

PHARMA SECTOR IS TRIPS COMPLIANT IN INDIA: ANALYSIS OF PHARMA GATEWAY

Reenu Chauhan*

Abstract

Our country was obliged to bring certain changes to its existing patent system in order to make it TRIPS compliant. Becoming TRIPS-compliant signifies the patent scenario and giving birth to a flourishing generic drug manufacturing industry which in a great way shaped India's glorious future in the field of pharmaceuticals and India emerged as one of the greatest hub for generic medicines in the world. India revenue shares in pharma sector on Research and Development (0.8 per cent of GDP) with its Asian companion China (1.9 per cent), Korea (3.8 per cent) and the United States (2.7 per cent). As per the International IP Index released by the Global Intellectual Property Center of the US Chamber of Commerce, India occupied 29th position among the IP friendly countries. China got the higher place of 19th in IP indexing. PwC-Association study on "Innovation-driven growth in India" conducted in January 2016 addressed India as the topmost industry with 500 brands globally in comparison to China had only 32. Top three Indian pharma companies registered in New York Stock Exchange (NYSE) in its international indexing conducted in 2013. This paper aims to analyse the link between Indian pharmaceutical industries vis-a-vis multinational companies in the Legal Framework of WTO-TRIPS Regulations.

Keywords: WTO-TRIPS, GATT, Pharma, Doha Declaration, WTO Ministerial Conference

Introduction

In 1995, the World Trade Organization¹ was born, one of the youngest of the international organizations, replacing the then operating General Agreement on Tariff and Trade² established around the time of Second

* Reenu Chauhan, Research Scholar, Department of Laws, Panjab University, Chandigarh.

¹The World Trade Organization hereinafter referred as WTO deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible, available at:

http://www.wto.org/english/thewto_e/countries_e/turkey_e.htm (last visited on December 5, 2016).

²General Agreement on Tariffs and Trade hereinafter referred as GATT was a multilateral agreement regulating international trade. According to its preamble, its purpose was the "substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis. "It was signed by 23 nations in Geneva on October 30, 1947 and took effect on January 1, 1948. It lasted until the signature by 123 nations in Marrakesh on April 14, 1994 of the Uruguay Round Agreements, established the (WTO) on January 1, 1995, India, has been a WTO member since 1 January, 1995 and a member of GATT since 8 July, 1948.

World War. It is an international organ having at its heart are the WTO agreements, among which one is Trade-related aspects of intellectual property right,³ till today, this plethora of Ministerial Conferences and Declarations of the WTO outline its position in the vast field of international trade and commerce.⁴ The effect of WTO-TRIPS on Indian pharmaceutical industry was a much discussed topic at that time. The TRIPS Agreement addressed the member nations to follow minimum standards for protection of their intellectual property rights, if they agreed. Member's countries are welcomed to amend their laws to fit into the regime of TRIPs agreement.⁵

In the year 1947, India was one of initiator of the GATT's legal agreement and in 1995 become the signatory nation of intergovernmental organisation i.e. WTO and then engaged in the one of most important agreement of WTO i.e. TRIPs. Initially India was not in favour to comply with TRIPs, the reason was developing country needs to revise their Patent system regime from patent process⁶ to product Patents in pharma and agrochemical sector. With the passage of time, India amended its IPRs policy in the year 1998-99. The IPR policy on pharmaceutical is around 120 years. The Confederation of Indian industry (CII),⁷ associated chambers of commerce and industry of India (ASSOCHAM)⁸ and also the Federation of Indian Chambers of Commerce and Industry (FICCI)⁹, are considered the best industrial hub of India which are in tuning with IPR. Indian Pharma industry is 3rd in size and the 13th biggest in revenue; being a huge country India is the generic hub of drugs around 20% of exports worldwide; approximately 80% antiretroviral drugs of AIDS delivered by India's Pharma giants. "Pharma Vision 2020" of the Indian government targeted the pharma industry to be number one in global ranking. Government of India working on cost reduction to minimise the price of medicines as per the

³The Agreement on Trade-Related Aspects of Intellectual Property Rights hereinafter referred as TRIPs is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property rights hereinafter referred as IPR regulation as applied to nationals of other WTO Members. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994, *available at*:

https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm+&cd=3&hl=en&ct=clnk&gl=in (last visited on December 5, 2016).

⁴The Ministerial Conference is the topmost body of the WTO under the governance structure set up by the "Agreement establishing the WTO", *available at*: https://www.wto.org/english/thewto_e/minist_e/min_declaration_e.htm, (last visited on December 5, 2016).

⁵Correa, C. M. 2002: Intellectual Property Rights, the WTO and the Developing Countries: The TRIPS Agreement and Policy Options. Zed Books Ltd, London.

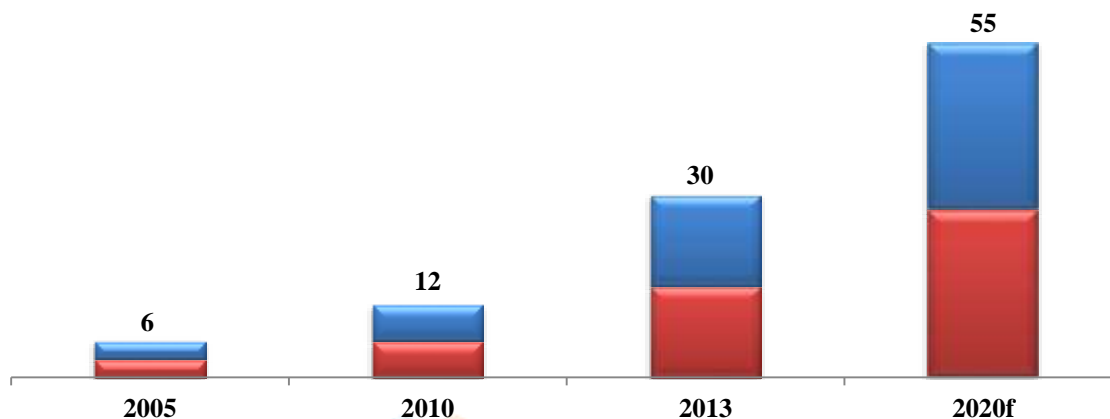
⁶Under a process patent, the patent is granted for a particular manufacturing process, and not for the product itself. Weakness of the process patent regime is that it gives less protection for the inventor. Benefit of process patent regime is that it reduces the element of monopoly, *available at*: <http://www.indianeconomy.net/splclassroom/98/what-is-the-differencebetween-product-patent-and-process> (last visited on December 10, 2016).

⁷These are three major business lobbies in India: CII operates through National / Regional / State and Zonal Councils. It has specialised Industry Divisions and Affiliated Associations/ Institutions. It has 3,000 member companies.

⁸ASSOCHAM is the highest body of the Chambers of Commerce of India, providing a forum for dialogue between business and government. It produces a number of publications. It has a membership of about 65,000 direct and indirect corporate enterprises. A managing committee of 108 members governs the affairs of

⁹FICCI is backed by a nationwide network of Chambers of Commerce and Industry, Trade and Industry Associations, Professional Institutions, corporate bodies and private firms. It covers more than 100,000 business units.

guidelines of Drug Price Control Order and the National Pharmaceutical Pricing Authority for the accessibility of drugs. The following chart exhibits Indian pharma sector revenue trends-¹⁰



Indian administration is trying hard to minimise the price of necessary drugs, production of generic drugs and the total development of pharma sector is higher in their priority list.¹¹ Indian pharma industries Dr. Reddy's laboratories and Ranbaxy¹² are looking forward to be part of new patent regime to raise their revenue share in pharmaceuticals worldwide. The Patent Act 1970 amended thrice - *firstly*, The Patents (Amendment) Act, 1999, *secondly*, The Patents (Amendment) Act, 2002 and *thirdly*, The Patents (Amendment) Act, 2005 to be a TRIPS compliant country.¹³

Under the TRIPs agreement, all the member countries have to provide protection of Product Patents from January 1, 1995¹⁴. There are two schemes to provide protection to the inventor. India, a developing country has a regime of Process patent which is preferred by most of the developing nations, having a transition period of

¹⁰Indian Pharmaceutical Industry, "Increasing investments in the pharma sector, sectoral report" (2017), Source: Department of Pharmaceuticals, PwC, And McKinsey, Tech Sci Research Notes: F - Forecast, CAGR - Compound Annual Growth Rate, available at: <http://www.ibef.org/industry/pharmaceutical-india.aspx,htm> (last visited on 20 January, 2017)

¹¹India in Business, Ministry of External Affairs, Govt. of India, Economic Diplomacy Division, available at: http://indiainbusiness.nic.in/newdesign/index.php?param=industryservices_landing/347/1 (last visited on January 20, 2017).

¹² Dr. Reddy's manufactures and markets a wide range of pharmaceuticals in India and overseas. The company has over 190 medications. In 2014, Dr. Reddy Laboratories was listed among 1200 of India's most trusted brands. Reddy's the third largest pharmaceutical company in India, after Ranbaxy and Glaxo (I) Ltd.

¹³The Patents Act, 1970 is the legislation that till date governs patents in India. It first came into force in 1972. The Patents Act has been repeatedly amended: 1999, 2002, 2005, and 2006. These amendments were required to make the Patents Act TRIPS-compliant. The major amendment was in 2005, when product patent was extended to all fields of technology like food, drugs, chemicals and microorganisms. 2005 was the final deadline for complete compliance with TRIPS. The Rules under Patent Act were also amended in 2012, 2013, 2014.

¹⁴Process patent regime is that it gives less protection for the inventor. There is high tendency for competitors to reengineer the original invention by discovering a new process with less strain and investment. It reduces the element of monopoly. In the case of Product patent, it is an exclusive right given to the original inventor of a product. This means that no other manufacturer can provide the same product through the same or any other process. TRIPs follow the product patent regime. For e.g. iPhone can be produced with around six thousand rupees in terms of material cost. But its price is nearly Fifty five thousand Rupees because there are big royalty payments to large number of inventors who have invented its different components, available at: <http://www.indianeconomy.net/splclassroom/98/what-is-the-differencebetween-product-patent-and-process#sthash.bsPOj22K.dpuf> (last visited on December 11, 2016).

10 years to be effective till 2005 to modify its patent regime system from Process patent to product patent. This transition time was allowed to those countries whose applications were filed after January 2005 and the countries agreed to provide Exclusive Marketing Rights (EMR) ¹⁵ to the patented drugs. This transition period for LDCs was stretched to 2016, and could be stretched beyond that. This distinction of patent protection is made to reduce cost discernment in the developing and LDCs states to access the drugs and invention of new drugs. The motive behind this transition period is to strengthen the import of developing countries' pharma industry. The vision is supported in numerous international conferences-¹⁶

1. International Perspective Regarding Pharmaceuticals

1.1. Doha Ministerial Conference

On 14 November, 2001 member nation's administrators pointed out that the TRIPs must be construed in such a way to favour community health to promote access of essential medicines. So they demanded for a special clause to be added in TRIPs agreement on public health. Flexibilities in the TRIPs must not come in way to hinder the safety of public health. Access of essential drugs and the right to protect public health is a fundamental duty of every nation. TRIPs allowed the member to use the flexibilities of compulsory licensing of essential medicines and parallel importing. TRIPs council on the recommendations of members enumerated additional facilities in the agreement so that pharma industries can manufacture generic version of patented drugs domestically at low cost. These were the three key issues of TRIPs raised in Doha ministerial conference.¹⁷ The Doha Declaration considered the subsequent implications in the agreement -

Firstly, TRIPs must be harmonious with public health and addresses the challenges come in way of public health. *Secondly*, member nations must be free to transform their laws in absence of any command of super powers. *Thirdly*, the greatest concern was the use of flexibly (compulsory licensing / parallel importing) by the member nation to manufacture the drugs nationally. The questions were whether TRIPs are/will be able to tackle such challenges.¹⁸

The Doha Pronouncement on TRIPS and Public Health was totally focused on the access of drugs to the developing countries and least developing countries (LDCs). The main concern of the declaration is the alliance

¹⁵The term Exclusive Marketing Rights (EMRs) means the right to sell or distribute the article or substance covered in a patent or patent application in the country. EMRs is granted when there is no system of product patent in a country. It is only a temporary arrangement which will cease to have effect when product patent regime is introduced, *available at*: <http://www.legalservicesindia.com/article/article/product-patent-&-exclusive-marketing-rights-929-1.html> (last visited on December 12, 2016).

¹⁶Research and Development, "Exports and Patenting in the Indian Pharmaceutical Industry: a Post TRIPS Analysis" 4(7) *EJBE* 53-67(2011), *available at*: <http://ejbe.org/EJBE2011Vol04No07p53KIRAN-MISHRA.pdf> (last visited December 13, 2016).

¹⁷The Doha Declaration on TRIPS and Public Health, *available at*:

http://www.wto.org/english/tratop_e/trips_e/healthdeclxpln_e.htm (last visited on December 18, 2016).

¹⁸ *Id.*

of developing countries and LDCs with TRIPS to support public health. The purpose is the protection of intellectual property rights for the invention of new medicines with low cost in pharma sector.¹⁹

It again raised the questions on the use of flexibility mentioned in the agreement e.g. exceptions to patent rights²⁰ and data protection measures of pharmaceutical (biochemical and agrochemical) products.²¹ Member nations is not free to regulate the own patent standards in the pharma sector. In other words, they can't legislate without the influence of developed nations.²²

1.2. TRIPs approach on Pharmaceutical -

TRIPs agreement deals with patents of new innovation; Patents are those methodologies of intellectual property rights which ensure the special rights to the owner of the innovation for a limited duration in the invented country. This agreement is based on two principles "national treatment²³ and most-favoured-nation treatment".²⁴ Regarding the pharmaceutical sector and patents, these articles 4, 7, 27, 28 and 33 mentioned in the TRIPs Agreement²⁵ provides the protection and enforcement of IPR.²⁶

The owner of patent can produce and export that invention as TRIPs unequivocally defines a settled duration of 20 years of protection of the invention. Research work in pharma sector is full of challenges and time taken. Hypothetically, a new drug invention took a minimum duration of 9 to 13 years for human ingestion; expense on it is approximately 802 million USD which is equitant to 30% of the entire cost of company's expenses.²⁷

¹⁹Carlos Correa, "Implications of the Doha Declaration on the TRIPs Agreement and Public Health" WT/MIN (01)/DEC/W/2, 14 November 2001, available at: <http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf> (last visited on December 15, 2016).

²⁰ Article 30 of the TRIPs agreement says exceptions to Rights Conferred.

²¹ Article 39.3 of the TRIPs agreement says protection of undisclosed information.

²² *Supra* note 17.

²³ Article 3, TRIPs Agreement deals with National Treatment, 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.

²⁴ Article 4, TRIPs Agreement deals with Most Favoured 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 Member.

²⁵ Article 7, TRIPs Agreement lays down the objectives for protecting and enforcing intellectual Property rights as they "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."

Article 27 (1) TRIPs Agreement says that "patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

Article 28 TRIPs Agreement provides the exclusive rights for the patent owner on "making, using, offering for sale, selling, or importing for these purposes that product."

Article 33 TRIPs Agreement determines the term of protection which "shall not end before the expiration of a period of twenty years counted from the filing date". Consequently, when the TRIPs Agreement comes into force, the Patent protection has to be provided, for both the pharmaceutical products and process.

²⁶ The Agreement on Trade-Related Aspects of Intellectual Property Rights, available at:

https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited on December 20, 2016).

²⁷ DiMasi, *et. al.*, – using micro-level data, analysed the innovation costs of a new product in the pharmaceutical sector. Their findings show that the cost of a new drug reaches 403 million USD comparing these results with their earlier findings. DiMasi, J. A. – Hansen,

Patent protection leads to the monopoly of product by reducing the competition in market. TRIPs ensure the protection of patented goods for 20 years. The inventor of patented product receive the royalties for approximately 7-11 years for the time and cost on research with further scope of research in invention. Patent provides the protection in two ways it raises the price of medicine to compensate the cost endured by the owner also the profits on the other side by creating the monopoly. There are 265 nations worldwide out of which 153 are WTO member nations²⁸; it can be predicted that the patents of the pharmaceuticals will be phenomenal in the near future. Member nations have to amend their laws to be a TRIPs compliant nation.²⁹

1.3. The WTO's most recent Ministerial Conference-

1.3.1. *The Latest World Health Estimates released in December 2016*, a number of 212 million cases of malaria, almost one million fatal –reported among African children. HIV infection remains to be a major global public health issue, more than 35 million lives so far.³⁰ In 2015, 1.1 million people died from HIV-related causes globally. There were approximately 36.7 million people living with HIV at the end of 2015 with 2.1 million people becoming newly infected with HIV globally. Sub-Saharan Africa is the most affected region; with 25.6 million people living with HIV 18.2 million people were accessing antiretroviral therapy till June 2016.³¹ Also sub-Saharan Africa accounts for 1/3 of the worldwide total of new HIV infected. Human cases for avian influenza H5N1 (Bird flu) conveyed to WHO from 2003-2016. The bird flu has a history of extremely high death rate. In some parts of the world, more than half the people infected with it die.³² Public health, essential drugs, access and availability of drugs and the role of pharma sector is the most important concern of WTO. Apart from shortcomings in the agreement, this is first agreement which provides access of drugs to the developing plus least developing countries free from the clutches of developed one.³³

1.4.1.1. *In a press release of World Trade Organisation-* WTO works in multiple sectors, its main concern is in the advancement of trade sectors. TRIPs were first in this regard, to afford protection of intellectual property.³⁴

R. W. – Grabowski, H. G. 2003: The price of innovation: New estimates of drug development costs. *Journal of Health Economics*, 2, pp. 151–185 (last visited on December 21, 2016).

²⁸Moerman, L. – van der Laan, S.: TRIPs and the pharmaceutical industry: Prescription for profit? *Critical Perspectives on Accounting*, 17, pp. 1089–1106, 2006 (last visited on December 21, 2016).

²⁹CIA 2009, US Department of State 2009): The world fact book, *available at*: <https://www.cia.gov/library/publications/the-world-factbook/geos/xx.html> (last visited on 21December, 2016).

³⁰The WHO Global Technical Strategy for Malaria 2016-2030 – adopted by the World Health Assembly in May 2015 provides a technical framework for all malaria-endemic countries, *available at*: <http://www.who.int/mediacentre/factsheets/fs094/en/> (last visited on December 25, 2016)

³¹At the end of 2015, US\$ 19 billion was invested in the AIDS response in low- and middle-income countries (not including the countries that have recently transitioned into high-income categories), *available at*: <http://www.unaids.org/en/resources/fact-sheet> (last visited on December 25, 2016)

³²WHO publish information on human cases with H5N1 avian influenza, *available at*:

http://www.who.int/influenza/human_animal_interface/H5N1_cumulative_table_archives/en (last visited on 24 December, 2016).

³³Amended TRIPs Agreement close To Ratification, director general of the World Trade Organization Roberto Azevêdo by Peter Kenny for Intellectual Property Watch in November 25, 2016, *available at*: <http://www.ipwatch.org/2016/11/25/amended-trips-agreement-close-ratification-says-wtos-azevedo/> (last visited on December 27, 2016).

The then UN Secretary-General, Kofi Annan also emphasis that by safeguarding the IP pharma market it will be able to fulfil the needs of developing and least developing countries too.³⁵

1.4.1.2. *WTO's Workshop on trade and public health –*

On 17-21 October 2016, 35 states representatives of 30 developed nations and 5 developed countries participated in an international workshop on trade and health at the WTO's headquarters. The participant countries opened on policy making, health and WTO agreements on trade related. This is approach of international trinity i.e. WHO with WIPO further with WTO to strengthen the public health and innovation via intellectual property to comprehend its impact on trade.³⁶

1.4.1.3. *The joint symposium on antimicrobial resistance (AMR) -* The joint symposium was held by the WTO, WIPO and WHO,³⁷ in the year 2016 global cooperation focused on innovation in pharmaceuticals sectors and access to antibiotics; as well as WTO's starring involvement to afford antimicrobial resistance and the challenges encountered in their resistance. A number of Trade agreement safeguards access to the affordable medicines. Trade Facilitation Agreement of WTO accelerates the measures for the protection of delicate and frozen foods containing drugs. TRIPs agreement ensures the legality of generic medicines through compulsory license for the betterment of the countries having no access to afford medicines. WTO agreements in consensus with member nation's toil on health and environment issues such as WTO Agreement on Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade (TBT) Agreement settle down the international criterions, procedures and sanctions for the usage of antibiotics.³⁸

1.4.2. *The UK's Appraisal on Antimicrobial Resistance -*

According to the U.K's review on Antimicrobial Resistance or AMR, by the year 2050, 10 million populations will be no more in the absence of Antimicrobial Resistance and 100 trillion dollars of Gross Domestic Product will be gone astray if no appropriated measure is taken timely to review Antimicrobial Resistance. The

³⁴WTO Director-General Supachai Panitchpakdi, "The June deadline passed without any consensus, the deadline was then extended to March of 2005. The March deadline also passed without any agreement, however on the 6th of December 2005, the WTO finally came to a consensus on the amendment to be made to the TRIPS Agreement. This amendment follows the principles agreed to on the 30th of August 2003. Member nations have until the 1st of December 2007 to ratify the amendment so that it can be formally included into the TRIPS Agreement."

³⁵Interview with Kofi Annan, the then UN Secretary-General, World Health Organization, 2001, available at: <http://www.who.int/inf-pr-2001/en/pr2001-19.html> (last visited on December 27, 2016).

³⁶Workshop takes a holistic view at trade and public health, WHO-WIPO-WTO trilateral study "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", available at: https://www.wto.org/english/news_e/news16_e/trip_28oct16_e.htm (last visited on December 28, 2016).

³⁷ World Health Organisation hereinafter referred as WTO. TRIPS and Public Health, WHO, WIPO, WTO symposium to examine how to foster appropriate use of antibiotics, access and innovation, August 29, 2016, available at: https://www.wto.org/english/news_e/news16_e/heal_29aug16_e.htm (last visited on December 29, 2016).

³⁸This symposium is the sixth in a series of joint technical symposia convened by WHO, WIPO and WTO on September 2016. It builds on the collaborative work undertaken by the three agencies to enhance capacity, including the trilateral study *Promoting Access to Medical Technologies and Innovation*, available at:

http://www.wipo.int/meetings/en/2016/wipo_wto_who_technical_symposium.html. (last visited on December 29, 2016)

reasoning is measures of antibiotics Resistance are looking for the innovative marketing. Production of new drugs is not the way out rather development, preventive measures, safeguards and exploring the new mechanisms in the field of medicinal technology is required. On the preventive measures, international organisations like G20 nations along with Economic Co-operation and Development (OECD), WHO, the UN General Assembly stressed on better sanitation, vaccination with accurate diagnostics.³⁹

1.4.2.1. *The Global Antibiotic Research and Development Partnership (GARDP)-*

make a speech to raise funds for the invention of new drugs enter into the drug market with the help of international enterprises and the problems encountered in the way of innovation including intellectual problem issues, R&D, cost and price of the drug manufacturing. The entire procedure of researches on medicines is very lengthy apart from cost, time, and finances there are issues like administration acceptance, government policies and its impact on society. This discussion underlined the international collaboration to promote safer trade with equal access to drugs and antimicrobial resistance.⁴⁰

1.4.2.2. *The symposium convened by WHO, WIPO and WTO in 2016.*

On September, 2016 the sixth symposium also known as *joint technical symposia* called together by the three international bodies WHO, WIPO and WTO to construct a joint mechanism to the access of drugs and promotion of new invention. In today's era IP laws are the backbone of e-commerce. TRIPs agreement has taken IP issues to the international level as well. Member countries have changed their IP laws in accordance with TRIPs agreement. These new IP laws are so modernised to fit into the long run as well.⁴¹

2. Indian Perspective regarding Pharma Industry

Pharmaceutical sector of India is on such a strong foothold that is going to be topmost pharma hub around 2020.⁴² India is having the largest empire of generic drugs by manufacturing 70% of market share domestically and 20% internationally. Over the Counter (OTC) medicines (for minor illness) and their patent protection

³⁹Ms Hala Audi, delivered the keynote speech in the *United Kingdom's Review on Antimicrobial Resistance*, available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=356156 (last visited on December 29, 2016).

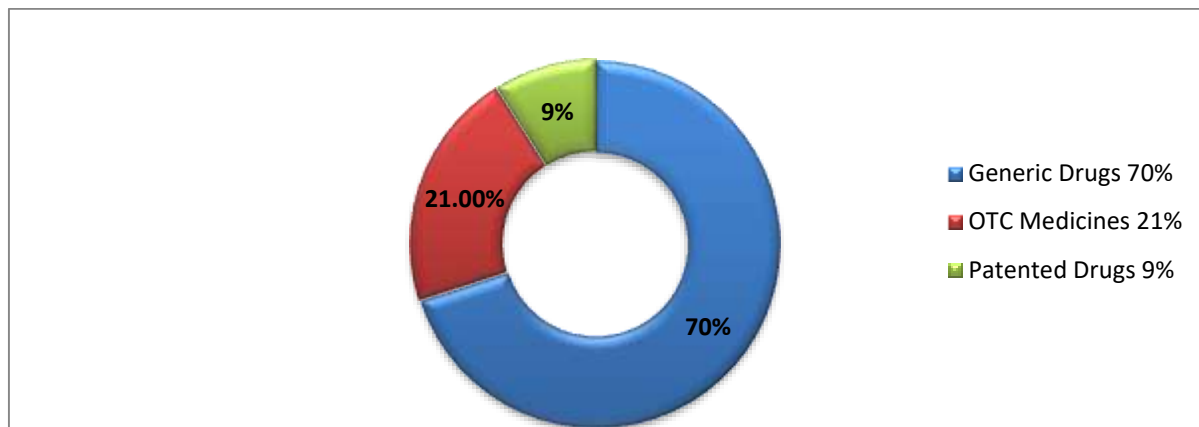
⁴⁰Mr Jean-Pierre Paccaud, in another panel on business models for antibiotic innovation, *Global Antibiotic Research and Development Partnership (GARDP)*, available at: https://www.wto.org/english/news_e/news16_e/trip_02nov16_e.htm (last visited on 30December, 2016)

⁴¹WIPO, WHO, WTO Joint Technical Symposium on Antimicrobial Resistance, *How to Foster Innovation, Access and Appropriate Use of Antibiotics*, available at: http://www.wipo.int/meetings/en/2016/wipo_wto_who_technical_symposium.html (Last visited on December 30, 2016).

⁴²PwC – CII report titled “India Pharma Inc: Gearing up for the next level of growth”. *India's Pharmaceutical industry is on a good growth path, but will have to watch out for the regulatory interventions*, available at: <http://www.pwc.in/press-releases/india-pharmaceutical-industry-is-on-a-good-growth-path.html> (last visited on January 1, 2017).

constitute respectively 21% and 9% as well. In terms, total market capture of Indian pharma industry is approximately US\$ 20 billion. The following chart exhibits the share of generic drugs manufactured by Indian Pharmaceutical segment⁴³ -

Profit sharing of Pharma sector in India



India's government is on the track to focus on "MAKE IN INDIA" to be more independent in manufacturing the drugs by reducing the dependence on importations of foreign drugs. As it is mentioned above more than 85% of Active Pharmaceutical Ingredients (API) imported from China.⁴⁴

Conclusion and suggestions

Our country is the most populous where the health graph is not satisfactory as the number of AIDS and diabetics patients are getting hire day by day. As per the official statistics the HIV/AIDS infected people are 2.31 million worldwide. The medical policies are not developed much, having its own challenges which enhance the price of medicine and makes its non-accessible to the poorer. As per the WHO survey 20 per cent medicines are duplicate, 1/4 population is having a very poor standard of living, public health is at a very poor state. The only solution lies for a developing country like India is to switch over from process patent to product patent. So the researcher considered this phrase, "there is a light at the end of every tunnel, and there is an opportunity hidden in this agreement." There is need to focus on off patent medicines to enter into pharma industry also list of drugs which are not patented yet. The pharma industry/ big MNCs must come forward to confront such serious issues. TRIPs agreement is a greater hope in this regard; as it puts pressure on the

⁴³India Pharma Summit 2014-15, *Policy Landscape Reforms for Strengthening Indian Pharmaceutical Industry* Source: *Business Monitor International, FCCI Indian Pharma Summit 2014-15, TechSci Research*, available at: http://www.searo.who.int/india/mediacentre/events/2015/brochure_india_pharma_summit_2014-15.pdf (last visited on January 20, 2017).

⁴⁴ Indian Pharmaceutical Industry, *Increasing investments in the sector*(2017), available at: <http://www.ibef.org/industry/pharmaceutical-india.maspx> (last visited on January 31, 2017)

member nations to allow compulsory licensing, parallel importation and the measures which are essential for development. Developing countries are still fighting for their existence for not getting the opportunity to address their problems. TRIPS ensure the member nations to properly addressed in international platform to become a TRIPs compliant nation for expansion of international intellectual property. India has issued compulsory license in a very limited way but now started favour to grant CLs in case of inaccessible and high-priced drugs. Government of India encouraged more generic medicine to be produced domestically. In this regard, Like-Minded Group or states (assembly of 133 developing Nations) demand for the access and availability of life saving drugs through international channels. The director general of the World Trade Organization, Roberto Azevêdo on 28 of November 2016, stressed that an improvement to the TRIPS Agreement that affects access to pharmaceuticals for developing countries remains a priority of the WTO. India's Finance Minister Arun Jaitley also amended the National intellectual property policy, 2016 with the aim to be in compliance with TRIPs agreement, and followed Prime Minister Narendra Modi's pet slogan **“Make in India** “in intellectual way.

