PUBLIC HEALTH AND PATENTS: AN ANALYSIS OF THE POST-TRIPS POLICY REGIME AND ACCESS TO MEDICINES

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Abstract

The IP rights of innovators were introduced and recognized to promote and accelerate innovation and advancement in technology but there is also other side of the coin. In other words, we can say that IP right recognition is a positive step and promotes Research & Development but at the same time, it has its own adverse effects. One such effect is on public health. Focusing on the public health aspect of intellectual property rights the research has been conducted to achieve the following main objectives: to highlight problems of public health in India and to analyse how far India has been able to resolve the issues concerning public health; to analyse nature and dimensions of public health under TRIPS; to analyse the impact of the new patent regime in India i.e. after the introduction of product patents in 2005) on the pharmaceutical sector in India and to suggest measures to combat public health issues in the light of present IPR regime. This research contributes to the body of knowledge on TRIPS and intellectual property by examining the contemporary literature on TRIPS, and its effect on access to medicinal drugs in India. It also presents a case-study using a survey to evaluate the status of the perceptions of certain stakeholders regarding access to generic drugs after India became fully TRIPS compliant.

I. Introduction

THE WORLD is facing a fundamental dilemma. In the last few years, there has been an evident growth in technological advancement and economic efficiency, improving the ability of nations to solve poverty and public health-related problems. But at the same time, on the other hand, the health status has deteriorated in developing countries, including India largely because of an increase in communicable as well as

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non-communicable diseases and a growing burden of infectious diseases. The character of world trade has also undergone significant change in the last few decades because of liberalization, privatisation and globalisation (LPG). Many issues have come to the fore to influence the trade patterns.

The traditional concept of the factors of the production in economics is changing in the present era of liberalized economy, particularly with coming into force of the World Trade Organization in 1995. The World Trade Organization (WTO) was created as an international body to promote liberalization of trade in goods and services. The universal implementation of minimum standards for Intellectual property under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is one of the Agreements of WTO, has been a subject matter of debate, particularly concerning its potential impact on the availability of patentable medicines and health including the local legal regime relating to patents.

The paper examines the provisions under TRIPS and the flexibilities along with the alternatives or options available for the implementation of public-health-sensitive patent policies in India that have been introduced in the light of the TRIPS Agreement. The paper analyses approach to certain issues in patent law that may guide to maintain a balance between the public and private interests involved in the protection of health-related inventions, including those of States, patients, and the suppliers of health-related goods and services. This paper aims to explore health-related aspects of the patent law that may be used to meet the requirements of those who do not have enough means. It is primarily addressed to the framers of policies in the country and those who are concerned with public health in the society.

The World Trade Organization (WTO) was created as an international body to promote liberalization of trade in goods and services.[1] The universal implementation of minimum standards for Intellectual property under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been the subject of

[1] What is the WTO?, *available at:* https://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited on December 23, 2020).

debate,[2] particularly about its potential impact on the availability of patentable medicines and health including the local legal regime relating to patents.

Against the background of an ongoing international debate revolving around the relationship between IPRs, innovation ,and public health, the research aims to focus on the public health and patent law dichotomy to throw light on the adverse effects of IP protection on public health and access to essential medicines.

II. Public Health

The Pharmaceutical industry occupies an important place in the Indian economy as a major emerging research-oriented and research-based industry.[3] Trade Related Aspects of Intellectual Property Rights (TRIPS) has brought new challenges and opportunities for this sector.[4] The Indian pharmaceutical industry's success and survival will depend on how strategically and effectively it faces the upcoming challenges and opportunities in this sector.

As product patent was not introduced in India till 2005, it was anticipated that the switchover from a non-patent regime to a patent regime for drugs would not be a smooth procedure. India has high technical expertise and infrastructure to manufacture medicines. Even then, almost 65% of the Indian population is not under the reach of modern medicines and depends on local treatments or herbal formulations; they lack access to essential medicines.[5] The low coverage of modern medicine is mainly due to low earnings, poor accessibility of medical facilities, and low awareness or education among the mass. Even in the last few years, the price of many of the medicines including essential antibiotics has skyrocketed due to

[2] J.H. Reichman "Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement." 29 (2) *The International Lawyer* 345 (1995), *available at:* www.jstor.org/stable/40707772 (last visited on December 23, 2020).

[3] Arvind Sahay, "India can become the Pharmacy of the World*" The Hindu Business Line*, May 06, 2020, *available at:* https://www.thehindubusinessline.com/opinion/india-can-become-the-pharmacy-of-the-world/article31516558.ece (last visited on April 18, 2020).

[4] The TRIPS Agreement, art. 7 "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." Also see, art. 27 that defines patentable subject matter.

[5] "Many Indians lack access to essential medicines: Report", *The Times of India*, June 24, 2010, *available at:* https://timesofindia.indiatimes.com/city/hubballi/Many-Indians-lack-access-to-essential-medicines-Report/articleshow/6087897.cms (last visited on January 17, 2020).

organized efforts of the manufacturing firms and monopolistic conditions existing in the drug industry.[6] Low profit margin on the low cost medicine for the poor has desisted many of the pharmaceutical companies from venturing into that sector.[7] Moreover, the focus of people involved in the pharmaceutical industry and research and development is on curing lifestyle diseases in developed countries most of people involved in medical R&D are focusing on catering to the needs of developed countries for curing lifestyle diseases and neglecting the developing countries and least developed countries where even basic health care facilities are not available. In these circumstances, it will not be improper to expect a price rise for many of the medicines in India. Comparing the price for the same medicine among countries with and without patent regime for medicines i.e. where drug patent/product patent is allowed, it was found that in some countries with the patent right, the drug price was higher up to 41 times than in India before 2005 (with no drug patents).[8]

The policy option in this sector mainly lies in the development of low-cost medicines in the country itself with an eye on bringing more and more rural poor under modern medical facilities. Similarly, there is an option for controlling the price by provisions available in the TRIPS itself like compulsory licensing and parallel import (which requires political will).

Besides, the other important issues are that awareness about IPRs is relatively low in India as compared to developed countries. Entrepreneurs, researchers, technocrats, and concerned persons should be given proper awareness through mass media and seminars in this area. The legal base is also required to be strengthened. Further, the IPRs should be viewed not only from the viewpoint of 'strategic management' but also from the viewpoint of business ethics and 'Corporate Social Dharma'. Again there is an urgent need to protect the traditional knowledge and folklore wisdom from being

[6] Rupali Mukherjee, "Government allows 50% hike in prices of 21 widely used pharma items", *The Times of India*, December 14, 2019, *available at:* https://timesofindia.indiatimes.com/business/india-business/key-medicines-likely-to-get-costlier-soon/articleshow/72569032.cms (last visited on January 12, 2020).

[7] The decisions of the Supreme Court of India in *Novartis Ag.* v. *Union of India,* (2013) 6 SCC 1 and *Bayer Corp.* v *Union of India*, AIR 2014 Bom 178 have been criticized worldwide for promoting public interest over intellectual property rights (private rights of MNCs).

[8] Juan He, "Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?" In: Kung-Chung Liu, Uday S. Racherla, *Innovation, Economic Development, and Intellectual Property in India and China. ARCIALA Series on Intellectual Assets and Law in Asia* 251-269 (2019).

appropriated by the corporate in their search to increase their bottom-lines. In this regard, proper measures are required to be taken to protect indigenous knowledge mainly in the fields of the traditional Indian System of Medicine.[9] This would help in achieving a balance between corporate and communities by balancing the return on investment (ROI) approach and returns to community (RTC) approach to intellectual property issues.[10]

III. International Viewpoint with reference to Treaties and Conventions

Enforcement of TRIPS complaint provisions in developing countries is having an adverse effect on public interest and access to medicines. Introducing product patents gives exclusive rights to the manufacturer resulting in the elimination of competition and empowering the manufacturer to sell drugs at exorbitant prices. This has brought even life savings drugs at par with the ordinary consumer goods raising public health concerns. The balance between public interest and private rights is adversely affected.[11]

United Nations

An important issue at the Special Session of the UN General Assembly (UNGASS) on Social Development was the right of individuals to affordable drugs and the weakening of this right by granting of patents and the IP protection framework developed by the WTO's TRIPS Agreement.[12] In Geneva, by the end of the 24th Session of the United Nations General Assembly Special Session (UNGASS), governments mutually agreed, after exhaustive negotiations, that they would be

[9] The introduction of Traditional Knowledge Digital Library is positive step in this direction. *Available at:* http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng (last visited on November 07, 2019).
[10] Pradeep Kumar and Deoki Nandan, "Intellectual Property Rights and Public Health" 32 (1) *Health and Population: Perspectives and Issues* (2009), *available at:* http://medind.nic.in/hab/t09/i1/habt09i1pi.pdf (last visited on November 11, 2019).
[11] Spotlight on: TRIPS, TRIPS Plus and Doha, *The Access Campaign*, *available at:* www.msfaccess.org/content/TRIPS-TRIPS-plus-and-doha (last visited on November 11, 2019).
[12] UN General Council, *Amendment of the TRIPS Agreement*, WT/L/641, (December 6, 2005), *available at:* https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (last visited on November 11, 2019).

granted free exercise options that are already available to them under international trade agreements to protect, safeguard and advance access to essential medicines.[13]
Not much was attained to the actual development in tackling the necessity of developing countries and access to life-saving drugs by people in need. In terms of bringing to spotlight the attempts of some of the developed countries in promoting the objective of pharmaceutical MNCs, quite a bit was attained.[14]

Patentable subject matter and Patentability Criteria under TRIPS

The issue of patentable subject matter in patentability criteria is addressed in article 27 of the TRIPS Agreement.[15] The general rule on the patentable subject matter in the criteria for patentability under the TRIPS agreement is contained in article 27(1) which provides inter alia that, subject to the exception set out in the Agreement, the patent shall be available for all inventions, products or processes, all fields of Technology, provided that they are new, involve an inventive step and are capable of industrial application. Article 27(2) provides discretion for members to exclude from patentability subject matter where it is necessary to prevent the commercial exploitation of such inventions to protect public order or morality including protecting human health and the environment. Article 27(3) provides for discretion concerning the patentability of diagnostics, therapeutic and surgical methods for the treatment of humans are animals and plants and animals and provides for a review.

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[13] UN General Assembly, *Further initiatives for social development*, GA RES/S-24/2, GAOR, UN Doc A/RES/S-24/2 (December 15, 2000), *available at:* https://undocs.org/A/RES/S-24/2 (last visited on Jan. 12, 2019).
[14] James Malar, APCASO, *UN General Secretary's High-Level Panel on Access to Medicines*, February 28, 2016, *available at*: http://www.unsgaccessmeds.org/inbox/?offset=1456712060462 (last visited on Jan. 11, 2020).
[15] The TRIPS Agreement, art. 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 public order 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;
(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.

The provisions on patentable subject matter work and remain contentious. As already noted, this is because while developed countries wanted to get mandatory patent protection for pharmaceutical products as well as agrochemicals, important developing countries such as India, Brazil, and Argentina, which were active in the TRIPS negotiations were particularly sensitive as they did not grant patent protection to these products as a matter of public policy. Although developed countries prevailed, the strong resistance and the resulting compromises are reflected in the provisions of article 27(2) and 27(3) on subject matter that can be excluded from patentability, and also by a review of article 27 (3)(b) and the transitional provisions and article 65 (4).

The main implications of article 27 for public health are twofold. First, it means that as a general rule, subject to the exclusions and transitional arrangements, it is mandatory to grant patents to all Pharmaceutical products and processes. The effect of this provision on innovation may be indeterminate, it is clear that the effect will vary between developed countries and developing countries. For developing countries, in particular, it could be that the development of capacities in the Pharmaceutical sector may be affected. The developing countries are not prepared to grant product patents. Since after the granting of product patents the MNCs involved in manufacturing medicines and essential drugs will have the opportunity to commercially exploit their invention by raising prices and the majority of the population in these countries lack the paying capacity. In terms of access, the effects of the provision are likely to be negative. Patent protection results in higher prices, which have the effect of restricting access.[16]

Second, the provisions also establish the patentability criteria under the TRIPS agreement. The patentability criteria for pharmaceutical products or processes are that they should be new, inventive step and be capable of industrial application. These criteria are particularly important for innovation in the Pharmaceutical sector and especially in developing countries. From an innovation standpoint, the interpretation

[16] Gerard T. Vondeling, Qi Cao, *et.al.,* "The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review", 16 *Applied Health Economics and Health Policy* 653–660 (2018).

and implementation of matters such as the novelty standards have critical implications.[17]

Rights Conferred by Patents

Traditionally, a patent confirms a monopoly right to the innovator, that is, an exclusive right over the invention empowering the holder of that right to exclude others from the use of the patented product or process. The TRIPS Agreement under article 28 generally adopts this traditional approach in particular for the Exclusive rights.[18]

In addition to these exclusive rights, the patent holder like any other property holder has the right to transfer his rights in the patent by assignment of the right, by succession or, by entering into licensing contracts.

In a public health context scrutiny of rights conferred under article 28 essentially establishment conditions for patented medicinal products and processes, which allow the patentee to put in place monopoly pricing and to enjoy considerable market power over consumers and competitors. The right to assign or transfer the patent by succession gives the Pharmaceutical patent owner the power to pass on the Exclusive rights to third parties who can exercise such rights although they did not invent the product or process, respective of the price at which they obtained the rights to the patent. It is for this reason, for example, inventions made at universities are funded by MNCs that enter into licensing contracts with the universities.[19]

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[17] For a detailed discussion of some of the implications see e.g. Carlos Correa and Sisule Musungun "The WIPO patent agenda: The risks for developing countries", T.R.A.D.E. working papers 12, South Centre Geneva 2002; Commission on IPRs, Integrating Intellectual Property Rights and Development Policy, IPRs, London (2002); Carlos Correa, "An Agenda for Patent Reforming and Harmonization for Developing Countries," presented at the UNCTAD –ICTSD organised Bellagio Dialogue on IPR and Sustainable Development, 24-28 October 2005, *available at:* www.iprsonline.org/unctadicstsd/bellagio/Bellagio2005/bell5_ documentation.htm (Last visited on March 02, 2018).

[18] For product patents: To prevent third parties from making, using, offering for sale, selling, are importing products (subject to article 6) for this purpose is without the patent owner's consent; and,
For process patents: To prevent third parties from using the process and from using, of cell important products for these purposes, at least the products obtained directly by that process without the patent owner's consent.

[19] For a discussion of how IP and technology transfer practices at academic institutions as well as government bodies and non-profit entities affect access to medical Technologies see e.g., Anthony D. So, Aarti K. Rai and Robert M. Cook Deegan, "Intellectual Property Rights and Technology Transfer: Enabling Access for Developing Countries" study prepared for the CIPIH, *available at:*

The right to conclude licensing contracts means that, in addition to recognising the right to enter into contracts, the patent owner is entitled to prevent the government, subject to certain exceptions, from granting licences to third parties without requiring those third parties to first negotiate with the patent owner. In other words, this underpins the requirement in art. 31 (b) that before the issue of compulsory licence, the applicant for a compulsory licence must have made an effort to negotiate with the patent owner.

The impact of TRIPS compliant Patent Law Reforms in Brazil and China- Lessons for India

Brazil, China, and India are already TRIPS compliant and have implemented TRIPS flexibilities as well. Although TRIPS allows flexibility, these flexibilities at the stage of implementation need to be applied after taking into consideration the national development goals, the interest of the public, and the stage of development of the country.

Brazil was one signatory to the Paris Convention in 1883.[20] This pre-TRIPS Convention paved way for the signatory countries to introduce an IP protection regime according to their conditions. , Brazil was the 4th country in the world and 1st in Latin America to introduce the protection of intellectual property in its most advanced form. Brazil's Industrial property law protected pharmaceutical patents as well as a process until 1945 when it was modified to exclude foodstuff, medicines, and materials obtained from chemical processes.[21] In 1969, Brazil completely removed patenting in the pharma sector as a public health measure but when it became a Member of the TRIPS Agreement post the establishment of WTO it had to

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https://www.who.int/intellectualproperty/studies/ip_technology_transfer/en/ (Last visited on March 12, 2018).

[20] Paris Convention (Total Contracting Parties), *available at:* https://wipolex.wipo.int/en/treaties/ShowResults?start_year=ANY&end_year=ANY&search_what=C&code=ALL&treaty_id=2 (Last visited on December 23, 2020).

[21] Kenneth C. Shadlen, "The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies", 42.1 *Comparative Politics* 41-58 (2009), *available at:* http://eprints.lse.ac.uk/27051/1/politics_of_patents_and_drugs_in_Brazil_and_Mexico_(LSERO).pdf (Last visited on March 12, 2018).

reintroduce its earlier policy to become TRIPS compliant in 1997.[22] This implementation of TRIPS in Brazil was criticized all over the world by public health groups since it failed to fully utilize the flexibilities granted under TRIPS. Due to this criticism, it subsequently introduced a strong compulsory licensing regime, which was subsequently contested by the US in the WTO dispute resolution mechanism.[23] The complaint was withdrawn due to pressure from human rights groups and public health organisations within and outside the US.

The weakness of the position of Brazil was known to the US but the main objective of the institution of the dispute at the international level was to convey to the third world the displeasure towards their initiatives and indicated possible action against weak and poor countries so that they would not dare to include such provisions under their domestic patent regime, and in case they had already incorporated they wouldn't use it. The success of the US action can also be seen from the fact that many developing countries did not make use of the flexibilities even though such provisions were available under their local legislation to provide drugs for serious diseases such as AIDS and a substantial number of their population was suffering from such diseases.[24] The Brazilian Industrial Property Law contains provisions relating to Bolar Exception. Apart from the TRIPS oriented flexibilities, the local Brazilian pharma sector has also benefitted from investments from the government in research and production through the Brazilian Ministry of Health.[25]

By using the two-fold mechanism namely the use of TRIPS flexibilities and investment support from the government Brazil has been able to strike a balance between IP protection in the pharmaceutical sector and the public health system to ensure access to essential drugs.

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[22] Samira Guennif and Shyama Ramani, "Catching up in pharmaceuticals: a comparative study of India and Brazil", *HAL* (2010).

[23] On January 8, 2001, the US requested a WTO dispute settlement panel to resolve its differences with Brazil over Brazil's Industrial Property Law, 1996.

[24] This can be seen in case of South Africa, Kenya and many other African countries. See, Shankar Daya (2002); See Also, Amir Attaran and Gillespie Lee, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?," *Journal of American Medical Association* 286 (2001).

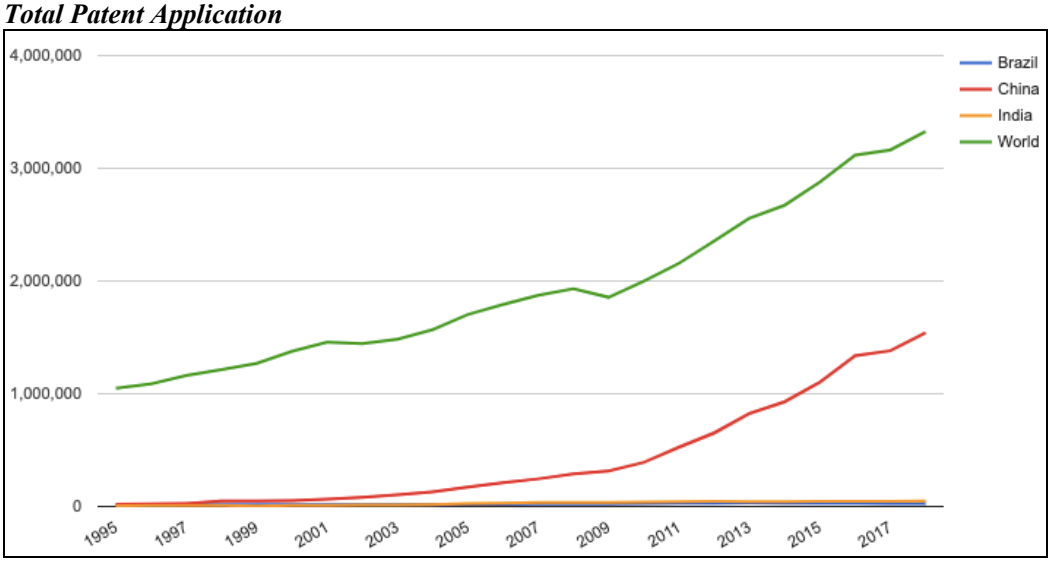
[25] The Government of Brazil invested in 18 public sector laboratories that mostly engage in formulation of final dosages and, to a lesser degree, of pharmaceutical inputs.

The patent laws were introduced in China in 1984 and have been amended several times since then in the year 1992, 2000, 2008, and 2012.[26] It enforced the Bolar exception in 2008 after the Doha declaration. China's State Intellectual Property Office (SIPO) approved an amendment in 2012 thereby introducing the compulsory license procedure.[27] An important feature of China's IP law is that the Chinese Government encourages and promotes research on traditional knowledge and genetic resources as an effort to protect the interests of local producers.

All developing countries including India have an objective similar to that of Brazil but have been following different policy paths to achieve this objective.

Figure 5.1: Number of Patent Applications for India, Brazil, China, and the World after TRIPS

Source: RIS Database on WIPO Statistics
Total Patent Application



An observable feature reflected in the figure is that the developing countries have been making efforts to catch up with the developed countries. The largest number of patent filings by China supports this argument. China's filings increased from 18,699 in 1995 to 1,542,002 in 2018. In India, there has been an increase from 6566 in 1995

[26] Fangming Xu, "Added Subject-Matter in Chinese and European Patent Law", *46 IIC*155–174 (2015).
[27] Mike Palmedo, "China Revises Law to Facilitate Compulsory Licenses for Generic Medicines", 2012, *available at:* http://infojustice.org/archives/26344 (Last visited on December 23, 2020).

to 50,055 in 2018 and Brazil from 7448 in 1995 to 24,857 in 2018. In India, out of the total 50,055 patents in force, the share of patents owned by non-residents is 67.46 percent. The share of patent filings by developing countries in other countries has also improved from 5% to 15%.

IV. New patent regime and the Pharmaceutical Sector in India

One major concern is that the TRIPS strict compliant patent system will harm the Indian Pharmaceutical industry. The TRIPS agreement may have an adverse effect, mainly in the high technology sectors, working in favour of developing countries in the following respects: the local producers will be forced to issue licenses in exchange for payment of royalty so that they can commercialize their products; while research and development activities may be hindered since the TRIPS Agreement is likely to inhibit reverse engineering, the process by which research-based industry products are duplicated and adapted for developing country usage.

Policy options for access to patentable medicines after TRIPS

The question that needs to be determined is that what options or measures may be adopted by less developed countries within the framework of new TRIPS patent policies to improve the accessibility to the low-cost drugs, benefits they enjoyed in the pre-TRIPS era if they pursued aggressive generic substitution policies previously? The following policy options viz. utilizing parallel trade, enforcing price controls and compulsory licensing might be adopted without running afoul of the obligations imposed by TRIPS.

- Parallel Imports: Provision for parallel imports is there under the TRIPS Agreement but under what specific circumstances they may be allowed has not been defined.[28] The provisions relating to parallel imports have also been incorporated in the Indian Patent Act, 1970.

It involves the import and resale of patented goods in a country 'B', without the consent of the patent holder, from a market of the exporting country 'A' where the product is marketed by the patent holder. Parallel imports help an importing country

[28] The TRIPS Agreement, 1995, art. 6.

to source a patented commodity from the cheapest source as an industry (particularly the pharma industry) generally uses differential pricing policy to gain the maximum profits.

The principle of exhaustion of rights is the foundation of the concept of parallel imports, which is based on the principle that if the patent holder gives away his right by way of transfer of that right in the invention either by sale or distribution he loses the right to regulate the use or resale of the product/process. TRIPS Agreement allows every Member State the freedom to incorporate the principle of international exhaustion of rights in its national legislation and further excludes the Members from the applicability of WTO dispute settlement system for disputes relating to exhaustion of rights.[29] Therefore, there is a need to specifically clarify the status of parallel imports under the TRIPS Agreement itself.

Parallel importation is permissible under the following situations: (a) the patented product has been marketed in another country by the patentee; (b) the product is sold under a compulsory license; and (c) the product is marketed in another country through legitimate means without the country (i.e., in the case of a generic producer of medicines such as Ranbaxy in India).

- Differential Pricing: under this option, the general expectation from pharma MNCs is that they would price their drugs differently according to the purchasing power of markets. Therefore, a poor person in an African country has to pay a marginal price for a medicine, which is available at a much higher price to a person in the US. The pharma companies to a certain extent apply this strategy. But only in selected markets under the pressure from the local regulatory bodies.
- Compulsory Licensing: An option available to developing countries is the authorization by the government to make, use or sell a patented invention by a third party by issuing compulsory licenses without the patent owner's consent. TRIPS is silent about the scenario in which compulsory licenses can be issued. The Doha Declaration under TRIPS in 2001 threw light on the concept of the use of compulsory licensing provisions for public health concerns. The

[29] *Ibid.*

> Declaration unequivocally stated, "each member has the right to grant compulsory licenses and freedom to determine grounds upon which such licenses are granted." Despite the developments, the compulsory license system under the amended Indian Patent regime may not fulfill the requirements of the domestic pharmaceutical industry.

Thus, the fate of the developing countries with under-developed or non-existing pharma sector is still under dark. Though Doha Declaration stipulated the TRIPS council to solve this problem by December 2002, there is still no hope for such developing countries. In contrast to what they have committed in Doha, developed countries are creating procedural hurdles for developing countries for granting compulsory licenses. India granted its first compulsory license in March 2012 to Natco against Bayer.[30] Chapter XVI (sections 82 to 95) of Indian Patent Act deals with the working of patents, compulsory licences and revocation.

The Controller under the Indian Patent Law has been empowered to grant a compulsory licence to interested persons to secure the objects of the patent law system, upon such terms as he may deem fit if satisfied that:

1. The reasonable requirements of the public have not been satisfied, or
2. The patented invention is not worked in the country, or
3. That is not available to the public at a reasonably affordable price.[31]

The Patents (Amendment) Act 2005 inserted section 92A in the Patents Act 1970 makes provision for issuance of compulsory licence to countries that have inadequate or no manufacturing capacity subject to the condition that compulsory licence has been granted by such countries or those countries have allowed the importation of the patented pharmaceutical products from India. In case a country applies, the Act authorizes the Controller to grant a compulsory licence solely for manufacture and

[30] Maricel Estavillo, "India Grants First Compulsory Licence, For Bayer Cancer Drug" *Intellectual Property Watch,* March 12, 2012, *available at:* http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ (Last visited on March 12, 2018).

[31] Gaurav Wahie and Siddhartha Bhardwaj, "Patenting of Medicines: Access to Affordable Medicines" (2017), *available at:* http://www.legalservicesindia.com/articles/patent_med.htm (Last visited on June 15, 2018); Also see, The Indian Patent Act, s. 84.

export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.[32]

The provisions also allow, after the expiry of a duration of three years, for applying for a compulsory licence to the patentee exporter company to commence domestic manufacturing of a drug to treat chronic disease.[33] In the case of non-grant of rights by the patentee company, the discussions can continue for a year. After the expiry of the said period, the government can authorize a domestic company to manufacture a generic version of the drug with a different procedure or the exporting company can also agree to manufacture the drug in India. In both these situations, the drug for chronic disease will be available to the patients at a cheaper price.

Issuance of compulsory licence was seen by developed countries as a tool to strike a balance between abusive practices and limiting exclusive rights. The grounds on which compulsory licences have been granted and regulated in developed countries showcase the potential and flexibility of the compulsory licensing system to deal with a plethora of public interests.

This evidence shows that claims raised by governments and companies in developed countries against compulsory licences are a departure from appropriate intellectual property rights requirements and are not reflected in the policies that are applicable in those countries. In doing so, they practice a double standard –denying developing countries to utilize the effective policy mechanisms that they have utilized and continue to utilize. India has in the last few years through its policies and landmark judgments proved to be more inclined towards public interest compared to private rights when it comes to intellectual property rights. This statement can be supported by the Natco –Bayer[34] and Novartis[35] judgments.

V. A survey based on current scenario on branded and generic drugs

[32] V.K. Ahuja, *Law Relating to Intellectual Property Rights* (Lexis Nexis Student Series Edition, 2011).
[33] The Indian Patent Act, 1970 (Act 39 of 1970), s. 84.
[34] *Supra* Note 16.
[35] *Novartis Ag.* v. *Union of India,* (2013) 6 SCC 1.

The branded versions of life-saving drugs are generally highly-priced in most developing countries relative to their generic counterparts. Patients end up paying twice as much as the generic versions of the same branded drugs. This price difference may go up to ten times in some developing countries. When the quality and efficacy of the generic drug is the same as that of the originator branded drug, there is a potential for patients and health outcomes to improve at a lower cost. Therefore, in such a situation the use of generics is always promoted to reduce the costs and increase the availability and accessibility of such medicines.[36]

A generic drug is equivalent to an originator branded drug in all aspects whether it be dosage form, safety, strength or quality, performance, and characteristics. After the expiry of the branded drugs' patent protection, the generic drug manufacturer may request market approval by applying to the regulatory authority and distribute generic versions of the branded drugs. Generic can be sold in the market as a non-proprietary name or as a generic brand. Usually, branded generic drugs are referred to as a combination of the name of the manufacturer and the name of the non-proprietary name. This makes it convenient for the manufacturer to market the product in a way similar to the proprietary product. Since in for manufacturing generic drugs no research costs are involved, they are cheap when compared to the branded versions. The cutthroat competition in the market often lets the product sell to consumers at a comparatively lower price. [37] At present, either large Indian companies or Multinational Companies manufactures the branded medicines, in circulation. These branded medicines are mostly expensive and not affordable to a large population since there are huge costs involved in the R & D of these new drugs and since its costs of production are high they are strongly promoted by these companies through doctors, chemists, and via other sources of advertisement to gain maximum profit. The practice of bribing doctors by the big pharmaceutical companies to create a market for these drugs is a well-known fact.[38]

To reduce healthcare expenses, one of the most feasible ways is to encourage the use

[36] O.R. Gattani, "An overview: Branded to Generic Drugs" *The Indian Pharmacist* 15-21 (2012).
[37] A. Dadhich and M. Upadhyaya, "A Review: Exploring branded generic drugs by Indian Pharmaceutical Multinational Companies as a New Prospect" 2(6) *Pharmacophore* 271-275 (2011).
[38] G.L. Singhal, *et. al.,* "Jan Aushadhi Stores in India and Quality of Medicines therein" 3(1) *International Journal of Pharmacy and Pharmaceutical Sciences* 204-207 (2011).

of generic drugs in place of equivalent branded drugs. These savings can be utilized for treating more patients and can also be used for other treatment modalities.[39] The generic drugs are manufactured using the same active ingredient and have the same effect, quality, strength, purity, and stability as that of the branded counterparts conforming to the International Standards.. They work within the same time and way as branded drugs. The new drugs are given patent protection to protect the investment and related expenses, viz. R & D, marketing and promotion. The duration of patent protection under TRIPS as well as in India is now 20 years. This time is apt for the manufacturers to recover the expenses incurred in the manufacturing, promotion, circulation, etc. of the drug. Only in rare circumstances, it is seen that the generic drug is not suitable for a particular patient probably due to some inactive ingredient, the shape, colour, or like characteristics of the drug and therefore the branded drugs are prescribed in place of a generic drug. At the time of the expiration of patents, the manufacturers tend to approach the government or drug control department to manage the distribution of generic drugs. A lot of pharmaceutical companies get into manufacturing generic versions of the patented drug once the patent expires. It is expected of the patients to be assertive and insist that the doctors prescribe the generics drugs where available so that the patients get the product at an affordable price. Pharmacists can also play a significant role in educating the doctors about generic drugs' availability. Therefore, patients may have access to life-saving or essential drugs at the best possible price. The concept of generic drugs, as has been adopted by many developing countries is the promotion of drugs with the same composition as that of branded drugs but at a lower price since the expenditure on research is not involved, further leading to access to essential medicines.[40]

According to a recent survey, about one-fourth of physicians expressed concerns about the effectiveness, nearly one-half reported concerns about consistency, and one-fourth did not choose to use generics for themselves or their families as first-line medicines. Due to the huge cost differences between generic and branded medicines, these negative views could have important implications for national expenditures on

[39] G.N. Chua, *et. al.,* "A Survey exploring Knowledge and perceptions of general practitioners towards the use of Generic Medicines in the Northern State of Malaysia" 95 *Health Policy* 229-235 (2010).
[40] A.M. Olusola, *et. al.,* "Equivalence of two generic brands of Amlodipine besylate under biowaiver conditions" 4(2) *International Journal of Pharmacy and Pharmaceutical Sciences* 265-268 (2012).

health-care.[41] Because of the expiry of the majority of drugs of patents, the generic drugs' market is growing at a rate of 12% per year. Despite this, the growth of generics in India is still very low and most available and used at government hospitals. The situation can improve with support not just from the government but also from the industry and medical practitioners to promote the use of generics by changing mindsets[42]

Methodology

The high costs of medicines have always been a concern for patients In India, there are variations in the price of the same drug due to the prices quoted by pharmaceutical companies. The objective of the survey was to review and analyse various facts about generic and branded drugs.

A survey of stores price lists and other resources by the author was conducted and it was found that there is a vast difference between prices of branded and generic medicines. A survey was further conducted on about 100 individuals from non-science backgrounds (educated) of all age groups and pharmacists. For each group, different sets of questionnaires were prepared to determine their preferences, the approach of their respective doctors, and the general awareness regarding generic drugs (its availability and nature).

From the result of the survey, it could be determined that more consumers would prefer cheaper drugs provided their doctor approves them. They would also get to know more about generic drugs and where they could easily get generic drugs from. But there was also a substantial number of people who were misinformed about the consequences of the use of generic drugs and were reluctant in switching from a branded drug to a low price drug. It could also be determined that a large number of doctors do not prescribe low priced drugs. They would only suggest a cheaper drug when being specifically asked for it, the main reason being, it does not give them business.

[41] W.H. Shrank, *et. al.,* "Physician perception about Generic Drugs" *The Annals Pharmacotherapy* (2011).
[42] *Supra* Note 9.

For Educated individual (non-science background)

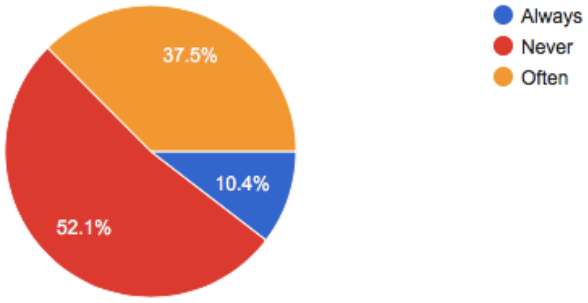
A survey was conducted on educated non-science background individuals to determine the position of availability/ accessibility of generic drugs in the State of Madhya Pradesh, particularly in Gwalior, Bhopal, Jabalpur and Ujjain region. The survey was also conducted to establish that whether after the enactment of TRIPS compliant provisions under the Indian patent regime the position of public health in India for accessibility of generic medicines has improved or deteriorated.

In a survey conducted on 100 individuals, 80.02% knew about generic drugs whereas 19.80% were not aware of the existence of generic drugs in India. Even though the majority knew what generic drugs are 37.5% did not know that the generic drugs are available at a cheaper price in medical stores in India. Despite several initiatives by the Government such as the running of Jan Aushadhi Stores under the Pradhan Mantri Jan Aushadhi Yojana that aims to make healthcare affordable and encourage Ease of Living[43] the lack of awareness regarding generic medicines is prevalent not just in the uneducated sections of the society but in the educated masses as well. India has been an advocate of manufacturing and circulating generic drugs at international forums and has been trying to come up with options within the International flexibilities granted against the exclusive IP rights.

52.1% of the educated non-science background individuals stated that the doctors never give preference to medicine at a cheaper price, 10.4% said that their doctor always prefers prescribing cheaper medicines, whereas 37.5% stated that their doctor often prescribes cheaper medicines.

[43] Medicines available at the Jan Aushadhi centres are 50-90 per cent cheaper than branded drugs available in the market.

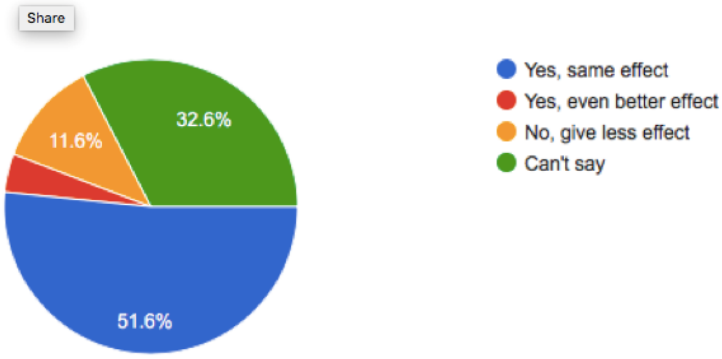
Figure 5.2



78.1% have never asked the doctor for medicines at a cheaper price.

The response of the individuals when asked that medicines with lesser price give the same effect the following were the responses: Figure 5.3

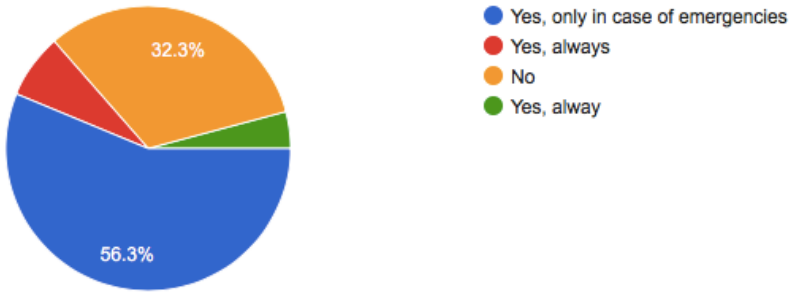
Figure 5.3



26.9% of individuals believe that generic drugs are not as safe as branded drugs.

If you are aware that generic drugs are comparatively lower in price would you still opt for branded drugs? See Figure 5.4

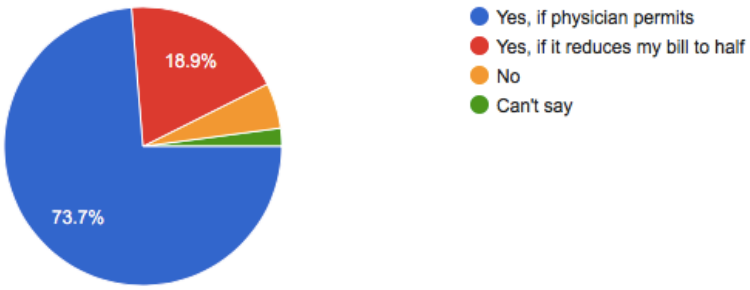
Figure 5.4



15% of the people were reluctant to use cheaper alternatives to branded medicines even after being informed about the generic drugs.

In case of availability of generic version of the same branded drug, would you opt the generic version over the branded one? See Figure 5.5

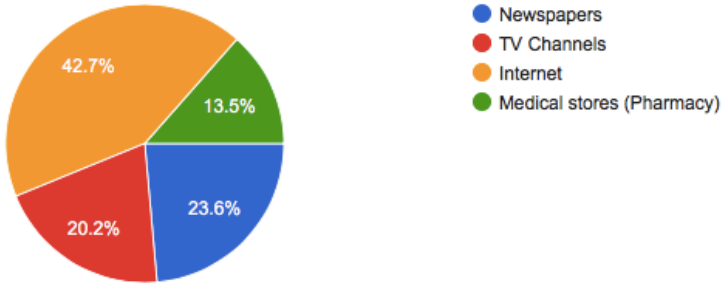
Figure 5.5



In the last three months did you come to cross any news, advertisement, or other information motivating people to use generic medicines? 76.8% responded in negative to this question, which indicated that there is a need to publicize the availability of such drugs.

About 50% of the individuals are not aware of the real effects of generic drugs.
The response to being aware about generic drugs is the following: See Figure 5.6

Figure 5.6

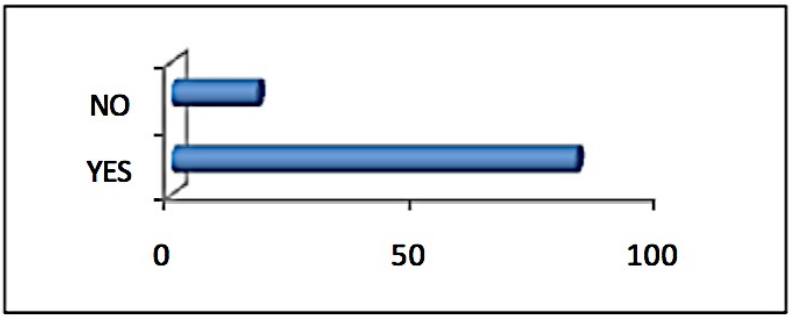


Would you select your medication based on TV promotions? 81.9% said they are not affected by advertisements.

For professionally qualified (Science Background) Individuals

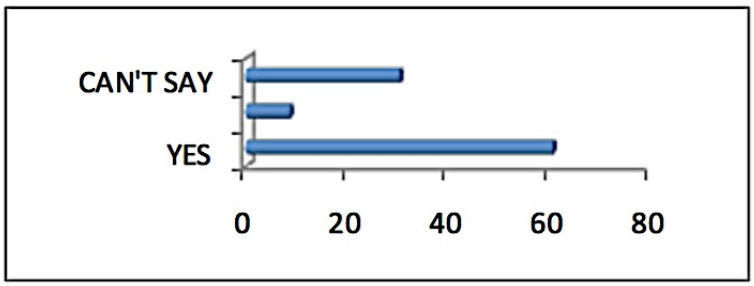
1. Are you aware that Government has passed a law for the availability of generic drugs in India?

	Number in %
YES	82.6
NO	17.40



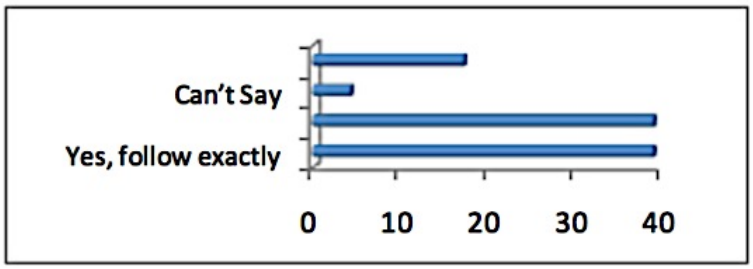
2. Is the effect of generic version of the drug same as that of the branded one?

	Number in %
YES	60.86
NO	8.69
Can't Say	30.43



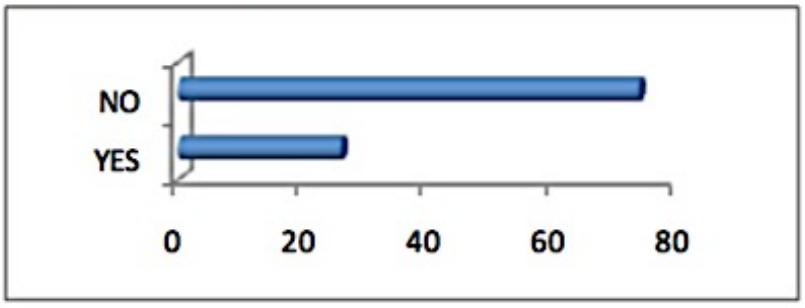
3. Are FDA guidelines as followed by branded drugs followed by generic drugs as well?

	Number in %
Yes, follow exactly	39.21
Yes, certain parameters	39.21
Can't Say	4.34
NO	17.39



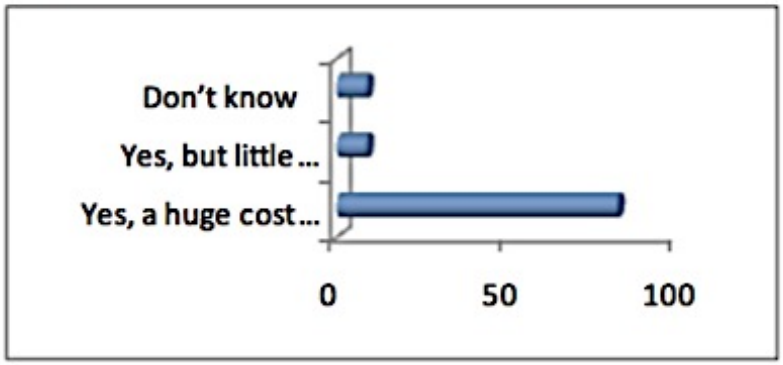
4. Are you using any generic drug currently?

	Number in %
YES	26.08
NO	73.92



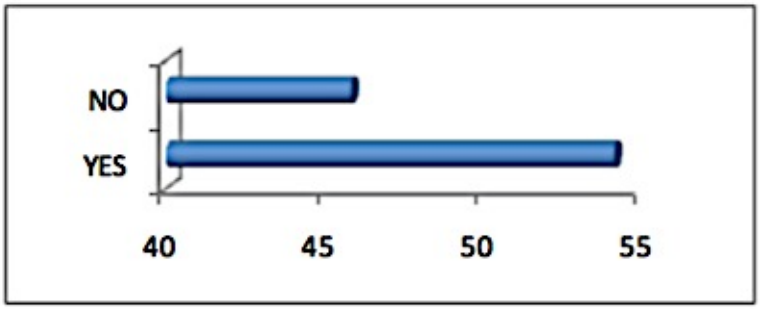
5. Do you see any difference between branded and generic drugs?

	Number in %
Yes, a huge cost difference	82.60
Yes, but little cost difference	8.69
Don't know	8.69



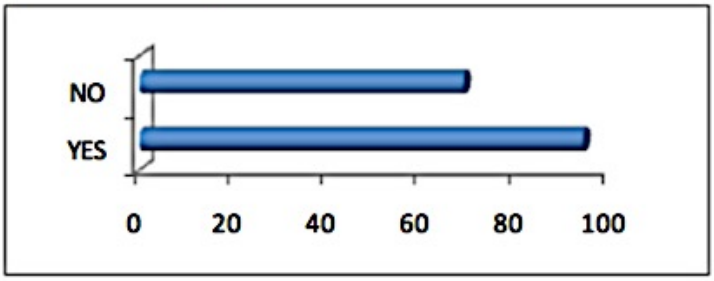
6. Do you know any pharmacy store where generic drugs are available?

	Number in %
YES	54.16
NO	45.84



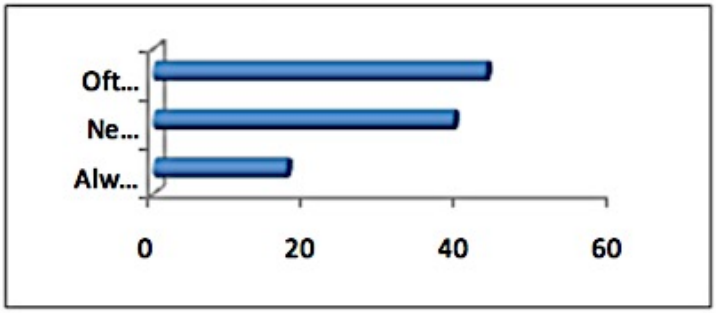
7. If no, would you like to know about such stores?

	Number in %
YES	94.44
NO	5.56



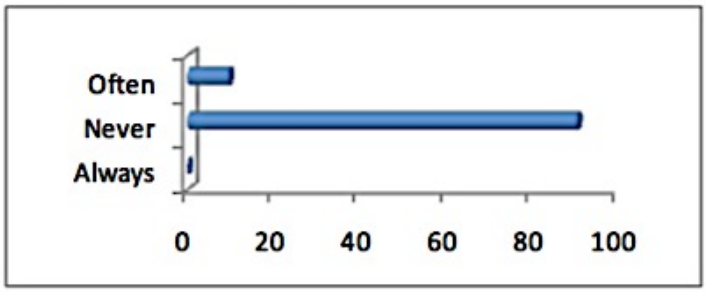
8. Have you ever asked for generic drugs in a pharmacy?

	Number in %
Always	17.39
Never	39.213
Often	43.47



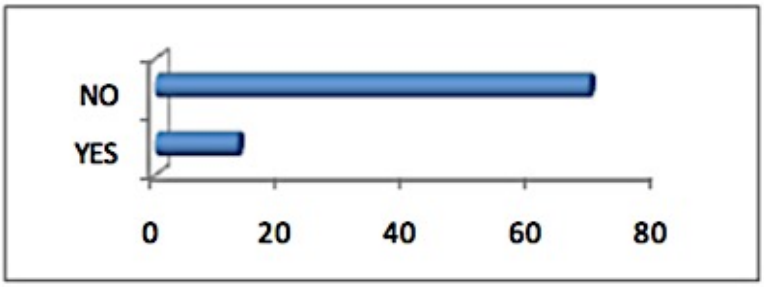
9. Does your doctor ask you before prescribing a medicine if the cost of the medicine is your concern?

	Number in %
Always	0
Never	90.47
Often	9.53



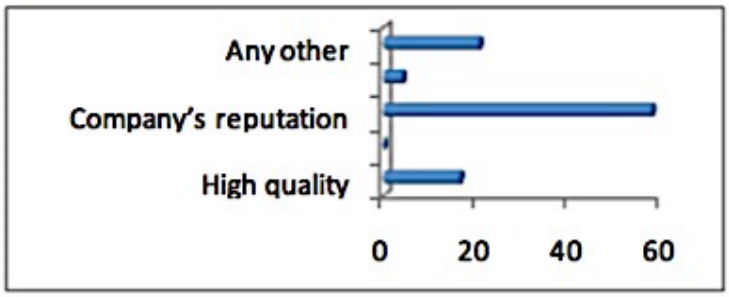
10. Does your doctor or pharmacist ask you to choose the generic version of the drug over a branded drug?

	Number in %
YES	13.05
NO	86.95



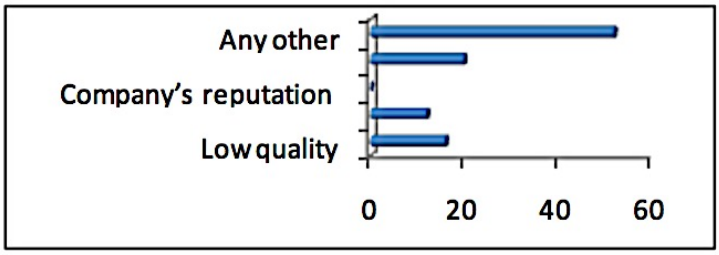
11. Why are branded drugs highly-priced?

	Number in %
High quality	16.66
Better therapeutic Effect	0
Company's reputation	58.33
Can' Say	4.16
Any other	20.83



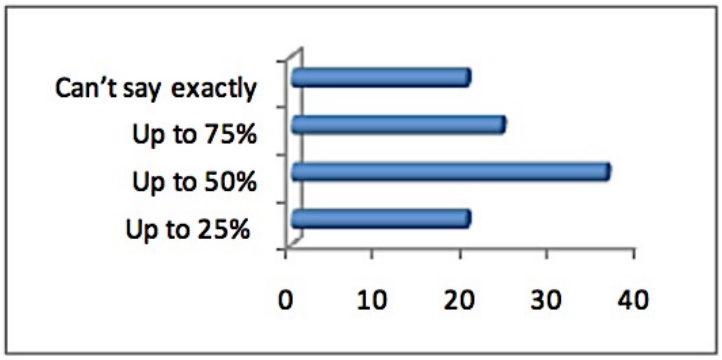
12. According to you what is the reason that generic drugs have lessor cost?

	Number in %
Low quality	16
Lesser therapeutic effect	12
Company's reputation	0
Don't know	20
Any other	52



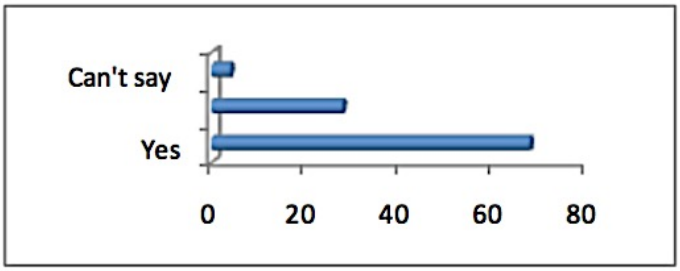
13. How much can you approximately save by using generic medicines?

	Number in %
Up to 25%	20
Up to 50%	36
Up to 75%	24
Can't say exactly	20



14. Are you of the view that the Madhya Pradesh Government should introduce stringent laws to ensure the availability and accessibility of generic drugs?

	Number in %
Yes	68
No	28
Can't say	4



15. Can you think of any disadvantages of generic drugs?

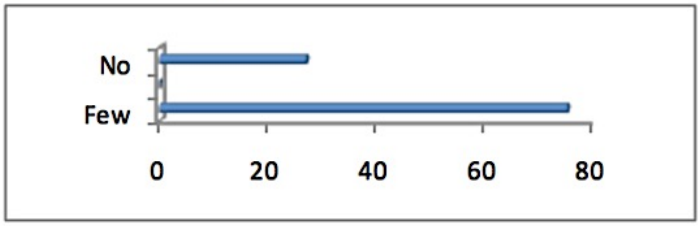
Majority of the individuals of science background said that the generic drugs are not of good quality and since low cost of production is there, the final product is also low in quality and therefore ineffective.

For pharmacists

Survey conducted on 50 pharmacists working in medical stores (pharmacy)

1. Are generic drugs available in your store?

	Number in %
Few	75
All	0
No	25



2. If no, why? Specify a reason:

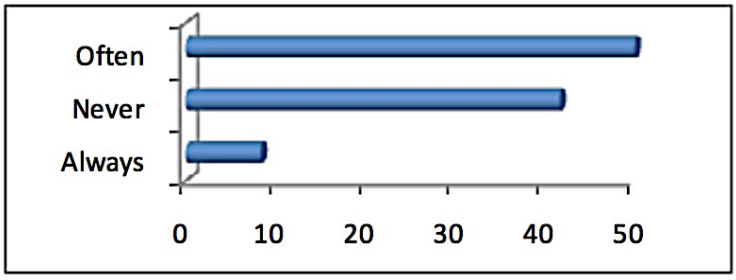
To this different pharmacists gave different answers. The majority of them said that there is less demand or no demand at all. Others said that doctors do not prescribe generics. Some could not specify a reason.

3. How many customers/patients ask you for generic drugs/cheaper alternatives for branded drugs?

A large number of pharmacists said that none of their customers ask for branded drugs followed by few and less. According to them about only 10% of the patients may have asked for generic drugs.

4. Do you suggest alternatives to branded drugs to your customers?

	Number in %
Always	8.33
Never	41.66
Often	50



5. Do you face the availability issue in case of generic drugs?

A majority of about 90% said that there is no availability issue, the generic drugs are easily available.

6. What are the difficulties that you face relating to generic medicines?

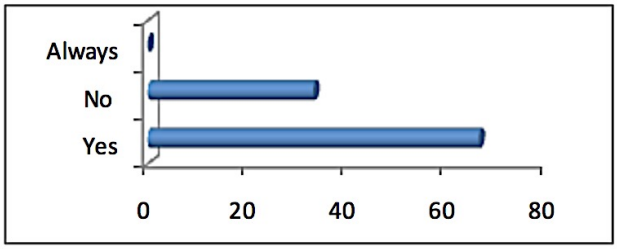
One of the major difficulties relating to providing generic drugs to patients as stated by the pharmacists was the approach of patients that they prefer sticking to the doctor's prescription. Despite informing the patients about the cheaper alternatives, they are reluctant to switch without the doctor's approval.

7. Which pharmaceutical companies make generic drugs?

Most of the pharmacists were aware of the generic pharmaceutical companies. They also named a few including Cipla, Ranbaxy, Emcure, *etc.*

8. Do you yourselves prefer generic drugs over branded?

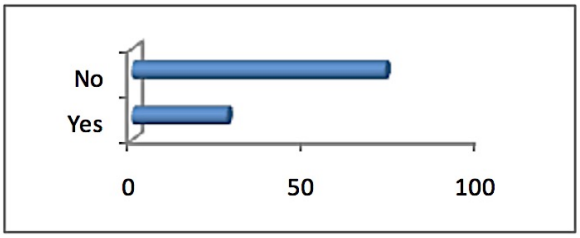
	Number in %
Yes	66.66
No	33.33
Always	0



Some out of the 33.33% state the reason that they go by the doctor's prescription.

9. Does the quality get affected in generic drugs compared to branded drugs?

	Number in %
Yes	27.27
No	72.73



10. Why are the prices of generic drugs less than those of branded medicines?

Pharmacists gave reasons such as less or no marketing, market value and reputation of the company may not be that good. Very few stated that quality difference in the

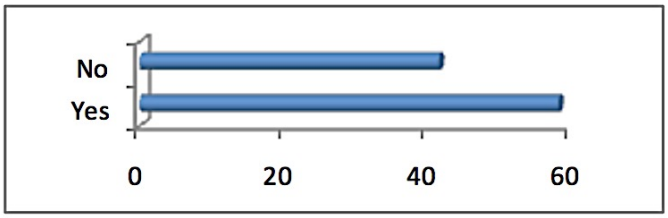
drugs could also be one of the reasons and low cost of manufacturing. No pharmacists were aware of the patent expiration of parent drugs.

11. Are there any disadvantages of generic drugs?

More than 94 % of pharmacists responded saying none and few said low quality is a disadvantage.

12. The new law introduced by the government is making free generic drugs at government hospitals and other centers, will your business be affected?

	Number in %
Yes	58.33
No	41.67



There is still a need to create awareness amongst the masses.

Pharmaceutical companies in India develop two categories of formulations for the same medicine; First, the branded drug that they circulate via doctors; Second, branded-generic, that they expect retailers to circulate in the market. The fact is that the Indian market does not have branded medicines since 2005, product patentability was not applicable in India. This category closely resembles formulations referred to as 'generics' worldwide.

21 (g) (I) U.S. Code § 321 of the United States Federal Food, Drug, and Cosmetic Act provides for the definition of a drug. It does not categorize drugs as prescription and non-prescription drugs. The term 'drug" means (1) The term "drug" means "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any

article specified in clause (A), (B), or (C). Food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made following the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made under section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement."

The term 'generic medicines' is also specifically classified in Brazil; in Australia generic medicines are defined by the Therapeutic Goods Administration (TGA), which is the regulatory body for registering and licencing medicinal products in Australia. European Union, China, Canada too have specifically provided for a proper definition of generic drugs to avoid confusion of any kind.

On the other hand, the Indian drug laws namely, the Drugs and Cosmetics Act, 1940 and the drug Regulations do not provide any definition for the term, however, the term "Drug" has been defined under section 3(b) of the said legislation which includes generic drugs. There is an immediate necessity of definition of term generic drugs under the Indian drug laws to promote and popularize generic medicines in the country.

VI. Conclusion

India's pharmaceuticals market has undergone a makeover. It was largely dependent on imports of costly medicines between 1947 and the 1970s. But post-1970 India removed the concept of product patents and re-introduced it with the Patent Amendment Act in 2005.

Industrial policy initiatives and public sector research institutions were also put in place by the Indian Government to partner with local producers. As a result, the Indian generic drugs industry grew strong and became vibrant. The entry of generics decreased costs and increased access to medicines. And in achieving these outcomes it is much more effective than philanthropy or the concept of tiered or differential pricing strategies that MNCs support. Drug patenting after the

introduction of minor changes, known as "evergreening", is one of a host of "life-cycle management" techniques used in response to generics competition.[44]

Nevertheless, the Indian government will continue to face challenges from multinational pharmaceutical MNCs that aim to stifle generic competition. In 2012, Bayer sought to revoke a compulsory license setting precedent for another cancer drug awarded to Hyderabad-based Natco Pharma. The cases of Novartis and Bayer show that India is in a strong position to defend and extend pharmaceutical and IPR policies drafted to achieve a balance between economic growth and public interest.[45] The significant point is that the trade negotiators and pharmaceutical industry must not forget the true goal of drug development and innovation: saving lives. Profit-making should not be the sole objective. It should always be remembered that the pharmaceutical industry has a moral duty and responsibility towards society. The exclusive rights granted by Drug companies should not be exercised without responsibility they should always be in the public interest. By keeping this principle in mind and achieving an optimum understanding of the modern world health situation we can hope to ensure the safety and well-being of the people of India efficiently and effectively.

With the implementation of the TRIPS Agreement after the expiry of the transition period given to developing countries, India became fully TRIPS compliant post-2005. The introduction of product patents was speculated to affect the position of public health in India to a greater extent but with the introduction of several flexibilities under TRIPS in its local regime, India has been able to cope up with the situation to some extent. The steps taken up by the government such as the introduction of schemes and programs to ensure availability and accessibility of medicines at a cheaper price has contributed to the fulfillment of the aim and objective of these schemes but has not entirely served the purpose as can be determined from the results of the survey. The availability of generic drugs at government hospitals or stores free of cost or at marginal prices is not going to stop the war of prices between branded and generic. It is required that more stringent rules and regulations be made for

[44]A. Chapman, "Approaching intellectual property as a human right: Obligations related to Art. 15(1)(c)" 35 *Copyright Bulletin* 10–11 (2001).
[45] E. R. Gold, "Patents and human rights: A heterodox analysis" 41(1) *Journal of Law, Medicine & Ethics* 186–187 (2013).

ensuring the availability at a reasonable cost for those whose interests would otherwise be affected. The law should grant the freedom to the pharmacists to change a brand for generic medicines to safeguard the interest of the patients. There is also an immediate need to include a definition of "generic drugs" under the relevant law.

The surveys were conducted to analyse the impact of the TRIPS compliant regime on the availability and accessibility of the generic drugs. It is concluded that the TRIPS compliant regime initially had an adverse impact on the availability of cheaper drugs but there are enough safeguards under TRIPS (the flexibilities) that ensure that the public health concern is duly addressed.

The surveys were also conducted to analyse the availability and accessibility of generic drugs post TRIPS compliant regime from three different perspectives. First, from the point of view of consumers (educated individuals of non-science background); Second, from that of the people of the science background and third from that of pharmacists who are involved in the market of drugs/medicines directly. It is obvious from the survey that whether educated or non-educated people both would like to know about the availability and accessibility of generic drugs. In particular they would like their doctors to provide them the information on generic drugs since they do not want to violate the doctor's prescription.

The step was taken up by Government to set up Jan Aushadhi Stores and Distribution Centres is a remarkable initiative. But the lack of a proper definition of the term 'generic drugs' from all relevant legislation is having an adverse effect.

It is suggested that the doctors could include generic alternatives as well in their prescriptions. Even the educated mass believes that if the doctor has prescribed branded medicines they should not switch to cheaper ones. Therefore, there is a need to create awareness. The pharmacists are already aware of the fact that generic drugs can be as good as the branded ones. From all the three surveys it has been observed and concluded that the main reason for less accessibility of generic medicines is because of lack of prescription of such medicines by doctors even though there is availability. The problem is that the demand is less. The pharmacists also want to help people by supplying them generic medicines but there is reluctance by patients to deviate from the prescriptions. The author believes and suggests that the problem can

be resolved if there is enough support by law. If sufficient guidelines are made to support the mission then the purpose can be served.