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PHARMACEUTICAL PATENTS AND PUBLIC HEALTH

S K. Verma[*]

Abstract

After the coming into force of the Agreement on Trade-Related Intellectual Property Rights (TRIPS) on the January 1, 1995, the access to medicine and health technologies became a challenging issue for developing countries, particularly for those with no or insufficient manufacturing capacity to produce drugs to meet national health emergencies, *viz.,* HIV/AIDS, TB, Malaria and other epidemics. In 2001, the WTO Ministerial Meeting adopted the Declaration on the TRIPS Agreement and Public Health, which allowed WTO members to use TRIPS flexibilities. In 2003, it was followed by the waiver decision on the Implementation of paragraph 6 of the Doha declaration to overcome the difficulties in invoking article 31 (on compulsory licenses) of the TRIPS. The changes brought in by the decision were approved by the members in December 2005 in the form of article *31bis* (Protocol amending the TRIPS Agreement). The amendment is in force since January 23, 2017. These measures by the TRIPS have, however, failed to resolve the problem of accessibility to medicines. The UN Secretary-General's High-Level Panel on Access to Medicines (HLP), 2016 has also reiterated the use of TRIPS flexibilities by the countries and has recommended certain other measures by the governments and the international organisations to realise the goal of access to essential medicines and vaccines.

I Introduction

THE CONCLUSION of the Agreement on Trade-Related Intellectual Property Rights (TRIPS) and its coming into force on January 1, 1995, has radically transformed the international intellectual property system from permissive to a prescriptive regime. By narrowing the scope for differentiation within national patent policies, it has adversely impacted 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.

By strengthening the international level of patent protection, TRIPS has impacted significantly the access to life saving pharmaceuticals in developing countries, especially poor countries with insufficient or no pharmaceutical manufacturing capacities and are often afflicted with pandemics. Further, due to introduction of product patents in

* Former Professor of Law, Delhi University; Director, ILI; Secretary-General and Director, ISIL, New Delhi.

pharmaceuticals in many countries, like India, from January 1, 2005, many countries that were earlier dependant on the importation of life-saving drugs at low prices are now finding it difficult to access of them. 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 lacks access to essential medicines.[1] Approximately 3 million people had died from HIV/AIDS in 2001, 2.3 million of these deaths occurred in Sub-Saharan Africa. Nearly 1.7 million people worldwide had died from tuberculosis in the same year and there had been as many as 10.2 million new cases in 2005.[2] 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 steps taken by some of the countries afflicted with these epidemics by resorting to compulsory licenses to import generic copies of the patented drugs in the past had met with strong opposition from developed countries and pharmaceutical companies. The US trade pressure on South Africa and Thailand in 1997 galvanized criticism of TRIPS,[3] which laid the basis for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health[4] at the WTO Ministerial Meeting in Doha in 2001.

The Declaration was followed by the Implementing Decision on its paragraph 6 of August 30, 2003.[5] The declaration and decision are 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 December 6, 2005 approved changes to the TRIPS Agreement in the form of article 31*bis* (Protocol amending the

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

2 See Report of the Commission on Intellectual Property "Integrating Intellectual Property Rights and Development Policy", (Sep. 2002), available at http://www.iprcommission.org/documents/final_report.htm at 1 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/newscript/home.htm> (last visited on June 10, 2019).

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

4 WTO, 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>(Last visited on May 30, 2019).

5 WTO, 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

Decision is also referred "waiver" on public health

TRIPS Agreement) making permanent the decision on patents and public health.[6] It has entered into force on January 23, 2017 after acceptance by 110 member countries (comprising two thirds of the WTO Members).

The adoption of the Doha Declaration, the Waiver Decision of August 30, 2003 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.

The new rules under the declaration and article 31*bis* (also called as para 6 System), however, have raised few pertinent questions, viz., whether the nations with no or insufficient manufacturing capacity would benefit from the system? 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 now switched over to product patents from January 1, 2005, thereby reducing the scope for generics and making access to cheaper drugs more difficult. The problem of access to drugs has further been aggravated by TRIPS-plus agreements concluded by developed countries with developing countries and least-developed countries (LDCs) 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 paper examines the Doha Declaration, the decision of 2003 and article 31*bis*, followed by an account of the implementation by countries of the decision/article 31*bis*. It also takes into account the UN High Level Panel (HLP) Report and its recommendations to overcome the problem of access to drugs and to promote access to health technologies. 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

6 Implementation of paragraph 11 of the General Council Decision of August 30, 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, Dec. 6, 2005.

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.[7] South Africa and Brazil 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. 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 (US) before the WTO panel opposing the action of the Brazilian government.[8] In the case of South Africa, 39 pharmaceutical companies instituted a court case against the South African government for enacting a new patent law in 1997,[9] which allowed parallel importation, compulsory licensing and price regulations of medicines in the wake of the HIV/AIDS pandemic in the country.[10] 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 lack of access to medicines in Africa and other less developed countries and the resulting public health crises caught widespread international attention.[11]

In 2001, the United Nations General Assembly in its Special Session on HIV/AIDS, adopted the Declaration of Commitment.[12] In the same year, the African leaders adopted

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7 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.

8 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. See the Joint Communication of Brazil- United States, June 25, 2001.

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

10 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 (last visited on May 29, 2019).

11 See Commission on Human Right, *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. 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), Ebenezer Durojaye, "Compulsory Licensing and Access to Medicines in Post Doha Era; What Hope for Africa?" *LV Netherlands Int'l Law Review* 33-71 (2008).

12 UN General Assembly, *UN Declaration of Commitment on HIV/AIDS*, UN GAOR, 26th Special Session, Res. 33/2001(25-27 June 2001).

the Abuja Declaration on HIV/ AIDS and other related diseases.[13] 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.[14] As 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.[15]

TRIPS flexibilities

A close look at the TRIPS Agreement makes it quite clear that a proper balancing between the rights of the IP owner and social objectives of the TRIPS Agreement are well evident from articles 7 and 8 of the Agreement,[16] and its "regulatory exceptions" (in articles 6, 31 and 40). These provisions 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 to the countries. 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. Article 30 also 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. Acts like the use of the patented product for scientific research and experimentation purposes, and early working or 'Bolar Exception' may also be exempted under article 30. In national emergencies, countries can adopt a range of other measures to improve access to medicines in line with articles 7 and 8 of the TRIPS.

Apart from these, there are certain other in-built flexibilities in the TRIPS Agreement. The agreement does not define the standards of patentability except to say that invention must be new, non-obvious and industrially applicable, *i.e.*, useful, *i.e.*, without defining the terms 'invention' 'new', 'inventive step/non-obviousness' and 'industrially applicable'

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

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

15 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, *available at:* <http://www.who.int/medicines/areas/policy/WHO-EDM-PAR-2002.3.pdf>, at 1-3 (last visited on June 6, 2019).

16 TRIPS, art.7 reads– "The protection and enforcement of intellectual property rights should [be] … in a manner conducive to social and economic welfare"; TRIPS, art. 8 provides – "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition…."

for an invention to be patentable. This gives a leeway to members to define these terms in their national interest.

It is, however, pertinent to note that despite these flexibilities, many developing countries lacks even the capacity to produce formulations and only a few of these countries invest in research and devolopement or have pliable research and devolopement capabilities for new drugs or even to conduct research in pharmaceutical sector through which they can meet the needs of their people. 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 was remote and debatable under the then unamended WTO/TRIPS regime.

Compulsory licensing regime of TRIPS

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, [17] reducing incentives for enterprises to engage in R and D. However, there is no evidence that the granting of compulsory licenses has led to a reduction in research and devolopement investment.[18] Compulsory licenses may help in putting a downward pressure on prices. 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 the granting of compulsory license for the domestic use under article 31 with certain terms and conditions, which include a case-by-case determination of compulsory license 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), termination of license 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

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17 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) at 7.

18 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).

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 are empowered, under article 31, to issue 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."[19] 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.[20] 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.[21] But it is doubtful whether it will help in exporting the generic drugs to countries in dire need of drugs for epidemics/pandemics, with no manufacturing capacity. It will hamper the access to medicines to countries with no or insufficient capabilities by requiring licensees to restrict their production predominantly to domestic market. This limits flexibility of countries to authorize the export of drugs under compulsory license,[22] though 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 (article 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.[23] On the other hand, for the granting of compulsory license, it is necessary to establish

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19 As an exception, TRIPS, art. 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."

20 E. Durojaye, *Supra* note 11 at 50.

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

22 F.M. Abbott (Intellectual Property Rights Commission), "WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries", 17 (Washington DC, Intellectual Property Rights Commission 2002)

23 "Patents: Non-Voluntary Uses (Compulsory Licences)", in UNCTAD –ICTSD - Resource Book on TRIPS and Development 474 (Cambridge University Press, 2005).

that (a) the party being granted license 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 may not use them. Many LDCs lack financial resources and technical expertise to meet these pre-conditions. Hence, 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 facilitate access to cheap drugs.[24] Article 31(b) of TRIPS, on the other hand, states that governments do not need to consult with patent holders when issuing a compulsory licence for national emergencies or public non-commercial use.

To make the compulsory licenses workable, however, 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 authorizes the members to provide limited exceptions to exclusive rights conferred on the patentee, " 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...."[25] 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.[26]

Compulsory licenses under article 31 of the TRIPS have rarely been used by developing countries for number of reasons, *viz.*, absence of administrative and legal infrastructure;

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24 The provisions for compulsory licenses are provided in the developed countries' legislations. Even Canada and the United States had threatened to use compulsory license over Bayer's ciprofloxacin, which was useful for the treatment of anthrax after the events of 9/11/2001. 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* (Nov. 1, 2001).

25 The use of this provision by Canada to speed up the introduction of generic drugs in Canada became 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 April 7, 2000. The use of this provision in public health crisis is a matter of interpretation.

26 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.

fear of sanctions; use predominantly for the domestic market; non-exclusive nature and limited duration, which make them less attractive to the holder. Without addressing these issues, compulsory license will remain only a paper-tiger, though aimed at preventing abuses of the IP system.

III Doha Declaration on public health

In 2001, a special Ministerial Declaration at the WTO Ministerial Conference in Doha on "The TRIPS Agreement and Public Health"[27] was adopted to clarify ambiguities between the need to apply the principles of public health and the terms of the TRIPS Agreement. 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" [Para 4]. 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 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 5(b) relates to members' discretion with regard to the grounds upon which compulsory licenses are granted, paragraph 5(c) refers to article 31(b), making it clear that the definition of the term 'national emergency' and 'other circumstances of extreme urgency' is up to members' discretion. Paragraph 5(d) reiterates article 6 of TRIPS Agreement. This leaves members considerable room to

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27 *Supra note* 4.

pursue public policy objectives 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, the issue of the incapacity of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector also came up, which could be a hurdle in making effective use of compulsory license to meet the public health crisis. Therefore, the declaration recommended 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.[28] 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. From a public health perspective, this extension of the transition period for LDCs was of significant importance. It was a recognition of the implications of patent protection on public health, and was 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 LDCs were already granting patent protection to pharmaceuticals under different bilateral or regional FTAs, thus leaving 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. The declaration responds to the concerns of developing countries about the obstacles they face 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"[Para 3], the declaration specifically recognizes concerns about its effects on prices [Para 7]. 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. The declaration clarifies that all Members States have the right to grant compulsory license to protect public health

28 Doha Declaration, para. 7 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. Under art. 66, this period was up to January 2010. In 2013, TRIPS Council extended this period until July 1, 2021.

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"[29], including those that may be derived from diseases that affect the population in developing as well as developed countries. It may be invoked in all public health emergencies and may cover not only medicines, but any product, method or technology for health care.[30]

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 has also remained a debatable issue. Being a declaration, it was considered to be merely of persuasive value in interpreting the TRIPS Agreement and 'legally not binding'.[31] On the other hand, view was also expressed that being a ministerial decision, it has legal effects on the Members and on the WTO bodies, particularly the Dispute Settlement Body (DSB) and the Council of TRIPS.[32] However, its persuasive value certainly could not be denied 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

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29 Doha Declaration, para. 1, 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."

30 Carlos M. Correa, *Supra* note 16 at 5. The Report of the UN Secretary General's High-Level Panel on Access to Medicines, 2016 covers health technologies also. The Panel was constituted in furtherance of Goal 3 of the Sustainable Development Goals 2030.

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

32 Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health (WHO, 2002)*. WHO Doc. WHO/EDM/PAR/2002.3, at viii and 34.

TRIPS Council adopted a Decision (the Decision)[33] on August 30, 2003.[34] The decision laid down the grounds for the use of compulsory license by the importing and exporting countries. It established a mechanism to overcome the restriction of Article 31(f), which limits compulsory license *predominantly* to the supply of the domestic market. It will be waived for an exporting member when 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 license under article 31(h) is waived for the importing country. The Decision laid down the grounds for the use of compulsory licence by the importing and exporting countries.

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.' This definition is sufficiently broad and requires members other than LDC members to submit a notification of their intention to use the system in whole or in part, which may be modified at any time.[35] The notification establishes a member as an 'eligible importing member'.[36]

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. Conditions for use of the waiver are detailed in paragraph 2. The importing member must notify the TRIPS Council of its needs and (except for

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33 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 Para 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).

34 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

35 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.

36 '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.

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.[37] 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.

Paragraph 3 provides waiver from remuneration to the importing country under article 31(h) if adequate remuneration for the same product has been paid by the exporting country under a compulsory license. Paragraph 4 requires an importing member country to take reasonable measures to prevent diversion of products imported under the system. The decision does not specify the nature of such measures 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. 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 to 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 LDCs, 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 same 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. The need for the grant of regional patents has also been recognized.

Paragraph 7 recognizes the desirability of promoting transfer of technology to LDCs and capacity building in the pharmaceutical sector in pursuance of article 66.2 of the TRIPS Agreement and paragraph 7 of the declaration. The annual review of the system

37 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.

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.

While the Decision was a consensus statement of the members of the WTO in protecting the public health under the TRIPS Agreement, it has been criticized as administratively too complex and burdensome to be a truly effective means to remove obstacles to access cheaper drugs. Among the scholars, it is a common view that the decision creates more hurdles than solution to paragraph 6 problem of the Doha Declaration. It is saddled with many administrative pre-requisites, which 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 has 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 delay the manufacture and supply but increase the cost of the drugs.[38] Decision is termed to be a temporary solution which is difficult to operate and that is not faithful to Doha Declaration on Public Health.[39]

Article 31 *bis*

Two years after the adoption of the Decision, on December 6, 2005, the TRIPS Council adopted the Protocol amending the TRIPS Agreement, by inserting article 31*bis* after article 31 and an Annex after article 73.[40] The Annex to the Protocol specifies the provisions of article 31*bis*. The new article reiterates the provisions of the Decision. The amendment, the first ever to the 1994 TRIPS Agreement, implements the waiver that was temporarily agreed on August 30, 2003, making it possible for countries to export medicines under compulsory license to countries with no or inadequate production facilities. Article 31*bis* provides 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.

38 K.R. Srinivas, "Interpreting Paragraph 6 Deal on Patents and Access to Treatment" *EPW* (2003)

39 Ebenezer Durojaye, *Supra* note 11 at 52.

40 *Supra* note 7. For the text of TRIPS, art. 31bis, *available at*: WTO website <http://www.wto.org/english/tratop_e/trips_e/pharmapatent_e.htm> (last visited on may 20, 2019).

The amendment substantially is in no way different from the decision, save for some slight changes in structure. 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, 2003 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).

The Protocol amending the TRIPS Agreement has three main parts. *Firstly,* there is article 31*bis* 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 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.

In its five paragraphs, article 31*bis* contains three 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.[41] Paragraph 4 is paragraph 10 of the decision and paragraph 5 is the reiteration of paragraph 9 of the decision.

The 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 for the exporting and importing members. The eligible importing member(s) needs to make a notification to the TRIPS Council, which should:

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41 In the case of least developed 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), and establishing that it intends to or has granted compulsory license (where the product is patented in its territory) in accordance with Articles 31 and 31bis, 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.

(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. 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[42] 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 TRIPS Council 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.[43]

Reiterating paragraph 4 of the decision, paragraph 3 of the annex requires importing country to take measures to prevent diversion of products imported under the system. Paragraph 4 requires other members to take effective measures to prevent the importation of such products into their territories. Paragraphs 5, 6 and 7 of the annex

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42 See 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.

43 See footnotes 2 and 5 of the Annex. *available at*: WTO website fohttp://www.wto.org/English/tratop_e/public_health_e.htm .

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.[44]

The new rules of para 6 system are 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. 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 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* came into force on January 23, 2017 after the acceptance of 110 member countries (comprising two thirds of the WTO members) and replaced the 2003 waiver for members who have accepted the amendment.[45] This amendment 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,[46] as of the decision to the extent of making it unworkable. This is evident from the case of Médecines Sans Frontières (MSF)/ Rwanda.

In May 2004, the MSF placed an order under the new rules for its project in Rwanda, a least-developed country, which required the MSF to locate a local generic manufacturing company within Canada.[47] The MSF approached Apotex, a generic pharmaceutical company 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 for HIV recommended by the WHO. Apotex had to develop a fixed-dose combination of these drugs to simplify treatment. As the new fixed-dose combination drug was not included in the schedule of drugs

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44 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.

45 Other WTO Members can accept the amendment until Dec. 31, 2019 (document WT/L/1024)

46 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).

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

qualified to be exported under the Canadian legislation, it required an amendment of the Canadian law. Canada's Access to Medicines Regime (CAMR), which implements the paragraph 6 system, had to be amended to cover the product because Canada limits the scope of its law to a specified list of products. The three medicines combined in the product were each covered by a separate patent owned by a separate company. In July 2007, Apotex sought, without success, voluntary licenses from the three patent holders. 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 2007. In the meantime, the MSF 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.

In the meantime, Rwanda notified the WTO on July 19, 2007 to import medicine produced under a compulsory license, as ordered by the MSF.[48] Product wanted by the MSF/ 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 in which the Indian companies had an edge in terms of price.[49] It took four years to complete the process of Apotex's delivery of drug to Rwanda. This case indicates the inadequacy of the new rules under article 31*bis* and the August 2003 decision of the TRIPS Council devised to resolve the problem of inaccessibility to drugs faced by poor countries. It also highlights the difficulties in successfully invoking the use of compulsory licensing even in developed jurisdictions.

V Implementation of Para 6 System

The Doha Declaration was devised to resolve the pressing problem of access to medicines, which had remained a burning issue since the coming into force of the TRIPS Agreement. 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 31*bis* on the amendment of the TRIPS Agreement, international consensus has for the most part still not been translated into domestic policy and

48 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 (last visited on June 2, 2019).

49 See Canadian Notification to the TRIPS Council by Canada dated October 5, 2005 under art. 63.2 of the TRIPS Agreement (IP/N/10?CAN?1); under Para 2(c) of the Decision, 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 .Canada sent 15.6 million pills to Rwanda.

law.[50] To make para 6/art. 31*bis* effective, members are required to legislate to make it a part of their internal law to enable them to use the provisions of the Para 6 system as an importing or exporting member. Till January 21, 2016, only 19 countries have legislated on Para 6 system.

Implementation of the new rules is, however, independent to whether or not the country has accepted article 31*bis*. They can be implemented under Para 6 system of the decision. So far only a handful of countries, the potential exporters, have taken legislative measures. Canada,[51] Norway,[52] India[53] and EU[54] were the first to implement the rules. Hong Kong-China, China, Switzerland, Philippines, Singapore, Albania, and Croatia have also made the changes in their laws and notified the WTO.[55] 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 have curtailed their flexibilities in utilizing the new Para 6 system rules.

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.[56]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 prohibited product patent for pharmaceuticals, drugs and chemicals. This helped in the growth of a strong

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50 See http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

51 Bill C -9, An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chretien Pledge to Africa) assented on May 14, 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.

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

53 India inserted a new sec. 92A and amended sec. 90(1) of the Patents (Amendment) Act, 2005. See WTO Doc. IP/N/I? IND/D/2-5.

54 EC Regulation No. 816/2006 of the European Parliament and of the Council of May 17, 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.

55 For the list of countries that have legislated on Para 6 System, *available at*: https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (Last visited on May 30, 2019).

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

generic pharmaceutical industry in India, which now accounts for more than 70 percent of the domestic market, meeting nearly all the demands for formulations.[57] 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.

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 licensing, parallel imports and exportation of drugs to countries with no or insufficient manufacturing capacity to manufacture drugs. 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.[58] *Explanation* to section 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 derivates 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. This provision was challenged in *Novartis AG* v *Union of India,*[59] but the court decided against the Novartis. Since then, this provision has been invoked in other patent applications as well.

India accepted article 31*bis* on March 26, 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:

(i) 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

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

58 S. 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.

59 (2013) 6 SCC 1.

granted by such country or such country has, by notification or otherwise allowed importation of the patented pharmaceutical products from India.

(ii) 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.

(iii) 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 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 Roches 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.[60]

Free Trade Agreements (FTAs)

The main thrust of the para 6 system revolves around the rights to issue compulsory licenses to access essential drugs and to manufacture and export generic versions of brand name patented drugs to expand access. However, it may become impossible to use new rules if the countries in question have implanted provisions that go beyond the TRIPS (TRIPS-plus). The US and European Union have sought to limit the practical effects of Para 6 system of the Doha consensus through bilateral and regional FTAs

60 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.

with many countries with TRIP-plus provisions that will ensure the access to their markets in exchange of regulatory frameworks.

The US have concluded 20 FTAs including many countries from Latin America, Middle East, South Korea, and Singapore, besides concluding many Bilateral Investment Treaties (BITs) and regional trade agreements (RTAs). The EU has similarly concluded FTAs and Associated Agreements (AAs) with more than 30 countries. Two of the world's poorest nations, Laos and Cambodia, have concluded agreements with both of them. 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. This is a significant obstacle in the use of Para 6 System. In the case of the EU, these agreements are aimed at higher standards of enforcement of intellectual property rights.

The US has been the first country to accept article 31*bis* and join the consensus of Doha, but the FTAs have undermined this effort. The FTAs restrict the use of TRIPS flexibilities, and the United States threatens countries using the flexibilities by 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.[61] The EU also uses political pressure to get higher standards of enforcement of these rights.

The common TRIPS-plus features in bilateral and regional trade agreements concluded by the EU and the United States with developing countries include the elimination and reduction of transitional periods allowed under the TRIPS Agreement; data exclusivity protection; extension of patent protection term (minor improvements 20 years protection mandated by the TRIPS Agreement); restrictions on parallel importation; patentability of new uses of known medical substances (ever-greening) or patent protection to minor improvements; restrictions/limitations on compulsory licensing; patenting of life forms; limitations on patentability criteria; and accession to a number of international TRIPS-plus agreements. These features often result in the strengthening of the levels of IP protection, which erode the flexibilities available under the TRIPS, besides containing additional demands/protection levels on developing countries beyond that required under the TRIPS/WTO.

These provisions clearly undermine the Doha Declaration. This trend is obviously an indication of asymmetrical power relations that continue to shape IP policy, reducing

61 Thai case in 2006 is a good example of these measures when Thailand issued compulsory license to import HIV/AIDS drug from India that led Abbott withdrawing all drugs from Thai market and USTR putting Thailand on the 'priority watch list' of Special 301. The EU also criticised the compulsory licence as detrimental to medical innovation.

the amount of leeway that poorer and weaker states have in devising regulatory approaches that are most suitable for their individual needs and stages of development.[62]

Developments in the use of compulsory licenses under para 6 System

So far poor countries with insufficient or no manufacturing capacity have been slow to act under para 6 system to expand access to medicines, except the solitary case of MSF/Rwanda. Few have made use of their existing laws to increase access to essential medicines.[63] It was hoped that the new rules, with the possibility of compulsory licenses, would improve the importing countries negotiating position and may help in lowering the prices. One reason for this inaction could be that until fairly recently it was possible for these countries to import cheap medicines from India, which is now hampered due to the introduction of product patents for pharmaceuticals by India in 2005, as per the TRIPS mandate (article 65). Now the new drugs are required to be patented in India. In this context, there is a greater likelihood that importing countries may use the waiver. It is also pertinent to note that many first-line treatment drugs for HIV/AIDS are out of the patent protection. It is the second and third-lines treatment drugs, better in potency, may not be accessible to these countries.

However, as noted above, the para 6 system is plagued with many administrative hurdles. The use of compulsory license – whether for import or to manufacture drugs locally – requires essentially both technological capability and political commitment on the part of a government, which is absent in most of these countries. The administrative hurdles, as highlighted in MSF case, is not a singular problem. The case of Zimbabwe points out towards another pertinent problem, *i.e.,* where almost 350,000 people were afflicted with HIV/AIDS and the harsh economic realities led to a critically low supply of ARVs in the country. [64] This is in contrast to the situation that existed in 2002, when Zimbabwe issued compulsory license to import the drug. The situation of Zimbabwe in 2007 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. In the case of exports, the licensee would like to be assured of some financial returns for

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62 Susan K. Sell, "TRIPS-Plus Free Trade Agreements and Access to Medicines" 28 *Liverp Law Rev* 41-75 (2007).

63 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 and 35 to import generics of Antiretroviral drug from India which was substantially cheaper than the patented drug, *available at*: www.cptech.org/ip/health/c/zimbabwe/msf05292002.html.

64 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> (last visited on June 6, 2019).

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.

VI United Nations high level panel on access to medicines

It is evident from the above discussion that access to health technologies by poor countries is still a distant dream. The mandate of the Doha Declaration to the TRIPS Council was to find an 'expeditious' solution to the problem facing the member states, but the para 6 has not fulfilled that mandate. It has been used only once so far in Canada/Rwanda case. The case illustrated the interplay between trying to use the system and the generic entry into the market which actually provided a much quicker and easier solution for a country to choose the generic producer through the WHO prequalification without any conditions attached enabling purchase of the product from the qualified source.

In 2015, the UN General Assembly adopted the Sustainable Development Goals (SDGs 2030 Agenda). Goal 3 sets the health targets to be achieved, with specific targets for supporting research, development and access to essential medicines and vaccines. To realize this, the UN Secretary-General, in November 2015, appointed a high-level panel on health technology innovation and access, or for short, High-Level Panel on Access to Medicines (HLP) to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."[65]

The panel submitted its report in September 2016. Chapter two of the report (Intellectual Property Laws and Access to Health Technologies) discusses in detail the prevalent international IP regime.[66] The report is not only confined to medicines but extends to health technologies, *viz.*, diagnostics and medical devices, which usually do not receive the same attention as medicines, but for which prices also are highly influenced by intellectual property protection. For example, some drugs may be out of patent but remain highly priced because they are delivered through medical devices.

The report has highlighted the importance of TRIPS flexibilities and the obstacles in their use, such as the political and economic pressures to dissuade the governments from using the flexibilities; FTAs & RTAs and TRIPS+ provisions, which invariably

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65 *Available at*: https://www.who.int/phi/implementation/ip_trade/high-level-panel-access-med/en/ (last visited on June 10, 2019).

66 UN Secretary general, Report of United Nations Secretary-General's High-Level Panel on Access to Medicines, Ch. 2, at 21- 28, *available at*: unsgaccessmeds.org/

compromise the TRIPS flexibilities and impede their use on each account; pressure tactics by governments, particularly of developed countries and their private entities.[67] the flexibilities contained therein (TRIPS Agreement) that can be used to promote access to health technologies and examines why flexibilities have not been used, as well as other developments such as FTAs and BITs that may impede the use of TRIPS flexibilities.

The HLP Report found that the para 6 system proved not to be a viable solution for countries with insufficient or no manufacturing capacity. This is not only for technical reasons, but also due to political pressure put on countries considering using it. Taking note of the cumbersome procedure of the para 6 system, the Panel Report recommends that "WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform." They should provide legal mechanism to make para 6 workable at national level.[68]

The report reiterated the use of TRIPS flexibilities as stated in the Doha Declaration to promote access to health technologies. It recommended for the use of flexibilities related to substantive standards of protection- by laying down the patentability criteria suitable for the access to health technologies- by defining 'invention, 'inventive step', and 'industrially applicable' or 'useful' in national interest. It called for the curtailing of 'ever-greening' of patents and discouraging frivolous patents. Governments should restrict 'patent-thickets'. On compulsory licenses, it recommended that the governments should retain the freedom to determine the grounds for issuing compulsory licenses and should facilitate the prompt and expedient use of a compulsory licence for non-commercial purposes (through legislation) and augment the technological capability. However, it is doubtful that whether in the absence of necessary administrative and legal infrastructure for the use of a compulsory licence and fear of sanctions, will it be possible for these countries to take effective steps to realise the goal of access to health technologies.

The report further recommended that the governments should devise competition law and policy in accordance with TRIPS articles 8(2), 31(k) and 40 to check market distortions by anti-competitive practices of right holders in health technologies. Competition is conducive to freedom of choice and low prices of drugs for consumers, and an important driver of fostering innovation and productivity improvement.[69] Further it recommended that knowledge generated through public funded research should be freely and widely available. The funding should prioritize the health-related

67 *Id.* at 24-26.

68 HLP Report, *supra* note 61 at 27.

69 *Id.* at 23-24

R&D. 'Open-access approach' to be encouraged for the public funded R&D that will lead to healthy competition.[70] More collaborative research among the developing countries must be encouraged in health technologies and they should jointly augment the manufacturing capabilities.

Governments and private sector should refrain from any action that will limit implementation and use of flexibilities in order to promote access to health technologies (reference to TRIPS+ provisions in agreements). It calls upon governments to refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO secretariat during the Trade Policy Review of Members. WTO Members must also register complaints against such pressures and take punitive measures.[71] However, this seems to be difficult to implement when the negotiating parties are not in an equal bargaining position.

The report called upon the national governments to avoid entering into FTAs, RTAs and BITs (Bilateral Investment Treaties) with TRIPS+ provisions that may compromise the TRIPS flexibilities and reduce access to medicines. The governments engaged in such agreements should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health.[72] Way back, the 2006 Report of WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH Report) has also warned against the TRIPS+ measures in bilateral trade agreements.[73] The HLP Report recommends that Members should jointly resist agreements that compromise their freedom to access health technologies. At the same time, they should renegotiate the health-related TRIPS+ provisions in the existing Agreements.[74]

Recommendations for WHO/International Organizations

The report has made specific recommendations for international organisations to meet the public health goals. Its important recommendations are as follows:

- The United Nations agencies and multilateral institutions, particularly UNDP, WHO, WIPO, WTO and other relevant bodies should support developing countries to apply public health-sensitive criteria and in boosting R&D in health

70 *Id.* at 28, recommendation 2.6.2 of the Report.

71 *Id.* at 27, recommendation 2.6.1 of the Report.

72 *Id.* at 27-28.

73 *Available at*: https://www.who.int/intellectualproperty/en/(last visited on May 31, 2019).

74 FTAs concluded by the USA after 2004 or those concluded earlier have now appended with 'Understanding regarding certain public health measures', e.g. US-Peru agreement (2006); CAFTA-DR-USA agreement (2004), to take necessary measures to protect public health. The Dominican Republic, Costa Rica, El Salvador, Guatemala, Nicaragua, and Honduras are the current members of CAFTA-DR.

technologies and improving their manufacturing capacity.[75] They should strengthen the capacity of the patent examiners at both national and regional levels to apply health-sensitive standards of patentability taking into account public health needs (Art. 67 TRIPS Agreement puts the onus on developed countries).

- WTO Members should revisit and examine Para 6 system to make it workable. They should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.
- Governments should be encouraged to raise the instances of undue political and economic pressure on their policies during the Trade Policy Review Mechanism ("TPRM") of WTO. Instances of undue political and commercial pressure should be formally reported to the WTO secretariat during the Trade Policy Review of Members. WTO Members must also register complaints against such pressures to the WTO Secretariat and take punitive measures.
- WHO should take necessary steps for the adoption of a binding R&D Convention that delinks the costs of R&D from the end prices to promote access to good health for all.[76]
- WHO should create a Help Desk to provide information on the current patent status of a drug to decide whether a compulsory licence is required to meet the national health needs.[77]
- Provide information on drugs out of patent protection, to facilitate the production of generics without delay.[78]

The report highlights the drawbacks in the present system that impedes the access to medicines and health technologies to all. It lays down the agenda and priority areas that must be addressed to improve the current situation in order to realise the SDG 3. This necessitates the action on the part of WTO Members and the international institutions/organisations.

VII Conclusion

It is now well-acknowledged that the Para 6 of the Doha Declaration – the Decision/ article 31*bis,* have given the WTO a human face by addressing the public health issue and crisis in poor countries. WTO amendment to TRIPS was made on account of

75 *Supra* note 66 at 24, 27.

76 *Id.* at 10, 29.

77 *Id.* at 36.

78 *Id.* at 11.

global health. IP, public health, and access to medicines are not mutually exclusive. The TRIPS agreement states that IP rights should be implemented in a manner conducive to social welfare and TRIPS flexibilities became policy spaces for WTO Members. The TRIPS flexibilities serve the purpose of bringing together IP and public health concerns. The amendment to TRIPS provides a solid legal framework for countries to insure the effective implementation of para 6. 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 not 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/Rwanda can be met where an insurmountable time was taken to address the health crisis? To answer these questions, it is important have a "good hard look at the system" and whether it serves its intended purposes.

The analysis above shows that the potential of new rules to address these issues is limited. The 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, as highlighted above, will also go a long way to make the new system work. The para 6 System/article 31*bis* 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 as is evident from the MSF/ Rwanda case. 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/article 31*bis*. 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. For small markets the decision/ article 31*bis* may be totally unworkable. Hence, economic difficulties of production costs and market potential would need to be addressed to make the system work.[79] In this context, the goal of 'access to health technologies' for all, addressed in the para 6 of the Doha Declaration and HLP Report

79 Report of the Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy" 45 (UK, 2002)

remains an unmet goal. In fact, the new rules, underlying the Para 6, 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 license. If and when the WTO Members revisit the Para 6 system as incorporated in article 31*bis*, they should make it a predictable firm legal pathway to secure access to medicines.

The fact also remains that so far not many countries have put in place the required national measures to make the new system work. The HLP Report has put a high-level of commitments on the part of governments to avoid any action that undermines the balance drawn in the TRIPS Agreement to fulfil the governments' commitments to their people. It is, nevertheless, necessary that the WTO should provide technical assistance to countries so they can craft legal measures to incorporate the amendment (art. 31*bis)* in their domestic legal systems.

Recommendations made in the HLP Report also require the political will on the part of WTO Members. Though the developing and poor countries constitute the two-third membership of the WTO out of its total of 164 (and 23 observer governments), however, because of their strategic interests and week bargaining power, they are unable to withstand the pressure of developed countries and their private sector. Nevertheless, they should not "self-impose" TRIPS-plus measures undermining their ability to use TRIPS flexibilities such as compulsory licensing, and also to set up domestic production of pharmaceuticals. They should jointly act on this aspect.

In this scenario, however, if no viable solution could be found to make the para 6 system/article 31*bis* to work, 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.[80] The developed countries must help in improving the manufacturing capacity of poor countries through transfer of technology and helping them in capacity building. As a last resort, pharmaceuticals may be kept out of the realm of patents. The adoption of the Doha Declaration, the Waiver Decision of August 30, 2003 and the article 31*bis* Protocol of amendment, reflects international consensus on the true balance TRIPS strikes in patent protection. These efforts highlight that the pharmaceutical patents need to be treated differently.

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80 *Id.* at 41