

## **Trips & Public Health: With Special Reference to Doha Declaration & Indian Patents Law**

**Amit K Kashyap<sup>1</sup>**

**Dr. Anjani Singh Tomar<sup>2</sup>**

### **Abstract**

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*World Trade Organization TRIPS Agreement in 1995 has completely altered the international intellectual property system. The harmonization of basic intellectual property standards has operated to protect investment in innovation. But these same harmonized standards had stridently condensed the traditional capacity of suppliers of public goods, such as health care and nutrition, who were catering to the priority needs of developing countries. The paper briefly examines the emergence of TRIPS and the relevant concepts as well as the provisions under the TRIPS pertinent to the access to medicine and the implications of Doha round on public health and access to medicine with special reference to Indian scenario. Through this paper an attempt has been made to critically appraise the controversies surrounding the TRIPS agreement with reference to pharmaceuticals and public health.*

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**Key Words:** Patents, Medicine, Public Health, Pharmaceutical, TRIPS, Compulsory Licensing, prices, IPR, developing countries, India, patent reform

### **Introduction**

Health is one of the fundamental basic needs of all human beings. In legal terms, fundamental human rights treaties recognize the right to the “enjoyment of the highest attainable standard of physical and mental health”.

*My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death*

**- Indira Gandhi**

*Poverty is in fact, a socio-economic disease. The biological manifestations of this socio-economic disease are referred to as “diseases of poverty” and are the common communicable diseases. Poverty is, therefore, not only the deadliest disease, but also the commonest cause of ill-health in the world.*

**-The World Health Report 1995**

It needs to be underscored that access to medicines is one of the means to an end and not an end by itself. The end is Health for All. It is therefore very important not to discuss access to medicines in isolation, as an end in itself, but in the wider context of health for all, which is our final goal.

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<sup>1</sup> Asst. Prof of Law & Director, Center for Banking Investment & Taxation, Gujarat National Law University, Gandhinagar.

<sup>2</sup> Asst. Prof of Law, Gujarat National Law University, Gandhinagar.

Globalization is a major driving force in development. Many national and international development dialogues have focused on the positive and negative effects of globalization, including trade liberalization on health and health care.<sup>3</sup>

Globalization may help countries to scale up effective public health interventions. It could also make positive and negative impacts on health systems in many other areas, such as government budget for health, access to health goods and products (drugs, vaccines, medical supplies, etc.), international mobility of health care services, and influencing knowledge on policies. There are several aspects of globalization which can make a positive influence on the health of the poor population.<sup>4</sup>

The patent system is social policy tool that aims to stimulate innovation. Patent protection under Intellectual property rights law covers the entire spectrum of innovations. Nevertheless, this paper focuses only on pharmaceuticals and health inventions. The aspect of patenting of pharmaceutical products relating to healthcare are matter of concern and the application of this patenting on actual access to medicine and health is kept the theme of entire paper.

Internationally, patent protection is governed by the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement<sup>5</sup>. TRIPS does not establish a uniform international law, but sets out minimum standards of patent protection that must be met by all WTO members<sup>6</sup>. Least-developed countries are not obliged to do so until 2016.

The Agreement on Trade Related Aspects of Intellectual Property Rights<sup>7</sup> attempts the arduous task of balancing private and public interests. On the one hand, it protects the interests of the pharmaceutical companies that invest heavily in research and development of drugs and, on the other, it allows nations that belong to the World Trade Organization (WTO) to promote public health in their respective countries.<sup>8</sup>

Since 1995, the experience of countries who have implemented the TRIPS agreement shows the increasing skewing in the balance between the rights of patent holders and consumers in favor of the former. The most dramatic effect is being felt in pharmaceutical sector. The net result of the TRIPS accord has been high cost of medicines and the consequent denial of access to medicines to the income poor across the globe.<sup>9</sup>

Medicines are expensive when they are protected by patents. The patent holder has a monopoly on the drug for a minimum of 20 years, and uses that period to maximize profit. But as soon as generic competition is possible, prices of medicines plummet: for instance, after the Brazilian government began producing generic AIDS drugs in 2000, prices dropped by 82%.<sup>10</sup>

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<sup>3</sup> *Report of an Inter-country Expert Group Meeting: "Globalization, Trade and Public Health: Tools and Training for National Action"* World Health Organization, Regional Office for South-East Asia New Delhi, 12–14 December 2000, (WHO Project No: ICP OSD 001) available at [http://203.90.70.117/PDS\\_DOCS/B3482.pdf](http://203.90.70.117/PDS_DOCS/B3482.pdf) last visited on 17 December 2012.

<sup>4</sup> Ibid.

<sup>5</sup> [www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) last visited on 9 December 2012

<sup>6</sup> "Will the lifeline of affordable medicines for poor countries be cut? Consequences of medicines patenting in India" External Briefing document of Médecins Sans Frontières February 2005 available at <http://www.who.int/hiv/amds/MSFopinion.pdf> last visited on 19 November 2012

<sup>7</sup> Hereinafter referred to as TRIPS

<sup>8</sup> "Trips & Public Health" by Vishwas H Devaiah <http://infochangeindia.org/200405096068/Trade-Development/Intellectual-Property-Rights/TRIPS-and-public-health.html> last visited on 12 November 2012.

<sup>9</sup> "Final Amendment To India's Patent Act" By Amit Sen Gupta available at [pd.cpim.org/2004/1003/10032004\\_snd.htm](http://pd.cpim.org/2004/1003/10032004_snd.htm) last visited on 12 November 2012

<sup>10</sup> Supra note 1

Since 1970, India's Patent Act has allowed Indian manufacturers to legally produce generic and cloned versions of medicines patented in other countries<sup>11</sup>. India's expertise in reverse drug engineering and the efficiency of its pharmaceutical manufacturing industry fast established it as the prime source of generic medicines in the world.

An estimated 70% of the 25,000 AIDS patients treated by Médecins Sans Frontières in 27 countries are taking Indian generics. The absence of drug product patents has also allowed Indian generic manufacturers to develop fixed-dose combinations of AIDS drugs, combining several pills originally produced by different companies into one tablet that is easy to take. This simplification of treatment regimens has been crucial to the scale-up of AIDS treatment programmes in poor countries<sup>12</sup>.

India was required to amend its Patent Laws to provide for a TRIPS compliant regime by January 1, 2005 as indicated by the provisions of the TRIPS agreement under the WTO. There was, however, a wide consensus that domestic laws, while being TRIPS compliant, need to make full use of "flexibilities" available in the TRIPS agreement.

This was reiterated in unequivocal terms by the WTO Doha Declaration on TRIPS Agreement and Public Health (2001), which, inter-alia, commented that countries have the sovereign right to enact laws that safeguard domestic interests. It recognized the gravity of public health problems in developing countries and clearly provided that the member countries had the right to protect public health and to promote access to medicines for all<sup>13</sup>.

On December 26th 2004, to comply with the terms of the TRIPS Agreement, the President of India issued the Patents (Amendment) Ordinance, which requires patents to be granted on new medicines as from January 1st 2005, and on medicines for which companies filed a patent application after 1995. Later this was incorporated in the Act and now it is a law.

It was projected that if the government does not establish measures to bring prices down, the cost of new drugs will remain very high, because patents prevent competition. Estimates suggest prices of new drugs will increase by a mean of 200%<sup>14</sup>. It is also a devastating development for many poor countries that rely on India as a source of affordable quality medicines.<sup>15</sup>

### Trips Agreement

In 1994, during the creation of the World Trade Organization<sup>16</sup>, TRIPS Agreement was formed. TRIPS Agreement is an integral part of the WTO Agreements, which create binding international obligations among WTO Member States.

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<sup>11</sup> "Pharmaceutical patents and the quality of mental healthcare in low- and middle-income countries" by Varuni De Silva, *Psychiatric Bulletin* (2008), Faculty of Medicine, University of Colombo available at <http://pb.rcpsych.org/cgi/content/full/32/4/121> last visited on 15 December 2012

<sup>12</sup> Supra note 4

<sup>13</sup> Supra note 5

<sup>14</sup> F.M. Scherer by Jayashree Watal "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" Commission on Macroeconomics and Health, Working Paper Series, Paper No. WG4:1, June 2001, 15-16

<sup>15</sup> "Patent reform and compulsory licensing: a case study from India" by Sagarika Chakraborty and Angira Singhvi available at [inderscience.metapress.com/index/2051440R822T3K77.pdf](http://inderscience.metapress.com/index/2051440R822T3K77.pdf) last visited on 11 December 2012

<sup>16</sup> Most of the WTO agreements are the result of the 1986–94 Uruguay Round negotiations, signed at the Marrakech ministerial meeting in April 1994. There are about 60 agreements and decisions totaling 550 pages. The "Final Act" signed in Marrakech in 1994 is like a cover note. Everything else is attached to this. Foremost is the Agreement Establishing the WTO (or the WTO Agreement), which serves as an umbrella agreement. Annexed are the agreements on goods, services and intellectual property, dispute settlement, trade policy review mechanism and the plurilateral agreements. The schedules of commitments also form part of the Uruguay Round agreements

The TRIPS Agreement is subject to the WTO's dispute settlement mechanism<sup>17</sup>, which may -as a last resort- allow Member Countries to apply trade sanctions against a noncompliant Country, thereby ensuring enforcement of the WTO's rules and agreements. The three main features of the Agreement are: Minimum standards of protection, Enforcement & Dispute Settlement.

The TRIPS Agreement has considerably harmonized the standards for patents; especially, it makes it mandatory for countries to ensure that patent protection is available in all fields of technology, for both process and product inventions.

Thus, it is no longer possible for countries to exempt pharmaceuticals from patent protection (as a number of countries did, before TRIPS came into force). Nor can countries like India continue to limit pharmaceutical patents to process patents only.

*The distinction between product and process patents is important, in view of the fact that if a product is patented, only the patent holder may make or sell that product; nobody else may do so, unless the patent holder has given permission (a license).*

*In the case of a process patent, nobody may make that product by using the process that is protected. Nevertheless, if someone can produce the same product in a different way, he/she may do so. Since for most pharmaceuticals multiple routes of synthesis can be devised, process patents offer considerably less protection than product patents.*

Until 2004, India recognized only process patents for drugs. Thus, India implicitly provided incentives for local manufacturers to "invent around" the patent (i.e. to develop a different production method); generics thus produced were legal in India, and, as a result, generic versions of newly developed drugs used to be available relatively quickly in India. This has changed, because from 2005 onwards India has implemented this.

TRIPS moreover requires that the minimum duration of patent protection is 20 years (prior to TRIPS, the patent term was 20 years in certain industrialized countries, but shorter in many developing countries), and mandates effective enforcement.

The introduction of these TRIPS higher standards will delay the marketing of generic versions of new drugs<sup>18</sup>, and, thus, the competition they entail; hence it is anticipated that prices of new drugs will remain high for a longer time which will result in reduced access for many people, notably in developing countries. TRIPS does not apply retroactively, therefore there are no implications for drugs that were already off-patent when TRIPS came into force.

TRIPS is to be operationalized via countries' national laws. Moreover, TRIPS does contain - limited- flexibility, as well as some safeguards, which can be used to mitigate the anticipated negative impact on drug prices and on access to drugs.

The most important safeguards are:

- (i) Compulsory licensing<sup>19</sup>,
- (ii) Parallel importation and
- (iii) Provisions for early working (frequently referred to as "Bolar provision"<sup>20</sup>)

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<sup>17</sup> The Dispute Settlement Body (DSB) of the World Trade Organization (WTO) makes decisions on trade disputes between governments that are adjudicated by the Organization. Its decisions generally match those of the Dispute Panel.

<sup>18</sup> Karin Timmermans, "Harmonization, Regulation, And Trade: Interactions In The Pharmaceutical Field" International Journal of Health Services, Volume 34, Number 4 / 2004 pages 651 - 661.

<sup>19</sup> A *compulsory license* is a license to use an invention, which has been granted without the permission of the patent holder.

The TRIPS Agreement states that parallel importation<sup>21</sup> cannot be challenged under the WTO dispute settlement mechanism, thus de facto leaving countries the freedom to choose whether or not to allow parallel importation.

Moreover, during the WTO's Ministerial Meeting in November 2001, the Ministers clarified, in the Doha Declaration on the TRIPS Agreement and Public Health, that countries are free to use parallel importation.

As regards the *compulsory license* provision is concerned it can be used to allow the production and sale of generics before expiry of the patent - thus, again, increasing opportunities for competition and competition drives prices down.

The basic rationale for a compulsory license is that, since a patent is a privilege granted by the government, the government retains the right to limit that privilege if necessary. Many countries, including many developed countries, have provisions for compulsory licenses in their national laws, and compulsory licenses are allowed under TRIPS.<sup>22</sup>

But the TRIPS Agreement does specify *conditions*, which are to be imposed by governments when issuing a compulsory license. These conditions include:

- Case-by-case decision
- First try to obtain a voluntary license
- Adequate remuneration to the patent holder
- Predominantly for the supply of the domestic market
- A compulsory license should be non-exclusive and non-assignable.

The list is not exhaustive; moreover, certain conditions may be waived in specific circumstances. For instance, the condition to first try to obtain a voluntary license does not apply if a compulsory license is issued to remedy anticompetitive behavior of the patent holder, in case of an emergency or in case of public non-commercial use.

So while these conditions have made the process somewhat cumbersome, it is possible to issue a compulsory license in a TRIPS-compliant way.

A special case of compulsory licensing is '*Government use*' or a compulsory license for public non-commercial use. The TRIPS Agreement obliges less rigid conditions in case of '*Government use*'; therefore countries may find that using this mechanism is easier/faster than compulsory licensing.

However, the safeguards provided for in TRIPS can only be used when incorporated in the national law. In addition, as mentioned above, there is some flexibility in TRIPS. For example, one of the conditions for issuing a compulsory license is that the patent holder should receive adequate remuneration. But TRIPS does not define "adequate"; thus, countries have some leeway in this respect.

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<sup>20</sup> The "*Bolar provision*" allows testing and regulatory approval of generic versions of a drug, *before* its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires. In this way, a Bolar provision facilitates generic competition.

<sup>21</sup> *Parallel importation* refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price; for example, if a company sells drug X in country A at a price of \$10, while the same company sells the same drug X in country B for \$1, then someone may import drug X from country B and sell it in country A, charging for example \$3. As a result, in this example, country A would save \$7 on product X. In other words, parallel importation also enables competition, but in a different way.

<sup>22</sup> Tarun Jain, "Compulsory Licenses of Intellectual Property: A survey" The Icfai University Journal of Intellectual Property Rights, Vol. VIII, No. 1, pp. 27-50, February 2012.

Applying flexible criteria of novelty and inventiveness enables for instance the issuing of patents for formulations or for isomers of known drugs, thus allowing pharmaceutical companies to apply for additional patents, and providing them with opportunities to expand the duration of protection beyond that of the original patent. In this way, originator companies can seek to postpone generic competition.

Hitherto, whether this flexibility is in point of fact used in order to facilitate access to medicines eventually depends on national standards and (administrative) procedures.

*For example*, TRIPS mandates protection of undisclosed data submitted to National Drug Regulatory Authorities in order to obtain marketing authorization for new drugs, these registration data have to be protected against disclosure, and against unfair commercial use. Thus, the national authorities may not publish such data or share them with competing (e.g. generic) companies.

Some parties however try to argue for *data exclusivity*, which means that the regulatory authorities would not be allowed to rely on these data for the purpose of registration of generic versions of the drug. By implication, as long as the exclusivity lasts, generic producers would either have to submit their own data - which would oblige them to repeat the clinical trials and other tests- or they would have to delay the launch of their product until the end of the exclusivity period.<sup>23</sup>

Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

TRIPS, though, mandates data protection, but not data exclusivity and national laws need not have requirements that are more stringent than TRIPS.

Similarly, it is important that national trademark laws do *not* hinder pro-public health measures such as generic prescription, generic substitution and/or requirements that a drug's label includes the generic name.<sup>24</sup> Unfortunately, data exclusivity and other requirements that go beyond TRIPS are increasingly being incorporated in bilateral/regional free trade agreements.

## **Trips & Public Health**

*Access to medicines depends on several factors, remarkably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems. Prices are only one factor.*

Hitherto, prices are an important factor, especially in developing countries, since, while in developed countries pharmaceuticals are largely publicly funded, through reimbursement and insurance schemes, in developing countries, typically, 50-95% of drugs are paid by the patients themselves.

Thus, in developing countries, prices have direct implications for access to medicines. Further, it should also be noted that patents are not the only reason for high drug prices; distribution costs, high mark-ups and taxes can also play an important role.

The WTO, principally the Secretariat, the European Commission (EC) and the US, argue that the current TRIPS framework permits a great deal of flexibility in allowing governments to take measures to protect national public health. They therefore are resistant to any attempt to weaken the TRIPS agreement<sup>25</sup>.

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<sup>23</sup> HEALTH-INDIA: Anger Grows at Novartis' Bid to Hog Cancer Drug by By Keya Acharya available at <http://ipsnews.net/news.asp?idnews=36363> last visited on 9 December 2012

<sup>24</sup> Erika Reinhardt, "Access to Medicines" UN Chronicle Online Edition, Issue 3, 2006 available at <http://www.un.org/Pubs/chronicle/2006/issue3/0306p56.htm> last visited on 7 December 2012

<sup>25</sup> *Mariama Williams* "The TRIPS and Public Health Debate: An Overview" International Gender & Trade Network August 2001 available at <http://www.ppl.nl/bibliographies/wto/files/3487a.pdf> last visited on 7 December 2012



*Many developing countries are concerned about the presumed flexibility of TRIPS and worry that the provisions are vague and subject to narrow or restrictive interpretation which can leave them vulnerable to dispute settlement proceedings and or legal suits which are not only protracted and costly but often tend to delay the implementation of measures necessary to remedy public health problems.*<sup>26</sup>

They, therefore, would like to see the WTO take a strong, clear and firm position on the public health safeguard mechanisms available under TRIPS.

Articles 7 and 8 of the TRIPS Agreement<sup>27</sup> specify a quantity of the broad objectives of the agreement, including:

- Promotion of technological innovation,
- Transfer and dissemination of technology; and
- Measures to protect public health and nutrition and to promote the public interest

Further, the Doha Declaration (at the time of the WTO Ministerial meeting in 2001) affirmed the right of countries to use to the full, the flexibility in TRIPS.

Further, the *Minimum protection standard* requires every Member to offer the same level of protection to patent holders. This so-called minimum standard is in fact a high standard for many developing countries reflected by the *non-discrimination principle* in Article 27<sup>28</sup>, which enlarges the scope of protection to almost all possible subject matters.

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<sup>26</sup> Ibid

<sup>27</sup> URUGUAY ROUND AGREEMENT: TRIPS  
Part I — General Provisions and Basic Principles

Article 7

Objectives

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.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

<sup>28</sup> URUGUAY ROUND AGREEMENT: TRIPS

Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Section 5: patents

Article

27

*Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *order public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

This principle facilitates developed countries to gain monopoly from market to research and increase the difficulties for developing countries to enter the market.

Meanwhile, the 20 year patent term requirements in Article 33<sup>29</sup> and the clarification to use the dispute settlement mechanism for incompliance of the minimum standard are also strict. Furthermore, Article 1 also allows higher standards adopted by national law, which result in the emergence of TRIPS-Plus standard in bilateral agreements. The monopoly of patent holders and the barriers for technical transfer are both strengthened. It increases the cost for national industry development in developing countries<sup>30</sup>.

*National treatment principle* in Article 3<sup>31</sup> enables TRIPS agreement to upgrade national treatment principle, which formally applies to importation of foreign goods in GATT, to an international standard which covers multilateral trade and intellectual property protection.

However, National treatment principle does not offer real equal treatment to different Members because it provides equal chances rather than guarantee of equal result. *Most-favored-nation treatment principle* is expressed by Article 4<sup>32</sup> as an important principle of WTO; MFN applies to all kinds of WTO decision. TRIPS adopted it at international level for patent protection for the first time.

(b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

<sup>29</sup> Article 33

Term of Protection :

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date

<sup>30</sup> LI Yang. (2005). On several specific problems about implementation of TRIPS agreement in China. *Chinese Technology Law Annual*. Beijing University Press, 123

<sup>31</sup> URUGUAY ROUND AGREEMENT: TRIPS

Part I — General Provisions and Basic Principles

Article 3

*National Treatment*

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

<sup>32</sup> Article 4

Most-Favored-Nation Treatment:

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:



Prior to TRIPS agreement, international conventions on intellectual property did not adopt this principle, thus the favorable treatment offered in bilateral agreement does not necessarily applies to other Members. MFN principle under TRIPS Agreement is unconditional, multilateral and permanent. As a result, if two Members made an agreement which set up TRIPS-plus standard for patent protection, these Members should offer the same favorable treatments to other Members. The developing countries would then under intensive pressures to provide favorable treatments conceded in bilateral agreement to more Members.

### **Doha Declaration on Trips and Public Health**

The balance between patent protection and public health concerns have been further skewed through a number of Bilateral trade agreements that, in fact, provide for even higher degree of patent protection than what is mandated by TRIPS<sup>33</sup>. The response to the public health crisis has been inadequate even as regards the resources pledged for addressing it.

The Declaration is also a Ministerial decision with legal effects on the Member States and on the WTO bodies, particularly the Dispute Settlement Body and the Council for TRIPS<sup>34</sup>

The Declaration on the TRIPS Agreement and Public Health (Doha Declaration) provides responses to some specific concerns concerning the implementation of intellectual property rights in the field of health<sup>35</sup>

Doha Declaration can be said as first step in making the multilateral trading system attuned with public health interests.

The Declaration stresses the flexibility “for this purpose”, that is, for the purpose of adopting measures to protect public health. Any WTO Member could bring a complaint under the DSU on issues covered by the Doha Declaration and it would be theoretically possible for a panel or the Appellate Body to find an inconsistency between the Doha Declaration and the TRIPS Agreement<sup>36</sup>.

This is unlikely, however, since in adopting the Declaration, Members have exercised their exclusive competence to interpret a WTO agreement<sup>37</sup>, and it would be extremely difficult to challenge the adopted interpretation.

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

<sup>33</sup> [http://www.whoindia.org/LinkFiles/Trade\\_Agreement\\_section2\\_public\\_health\\_safeguards.pdf](http://www.whoindia.org/LinkFiles/Trade_Agreement_section2_public_health_safeguards.pdf) last visited on 9 December 2012

<sup>34</sup> It should be noted that the Ministerial Conference rejected proposed language (“*Desiring to clarify the provisions of the TRIPS Agreement, while preserving the rights and obligations of Members under the Agreement*”) that would have suggested that the Declaration would only *clarify* provisions of the TRIPS Agreement

<sup>35</sup> WTO, Declaration on TRIPS agreement & public health, Ministerial Conference-fourth session, WTO Doc. WT/MIN(01)DEC. 2 (2001) {DOHA DECLARATION} available at [www.wto.org](http://www.wto.org)

<sup>36</sup> Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, University of Buenos Aires June 2002 available at

[http://www.gefoodalert.org/library/admin/uploadedfiles/Implications\\_of\\_the\\_Doha\\_Declaration\\_on\\_the\\_TR.htm](http://www.gefoodalert.org/library/admin/uploadedfiles/Implications_of_the_Doha_Declaration_on_the_TR.htm) last visited on 9 December 2012

<sup>37</sup> Panels and the Appellate Body can only “clarify” the provisions of the WTO agreements; they “cannot add or diminish the rights and obligations provided in the covered agreements” (article 3.2 of the Dispute Settlement Understanding).

*The Doha Declaration is not self-executing it is required that both developed and developing countries should execute the legal amendments indispensable to implement it., especially Developing countries, should make sure that they are using to the full coverage possible the flexibilities allowed by the TRIPS Agreement to protect public health and facilitate access to health care by all.*

### **Interpretation of the Doha Declaration**

There were controversial debates leading up to the finalization of the content of the declaration. In the first paragraph itself this is reflected, where the US wanted to limit the scope of the declaration to a few selected diseases like TB, Malaria and HIV.

This was rejected by developing countries and finally it was agreed to include all diseases in the scope of the declaration, and also vaccines and diagnostic kits, in addition to medicines.

Paragraph four<sup>38</sup> is in many senses the key portion of the declaration. While the paragraph has been interpreted in differing ways by different interest groups, the importance of this section lies in the fact that in case of disputes -- national or international – *legal opinion would need to refer to this paragraph where a clear priority it gives to public health concerns.*

The other significant side of the declaration is the confirmation of flexibilities available in the TRIPS agreement.

The declaration is an authoritative interpretation of TRIPS confirming that members can decide their own grounds for application of the flexibilities. Further, *the declaration makes clear that Compulsory Licenses can be granted on a large number of grounds related to public health concerns, and countries have the freedom to define these. It is further clarified in the Declaration that governments can decide what constitutes an emergency as a ground for granting compulsory licenses and this decision cannot be challenged in DSU.*

The purpose of developing countries in putting forward sub-paragraph 5(a) of the Doha Declaration was to stress the importance of TRIPS Articles 7 and 8 in the interpretation of the Agreement, particularly in the light of Article 31 of the Vienna Convention<sup>39</sup>. They attained their objective without ignoring, however, that other provisions of the Agreement also contribute to the determination of its object and purpose.

In fact, the Doha Declaration goes beyond merely confirming the relevance of Articles 7 and 8 for the interpretation of the TRIPS Agreement. It provides an *understanding* about the purpose of the TRIPS Agreement in relation to public health issues, which should guide any future rulings by panels and the Appellate Body dealing with such issues.

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<sup>38</sup> Doha Declaration on TRIPS and Public Health: Paragraph 4

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Doha Declaration on TRIPS and Public Health: Sub-paragraph 5 (a)

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

<sup>39</sup> It is unclear why this interpretive rule has been considered as one of the “flexibilities” in paragraph 5. In fact, such rule, properly applied, should ensure that due deference to national law is given in appropriate cases; that is, that the flexibility left to Member States is respected by the DSB.

Sub-paragraph 5 (b) of the Doha Declaration deals with an issue central to the interests of developing countries. It simply states what is perceptible: Article 31 sets forth a number of *conditions* for the granting of compulsory licenses but it does not limit the *grounds* on which such licenses can be granted. Though Article 31 refers to some of the feasible grounds for issuing compulsory licenses, it leaves Members with full freedom to stipulate other grounds, such as non-working, public health or public interest.

Though sub-paragraph 5 (b) does not add anything substantively to the understanding of TRIPS, the Doha Declaration specifically employs the expression “compulsory license”, which is not found in the TRIPS Agreement itself.<sup>40</sup> The use of this terminology may help to create awareness, particularly among health ministries in developing countries and LDCs, about the possible utilization of compulsory licenses to meet public health and other objectives.<sup>41</sup>

Paragraph 5 (c) of the Doha Declaration affirm what is an unquestionable right of Members States: the right to determine “*what constitutes national emergency or other circumstances of extreme urgency*”. Such determination may be relevant for the granting of compulsory licenses, the establishment of exceptions under Article 30, or the adoption of other measures permitted under Article 8.1 of the Agreement<sup>42</sup>.

Paragraph 5 (d) provides the sought-after clarification. It specifically states that “the effect of the provisions in the TRIPS Agreement... is to leave each *Member free to establish its own regime for such exhaustion*<sup>43</sup> *without challenge*”

The authorization of parallel imports under an international principle of exhaustion has also been regarded by developing countries as a key component of a patent system sensitive to public health needs<sup>44</sup>.

Under the Declaration the provisions for technology transfers to LDCs under article 66.2 is continued but the LDCs are not obliged to implement Article 5 & 7 of part II of TRIPS Agreement till January 2016.

On one left over question, Ministerial conference assigned further work to the TRIPS Council - to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing.

This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in a separate Doha declaration on TRIPS and health.

<sup>40</sup> TRIPS Article 31 is entitled “[O]ther use without authorization of the right holder”.

<sup>41</sup> Despite the fact that the governmental use for a non-commercial purpose of a patent is not mentioned in the commented paragraph, such mechanism can also be important to attain public health objectives.

<sup>42</sup> In May 2002, the Minister of Justice, Legal and Parliamentary Affairs of Zimbabwe issued a Declaration of Period of Emergency (HIV/AIDS) (Notice, 2002). In view of the rapid spread of HIV/AIDS among the population of Zimbabwe, the Minister declared “an emergency for a period of six months, with effect from the date of promulgation of this notice, for the purpose of enabling the State or a person authorised by the Minister under section 34 of the Act (a) to make or use any patented drug, including any anti-retroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; (b) to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions”. A Declaration of Sanitary Emergency until 31 December 2002 was also issued by the Executive Power of Argentina (Decree 486, 12 March, 2002), but it does not make explicit reference to patent law provisions.

<sup>43</sup> This principle permits the import of a patented product into a country without the authorization of the title holder or his licensees, to the extent that the product has been put on the market elsewhere in a legitimate manner

<sup>44</sup> Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, , Essential Drugs & medicine policy, World Health Organization Health Economics and Drugs Series No. 012, June 2002. Available at <http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf> last visited on 9 December 2012

## **Problems of countries without manufacturing capability**

### **Paragraph six of the Doha Declaration**

*"WTO Members with insufficient or no manufacturing capacity 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 ... before the end of 2002."*

This part tackles the problems of countries without domestic capacity, as they cannot effectively exercise right to grant Compulsory Licenses as there are no domestic generic producers who can produce cheaper generics by making use of the Compulsory Licenses. Their only option is to import from foreign producers.

If they were to issue a Compulsory Licenses to import, they would be faced with the restriction in Article 31(f) of TRIPS which restricts exports of generics produced under a compulsory license "predominantly for the supply of the domestic market". It was also clear that the problem would be confounded after 2005 as countries which were able to supply generic drugs to such countries because patents on pharmaceuticals did not apply - viz. India – would have to change to a regime that allowed patents on pharmaceutical products.<sup>45</sup>

### **Solution by TRIPS Council (new section Art.31 (bis)):**

The WTO Paragraph 6 Decision which was finally agreed to permits manufacturers to produce and export under compulsory license to countries without manufacturing capacity. For such exports, it provides for waivers of TRIPS obligations in Art. 31(f) (necessity to manufacture predominantly for domestic market), and Art. 31 (h) (necessity to provide compensation to the patent holder in the importing company).<sup>46</sup>

*The decision also allows a regional Trade Agreement to export as a single entity. This decision has been in place since August 30th, 2003 and its formal incorporation in the TRIPS Agreement was agreed on 6 Dec. 2005. It becomes Art. 31 (bis) and comes into force in 1 December 2007, when two-thirds of WTO Members ratify the amendment. However, no country has yet made use of this system, which may point to its use being perceived as problematic.*

The country has to notify the TRIPS Council about its intention to use the system and In order to use the system the importing country is required to show that access to a needed product that is protected by a patent has been refused or delayed on grounds such as high price, inadequate production, etc.

Further, both the importing and the exporting countries must have enabling provisions in their national laws to allow this.<sup>47</sup>

The WTO August 2003 decision, as mentioned earlier, is yet to be used. Much of the reason for this is the cumbersome procedure involved requiring importing countries to notify the TRIPS Council about its requirement every time it wants to use the facility and the large number of legal provisions that need to be incorporated in national laws.

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<sup>45</sup> Supra note 31

<sup>46</sup> Ibid

<sup>47</sup> Enabling provisions need to include Compulsory Licenses provisions for import and export (in the importing and exporting countries respectively) and waiver of remuneration to Innovator Company in importing country. Enabling legislations allowing exports through this system have been passed in Canada, Norway, India, China, and is under preparation in the EU.

Moreover, given that each requirement needs to be notified and sanctioned, manufacturers in exporting countries do not see a ready and assured market, thereby making them reluctant to produce for exports in such conditions.

### **Compulsory licensing after DOHA declaration**

The joint declaration on the TRIPS agreement and public health<sup>48</sup> following the WTO, DOHA ministerial conference of November 2001 in Qatar doesn't alter the state of play fundamentally. At the time, however a consensus on this issue was seen as imperative for the successful conclusion of a new round of world trade negotiations.<sup>49</sup>

The ministerial declaration amounts to an understanding that for the time being members will not bring action before the WTO-DSB over compulsory licensing of essential patented drugs.<sup>50</sup> The Ministerial Declaration hinges on TRIPS Art.8 (1) and its exception for the institution of the measures necessary to protect public health that are consistent with the TRIPS provision. This means that the measure adopted should also have some effect on public health.

On the whole TRIPS agreement is much more precise in defining when a compulsory license may be demanded.

The issue arises because Article 31 (f) of the TRIPS Agreement states that products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies directly to countries that can manufacture drugs - it limits the amount they can export when the drug is made under compulsory license. And it has an indirect impact on countries unable to make medicines - they might want to import generics made in countries under compulsory license, but find that Article 31 (f) poses an obstacle to other countries supplying them.

The TRIPS Council was instructed to find a solution and report to the General Council on this by the end of 2002. However it was not until 30 August 2003 that consensus could be reached.

After deliberations, the Members arrived at a decision which was adopted by the General Council of the WTO in its meeting held on 30 August, 2003. The Decision is contained in WTO document WT/L/540. It provides waivers from the obligations of Article 31 (f) and Article 31 (h) of the TRIPS Agreement, i.e. a compulsory license may be issued not only for predominantly domestic use, but it can also be issued to the extent necessary for the purposes of production of a pharmaceutical product and its export to such countries that have insufficient manufacturing capacity, subject to certain conditions.

Para 11 of the document (WT/L/540) stipulates that this Decision, including the resultant waivers granted, would remain operative for a Member till the date on which an amendment to the TRIPS Agreement, replacing its provisions takes effect for that Member. It was also enjoined upon the Council for TRIPS to work on the preparation of such an amendment in the TRIPS Agreement based on the Decision<sup>51</sup>.

After deliberations in the Council for TRIPS, a decision was taken in the General Council about the amendment to the TRIPS Agreement, which is contained in WTO document number WT/L/641 dated 8 December, 2005. This document was later adopted at the Hong Kong Ministerial Conference of the WTO. India has accepted the Protocol amending the TRIPS Agreement, and notified the same to the WTO (WT/LET/572) on 26th March 2007.<sup>52</sup>

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<sup>48</sup> Hereinafter called as Ministerial Declaration

<sup>49</sup> Christopher Heath; Industrial property in the bio-medical age: Asia, 1st Edition, Kluwer Law International; 2003; vol.8; p. 178

<sup>50</sup> <http://jurybrain.com/images/COMPULSORY%20LICENSING%20IN%20INDIA.pdf> last visited on 16 December 2012.

<sup>51</sup> [commerce.nic.in/trade/international\\_trade\\_ip\\_trips3.asp](http://commerce.nic.in/trade/international_trade_ip_trips3.asp) last visited on 18 December 2012

<sup>52</sup> Ibid



The Patents (Amendment) Act, 2005 has already made provisions for taking advantage of the waiver arising out of the General Council Decision of 30 August, 2003.

### India's Compliance with Trips

The Indian patent system has experienced continuous adaptation over the past decade, partly as a reflection of the diverging standpoints and changing priorities of government, national industry, public health NGOs and other stakeholders.

India is a major source of supply of the world's generic medicines; it exports 66.7% of its Products to developing countries.<sup>53</sup> India's efforts to comply with its WTO obligations to protect product patents on medicines started on January 1, 2005<sup>54</sup>. India has sought greater flexibility and clarity in the interpretation of the TRIPS Agreement of the WTO in order to ensure affordable access to essential medicines and life saving drugs in keeping with the public health concerns of the developing countries.<sup>55</sup>

*The Indian Patents (Amendment) Act, 2005 introduced product patents in India and marked the beginning of a new patent regime aimed at protecting the intellectual property rights of patent holders. The Act was in fulfillment of India's commitment WTO on matters relating to the Agreement on TRIPS.*

The Indian Patents Act, 1970 has been primarily responsible for laying a strong foundation for growth and development of pharmaceutical industry in independent India.

One of the important provisions contained in this Act was permitting only process patents of drugs and pharmaceuticals, chemicals and certain food articles.

Nevertheless, during the period of 1995 to 2005, India carried out three amendments in the Indian Patent Act.

**In the first amendment<sup>56</sup>**, provisions were made for acceptance of product patent applications and for granting of Exclusive Marketing Rights (EMRs) on such applications in the field of pharmaceuticals and agro- chemicals.

**In the second amendment** in 2002, important substantive provisions, such as redefining patentable subject matter; extension of patent term to 20 years, amending compulsory licensing system, were included. parallel imports of products patented in India were allowed, subject to the condition that the foreign exporter was authorized by the patentee to sell and distribute. Under the amended Act (2005), the foreign exporter need only be duly authorized under the law.<sup>57</sup>

The Patents (Amendment) Act, 2002 had introduced the Bolar provision to allow for using and selling the patented product during the term of the patent, for obtaining regulatory approvals.<sup>58</sup>

**Finally by third amendment in 2005**, the Act provided for product patents which marked the beginning of new patents regime in India.

The TRIPS compatible Indian Patents (Amendment) Act, 2005 addressed few important issues regarding patent of products:

<sup>53</sup> The World Health Organization (WHO), *World Medicines Situation*, 2004

<sup>54</sup> [http://www.healthgap.org/press\\_releases/05/020105\\_HGAP\\_FS\\_INDIA\\_IPR.pdf](http://www.healthgap.org/press_releases/05/020105_HGAP_FS_INDIA_IPR.pdf) last visited on 15 December 2012.

<sup>55</sup> [http://commerce.nic.in/PressRelease/pressrelease\\_detail.asp?id=510](http://commerce.nic.in/PressRelease/pressrelease_detail.asp?id=510) last visited on 17 November 2012.

<sup>56</sup> Third Amendment to Patent Act in 1999, effective from January 1, 1995

<sup>57</sup> <http://www.thehindubusinessline.com/2005/09/23/stories/2005092300911000.htm> last visited on 12 December 2012

<sup>58</sup> Ibid



- Adopting the definition of ‘pharmaceutical substance’;
- Exclusion of ‘mere discovery of new form of known substance’ and the ‘new use for a known substance’; and
- Protecting the interests of those who are already manufacturing the products which may be granted patent protection in the new regime’.<sup>59</sup>

Furthermore, the Act brought in new definition of the term ‘new invention’ and also introduced restrictions in the scope of patentability [section 3(d)]. It is explicitly mentioned in section 3(d) that patents would not be granted on the following grounds:

- The mere discovery of a known substance, which does not result in the enhancement of the known efficacy of that substance,
- The mere discovery of any new property or new use for a known substance, and;
- 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”

The section has an objective of preventing pharmaceutical companies from obtaining patents on old medicines i.e. trivial patenting and new use patents etc.

Therefore, India while complying with the TRIPS agreement and introducing a product patent regime for ‘new drugs that were invented’, also added a safeguard enabling refusal of patents on discovery of new forms or new uses of old drugs (i.e. preventing ever-greening).

It is noteworthy that the TRIPS Agreement provides in its objectives and principle that each country can introduce a patent regime that is more suited to its socioeconomic context.

### **Compulsory License in India**

Compulsory license may be granted on diverse grounds. It is to be determined by national laws. The purpose of granting compulsory license in India is to see that the patented inventions are worked on a commercial scale in the territory of India and that the interest of any person working or developing an invention is not realized<sup>60</sup>.

The Indian Patent Act gives a pointer to the objects of compulsory licensing and requires that while granting a compulsory license the general considerations enunciated in the section have to be focused upon<sup>61</sup>. The Act imposes a duty on the patentee to work the patent in India.<sup>62</sup>

### ***License of rights under 1970 Act:***

The provision in this Act says that patents on food and drugs must be endorsed by the license of rights; anybody who is interested in the production of drugs indigenously can approach the government for the issue of license.

The government will issue the same as a matter of the right of the manufacturer and also it will be in the interest of public welfare. Now that this clause has been removed, we wanted the TRIPS clause 31(B) to be inserted in our legislation.

<sup>59</sup> Biswajit Dhar, “Post 2005 TRIPS Scenario in patent protection in the pharmaceutical sector: the case of generic pharmaceutical industry in India” available at <http://www.iprsonline.org/unctadictsd/docs/Dhar%20Indian%20Pharma%20November06.pdf> last visited on 12 December 2012

<sup>60</sup> Sec.89; Indian Patents Act 1970

<sup>61</sup> Sec.83, Indian Patent Act 1970

<sup>62</sup> [jurybrain.com/.../COMPULSORY%20LICENSING%20IN%20INDIA.pdf](http://jurybrain.com/.../COMPULSORY%20LICENSING%20IN%20INDIA.pdf) last visited on 20 December 2012

The time limit of six months for voluntary negotiations for issuance of compulsory license added by explanation 2 of sec.84 of the Patent Act is in accordance with the reasonable period of time provided in the TRIPS agreement.

The Patent Amendment Act, 2005 amends sec.90 (1) (vii) of Indian Patents Act and specify that the license have to be granted with principal purpose of supplying the Indian market, provided that the market for the patented article has not been met to an adequate extent or on reasonable terms’.

The Amendment Act has inserted a new section sec.92-A explicates "Compulsory License for export of patented pharmaceutical products in certain exceptional circumstances".<sup>63</sup>

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 health problems, provided compulsory license has been granted by such country or such country has by a notification or otherwise allowed importation of patented pharmaceutical products from India<sup>64</sup>.

Explanation to the section defines a pharmaceutical product as any patented product or products manufactured through a patented process of the pharmaceutical sector needed to address health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

The two sections included under the same chapter of the Act, contain in themselves a stark difference on certain prominent fronts. Section 84 clearly demands a lapse of a three year period to have taken place before a Compulsory Licensing application be made, while Section 92A is silent on this front. As regards the applicant, the general provision allows any person, notwithstanding a licensee<sup>65</sup>. The provision on Compulsory Licensing for export, however states that a compulsory license shall be "available" to an applicant to enable manufacture and export to any country having insufficient or no manufacturing capacity in the pharma sector for the product to address public health problems.<sup>66</sup>

In brief it can be summarized that:

- Has introduced product patent protection for pharmaceuticals from 1 January, 2005
- Hence unless otherwise authorized, Indian generic companies cannot produce new drugs developed abroad

It is widely believed that the Global product patenting of medicines will:

- Enhance the monopoly power of the MNCs and
- Result in higher prices and lesser access of medicines

But those in favor of TRIPS argue that Countries such as India with developed generic companies can gain economically

### Recent Development

The Supreme Court of India, in a recent landmark decision has rejected a patent application made by the drug manufacturer, Novartis AG (“**Novatis**”) in relation to its cancer cure drug *Gilvec*.

<sup>63</sup> <http://www.thefreelibrary.com/Contemplating+Compulsory+Licensing:+A+Comparison+Between+The...-a0184196104> last visited on 15 december 2012

<sup>64</sup> Patent Amendment Act 2005, sec.55; Indian Patent Act 1970, sec.92-A

<sup>65</sup> Supra note 61

<sup>66</sup> [www.belipo.bz/e\\_library/articles/TRIPS%20FLEXIBILITIES.pdf](http://www.belipo.bz/e_library/articles/TRIPS%20FLEXIBILITIES.pdf) –last visited on 7 December 2012

This case is very significant as it has come post TRIPS & Doha rounds. Not only has that but the judgment given way for the generic drug manufacturers a right over patent holders.

### **Brief History of the Novartis Case**

On 17 July 1998, Novartis filed an application before the Patent Office, Chennai for grant of patent on the beta crystalline form of Imatinib Mesylate (“**Drug**”), which is used for the treatment of leukemia. On 25 January 2006, the Assistant Controller of Patents and Designs passed an order rejecting the patent claim filed by Novartis on the grounds that the invention claimed by Novartis was obvious, anticipated and that the grant of patent on the Drug is not permitted under Section 3(d) of the Patents Act, 1970 (“**Patents Act**”). Against this order, Novartis filed an appeal in the Madras High Court, which was later transferred to the Intellectual Property Appellate Board (“**IPAB**”). The appeal was rejected by the IPAB on 26 June 2009. Aggrieved by the rejection of grant of patent on the Drug, Novartis approached the Supreme Court. The Supreme Court in its judgment dated 1 April 2013 (“**Judgment**”) has upheld the rejection of Novartis’ patent claim on the Drug<sup>67</sup>.

The Apex Court analyzed the words given under section 3(d) of the Patent Act and found that the concept of ‘ever greening’ used by the patent holder to get an extended patent does not hold good. As here the minor changes are made by the patentee and get the monopoly over the drug. Now since it was a matter concerning a society run by the principle of Socialism and where the drug was to cure many thousand crore affected patients, the judgment holds really fruitful for country like India.

Quoting the case, The Supreme Court held that, the term “efficacy” in Section 3(d) meant “*the ability to produce a desired or intended result*”. Therefore, the test of efficacy in the context of section 3(d) would depend upon the result, the function or the utility that the product under consideration is desired or intended to produce. Consequently, the court concluded that in the case of a medicine that claims to cure a disease, the test of efficacy could only be “therapeutic efficacy”, i.e. the capacity of the drug for beneficial change. Thereafter, the court concluded that the physiological properties of the Drug, i.e., more beneficial flow properties, better thermodynamic stability and lower hygroscopicity do not result in enhancement of “therapeutic efficacy”. Further, on Novartis’s claim that increase in bioavailability results in enhancement of therapeutic efficacy from the known substance, the Supreme Court held that the same will need to be collaborated with necessary data and research in each case and as Novartis did not submit any material to demonstrate this, the Drug fails to satisfy the test laid down in section 3(d) of the Patent Act.<sup>68</sup>

The judgment was condemned by many MNC pharma companies but here worth is notable that Apex Court of India does not banned the product patent, rather it has actually upheld the very basic instinct of the TRIPS. It has only saved the indigent population of India from becoming puppets in the hand of the monopolistic market strategies of mighty companies.

### **Conclusion**

Compliance with WTO is not a matter of simply aligning the national laws through legislations but it should be made after considering the interests of people. The present article has to be concluded with the words “*a lot many has to be done with regard to compulsory licensing under the existing Patent Act 1970 in order to secure a balance between interest of the producers and the users of technology*”. The objective of the Doha Declaration on the TRIPS Agreement and Public Health was to clarify the official stand on certain provisions of TRIPS relating to public health. It recognizes the concerns of developing countries and LDCs on the issue.

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<sup>67</sup> <http://pxvlaw.wordpress.com/2013/04/04/analysis-of-the-supreme-courts-novartis-judgement>

<sup>68</sup> Ibid

The Doha Declaration addresses real and urgent problems faced by many developing countries in the area of public health. The Declaration clarifies that 'public health crises' can represent 'a national emergency or other circumstances of extreme urgency', and that an 'emergency' may be either a short-term problem, or a long-lasting situation.

The Declaration also reiterates that the agreement should be interpreted and implemented in the light of members' right to protect public health and promote access to medicines for all.

Nevertheless, significantly, the Doha Declaration does not define the term 'public health'. A narrow interpretation of the term would clearly render many public health initiatives futile. While member countries are theoretically empowered by the document to decide what constitutes a national emergency or other circumstances of extreme urgency, the possibility of a narrow interpretation by the panel remains, leaving them at the mercy of the whims and fancies of the WTO Dispute Settlement Body.

The Doha Declaration does recognize the obvious problems faced by developing countries in promoting public health, especially in the wake of epidemics like AIDS, malaria, tuberculosis, etc. But the very fact that the document restricts itself to certain specific epidemics creates a problem as the flexibility may be allowed only in the case of these particular diseases, if at all.

The pharmaceutical industry would certainly like to interpret this provision restrictively, leaving out certain diseases prevalent in member countries which may not be internationally recognized as epidemics. For example, diabetes, cancer and certain tropical diseases that are endemic in the developing world may not be given the same importance even though they represent serious public health concerns in many countries

In theory, even the drugs used to cure cancer can be manufactured by compulsory license.

Thus, it is an event of significance for developing countries to take measures to determine the scope of disease which would cause 'national emergency' according to their own interests.

All the areas where flexibility of the TRIPS Agreement are not covered by The Doha Declaration, like

- The exceptions to patent rights (Article 30) and
- The protection of data submitted for the registration of pharmaceutical (and agrochemical) products (Article 39.3).

Further it does not refer to the room left to Members to determine the patentability standards in ways that prevent patenting strategies aiming at expanding or temporally extending the protection conferred in the pharmaceutical field.

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