the TRIPS Agreement were opposed by pharmaceutical companies.<sup>13)</sup> South Africa<sup>14)</sup> and Brazil<sup>15)</sup> came under pressure for introducing or maintaining legal provisions concerning compulsory licensing in their patent laws that were considered incompatible with WTO by the USA and EU.

The Brazilian patent law under Article 68 permits the use of compulsory licensing.<sup>16)</sup> A threat by the Brazilian government to invoke this law to ensure access to HIV/AIDS medications for its citizens led to the filing of a petition by the United States before the WTO panel opposing the action of the Brazilian government. This petition was later withdrawn, by which time the Brazilian government through its threat, had forced pharmaceutical companies to reduce prices of patented HIV/AIDS drugs in that country.<sup>17)</sup> In the case of South Africa, 39 pharmaceutical companies

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13) It is however to be noted that less than 5% medicines of WHO's essential drugs list are protected by patents; patent protection for HIV/AIDS exists in just over 20% of 53 African nations with no patents whatsoever in 13 countries.

14) South Africa in 1997 amended its law to provide new rules regarding compulsory licensing, parallel imports and price regulations of medicines. The Pharmaceutical Manufacturers' Association of South Africa challenged the Act and argued that it is against the South Africa's TRIPS obligations. The USA and EU supported their case. An international campaign in support of South Africa led to the withdrawal of the case in 2001.

15) In June 2001, the USA requested consultations with Brazil under the WTO dispute settlement mechanism. US argued that allowing compulsory licenses for failure to work locally is inconsistent with Art. 27.1 of the TRIPS. Dispute was subsequently settled bilaterally.

16) Industrial Property Law Act No. 23 (1998), which provides: 'A patent owner shall be subject to the grant of compulsory license of his patent if the rights resulting there from are exercised in an abusive manner or if the patent is used in abuse of economic power, as proven by an administrative or judicial decision pursuant to the provisions of the law.'

17) In June 2001, the USA requested consultations with Brazil under the WTO dispute settlement mechanism. US argued that allowing compulsory licenses for failure to work locally is inconsistent with Art. 27.1 of the

instituted a court case against the South African government for enacting a new patent law in 1997,<sup>18)</sup> challenging sections 15C and 22C of the law that permit the South African government to use both parallel importation and compulsory licensing respectively in the wake of the HIV/AIDS pandemic in the country.<sup>19)</sup> The pharmaceutical companies, backed by the United States, alleged that the new law contravened the TRIPS Agreement and the Constitution of South Africa 1996. However, under pressure from civil society groups and non-governmental organizations (NGOs) across the globe, the pharmaceutical companies withdrew the case in 2001. The case however provoked a clarification to the so-called TRIPS flexibility especially regarding public health. It also underlined the fact that developed countries that exercised trade pressures in order to safeguard interests of pharmaceutical companies would be under pressure even within their own territory.<sup>20)</sup> Thus, the lack of access to medicines in Africa and other less developed countries and the resulting public health crises caught widespread international attention.<sup>21)</sup> During this period two important meetings took place at the international level in 2001. One was the United Nations General Assembly Special Session on HIV/AIDS known as the Declaration of Commitment.<sup>22)</sup> The other was the Abuja Declaration on HIV/AIDS and other related diseases by African leaders.<sup>23)</sup> The issue of access to medicines was also taken up by the World Health Organization, and in 2001 its Assembly addressed the need to evaluate the impact of TRIPS Agreement on access to drugs, local manufacturing capacity and development of new drugs.<sup>24)</sup> As

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TRIPS. Dispute was subsequently settled bilaterally. See Joint Communication of Brazil- United States, June 25, 2001.

18) . See Medicines and Related Substances Control Amendment Act No. 90 (1997).

19) Pharmaceutical Manufacturers' Association of South Africa v. *President of the Republic of South Africa*, Case No. 4183/98 (filed 18 February 1998) (HC), available at <http://www.fordham.edu/law/faculty/patterson/tech&hr/materials/phamace.txt>.

20) E.'t Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines', 3 *Chicago JIL* (2002) p. 31. See also, Ebenezer Durojaye, "Compulsory Licensing and Access to Medicines in Post Doha Era; What Hope for Africa?", *LV Netherlands Int'l Law Review (NILR)* 33-71, at 41 (2008)., available at <[http://journals.cambridge.org/download.php?file=%2FNLR55\\_01%50165070X08000338a.pdf](http://journals.cambridge.org/download.php?file=%2FNLR55_01%50165070X08000338a.pdf)>

21) See Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria, Commission on Human Rights Res. 2004/26, UN Doc. E/CN.4/2004/127 (April 16, 2004), available at [http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN\\_4-RES-2004-26.doc](http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2004-26.doc). For discussions of TRIPS developments in relation to access to medicines, see generally UNCTAD-ICTSD, *Negotiation Health: Intellectual Property and Access to Medicines* (Pedro Roffe et al. eds., 2006); Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health", 99 *Am. J. Int'l. L.* 317 (2005).

22) UN Declaration of Commitment on HIV/AIDS, 25-27 June 2001, UN GAOR, 26th Special Session, Res. 33/2001.

23) African Summit on HIV/AIDS, Tuberculosis and other Related Infectious Diseases, Abuja-Nigeria, 24-27 April 2001, OAU/SPS/ABUJA/3.)

24) Resolutions WHA54.10 and WHA54.11, WHO website: <C:/Documents and Settings/Owner/Desktop/WHO> Doha Declaration on the TRIPS Agreement and Public Health.

a run up to the Doha Ministerial Meeting, upon the request of the African Group, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and Public Health.<sup>25)</sup>

The HIV/AIDS pandemic in Brazil and South Africa also generated a fundamental debate on the relationship between human rights and intellectual property particularly between patents and right to health in the different UN human rights bodies.<sup>26)</sup> According to some critics, the minimum standards of intellectual property protection set by TRIPS Agreement are too high for most of the developing countries, thereby putting them under tremendous pressure to adopt legislation that is not adapted to their specific needs. It limits their right to follow their human rights agenda and a large segment of society remains deprived of basic human rights. Right to health is recognized in major international human rights instrument<sup>27)</sup> which requires the easy availability and accessibility of all essential necessities to everyone. Right to health depends upon the availability, acceptability, quality and non-discriminatory, physical as well as economic, accessibility of health goods and health services.

The proper balancing between the rights of the IP owner and social objectives of the TRIPS Agreement are evident from Articles 7 & 8 of the Agreement,<sup>28)</sup> and its “regulatory exceptions” (in Article 6, Article 31 for compulsory licensing, Article 40 concerning abuses of IPRs), and the appropriate scope of IP protection raise numerous issues. These provisions however provide sufficient flexibility to TRIPS Members to address the health needs. Article 6 relates to exhaustion of IP rights and leaves the issue of parallel imports open and countries may decide for themselves

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25) For the background in the adoption of the Doha Declaration, see Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO, 2002). WHO Doc. WHO/EDM/PAR/2002.3, pp. 1-3, available at <<http://www.who.int/medicines/areas/policy/WHO-EDM-PAR-2002.3.pdf>>.

26) United Nations High Commissioner for Human Rights, Sub-Commission on Human Rights resolution 2001/21, “Intellectual Property and Human Rights”, Doc. E/CN.4/Sub.2?Res/2001/21, available at <http://www.unhchr.ch/huridoca.nsf>

27) Art. 25, UDRH states: “Everyone has the right to a standard of living adequate for ... health and well-being of himself and his family, including food, clothing, medical care and the right to security in the event of ... sickness, disability.... Motherhood and childhood are entitled to special care and assistance....” Articles 7, 11 and 12 of ICESCR; Articles 10, 12 and 14 of CEDAW; Art. 5 of CERD; and Art. 24 of CRC are related to health.

28) Art. 7 of the TRIPS provides: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” Art. 8 reads: “Members may, in formulating or amending their national 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.”

on this. Under Article 31, members may grant compulsory licenses for lack of or insufficiency of working of an invention, to remedy anti-competitive practice, for cases of emergency, government use and on other public interest grounds. Article 40 aims at curtailing the abuses of IPRs in contractual licenses. Art. 30 empower the Members to curtail the exclusive rights of the patentee, including the right to produce and export patented drug under compulsory licenses issued in the importing country. In national emergencies, countries can adopt a range of other measures to improve access to medicines in line with Arts. 7 and 8 of TRIPS.

The fact, however, remains that many developing countries lacks even the capacity to produce formulations and only a few of these countries invest in R & D or have pliable R & D capabilities for new drugs or even to conduct research in pharmaceutical sector. The only hope for these countries is to import generic drugs through compulsory licensing. Generic drugs can improve healthcare and reduce the monopoly of the patent holder, but the possibility to import is remote and debatable under the existing WTO/TRIPS regime.

### Compulsory Licensing Under TRIPS Agreement

To protect against abuses such as excessive pricing and a failure to satisfy local demand, many patent systems have historically made provision for compulsory licenses, which may allow for the introduction of generic competition without the patent holder's consent. But a systematic use of compulsory licenses is stated to effect adversely innovation and investments,<sup>29)</sup> reducing incentives for enterprises to engage in R&D, which may diminish global welfare by lowering the future stock of useful inventions. However, the benefit to developing countries of increased R&D in the developed countries is often remote, and there is no evidence that the granting of compulsory licenses has led to a reduction in R&D investment.<sup>30)</sup> Compulsory licenses may help in putting a downward pressure on prices. Compulsory licenses are permitted under Article 5A (2) of the Paris Convention. They may constitute a strategic tool for improving the negotiating position of the government vis-à-vis the patent holder to access a particular invention.

TRIPS Agreement allows compulsory license for the domestic use under Article 31. However, Article 31 of the Agreement sets forth a number of terms and conditions for the granting of compulsory licenses. These include a case-by-case determination of compulsory license

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29) Kommerskollegium, *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave health problems?* (Report of the National Board of Trade, Sweden, 2008:2 [www.kommers.se](http://www.kommers.se)) p 7.

30) See S.K. Verma, "TRIPS – Development and Transfer of Technology," 27 *International Review of Industrial Property and Copyright Law* 331 (1996); F.M. Scherer, *Comments* in Robert Anderson and Nancy Gallini (Eds.) *Competition policy and intellectual property rights in the knowledge-based economy*, University of Calgary Press, Alberta 1998.

applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary license, limited scope and duration of use of license, non-exclusivity and non-assignability of license, use predominantly for the supply of domestic market (this condition is not applicable in case to remedy the anti-competitive practice), license to be terminated after the circumstances cease to exist for its issuance, and the adequate remuneration to be paid to the right holder. Where compulsory licenses are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived to obtain a voluntary license from the patent holder. It leaves Members full freedom to stipulate other grounds, such as those related to non-working or failure to work of patents, public health or public interest as grounds of issuance of compulsory license.

While countries may authorize, pursuant to Article 31 of the TRIPS Agreement<sup>31)</sup>, the issuance of non-voluntary and non-exclusive uses of patents, paragraph (f) of Article 31 stipulates that “any such use shall be authorized predominantly for the supply of the domestic market” of the Member authorizing such use, “subject to certain exceptions.”<sup>32)</sup> The import of the provision is unclear. It has been argued that compulsory license, under this provision, can be used for local consumption and not for export. Thus, the provision is of no avail to developing countries and LDCs if they lack technological capacity to manufacture generics locally.<sup>33)</sup> However, the word ‘predominantly’ in Article 31 (f) does not quantify the share in the domestic market of the supply by the licensee of the production under the compulsory license, but it certainly is more than fifty percent. It means that under Article 31 (f), the government can authorize the licensee to produce for export, so long the licensee predominantly produces for the domestic market and imports are not in competition with the patent holder in the importing country.<sup>34)</sup> But it is debatable whether ‘predominantly’ will help in exporting the generic drugs to countries in dire need of drugs for epidemics/pandemics, with no manufacturing capacity, nor would it allow the importing country to issue license to import generics of life-saving drugs. It will hamper the access to medicines to countries with no or insufficient capabilities in two ways: (i) by limiting availability of imported drugs made under compulsory license, it invariably restricts countries that are unable to support manufacturing under compulsory license (or where patent protection is not in force, in the availability of supply of imported generic drugs); and (ii) requiring licensees to restrict to predominant part of their production to domestic market, limits flexibility of countries to authorize the export of

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31) Article 31 deals with the conditions in case of grant of compulsory licenses: “Other use without Authorization of the Right Holder”.

32) As an exception, Article 31 (k) provides: “Members are not obliged to [this condition] ... where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. “

33) E. Durojaye, *op. cit.* 20, at 50.

34) A.S. Lowenfeld, *International Economic Law*, 108 (Oxford University Press 2002, London)

compulsory licensed drugs and thus to exploit economy of scale.<sup>35)</sup> Apparently, Article 31 (f) does not prohibit *per se* the issuance of compulsory license for export purposes with some restrictions on such exports, viz., safeguarding the rights of the patent holder.

In the case of national emergency, other circumstances of extreme urgency and public non-commercial use, prior negotiation with the patent holder need not be pursued. The license can be terminated as soon as the circumstances which led to its granting no longer exist (Art. 31 (g)). This provision is a big disincentive for applicants of compulsory license, since the licensee may be exposed to the revocation at any time.<sup>36)</sup> On the other hand, for the granting of compulsory license, few policy considerations are necessary to establish, i.e., (a) the party being granted license within the country has the capability to exploit it through manufacturing or import. This requires financial ability or technical capability of the country concerned; (b) there must be evidence of an existing sound legal and political structure to permit the granting and monitoring of the license.

Going by these pre-conditions for exploiting compulsory licenses, only few developing countries and developed countries would be able to successfully use these exceptions. Countries without domestic production capacity could not use them, nor was it allowed for countries with production capacity to grant compulsory license for export to countries without such capacity. Many LDCs lack financial resources and technical expertise to meet these pre-conditions. Nevertheless, the issuance of compulsory license, especially in case of import, remains a viable tool in advancing access to medicines and right to health in most of these countries, because it may promote competition and break the monopoly enjoyed by the patent holder and facilitate access to cheap drugs.<sup>37)</sup>

In the recent past, both Brazil and Thailand have issued compulsory licenses for *Efavirenz*, a drug used to treat people infected with HIV/AIDS. Thailand overrode Merck & Co.'s patent on

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35) F.M. Abbott, *WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries*, a report prepared for Intellectual Property Rights Commission p. 17 (Washington DC, Intellectual Property Rights Commission 2002)

36) UNCTAD –ICTSD - Resource Book on TRIPS and Development, Ch. 25: Patents: Non-Voluntary Uses (Compulsory Licences) 460, at p. 474 (2005, Cambridge University Press).

37) The provisions for compulsory licenses are provided in the developed countries' legislations. Even Canada and the United States threatened to use compulsory license over Bayer's *ciprofloxacin*, which was useful for the treatment of anthrax after the events of 9/11/2001. Canada issued a compulsory license and ordered a million tablets of generic version from a Canadian company. Later Canada withdrew this decision and reached an agreement with the patent-holder. The USA could manage to win a major price concession from Bayer. See D. Alexander, "Duplicated' drugs life-line for millions in Africa: US anthrax scare renews debate on generic drugs law", *The Monitor* 15 (1 Nov. 2001; E. Durojaye, *op. cit.* 20, at 49

*Efavirenz* in December 2006<sup>38)</sup>. Brazil overrode it in May 2007.<sup>39)</sup> Both the countries justified their action under their national law.<sup>40)</sup> Both the countries acted under Article 31 of the TRIPS. Article 31 (b) of TRIPS, explicitly states that governments do not need to consult with patent holders when issuing a compulsory licence for national emergencies or public non-commercial use.

However, to make the compulsory licenses workable, developing countries need to establish workable laws and procedures to give effect to compulsory licensing, and provide appropriate provisions for government use. Article 30 of the TRIPS Agreement is also helpful in this connection, which authorizes the members to provide limited exceptions to exclusive rights conferred on the patentee under 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...”<sup>41)</sup> This provision can be used to produce and export patented drug to another member to meet the public health needs if a compulsory license has been issued in the importing country.<sup>42)</sup>

Compulsory licenses have rarely being used by developing countries for number of reasons, viz., absence of administrative and legal infrastructure; fear of sanctions; use predominantly for the domestic market; non-exclusive nature and limited duration, which make them less attractive for

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38) On 29 Nov. 2006, Thai government issued compulsory license for *efavirenz* (Stocrin), the HIV/AIDS drug, still under patent by Merck, details available at <http://www.ip-watch.org/weblog/index-php?p=499>. While other developing countries such as Zambia and Indonesia have issued compulsory licences for HIV/AIDS drugs in the past, the Thai move is significant for its longer duration and the fact that it opens the door to competitive imports of generics from India. Both steps will mean increased downward pressure on drug prices.

39) Ministerial Ordinance No. 866, dated 24 April 2007 was issued. See TWN Third World Network, May 3, 2007 <http://www.twinside.org.sg/title2/wto.info/twninfo05073.htm>. Brazil also used the threat of compulsory license against Abbott Laboratories over pricing of protease inhibitor Kaletra (lopinavir/ritonavir) for its STD/AIDS programme,

40) Both, the Thai and Brazilian governments justified their action under TRIPS and, “member countries have a right to issue a safeguard measure to protect public health, especially for universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products.” They maintained that where a compulsory license is issued for “public non-commercial use”, there is no requirement to engage in prior negotiations with the patent holder. See *op. cit.* 38 and 39.

41) The use of this provision by Canada to speed up the introduction of generic drugs in Canada has already become controversial on the EU’s complaint against Canada before the WTO dispute settlement body. See Panel Report in WT/DS114/R, *Canada—Patent Protection of Pharmaceutical Products*, adopted on 7 April 2000. The use of this provision in public health crisis is a matter of interpretation.

42) The European Parliament had adopted an Amendment to the European Directive on 23 October 2002, which provides, “*Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.*” Art. 10 (4), sub-Para 1a (new), Directive 2001/83/EC.

the holder of compulsory license. In certain cases, unless these issues are addressed, compulsory license will remain only a paper-tiger, though aimed at preventing abuses of the IP system.

### III. DOHA DECLARATION ON TRIPS AGREEMENT AND PUBLIC HEALTH

In 2001, a special Ministerial Declaration at the WTO Ministerial Conference in Doha on “The TRIPS Agreement and Public Health”<sup>43)</sup> was adopted to clarify ambiguities between the need to apply the principles of public health and the terms of the TRIPS Agreement. The Declaration was adopted in the background of growing concerns that patent rules might restrict access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, including HIV, tuberculosis and malaria. The Declaration has seven paragraphs. In the opening paragraph, the Members 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 need for national and international action to address the issue.

The Declaration affirms that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and 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.”<sup>44)</sup> . Paragraph 5 in its relevant part states:

5 (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

(c) Each Member has the right to determine what constitutes national emergency or other circumstances of extreme urgency...

(d) ... each member [is] free to establish its own regime of [...] exhaustion without challenge.... Thus, the use of exceptions such as compulsory licenses and their grounds for invocation are left to the Members to decide rather limited to emergency or urgent situation only as well as to determine its own regime of exhaustion of IPRs and may thereby decide to allow parallel imports. From a legal perspective, these provisions do not add any thing new to the TRIPS obligations. It merely clarifies the extent of existing rights and obligations of members under TRIPS and reaffirms their right to use, to the full, the provisions which provide flexibility for this purpose. While paragraph (b) relates to Members’ discretion with regard to the grounds upon which compulsory licenses are granted, paragraph (c) refers to Article 31 (b), making it clear that the

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43) Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, see WTO Doc. WTO/MIN (01)/DEC/2, 20 Nov. 2001 available at <[www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_TRIPS\\_e.doc](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.doc)>

44) Ibid. Para. 4.

definition of the term ‘national emergency’ and ‘other circumstances of extreme urgency’ is up to Members’ discretion. Paragraph (d) reiterates Article 6 of TRIPS Agreement. This leaves Members considerable room for the pursuit of public policy objectives, especially those related to public health. The Declaration, however, was unable to find a solution to Article 31 (f) of the TRIPS Agreement, perceived as a stumbling block to the use of compulsory licensing by developing countries.

During the Ministerial Meeting of WTO Members in Doha, the issue of the incapacity of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector also came up, which could face difficulties in making effective use of compulsory license under the TRIPS to meet the public health crisis. Therefore in the Declaration, recommendation was made to find ‘expeditious solution’ to this problem. Para 6 of the Doha Declaration recognizes that Members with no or insufficient manufacturing capacities in pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS Agreement and instructed the TRIPS Council to find an expeditious solution to this problem. Paragraph 6 of the Declaration reads:

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 report to the General Council before the end of 2002.

The Declaration also granted extension of transition period to least-developed countries under Article 65 of the TRIPS Agreement up to January 1, 2016.<sup>45)</sup> However, the extension is limited to the obligations under provisions in the TRIPS Agreement relating to patents and marketing rights, and data protection for pharmaceutical products.<sup>46)</sup> From a public health perspective, this extension of the transition period for LDCs is of significant importance. It is recognition of the implications of patent protection on public health, and thus, it is expected that all LDCs adopt the necessary measures to use the 2016 transition period in relation to pharmaceutical patents and test data protection. However, most of the least-developed countries already grant patent protection to pharmaceuticals under different bilateral or regional FTAs, thus leaving practically

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45) Para 7 of the Doha Declaration allowed the formal introduction of patent protection for pharmaceuticals and of the protection of undisclosed regulatory data in least developed countries until January 1, 2016. Earlier it was up to January 2010. See Para. 7 of the Doha Declaration.

46) The Decision was taken on Article 70.9, adopted by the General Council on 8 July 2002, with a view to ensure attainment of the objectives of paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health. It says least-developed countries will not have to give exclusive marketing rights to pharmaceuticals that are subject of a patent application until 1 January 2016. Thus, LDCs were still obliged to implement the rest of their obligations under the TRIPS Agreement as of 2006

very little effect of the apparent concession granted under the Declaration.

The Doha Declaration represents the first public acknowledgement by the WTO that all may not be well with TRIPS. In expressly identifying the Paragraph 6 problem, it instructed ‘the Council for TRIPS to find an expeditious solution to this problem’.<sup>47)</sup> The Declaration responds to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines in the interest of public health in general, without limitation to certain diseases. While acknowledging the role of intellectual property protection “for the development of new medicines”<sup>48)</sup> , the Declaration specifically recognizes concerns about its effects on prices<sup>49)</sup> . The TRIPS when taken together with the Declaration, does not say that a government has to declare a national or health emergency before issuing a compulsory license. A national emergency can be an implicit reason, but this does not have to be stated, as it is covered in TRIPS Article 31. The Declaration clarifies that all Members states have the right to grant compulsory license to protect public health and improve access to medicines. Under the Declaration, each Member can determine what constitutes a national emergency or other circumstances of extreme urgency; and that public health crisis, such as HIV/AIDS, Tuberculosis, malaria and other epidemic can constitute such circumstances.

The reference to some specific epidemics does not imply that the Declaration is limited to them. It covers any “public health problem”<sup>50)</sup> , including those that may be derived from diseases that affect the population in developing as well as developed countries, such as cancer or diabetes. Thus, it may be invoked in all public health emergencies and may cover not only medicines, but any product, method or technology for health care.<sup>51)</sup>

The Declaration, however, did not change materially the then existing situation under the TRIPS Agreement as it did not provide any mechanism or exception to TRIPS obligations under Article 31 for the use of compulsory licensing. The Declaration nevertheless recognized differentiation in patent rules necessary to protect public health and it may easily be concluded that pharmaceutical patents stand on a different footing under the WTO/TRIPS dispensation. It singled out public health, which had been the controversial issue since the adoption of TRIPS Agreement, particularly pharmaceutical patents.

The legal status of the Declaration is also a debatable issue. Being a declaration, it is considered

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47) Op. cit. 43, Para 6.

48) Ibid, Para 3

49) Ibid, Para 7.

50) In Para 1 of the Declaration, members 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.” (emphasis added).

51) Carlos M. Correa, *op. cit.* 25, p. 5 The definition of ‘pharmaceutical product’ in the Decision covers active pharmaceutical ingredients (APIs) and diagnostic kits.

to be merely of persuasive value in interpreting the TRIPS Agreement and is 'legally not binding'.<sup>52)</sup> Correa, however, states that it is a Ministerial Decision with legal effects on the members and on the WTO bodies, particularly the Dispute Settlement Body (DSB) and the Council of TRIPS.<sup>53)</sup> But it will certainly have the persuasive value for the interpretation of the text of the Agreement.

#### IV. DECISION ON PARAGRAPH 6 AND ARTICLE 31*bis*

In furtherance of paragraph 6 of the Doha Declaration, which mandated the TRIPS Council to find an *expeditious solution* (before the end of 2002) to the problem of WTO members with little or no manufacturing capacities in the pharmaceutical sector, the TRIPS Council adopted a Decision (the Decision)<sup>54)</sup> on 30 August 2003,<sup>55)</sup> preceded by the reading of the Chairperson's statement. The Decision lays down the grounds for the use of compulsory license by the importing and exporting countries. It establishes a mechanism under which the restriction of Article 31 (f), that limits compulsory licensing *predominantly* to the supply of the domestic market, will be waived for an exporting Member when it is requested by an eligible importing Member to supply products under compulsory license issued in the exporting country. Similarly, the requirement of payment of adequate remuneration to the right holder on compulsory licensing under Article 31 (h) is waived for the importing country.

The Decision in paragraph 1 (a) defines 'Pharmaceutical product' as 'any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active pharmaceutical ingredients (APIs) necessary for its manufacture and diagnostic kits needed for its use would be included.'<sup>56)</sup> This definition is sufficiently broad and requires members other than least-developed country members to submit a notification of their

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52) A.O. Sykes, "TRIPS, Pharmaceuticals, Developing Countries and the Doha 'Solution'", 3 *Chicago JIL* pp. 47-68 (2002).

53) Carlos M. Correa, *op. cit.* 25, pp. viii and 34

54) For an analytical account of the Decision, see generally, Paul Vandoren and Jean Charles van Eeckhaute, "The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", 6 *JWIP* 779 (2003); Frederick M. Abbott, *The containment of TRIPS to Promote Public Health: A Commentary on the Decision on Implementation of Paragraph 6 of the Doha Declaration* (2004); Carlos Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO, 2004).

55) See *op.cit.* 9. The 2003 Decision is often called the paragraph 6 System because it implements Para 6 of the 2001 Doha Declaration on TRIPS and Public Health

56) This subparagraph is without prejudice to sub paragraph 1 (b), which defines an 'eligible importing country'.

intention to use the system in whole or in part, which may be modified at any time.<sup>57)</sup> The notification establishes a Member as an ‘eligible importing Member’.<sup>58)</sup>

The Decision sets out a detailed process whereby one country can issue a compulsory license to import drugs and a second country can issue a compulsory license to export the drugs to the needy country. Paragraph 2 of the Decision establishes conditions for use of the waiver. The importing Member must notify the TRIPS Council of its needs and (except for LDC Members) must indicate that it has determined that it has insufficient or no manufacturing capacity for the product (s) in question. The latter determination is made in accordance with the Annex to the Decision.<sup>59)</sup> When there is a patent in the importing Member, it must indicate that it has issued, or intends to issue, a compulsory license (except for LDC Members that elect not to enforce patents pursuant to Paragraph 7 of the Doha Declaration). The exporting Member must notify the TRIPS Council of the terms of the export license it issues, including the destination, quantities to be supplied and the duration of the license. The products supplied under the license must be identified by special packaging and /or colouring/shaping. Before quantities are shipped, the licensee must post on a publicly accessible website the destination and means it has used to identify the products as supplied under the system.

Waiver from remuneration requirement for the importing country under Article 31 (h) is provided in paragraph 3, which provides that if adequate remuneration for the same product has been paid by the exporting country under a compulsory license, the requirements of Article 31 (h) shall be waived for the eligible importing member.

Paragraph 4 requires an importing member country to take reasonable measures within its means and proportionate to its administrative capacity to prevent diversion of products imported under the system. The Decision does not specify the nature of such means but if an importing member experiences difficulty in taking measures to prevent diversion, developed Member countries can, on request, provide technical and financial cooperation. Other Members are required to prevent the importation of diverted products into their territories by using the means which are available

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57) Such a notification does not need to be approved by a WTO body in order to use the system set out in the Decision, see paragraph 1 (b) of the Decision.

58) ‘Eligible importing Member’ under the Decision is any least developed country Member, and any other Member that has made a notification to the Council for TRIPS of the intention to use the system as an importer, it is being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use. It is understood that some Members will not use the system as importing Members and it lists 23 countries in this category, see fn 2 & 3 to paragraph 1 (b) of the Decision

59) The Annex established the criterion in either of the following two ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity, it is currently insufficient for the purposes of meeting its needs.

under the TRIPS Agreement. If these measures prove to be insufficient, the TRIPS Council may review the matter at the request of that Member (paragraph 5).

Paragraph 6 provides an additional waiver of Article 31 (f) for regional trading arrangements in order to enhance the purchasing power and facilitating the local production of pharmaceutical products, where at least half are least developed countries, like in Africa. This waiver allows a Member to export to countries throughout the region under a single compulsory license issued under Article 31 (f), although it does not expressly waive the requirement for licenses to be issued by importing countries of the region. The main benefit of the waiver may be to allow the import of APIs formulation into finished products and export throughout the region that share the health problem in question. It will also help in addressing the problem of the size of the market of importing country, which is a determinant factor for the licensee to export to make it financially viable. It is understood that this will be without prejudice to the territorial nature of the patent rights in question. The need for the grant of regional patents has also been recognized.

Paragraph 7 recognizes the desirability of promoting transfer of technology to least developed countries and capacity building in the pharmaceutical sector in pursuant of Article 66.2 of the TRIPS Agreement and paragraph 7 of the Declaration. The annual review of the system by the TRIPS Council will be enough as the renewal of the waiver (paragraph 8). This Decision is without prejudice to rights, obligations and flexibilities that Members have under the provisions of TRIPS Agreement (such as the potential for exports under Article 30 or Article 31 (f) to export pharmaceutical products under a compulsory license). Paragraph 10 precludes any nullification or impairment action under Article 23 of the GATT against any measure taken in conformity with the provisions of the waiver. The preceding Statement of the Chairman indicated, among others, that the Members will act in good faith in using the Decision, to protect public health and not to pursue industrial or commercial policy objectives by way of waiver. Any Member, if having concerns about the implementation of the Decision, may utilize the good offices of the Director-General of the TRIPS Council, with a view to find a mutually acceptable solution (paragraph 3 of the statement).

While the Decision was a consensus statement of the members of the WTO in protecting the public health under the TRIPS Agreement, it has raised a fair amount of criticism. It has been criticized as administratively too complex and burdensome to be a truly effective means to remove obstacles to access to cheaper drugs. Among the scholars, it is a common view that the Decision will create more hurdles than solution to paragraph 6 problem of the Doha Declaration. It is saddled with many administrative pre-requisites, which will hamper the very purpose of the Para 6 System. A country in need of required drugs to meet the health emergency, and lacking manufacturing capacity will have to go through many layers of procedure. It will have to invoke compulsory license to request another government or suspend the rights of patent holder and the

other government will provide license to local firm (s) to produce and export the needed drugs. They have to notify the TRIPS Council about the intention to use this system and the country that has issued the compulsory license has to meet many conditions. All these measures not only will delay the manufacture and supply but increase the cost of the drugs.<sup>60)</sup> Decision is termed to be a temporary solution which is difficult to operate. It is considered not faithful to Doha Declaration on TRIPS and Public Health.<sup>61)</sup>

### Article 31bis

Two years after the adoption of the waiver, on 6 December 2005, the TRIPS Council adopted the Protocol amending the TRIPS Agreement, by inserting Article 31bis after Article 31 and Annex after Article 73.<sup>62)</sup> Annex to the Protocol specifies the provisions of Article 31bis. The new Article reiterates the provisions of the Decision. The amendment, the first ever to the 1994 TRIPS Agreement, implements a waiver that was temporarily agreed on 30 August 2003, making it possible for countries to export medicines under compulsory license to countries with no or inadequate production facilities. Article 31bis provides for limited exceptions to Article 31 (f), by allowing members to issue compulsory licenses for the production and export of pharmaceuticals to an eligible importing Member.

The amendment is in no way different in elements substantially from the Decision, save for some slight changes in structure. It is merely a “technical exercise” with no change to Para 6 System. The small changes in the language between the two are inserted to bring the Article in the format of the TRIPS. The text of the Article contains the entire August 30 Decision barring the preamble and paragraph 11 of the Decision which contained the mandate to find a permanent solution and established a waiver from the requirements of Article 31 (f) of the Agreement. It is also to be noted that the Decision remains operative in a WTO member state until the amendment takes effect in that member state (Para 11 of the Decision). In other words, amendment has in no way abolished the Decision. Since the effective date of the amendment is not clearly ascertained, the implication of this is that the Decision may still be binding on members of the WTO.

The Protocol amending the TRIP Agreement has three main parts. Firstly, there is Article 31bis which contains about five paragraphs in which the substantive part of the Decision finds a place that tally with the main text of paragraphs 2, 3, sub-paragraph 6 (1), paragraphs 10, and 9 of the Decision respectively. Secondly, the other part of the amendment is the Annex to the TRIPS

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60) K.R. Srinivas, “Interpreting Paragraph 6 Deal on Patents and Access to Treatment,” *Economic And Political Weekly*, 20 Sep. 2003

61) Ebenezer Durojaye, *op. cit.* 20, at 52.

62) *Op. cit.* 10. For the text of Article 31bis, see the WTO website <[http://www.wto.org/english/tratop\\_e/trips\\_e/pharmapatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmapatent_e.htm)>

Agreement which contains 7 paragraphs corresponding in substance to paragraph 1, sub-paragraphs 2 (a), 2 (b) and 2 (c), paragraphs 4 and 5, sub-paragraph 6 (ii) and paragraphs 7 and 8 of the Decision respectively. Finally, there is the Appendix to the Annex to the TRIPS Agreement which corresponds to the Annex to the Decision and deals with assessment of manufacturing capacities for the product in question to be imported by the least developed or developing country concerned (former Annex to the Decision).

In its five paragraphs, Article 31*bis* contains 3 waiver provisions of the Decision: non-application of Article 31 (f), non-violation complaints, and preservation of TRIPS flexibilities. The Annex sets-out terms for using Paragraph 6 system. Paragraph 1 of Article 31*bis* restates paragraph 2 of the Decision; paragraph 2 of the Article reproduces paragraph 3 of the Decision; paragraph 3 incorporates paragraph 6 of the Decision.<sup>63)</sup> Paragraph 4 is paragraph 10 of the Decision and paragraph 5 is the reiteration of paragraph 9 of the Decision.

Annex to the TRIPS Agreement defines in Paragraph 1 the 'pharmaceutical product', 'eligible importing Member' and 'exporting Member' similar to the Decision. In order to give effect to paragraph 1 of Article 31*bis*, to export pharmaceutical product to an eligible importing Member (s), the Annex outlines the terms and conditions to carry out the exports and import of the product (s) by the exporting and importing members. The eligible importing Member (s) needs to make a notification to the TRIPS Council, which should:

- (i) specify the names and expected quantities of the product (s) needed;
- (ii) confirm that the importing member (other than the least developed country member) has insufficient or no manufacturing capacity as established in accordance with the Appendix; and
- (iii) confirm in case of a pharmaceutical product patented in its territory that it has granted or intends to grant a compulsory license in accordance with Article 31 and 31*bis* and the provisions of this Annex.

The compulsory license issued by the exporting Member should contain the following details:

- (i) the amount necessary to meet the needs of the eligible importing Member (s) that may be manufactured under the license and exported to the eligible importing Member (s);
- (ii) clearly identify products produced under the license through specific labelling or marking.

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63) In the case of least developing country, which is a Member of a regional trade agreement, the export to the markets of other developing or least developed country parties to the regional trade agreement facing the same health problem, the Annex clarifies that a joint notification providing the information about the required quantities of the product (s), establishing the insufficient or no manufacturing capacities of the importing countries and confirming that it intends to or has granted compulsory license (where the product is patented in its territory) in accordance with Articles 31 and 31*bis*, by the regional organization (s) on behalf of eligible importing countries, that are parties to the system, with the agreement of those parties, see footnote 4 to the Annex.

Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products, provided that such distinction is feasible and does not impact the prices significantly;

(iii) the licensee is required to post on the website<sup>64)</sup> the following details before the shipment starts:

- a. quantities supplied to each destination; and
- b. the distinguishing features of the product (s)

In addition, the exporting Member is required to notify the Council of TRIPS about the grant of the license and the conditions attached to it. The information will relate to the details of the licensee, the product (s) and the quantity, the importing country/ (ies) and the duration of the license. The notification to be issued by the eligible importing Member (s) need not to be approved by a WTO body, but it will be made available publicly by the WTO Secretariat on its website.<sup>65)</sup>

Reiterating paragraph 4 of the Decision, paragraph 3 of the Annex requires importing country to take measures proportionate to its means to prevent diversion of products imported under the system. In the same vein, paragraph 4 requires other Members to take effective measures to prevent the importation of the products diverted into their territories. Paragraphs 5, 6 and 7 of the Annex restate paragraphs 6, 7 and 8 of the Decision related to exports to regional trading arrangements, transfer of technology and the annual review of the waiver by the Council of TRIPS. In the adoption of Article 31*bis*, it was noted that certain Members will not use the system as importing countries specified in the footnote.<sup>66)</sup>

The new rules of Para 6 System will be applicable where the product is patented in both the exporting and importing countries, both are required to grant compulsory license, but if the product is not patented in the importing country but in the exporting country, only exporting country would grant the license. Where the product is not patented in the exporting country, but in the importing country, new rules will not be used and the importing country will issue the 'regular' compulsory license under Article 31. <sup>67)</sup> Where the product is not patented in both the countries, the new rules are not used, and the product may be imported from any manufacturer. The system will not to be used if local production is feasible, or voluntary licenses have been

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64) Footnote 9 of the Annex provides that for this purpose, the licensee can use its own website or, with the assistance of the WTO Secretariat, the page on the WTO website specified for the system.

65) Cf. footnotes 2 and 5 of the Annex. WTO website for this purpose is: [http://www.wto.org/English/tratop\\_e/public\\_health\\_e.htm](http://www.wto.org/English/tratop_e/public_health_e.htm) .

66) Countries mentioned in footnote 3 of the Annex are: Australia, Canada, European Communities with its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

67) Thailand and Brazil resorted to this option in 2006 and 2007 respectively to import generic drug of patented product of Merck from India, where there was no patent on the product in question. See *op. cit.* 38 & 39.

issued by the patent-holder, or if no patent exists for the pharmaceutical product in the exporting country, or the exporting country is not a member of the WTO.

Article 31*bis*, in accordance with Article X: 3 of the WTO Agreement will be formally built into the TRIPS Agreement after two thirds of the WTO members have accepted the change. As of 15 March 2011, 34 WTO members (including the European Union) have accepted the Protocol.<sup>68)</sup> The amendment will take effect in those members and will replace the 2003 waiver for them. Originally the Protocol was open for acceptance until 1 December 2007, which has since been extended twice until 31 December 2011.<sup>69)</sup> Meanwhile, the 2003 waiver remains in effect.

This amendment of the TRIPS Agreement is aimed at to make it easier for countries with insufficient or no manufacturing capacity for pharmaceuticals to gain access to essential pharmaceuticals at an affordable price. But as it is in the case of the Decision, Article 31*bis* regrettably is saddled with the same administrative hurdles,<sup>70)</sup> as of the Decision to the extent of making it unworkable. The cases in point are of Médecines Sans Frontières (MSF) and Rwanda, the only least developed country to put in use the new rules.

In May 2004, the MSF placed an order under the new rules, outlined in the Decision, for its project in a developing country, which required the MSF to locate a local generic manufacturing company within Canada.<sup>71)</sup> The MSF approached Apotex, one of the big generic pharmaceutical companies in Canada that agreed to produce a three-in-one antiretroviral combination of zidovudine, lamivudine and nevirapine (AZT + 3TC + NVP) drugs, which represent one of the first-line treatment regimens for HIV recommended by the WHO. Apotex had to develop a fixed-dose combination of these drugs to simplify treatment for those in need. As the new fixed-dose combination drug was not included in the schedule of drugs qualified to be exported under the Canadian legislation, it required an amendment of the Canadian law. After the required amendment was put in place, Apotex in 2006 negotiated with the company holding the patent over the proposed drugs to be exported under compulsory license. Apotex was only able to get the go-ahead from the patent holder sometime in August of 2007. In the meantime, the MSF

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68) These members are: the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong- China, China, European Union, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau- China, Canada, Bahrain, Colombia, Zambia, Nicaragua, Pakistan, Macedonia, Uganda, Mongolia, Croatia, Senegal and Bangladesh.

69) See, WTO/TRIPS Council Doc. WT/L/785 21 December 2009; see at <[http://www.wto.org/english/tratop\\_e/trips\\_e/pharmapatent\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharmapatent_e.htm)>

70) Frederick M. Abbott\* and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions", 10 *Journal of Int'l Economic Law* 921-987 (2007:4).

71) R. Elliot, 'Will They Deliver Treatment Access?: WTO Rules and Canada's Law on Generic Medicine Exports', 11 *Canadian HIV/AIDS Law Policy Review* (2006) p. 13.

abandoned the attempt when two Indian generic drug companies started marketing the copies of the certified quality of the same drug at a lower price than Canada. The drug was not patented in India.<sup>72)</sup>

In the case of Rwanda, it notified the WTO on July 19, 2007 to import pharmaceuticals produced under a compulsory license.<sup>73)</sup> Product wanted by the MSF and Rwanda was not on the list of Canadian law and it took three months to put it in the schedule of the Canadian law. Canadian company applied for the compulsory license to export to Rwanda. The license was granted and the patent holders agreed to forgo the compensation on certain conditions. The medicine was the same as in the case of MSF, in which the Indian companies have an edge in terms of price.<sup>74)</sup> These cases indicate the inadequacy of the new rules under Article *31bis* and the August 2003 Decision of the Council for TRIPS devised to resolve the problem of inaccessibility to drugs faced by poor countries. They also highlight the difficulties in successfully invoking the use of compulsory licensing even in developed jurisdictions.

## V. IMPLEMENTATION OF PARA 6 SYSTEM

The Doha Declaration has tried to resolve the pressing problem of access to medicines that had remained a burning issue since the coming into force of TRIPS. However, ever since its adoption in 2001 and the subsequent adoption of the August 30 Decision on the Implementation of paragraph 6 of the Declaration and Article *31bis* on the amendment of the TRIPS Agreement, international consensus has for the most part still not been translated into domestic policy and law. <sup>75)</sup> Legislative amendments are required to enable a country to use the provisions of the Para 6 System as an importing or exporting Member.

Implementation of new rules is, however, independent to whether or not the country has accepted Article *31bis*. So far only a handful of countries, the potential exporters, have taken

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72) See, *op. cit.* 29, p. 9

73) See Notification dated July 17, 2007 (IP/N/RWA/1) by Rwanda under Para 2 (a) on the Implementation of Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health, available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm)

74) See Canadian Notification to the TRIPS Council by Canada dated October 5, 2005 (IP/N/10?CAN?1) under Para 2 (c) on issuing first compulsory license to export generic drug, available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm) .Canada sent 15.6 million pills to Rwanda.

75) See [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm), last visited on 5 July 2011.

legislative measures. Canada,<sup>76)</sup> Norway,<sup>77)</sup> India<sup>78)</sup> and EU<sup>79)</sup> were the first to implement the rules. Now Hong Kong-China, China, Switzerland, Philippines, Singapore, Albania, and Croatia have also made the changes in their laws and notified the WTO.<sup>80)</sup> But most of the potential importing countries have yet to respond. A plausible explanation for this inaction is that most of these countries are now parties to bilateral or regional free trade agreements (FTAs), which has curtailed their flexibilities in utilizing the new Para 6 System rules. The other reasons for absence of notifications under the system could be: the availability of generic drugs outside the patent system (about 60% of drugs under patents have come out of that protection by 2006); legislative changes in many exporting countries, which switched over to product patents in pharmaceuticals, drugs and chemicals, viz, India, by 2005 are recent or they have not been done yet in some cases; and in many cases, there have been voluntary licenses and reduction of prices offered by patent owners.

### Implementation of Para 6 system in India

India is the first among the developing countries, with proven manufacturing capacity in the pharmaceutical sector, to give effect to the 2003 Decision. It has been one of the largest producers of generic drugs and has the capacity to produce them at a very cheap price. India is a major source of low-priced quality medicines and active pharmaceutical ingredients (APIs) as well as a major supplier of vaccines.<sup>81)</sup> India introduced product patents for pharmaceuticals and drugs from 1 January 2005 and amended its patent law in 2005, as mandated by Article 65.4 of the TRIPS. Prior to the adoption of Patents (Amendment) Act, 2005, the Patent Act of 1970

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76) Bill C -9, An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chretien Pledge to Africa) assented on 14 May 2004; see WTO Doc. IP/C/W/464, 15 Nov. 2005. Under the law, non-WTO members do not qualify as importing countries for the purpose of exports. It has been criticized for allowing patent holders to apply for a court order terminating a compulsory licensing or ordering a higher royalty. There is also restriction in lists of drugs that may be subject to compulsory licensing for export, two-year period for the production of the generic drugs and need to seek permission from patent holders before exporting manufactured generic drugs.

77) Regulations amending the Patent Regulations of 20 Dec. 1996, No. 1162, Ss. 107 -109, WTO Doc. IP/C/W/427, 17 Sep. 2004.

78) India inserted a new sec. 92A and amended sec. 90 (1) of the Patents (Amendment) Act, 2005. Published in the Gazette of India, April 5, 2005, and effective January 1, 2005. See also WTO Doc. IP/N/1? IND/D/2-5.

79) EC Regulation 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. Official Journal of the EU L/157/1, 9 June 2006.

80) See WTO Doc. IP/C/57, 10 December 2010 – Annual Review of the Decision on the Implementation of Para 6 of the TRIPS Agreement and Public Health

81) Cheri Grace, “The effect of changing intellectual property on pharmaceutical industry prospects in India and China”, DFID Issues paper – Access to medicines, June 2004.

prohibited product patent for pharmaceuticals, drugs and chemicals. This helped in the growth of a strong generic pharmaceutical industry in India, which now accounts for more than 70 percent of the domestic market, meeting nearly all the demands for formulations.<sup>82)</sup> A significant consequence of this development in the generic pharmaceutical industry is the lower prices of drugs in India compared to other countries of the world. India supplies about half the generic drugs in Africa. After the introduction of the product patents, this may not be possible, though the likely implication of this change has remained uncertain so far. While it may affect the poor countries, particularly which do not have manufacturing capabilities, it will also affect the local population in India, for whom the accessibility to public health services is still far from ideal.

While switching over to product patents in pharmaceuticals, drugs and chemicals, India gave effect to the Doha Declaration and the Decision to fulfill the health needs of its vast population. It contains provisions on compulsory licenses, parallel imports and exportation of drugs to countries with no or insufficient manufacturing capacity to manufacture drugs. Despite switching over to product patent, it is still possible that drugs under patent elsewhere, but which are currently manufactured and marketed in India; and those which are currently not manufactured in India but their patent applications were filed before 1 January 1995 will continue to be available in generic form in/from India. Only new drugs, whose applications were filed in India on or after 1 January 1995, would be product patent protected. They cannot be manufactured, sold or exported without appropriate authorization of the patentee.

In the case of 'mailbox' applications received by India under Chapter IVA (inserted in the Patents Act in 1999<sup>83)</sup> and has been repealed by the 2005), between 1.1.1995 – 31.12.2004, the right of the patentee shall accrue from the date of grant of patent. Enterprises, which were producing and marketing that drug prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of patent (ongoing generic production), will not be subjected to infringement action and patent holder will get reasonable royalty only (S. 11A), provided the manufacturers have made significant investment. The Act, however, does not quantify 'the significant investment' nor does it specify the parameters of 'reasonable royalty'.<sup>84)</sup>

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82) Government of India, Department of Chemicals and Petrochemicals, 'Annual Report (1999-2000)', available at <[chemicals.nic.in/annrep99.htm](http://chemicals.nic.in/annrep99.htm)>

83) The Patents (Amendment) Act, 1999, which became operative from 1 January 1995, formally gave effect to mailbox procedure and EMRs for patent applications related to pharmaceutical and agro-chemical products under TRIPS article 70.8 and article 70.9 respectively. The amendment was the follow-up action after India lost the case filed by the USA before the WTO's Appellate Body for India's failure to provide a legal regime for mailbox and EMR applications. For Appellate body Report, see India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (4 Dec. 1997), available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds50\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm)

84) G. Crues, 'India: New Patent Law May Restrict Access to HIV/AIDS Treatment', 10 *Canadian HIV/AIDS Legal*

In order to keep its generic drug industry functional and vibrant, and to meet its national and international obligations, the amended Act does not allow patents for relatively trivial changes, known as “ever-greening” the patent. It allows patents, under section 3 (d), only for new chemical entities, which will enable the generic firms to produce a wide range of affordable products.<sup>85)</sup>

*Explanation* to sec. 3 (d) has particular reference to pharmaceutical inventions. Accordingly, only new chemical entities are entitled for patents. The underlying assumption behind section 3 (d) is that derivatives, such as salt forms, polymorphs, isomers etc that are structurally similar to known pharmaceutical substances are likely to be functionally equivalent as well, and if this is not the case and the new form of an existing substance works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim. By making derivatives with enhanced efficacy patentable, section 3 (d) encourages the sequential development of existing products or technologies to help bring in improved products that address unmet public health needs.

Given that the majority of patent claims made are for minor changes, often verging on discoveries rather than innovations, it is arguably unlikely that patents will be granted to a substantial number of applications which are currently being held under ‘mailbox’ system.<sup>86)</sup> The new provision was challenged in *Novartis AG & Anr. v Union of India & Others*<sup>87)</sup>, but the Court decided against the Novartis. Since then, this provision has been invoked in other patent applications as well.<sup>88)</sup>

On the issuance of compulsory license to meet any shortfall in the supply of pharmaceuticals or national emergency, the amended Patents Act is TRIPS compliant (Chapter XVI). The grounds for granting compulsory licenses are that the: reasonable requirements of the public with respect to the patented invention have not been satisfied; or patented invention is not available to the public at a reasonable and affordable price; or patented invention is not worked in the territory of India

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*Network Policy and Review* 28 (2005); MSF, ‘The Beginning of the End of Affordable Generics’, 22 March 2005, available at <[www.accessmed.msf.org/prod/publications.asp?scentid=2232005174897&contenttype](http://www.accessmed.msf.org/prod/publications.asp?scentid=2232005174897&contenttype)>

85) Sec. 3 (d) of the Act provides: “The inventions which are ‘the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant...’ are not patentable.

86) A total of 8,926 mailbox applications were filed with the Indian Patent Office prior to 1 January 2005.

87) (2007) 4 MLJ 1153. The provision was challenged for allegedly being in contravention of TRIPS Agreement and in violation of the Constitution of India, when Novartis’ application for the drug Glivec (which was the beta crystalline form of imatinib mesylate) was rejected by the Patent Office.

88) The claim of *Boehringer Ingelheim Pharmaceuticals (USA)* for its invention related to a pediatric suspension of Nevirapine Hemihydrate used for treating HIV was rejected by the Controller of Patents in August 2007 under Sec. 3 (d) but in almost 12 cases, the provision was found to be not applicable and patents have been granted.

(sec. 84 (1). Reasonable requirements of the public shall be deemed to have not been met if due to patentee's refusal: (i) establishment of new trade/industry in India has suffered, (ii) the demand of the patented article has not been met, (iii) a market of export of patented article manufactured in India has not been supplied, and (iv) development of commercial activities in India has been prejudiced (sec. 84 (7)). Where the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and has not been successful within a reasonable period (i.e. 6 months), the Controller of Patents may process the application for compulsory license.

Compulsory licenses can also be issued on notification by the Central Government in the Official Journal in circumstances of national emergency or in cases of extreme urgency or in cases of public non-commercial use, which may include public health crises relating to HIV/AIDS, tuberculosis, malaria or other epidemic (sec. 92). The Controller, while granting the compulsory license shall endeavour to secure that the articles so manufactured shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. In order to control, under the Drugs Price Control Order (DPCO), 1995, the government sets price ceiling on many drugs. Also, the National Pharmaceutical Pricing Authority (NPPA) determines about drugs for price control.<sup>89)</sup>

India accepted Article 31bis on 26 March 2007 and in order to comply with Paragraph 6 system of the Doha Declaration and to give effect to the Decision of August 2003, the Patents Act, 2005 has added section 92A, which provides:

- “1. Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise allowed importation of the patented pharmaceutical products from India.
2. The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
3. The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

**Explanation** - ‘pharmaceutical products’ means any patented product, or product manufactured

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89) The NPPA is currently regulating the price of 73 drugs.

through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for the manufacture and diagnostic kits required for their use.”

Under this provision, compulsory license can be issued to facilitate export of patented pharmaceutical products by Indian companies to countries that have insufficient or no manufacturing capacities in the pharmaceutical sector to address public health needs, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. Products manufactured under this provision will be meant for exports to meet the public health emergencies in these countries. The provision was invoked in September 2007 by NATCO, an Indian generic drug manufacturing firm, when it made three separate applications to the Patent Office to export generic copies of Pfizer’s patented anti-cancer drug Sutent and Roche’s patented drug Tarceva to Nepal in view of the public health needs in Nepal. NATCO subsequently withdrew its applications in September 2008 for certain drawbacks in its applications.<sup>90)</sup>

Fears have already been expressed in many African countries with insufficient or no manufacturing capacities that the amended patent law of India may likely to hinder access to cheaper drugs in future. In AIDS pandemic cases, presently there are few pending mailbox applications before the Patents Office for Antiretroviral (ARVs) drugs, which are related to ARVs of pre-1995 patented medicines and India’s current production of these will not be affected by what is in the mailbox, unless patents are sought and granted for improvements. It is most likely that some of existing ARVs will remain available and off-patent in India (in the light of sections 3 (d) and 11A) even now. This is, for example, the situation with the medicines that MSF could buy from India without using the Decision as they would have had to do in Canada. But after switching over to product patent regime, India or any other developing country with manufacturing capacity in the pharmaceutical sector henceforth will not be able to produce generics of new medicines, introduced and patented after 1.1.2005.<sup>91)</sup> It is also important to note that HIV is a highly changeable virus and patients need to switch and change their medicines regularly. India may not be able to provide generics of second and third line of AIDS drugs without the consent of the patent holders. New second and third lines of AIDS medicines are

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90) Drawbacks identified were: Nepal government had not issued any TRIPS notification on pressing public health problem in Nepal; letter issued by the Nepal Government was merely a permission to import fixed quantities of drugs; it was not clear whether Pfizer is also selling in Nepal; and the failure of the applicant to set out the terms and conditions of the license which he is willing to accept under Rule 96 of the Patents Rules 2006, NATCO v. Pfizer/Roche Compulsory Licensing dispute, information gathered from the Official Journal of the Patent Office.

91) Op. cit. 29, pp. 42-43.

more expensive. Presently, India can supply generics of first line of AIDS medicines only. On the other hand, with limited financial resources and high cost of drugs for second and third line of drugs for HIV/AIDS treatment, most of the LDCs or countries with no manufacturing capacity will not be able to import these drugs, just like the situation existing in Zimbabwe. This may pose a great threat to lives in Africa and Asia.

### Developments in the use of compulsory licensing under Para 6 System

As noted above that despite WTO efforts to provide a mechanism for the access to medicines by poor countries with insufficient or no manufacturing capacity, these countries have been slow to act to expand access to medicines, except the solitary case of Rwanda.<sup>92)</sup> Few have made use of their existing laws to increase access to essential medicines.<sup>93)</sup> It is possible that the new rules, with the possibility of compulsory licenses, may improve the importing countries negotiating position and may help in lowering the prices. However, it is too early to predict with certainty about the price effects of these rules. But by their inaction, States are ignoring their international human rights commitments.<sup>94)</sup> One reason for this inaction could be that up to now it was possible for these countries to import cheap medicines or active substances, from India, which has introduced product patents for pharmaceuticals in 2005 only. Now the new drugs will be patented in India, there is a greater likelihood that importing countries may use the waiver.

Apart from that, as noted above, the Para 6 System is plagued with administrative hurdles. Pertinent questions remain to be answered: What is required to make the system to work? Is there a possibility of its becoming a viable mode of meeting the needs of countries with no or insufficient manufacturing capacity in pharmaceuticals? The use of compulsory licensing – whether for import or to manufacture drugs locally – requires essentially both technological capability and political commitment on the part of a government, which most of these countries do not possess. The administrative hurdles as mentioned in the case of MSF is not be a singular

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92) See *op. cit.* 73 & 74..

93) Brazil and Thailand made use of their existing laws to access the generic drugs. Zimbabwe, in 2002, before the Decision on paragraph 6 of the Doha Round was taken, issued compulsory license under its Patent Act (Chap 26:03), 1971, under Ss 34 & 35 to import generics of Antiretroviral drug from India which was substantially cheaper than the patented drug. See MSF, “Zimbabwe government takes emergency action against HIV/AIDS Overriding Patents will dramatically cut prices of treatment for patients”, available at [www.cptech.org/ip/health/c/zimbabwe/msf05292002.html](http://www.cptech.org/ip/health/c/zimbabwe/msf05292002.html) visited on 11 July 2011.

94) The International Guidelines on HIV/AIDS and Human Rights, which states in Revised Guideline 6 as follows: ‘States should enact legislation to provide for the regulation of HIV-related goods ... so as to ensure ... safe and effective medication at an affordable price ... [and] should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of ... safe and effective medicines ...’, See OHCHR & UNAIDS, HIV/AIDS and Human Rights, International Guidelines (March 2003, Geneva, New York) available at <<http://whqlbdoc.who.int/publications/2002/9291730254.pdf>>

problem. The case of Zimbabwe points out towards another pertinent problem, i.e., where almost 350,000 people are afflicted with HIV/AIDS and the harsh economic realities has resulted in to a critically low supply of ARVs in that country.<sup>95)</sup> This is in contrast to the situation that existed in 2002, when Zimbabwe issued compulsory license to import the drug.<sup>96)</sup> Present situation of Zimbabwe is an indication that the use of compulsory license, whether to import or to manufacture drugs, requires essentially both technological capability and political commitment/capability on the part of the importing government.<sup>97)</sup> In the case of exports, the licensee would like to be assured of some financial returns for undertaking the task of manufacturing and exporting the required drugs. In considering various approaches to the problem of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand, members must be mindful of choosing an approach that provides adequate incentives for the production and export of the medicines in need. This requires an analysis of the determinants for making a compulsory license to work, along with the parallel developments, like the bilateral and regional trade agreements, impacting thereby the working of the Paragraph 6 System.

In the recent years, the United States and the European Union have concluded a number of bilateral and regional free trade agreements (FTAs). These FTAs have TRIPS-plus provisions, which limit the practical effects of Para 6 System. These agreements have typically barred the compulsory licenses and protected the data exclusivity for pharmaceuticals and chemicals with a view to delay the entry of generics in the market. The common TRIPS-plus features in bilateral and regional trade agreements that the United States has entered with developing countries include

- Provisions establishing special 5-10 year exclusivity period over pharmaceutical test data. Data exclusivity may effectively bar compulsory licensing or generic competition for drugs that are not patent protected.
- Measures prohibiting drug regulatory agencies from granting marketing approval to a generic version of a medicine if the product is covered by a patent
- Patent extensions beyond the 20 years of monopoly protection mandated by the WTO.
- Restrictions on the ability of countries to undertake parallel importation.
- Obligations to extend patent protection to minor improvements in, or new uses of, older products.

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95) At the end of 2006, about 350,000 people in Zimbabwe were in need of ARVs, See WHO, "Towards Universal Access: Scaling up Priority HIV/AIDS Interventions in the Health Sector," April 2007, available at < [www.who.int/hiv/mediacentre/universal\\_access\\_progress\\_report\\_en.pdf](http://www.who.int/hiv/mediacentre/universal_access_progress_report_en.pdf)>.

96) In 2002, the Zimbabwe Government declared a state of emergency in the country under sections 34 & 35 of the Patent Act, 1971. See MSF *op.cit.* 93

97) E. Durojaye, *op. cit.* 20, pp. 59-60.

These provisions clearly undermine the Doha Declaration. To ensure compliance with TRIPS-plus standards, the United States also uses its “Special 301” instrument, which requires the United States Trade representative (USTR) to identify countries that deny ‘adequate’ and ‘effective’ protection for intellectual property to its goods. These countries could be put on “watch list” and “priority watch list” and may be subject to withdrawal of trade concessions. Thailand case is in point.<sup>98)</sup> The EU also uses political pressure to get higher standards of enforcement of these rights.<sup>99)</sup> Though Thai case is not directly linked to the new rules under the Decision/Article 31bis, but it has become a part of the political climate surrounding the new system, which reduces the amount of leeway for poorer and weaker States in devising regulatory approaches suitable for their individual needs and stages of development.<sup>100)</sup>

## VI. Conclusion

The Para 6 of the Doha Declaration – the Decision/Article 31bis, have given the WTO a human face by addressing the public health issue and crisis in poor countries. It has also worked to lower prices on medicines for diseases such as HIV/AIDS. However, the new rules touch on a small part of the interface of intellectual property and public health. They can be used when there is insufficient or no domestic production capacity in the importing country and the patent exists on the medicine in the exporting country. The countries that can't make their own generic drugs can import them under a compulsory license. So far there has not been enough empirical data to assess the credibility of the new rules on compulsory licensing. The analysis above reviews the potential for new rules to enable import of patented medicines to developing countries. Pertinent questions still remain to be answered: Are all the necessary pre-requisites in place? Can the countries with little or no capacity put the system in place effectively to meet the health emergencies? How to overcome the administrative obstacles to access the medicines within a reasonable time at affordable prices? How the cases like the MSF or Rwanda, discussed above, can be met where an insurmountable time was taken to address the health crisis?

The analysis above shows that the potential of new rules to address these issues is limited. The

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98) After Thailand issued compulsory license for the HIV/AIDS drug in 2006, it was threatened with the “Special 301” action and put on the ‘priority watch list’. See USTR, “2007 Special 301 Report”, <[http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2007/2007\\_Special\\_301\\_Review/asset\\_upload\\_file230\\_1122.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_1122.pdf)>.

99) See letter from EU Commissioner Peter Mandelson to Thai Minister of Commerce H.E. Mr. Krirk-krai Jirapet, 10 July 2007. 2007/CAB24/PM/PTH/cmp/D-900. Also available at <<http://www.actupparis.org/article3126.html>>

100) Susan K. Sell, “TRIPS-Plus Free Trade Agreements and Access to Medicines”, 28 *Liverpool Law Review* 41-75 (2007).

market size for exports will be a decisive factor. Beside the legal regime of the TRIPS Agreement, the other international commitments of the countries and the political factors will also go a long way to make the new system to work. The increasing use of FTAs by developed economies and threat of unilateral action under national laws by them, such as 'Special 301' actions by the United States are undermining the very object of the new rules.

Access to medicines by countries with insufficient or no manufacturing capacity in pharmaceutical sector and with small markets will depend upon their financial and political capacities rather than merely issuing the compulsory license to import drugs. But the mere issuance of a compulsory license will not be the panacea for the problems of poor countries related to medicines. The Para 6 System may not work efficiently for many other reasons. It will take time to develop a new drug and also to get necessary approvals/notifications as required under Para 6 System and the national laws. These provisions may be useful to an extent but not adequate to meet national health emergencies if the drug concerned is new and the generic copies of that has to be developed. It would take at least 36-48 months, because the production of a new generic drug requires investment in plant and machinery, as well as bio-equivalence tests and regulatory approval. Initial costs will be high. This will make it difficult to access the competitive procurement of the drug under the Decision. Furthermore, the new manufacturer has to be ensured of some returns, which will greatly depend upon the size of the market. A big market will be an incentive to off-set the costs. The case like Zimbabwe may be resolved through access to donor money, otherwise small markets will be left high and dry and thus make the Decision totally unworkable. Hence, economic difficulties of production costs and market potential would need to be addressed to make the system work.<sup>101)</sup> In this context, the 'expeditious solution' to the problem of Para 6 of the Doha Declaration remains an unmet goal. In fact, the new rules are too harsh for poor countries, imposing upon them an expensive, cumbersome and time-consuming process. At the most they can be used as a negotiating tool by importing countries in putting some pressure on pharmaceutical companies to lower prices under the threat of a compulsory licensing.

The fact also remains that so far not many countries have put in place the required national measures to make the new system work. Fears have already being expressed that failure to bring the Amendment into force will open the door to a campaign to undermine the Waiver Decision and will leave the present situation unchanged. The poor countries will be left at the mercy of pharmaceutical firms, which will hold these countries as captive markets for their products. Donations and differential pricing can improve access to some patented medicines, but cannot be a full solution for each and every country or for every product. Leaving it to the market forces will

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101) See Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* 45 (UK, 2002)

also not resolve the problem. A regional cooperation to solve the problem may similarly not work, if the region has no manufacturing capacity or if the market is small or economically not an attractive destination for the big drug companies.

In case *31bis* fails to materialize, this may require in some cases the comprehensive adoption and active use of the public health safeguards identified in Doha Declaration. The alternative lies in the in-built flexibilities in the TRIPS Agreement. The flexibilities which Doha Declaration talks about can be resorted to by these countries, with the issuance of compulsory licenses under Article 30 and 31. They may resort to safeguard provisions, such as parallel imports by making provision of international exhaustion in their patent laws under Article 6 of the TRIPS Agreement. On the other hand, in order to stop the entry of cheap drugs, originating from the same source into high-priced areas, developed countries can resort to “national exhaustion” principle, stopping thereby the parallel imports of those drugs coming from developing countries, where that product is being sold at a lower price.<sup>102)</sup> The developed countries must help in improving the manufacturing capacity of poor countries through transfer of technology. The cases of Brazil and Thailand illustrate both the opportunities and risks associated with implementing TRIPS exception mechanisms. As a last resort, pharmaceuticals may be kept out of the realm of patents. A WHO or WIPO Help Desk may be created to provide information about the current patent status of a drug to decide whether a compulsory license is required to meet the need of national health emergencies. If a drug is out of the patent protection, generics can be produced without any delay.

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102)Ibid. at 41