

Analysis On Generic Medicine V. Patented Medicine

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Abstract

The intention of the researcher is to study about the generic medicines and the patented medicines. discusses about the history of patent laws in India, here she does a thorough study of how Indian laws have emerged to be progressive from the erstwhile British laws which did not foster growth and development in India. The researcher then proceeds to talk about the circumstances which led India to amend its Patents act of 1970 in 2005 and the effects of this amendment. Further the researcher focusses on the generic medicines where she talks about how they are manufactured and various factors of genetic medicine. The researcher then proceeds to clear various apprehensions and misconceptions with regard to generic medicines such as its quality and effectiveness and its low price factor in concern to its quality. Moves on to clear the dilemma of majority of Indians of choosing between the generic and patented medicines, here she details on their respective advantages and disadvantages for this purpose. To a name a few - The advantages of generic medicines are cheaper prices, easily available, Bioequivalent and so on while its disadvantages are it halts the innovation, not easy to spell or remember and son; The advantages of patented medicines are high efficiency, promote innovation and so on while its disadvantages are Unaffordability, supports monopolies. Importantly, the researcher deals with various judicial cases relating to IPR in India. Finally concludes this chapter stating that generic and patented medicines support the country in their own way.

Keywords: Generic, Medicine, Patented

INTRODUCTION

India's Pharmaceutical Industry:

In the global arena, the growth of pharmaceutical sector had risen exponentially since the World War II. The huge demand for the antibiotics throughout the world war resulted in huge investment of resources and time for research and development to produce new medicines. In the following years of the war, the pharmaceutical companies started expanding into foreign markets and emerge as MNCs. As a result these MNCs are dominating the current global pharmaceutical industry. These MNCs are established in developed countries but not in developing countries and also hold an immense financial pull. The primary reason here is the availability of skilled work force, logistics to support the training, technology and also

capital required for manufacturing in the developed countries. Hence developing countries have started to be dependent on importing drugs from other nations like India.

In the meanwhile, India has emerged to be one of the leading manufacturers of generic medicines. The Indian pharmaceutical sector is now "considered the world's third-largest by volume" and generates roughly 20% of the world's generic pharmaceuticals as of 2010. Various experts estimate that by the year 2020, the pharmaceutical industry of India would grow in terms of valuation of \$74 billion. This will help India to solidify its position in the global arena as "a global leader in the pharmaceutical industry."¹

¹ Debarati Tripathi, Indian laws and Policy on Generic Drugs, iPleaders (Jan. 15, 2022, 1:30 PM), <https://blog.iplayers.in/generic->

History of Patent Laws of India:

In 1856, India's first law on patent was passed and its origin can be traced back to the British Patent Law of 1852, that granted inventors with privileges for fourteen years. Later with various changes this law was modified into Inventions and Designs Act of 1888. Though India's industrialisation started but the pharmaceutical sector was so far in its beginning stages. The Britishers enacted Indian Patents and Design Act of 1911 replacing the Inventions and Designs Act of 1888. This was the first act to set up patent administration in India which continued to be in effect up to 1972. This act also recognised the patent protection of foreign pharmaceutical drugs in India which meant that foreign firms can block the Indian firms from manufacturing their patented goods. This resulted in stagnation of domestic pharmaceutical industry till World War II. The independence of 1947, brought in various challenges for the country. Being among the poorest countries of the world, one of the serious problem was to provide health care at affordable rates. To provide cost effective health care medicines at cheaper prices is a must, hence the officials started a detailed study of Indian Patents and Design Act of 1911. In this steps, the government appointed the Patent Enquire Committee (1948–50), the Patents Revision Committee (1957–59). Their objective being, "review the patent laws in India with a view to ensure that the patent system was more conducive to national interests." The Patents Act of 1970 was the result of the reports by these committees. This act replaced the act of 1911 and came into effect from 1972 which significantly impacted the pharmaceutical sector of India. This act granted only process patents while developed countries were granting product patents. By this regime, Indian pharmaceutical firms can copy the patented pharmaceutical drugs of other nations which lead to the resounding start of manufacturing generic medicines in India. As a result, the Indian pharmaceutical sector prospered and fostered growth to the nation's "indigenous scientific and technological capacity."

The Patent Act of 1970 protects the patent of only the manufacturing process of

[drug/?noamp=mobile](#).

the drug which means that, with different manufacturing process the same drug can be legally produced. As a result, the expensive drugs were easily available to general public at lower prices. Also the local pharmaceutical industry boomed because of huge presence of low income population in the country who were keen to buy drugs which are less expensive but also equally efficient. The 2005 amendment to this act, offered product patent protection which means, the product is protected simultaneously the process and technology employed are also protected. India was contractually obligated under the TRIPS agreement to amend its patent laws to ensure compliance with the agreement. The agreement from January 1, 2005 offers product patents to pharmaceuticals, food products and other chemical processes for a period of 20 years².

This amendment encountered strong opposition from numerous sections of the society. Their principal argument is that if the pharmaceutical companies are awarded the product patents, then the general public could potentially loose access to the affordable medicines. Because the product patent protects the patent in a way that only the inventor can make the product applying the same or different process and nobody else can make that product using any process. Hence the product patent provides superior protection that process patents. Product patents in addition with process patents are beneficial to both the inventors and patent holders³.

The move to incorporate TRIPS complaint into the Indian laws, with all the flexibilities that were provided by the agreement, was widely accepted. However, there was growing concern that with the implementation of this agreement the general public would not be able access medicines as their prices might shoot up. As a result the

² Prachi Nayan, Pharmaceutical Patenting In India: Problems of Public Access to Health, Dissertation-NLUJA, Assam,(2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1>.

³ Medical Devices - Global Regulatory Partners, <https://globalregulatorypartners.com/countries/asia/india-cdsco/> (last visited on Jan. 15, 2022).

general health of the public could be hampered. The same issue was discussed during Doha declaration, 2001 where it was decided that member would be allowed to enact their own laws to uphold the interest of their people. In addition, the Indian constitution contains clauses that guarantee everyone the right to the best mental and physical health possible. "Article 21 of the Indian Constitution guarantees every citizen protection of life and personal liberty, which includes the right to health, making it a fundamental right that cannot be relinquished by anybody. Additionally the Supreme Court in the case of State of Punjab v. Mohinder Singh Chawla⁴ held that the right to health is incorporated in right to life and that makes it constitutional obligation for the government to provide health services." So in order to meet all these obligations certain provisions of compulsory license have been included in the Patents Act, 1970. Compulsory license can be generally defined as "authorization to the third party to make, use or sell the patented invention without the consent of the patentee with adequate compensation to the patentee".

The third party must always be a person of interest and they should be able to prove that because of the patentee the patented product is not available to the general public. The act through Sections 84 and 92 lays down several conditions related to compulsory license⁵.

On one side the Patent Act bestows product patents and process patents enabling complete protection to the patented products. It makes it illegal and infringing to make, use and sell the patented pharmaceuticals without any authorization, while on the other side, the Act makes provisions for compulsory license which exempts the exclusive rights of the patentee." In order to prevent the patentee from misusing the monopoly of patent and to safeguards the public interest the statutory

mechanism of Compulsory licensing was incorporated into the act.

Therefore compulsory license uplifted the generic medicine sector of India. Even the products with product patents are permitted to be manufactured by the local companies with a different or new process. As a result, a grand debate in terms of efficiency of the generic medicines and patented medicines has started. Both of them attack the claims made by one other. The purpose of this chapter to elaborately discuss this debate and arrive at a conscious conclusion with respect to the same⁶.

Impact of TRIPS on pharmaceutical patent and health care

Impact of TRIPS on pharmaceutical inventions

The member states of TRIPS get some flexibility in ensuring their public interests in health are not hindered while enforcing the intellectual property rights (IPRs). Patent protection plays a key role in making sure the research ecosystem of a country is healthy and progressive. The pharmaceutical industry had gone through radical changes when India was inducted into world trade organisation (WTO) as it was obligated to enforce the TRIPS Agreement⁷.

TRIPS initiatives, challenges and concerns of the developing countries

The TRIPS Agreement aims to set and implement an international standard to protect the intellectual property." It did not setup a universal IPR system to be followed by its member countries rather the member

⁴ State of Punjab v. Mohinder Singh Chawla AIR1997SC 1225

⁵ Compulsory licensing: law, challenges and strategies - Lexology, <https://www.lexology.com/library/detail.aspx?g=8efb1c00-65cd-4d66-8925-5ece8f8f2551> (last visited on Jan. 15, 2022).

⁶ Prachi Nayan, Pharmaceutical Patenting In India: Problems of Public Access to Health, Dissertation- NLUJA, Assam,(2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1> .

⁷ Anjeeta Rani, Effect of India's GMP standards on the competition law issues in the pharmaceutical industry, iPleaders, (Jan. 15, 2022, 1:38 PM), <https://blog.iplayers.in/effect-indias-gmp-standards-competition-law-issues-pharmaceutical-industry/?noamp=mobile> .

countries can setup their own regime. These regimes can even be stringent than the one needed by the article 1 of TRIPS Agreement. The WTO recognised that members have their own commitments to develop public health, so in matters relating to promoting their public health and also public interests in crucial sectors for socio-economic and technological advancement, the members have flexibility to enact their own legislations in this regard. The main intention of the TRIPS Agreement is to make that IPR is protected adequately without putting the developing countries public health interests⁸ at risk while ensuring that innovation is diffused into the world. The flexibilities provided by TRIPS agreement are – members have the freedom to not include new varieties of the known medicines in patent protection. According to Article 6, “members have the freedom to utilise the principle of international exhaustion of patent rights to promote the import of drugs parallelly.” The manufacturers of generic medicines can have the exemption from regulatory review and also exception to research. The marketing approval grant can be delinked.

The Doha Declaration of 2001, which was held to discuss the issues of TRIPS Agreement especially in terms of public health further augmented and advocated for the use of these flexibilities. Though domestic laws were enacted to support this flexibility to legislate, yet it is not being utilised by developing countries as they are under being pressurised by the developed countries. Hence the present global regime protecting IPR is not in the favour of helping developing countries to improve their public affect which is effecting their citizens generally but particularly the poor

Generic Medicines

“A generic medicines is the type of medicine which has the same chemical composition of the patented medicine and also proportionately efficient.” Though both the patented medicine and generic medicine have same active pharmaceutical ingredient (API)

⁸ Sanjeev Kumar & Kumar Akhilesh, Detail study on Indian Pharma companies Vs. European Pharma Companies, Scribd, p23 (2010), <https://www.scribd.com/document/33631014/Original-Final-Project>.

but important features such as manufacturing process, formulation, colour, taste, packaging, and excipient are different⁹.

In the global scenario, The industry of generic firms that manufacture generic medicines have huge presence in India. Generic medicines can be quickly availed at far cheaper prices compared to the patented medicines.

Because the generic medicines need not go through the repeated animal and clinical studies like a patented medicine as they are required to prove their safety and efficiency. Simultaneously numerous generic medicines based on a single product are permitted which leads to the competition in the market driving the prices low.

So just because generic medicines are cheaper does not mean that they are some pirated copies and less effective than the patented medicines because the government has itself been supporting the manufacturing and sale of the generic medicines.

Premier organisations like FDA (Food and Drug Administration) enforce stringent rules on the generic firms before approving a generic medicine into the market. These generic firms have to prove that their drug can used an alternative to the patented medicine while providing the same desired clinical benefits¹⁰.

In India, the medical council has laid down certain guidelines for the physicians to follow while prescribing generic medicines and also to not mention the name of branded drugs in the prescription of the patients.

The prices of some generic medicines in India are:

- a) Paracetamol (for fever) – ₹9.80 per 10 tablets
- b) Cefixime (for Bacterial Infection) - ₹225 per 10 tablets
- c) Amoxicillin (For Bacterial Infection) - ₹30.77 per 10 tablets
- d) Ofloxacin (For Diarrhea) - ₹92 per 10 tablets¹¹

⁹ Debarati Tripathi, Indian laws and Policy on Generic Drugs, iPleaders (Jan. 15, 2022, 1:30 PM), <https://blog.ipleaders.in/generic-drug/?amp=1>.

¹⁰ Debarati Tripathi, Indian laws and Policy on Generic Drugs, iPleaders (Jan. 15, 2022, 1:30 PM), <https://blog.ipleaders.in/generic-drug/?noamp=mobile>.

¹¹ Prachi Nayan, Pharmaceutical Patenting In India:

The government supports these generic medicines as they have lower prices which helps the people in purchasing them. Also the same efficiency makes these medicines a far more better choice compared to the patented medicines.

Generic Medicines and Their Misconceptions Cleared

There are several misapprehensions and queries to be answered with regard to the generic medicines. The government of India made numerous efforts to promote the generic medicines in the country yet they are not widely accepted because of the stigma surrounding them in the minds of people.

Several misinterpretations which are loose in the market are also lingering in the minds of Indian population. In the global arena, the generic medicines as a substitute of patented medicines are well received and widely accepted which is not the same in the case of India. There are several reasons for this practise namely – inaccessibility of the generic medicines, apprehensive doctors or physicians who believe them to be of subservient and pirated versions of the patented medicines¹².

1. Quality and Effectiveness

One of the great advantages of generic medicines is the cheaper price it has compared to the patent medicines. This is what enables them to penetrate markets easily which results in effective and affordable medicine to all the people. For instance, in the same platform Indiamart.com, Celgene corporation is selling per piece of a 100 mg vial of its patented product Abraxane for ₹18,000 while Cipla is selling per box of its generic medicine Imatinib 400mg for ₹6,000.

The popular belief in India is that if anything is cheaper then it is not up to the standard. Worryingly, they are applying the same belief to generical medicines as well

where they are assuming that because of its low price, it might be less efficient and might further compromise their health than strengthen it. The key argument to tackle this belief is that when the priority of the government is the wellbeing of its citizens, then why would its agencies support and approve such subservient products that could potentially endanger the health of the country. Additionally the government has established several institutions to regulate these generic medicines whose objective is to making sure that the drugs produced and marketed are approved only when they are up to the standards. Few of them are :

a) The Central Drug Standards and Control Organization (CDSCO): “This organisation is in charge of ensuring that drugs are safe and effective.”

i. It is overseen by the Ministry of Health and Family Welfare.

ii. It establishes national standards and measures to ensure the efficacy, safety, and quality of pharmaceuticals, cosmetics, diagnostics, and devices.

iii. It also governs the approval of new pharmaceuticals for sale and the requirements for clinical trials.

iv. It also regulates drug imports and grants licences to manufacturers of the aforementioned products.

b) The National Pharmaceutical Pricing Authority (NPPA) published a report in 1997.

i. The National Pharmaceuticals Policy Act is overseen by the Department of Chemicals and Pharmaceuticals.

ii. It also updates the price-control list on a regular basis by including and excluding medications in accordance with approved rules.

The Ministry of Chemicals and Fertilizers focusses largely on industrial policy, whereas the Ministry of Health and Family Welfare deals with the issues of pharmaceuticals in the broader category of public health.

The Department of Pharmaceutical was created by the cabinet secretariat under the Ministry of Chemicals and Fertilizers in July of 2008. The sole objective here was to provide necessary attention and momentum needed to develop the India's pharmaceutical

Problems of Public Access to Health, Dissertation-NLUJA, Assam,p.78(2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1> .

¹² Medical Devices - Global Regulatory Partners, <https://globalregulatorypartners.com/countries/asia/india-cdsc/> (last visited on Jan. 15, 2022).

industry, as well as to regulate various complex issues such as pricing and availability of affordable medicines, research and development, intellectual property rights protection, and international commitments with regard to the pharmaceutical industry, necessitates collaboration with other ministries.

The drug market of the country is controlled and regulated by two prominent bodies to ensure the quality of the drugs. So now it is clear that any drug cannot enter the market if it is not highly efficient and not of superior quality. Furthermore, a department was created to keep a constant eye on the drugs. Hence it is not easy for any drug of subservient quality to enter the market as it has to undergo stringent tests maintaining its efficiency and quality.

Moreover, the courts have laid down a complex criteria to grant a compulsory license for any applicant. The following key principles have to be looked into before granting a compulsory license:

a) The courts will examine the legitimacy, proactive behaviour, and attempts of the applicant toward the patentee for the award of a voluntary licence.

b) Three tests are used to determine if the reasonable standards have been met:

i. If, in complement to the patented medication, there are any other drugs available for the same ailment that might be made accessible to the public at a reasonable cost;

ii. If no substitute pharmaceuticals are accessible, if the patented drug can be made or imported by the patentee (commercial operating in India) at a reasonable cost to the general public; and

iii. "A cost comparison of the proposed drug, the patentee's drug, and any alternative drugs¹³."

¹³ Prachi Nayan, Pharmaceutical Patenting In India: Problems of Public Access to Health, Dissertation-NLUJA, Assam, p.77(2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1> .

2. Low cost means low quality

One more misconception of the people is that how can one sell a highly effective drug at cheaper rates because they believe that ensuring the quality of a drug is highly expensive. The primary factor that enables pharmaceutical companies to lower the prices of their generic drug is that they do not make huge bills to develop and market their drug.

The generic firms manufacture the drugs at a very minimal cost spending less or no money on research. Because all the fundamental work has been done by the pharmaceutical company that manufactured the original patented drug. This company incurs heavy expenses for research and development, patent filing and marketing of the drug. That is why these generic firms are awarded with compulsory license after 3 years post the expiration of patent. Furthermore, there is a huge demand for the generic drugs in the Indian market which drives the competition even more leading to lesser prices. The generic firms with low prices aim to earn their profits by selling in bulk amounts while the patented drugs earn profits in the short amounts for the pharmaceutical companies because of high prices.

All of the above arguments prove that even though generic drugs are cheaper yet they are highly efficient and highly beneficial which enables them to be easily available to the public.

Generic Medicine or Pharmaceutical Medicine

One of the huge dilemma the public face today is whether to opt generic medicines or pharmaceutical medicines. In order to clear this confusion we have to study their advantages and disadvantages in detail.

1) Generic Medicines

i. Advantages

(a) Cheaper Prices:

The affordability of the generic medicines is a major benefit for countries such as India because according to the 2011 census data 86.80% of population earns around US \$5.50 per day. So the medicines should be affordable in order to be accessible as a effective medicine with completely

unaffordable price cannot be accessed by majority of the population in India. Furthermore, medicines should be available in order to recover the sick population which determines the health of this nation. The healthy people are an asset to this nation while the sick people are a liability as the government needs to devote lot of resources for their treatment which could be otherwise spent on programmes for its development.

b) Bioequivalent:

Biologically, in order to be approved generic drugs have to meet a set of requirements imposed on them. The generic drug should deliver the same quantity of active ingredient into the body in the exact amount at the exact time and affect the body like the patented medicine.

c) Easily available:

The generic drugs can be easily accessed in pharmacies. In order to encourage the sales of generic drugs, Rule 96 of the Drugs and Cosmetics Act was amended to change the way generic drugs are labelled. As per this rule, the generic firms should ensure that font of the generic medicine is two units larger compared to the patented medicines when printed on the medicines. In 2018, the DGCI in its circular directed the pharmacies to store the generic medicines in a separate shelf. All these were attempts made by the government to support the accessibility of generic medicines in India.

d) Healthy competition in Market:

Competition in the market can be created if the small manufacturers are allowed to enter into the marketing a easy, cheap and fast way.

e) Quality Assurance:

Schedule M and Schedule M III of the Drugs and Cosmetics Act (DCA) cover India's GMP for medical devices and drugs¹⁴:

- Schedule M outlines the requirements for medical devices and pharmaceuticals in terms

¹⁴ Anjeeta Rani, Effect of India's GMP standards on the competition law issues in the pharmaceutical industry, iPleaders, (Jan. 15, 2022, 1:38 PM), <https://blog.iplayers.in/effect-indias-gmp-standards-competition-law-issues-pharmaceutical-industry/?noamp=mobile> .

of quality assurance, self-inspection and/or quality audit, and quality control systems, as well as the factory premises, materials, plant, and equipment¹⁵.

- These standards are based on World Health Organization recommendations.
- Small volume injectables, high volume parenterals, APIs, tablets, capsules, and other medications have extra particular requirements.

GMP rules in India are now more closely linked with ISO 13485. Standardizing quality norms will make it easier for Indian medical device makers to register their products.

- All drug manufacture requires a licence under the 1940 Drugs and Cosmetics Act. "This licence is only available to entities based in India. Most medication items can be supervised by the state government's drug controllers. New medications, large volume parenterals, vaccines, crucial IVD kits, and r-DNA derived drugs, for example, all require approval from the Drug Controller General of India (DCGI) before a licence can be issued." Each factory and the pharmaceuticals produced in that factory are issued a licence. In other words, depending on the product group, several licences are available.

ii. Disadvantages

a) There is difference in the rate of absorption and its extent among the different generic forms of the patented product.

b) It is not easy either to spell or keep in mind the names of generic medicines compared to their patented medicines.

c) At times generic firms use different excipients and colorants in their generic medicines compared to the patented medicines which might result in problems.

d) The innovation of the pharmaceutical industry is halted by the generic drugs. Because the generic firms gets to utilise the processes that are patent protected through compulsory license. These firms do not focus on research rather they include a simple change to the existing innovation which does

¹⁵ Prachi Nayan, Pharmaceutical Patenting In India: Problems of Public Access to Health, Dissertation-NLUJA, Assam,(2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1> .

not lead to any new way of curing the existing disease.

2) Patented Medicines

i. Advantages

- a) In order to avail patent protection in India, pharmaceuticals or drugs have to meet several requirements which are set at a high standard. This drives the firms to constantly innovate by investing on their research and development. Hence this innovation leads to new ways to cure the existing disease.
- b) These medicines are highly efficient because of huge resources devoted to their R&D.
- c) Patented pharmaceuticals boost public competitiveness in terms of ideas and inventions, resulting in a highly efficient sector.
- d) These medicines not only raise the income of their firms but also support the economy.

ii. Disadvantages

- a) Unaffordability: The manufacturers incur heavy expenses for the R&D, process, marketing and patent application of their drugs. This leads to pricing these drugs at higher prices which is completely justified. But with higher prices, these drugs can be accessed only by few making it completely inaccessible for the majority of the population.
- b) Patents support monopolies: the pharmaceutical firms artificially price their drugs at higher rates. The competition in the market would be hindered by this way of pricing, but the way the patent operates checks the competition in most of its forms.

Judicial approach to right to health: India

In Peoples Union for Democratic Rights v. Union of India case the Supreme court of India stated that “it is the constitutional obligation of the state to ensure that fundamental rights of the citizens are not violated. So the government should observe that the social welfare programmes should comply with the directive principles of state policy.”

In Consumer Education and Research Centre v. Union of India¹⁶ the Supreme Court of India ruled that,

“The right to health and medical care to protect health and vigour while in service or postretirement is a fundamental right of the worker under article 21. In the instant case the court also held that the health insurance while in service or after retirement, is a fundamental right and even private industries are enjoined to provide health insurance to the workman”.

In Bandua Mukti Morcha v. Union of India¹⁷ Bhagwati J case it was held that,

“It may not be possible to compel the state through the judicial process to make a provision by statutory enactment or executive fiat for ensuring these basic essentials which go to make up a life of human dignity but where legislation is enacted by the state providing these basic requirements to the workmen and thus investing their right to live with basic human dignity, the state can certainly be obligated to ensure observance of such legislation; for inaction on the part of the state would amount to denial to the amount to live with human dignity enshrined in article 21, more so in the context of article 256 which provides that the executive cannot remain inert when the administration does not provide adequate measure to provide access to health”.

Conclusion

In the health-care industry, the most crucial factor is that patients receive adequate medications and/or treatment. As a result, when it comes to the benefit of patients, deciding between generic drugs and patented pharmaceuticals is critical. Most medical professionals favour patented pharmaceuticals because one trust in patented medicines because patented medicines are well-known and have been approved by multiple agencies, making them very effective in their eyes. However, it has been demonstrated on numerous occasions that generic drugs are equally effective as proprietary pharmaceuticals, and the government has

¹⁶ Consumer Education and Research Centre v. Union of India, 1995 SCC (3) 42

¹⁷ Bandua Mukti Morcha v. Union of India, 1984 SCR (2) 67

backed them up. This being stated, the government would never promote a non-effective medical system since it would imperil the lives of the entire nation, which is a risk no authority would want to take. Both sets of medicines have their own set of advantages and disadvantages, making them both vulnerable and a strong choice for patients. While none of the disadvantages are life threatening, the high prices may be, as they make it unavailable to patients, and brand scams may also have an impact on patients' lives.

When comparing the two, one must only consider the patients' benefit, not just those who can afford all levels of healthcare, but especially those who lack even basic levels of healthcare and pharmaceutical items.

Though generic drugs are ineffective in the areas of research and development, innovation, and the country's economy, they reach patients at all levels. Furthermore, they are believed to pose a threat to patent holders' rights, which are just their rights, but the lives and health of patients must come first. To summarise, both generic drugs and patented pharmaceuticals are nearly equally effective, with the generic medicines having a cheaper cost. As a result, generic drugs are always a better alternative for patients and the general public if they are positively beneficial on the bodies of the patients.

Bibliography

Articles

1. Prachi Nayan, Pharmaceutical Patenting In India: Problems of Public Access to Health, Dissertation NLUJA, Assam, (2020), <http://www.dlnluassam.ndl.iitkgp.ac.in/bitstream/handle/123456789/283/Prachi%20Nayan.pdf?sequence=1>.
2. Debarati Tripathi, Indian laws and Policy on Generic Drugs, iPleaders (Jan. 15, 2022, 1:30 PM), <https://blog.ipleaders.in/generic-drug/?amp=1>.
3. Debarati Tripathi, Indian laws and Policy on Generic Drugs, iPleaders (Jan. 15, 2022, 1:30 PM), <https://blog.ipleaders.in/generic-drug/?noamp=mobile>.
4. Anjeeta Rani, Effect of India's GMP standards on the competition law

issues in the pharmaceutical industry, iPleaders, (Jan. 15, 2022, 1:38 PM), <https://blog.ipleaders.in/effect-indias-gmp-standards-competition-law-issues-pharmaceutical-industry/?noamp=mobile>.

5. Quality management for Medical Products in india - Pacific Bridge Medical, <https://www.pacificbridgemedical.com/regulatory-services/medical-device-pharmaceutical/quality-compliance/india/> (last visited on Jan. 15, 2022).
6. Medical Devices - Global Regulatory Partners, <https://globalregulatorypartners.com/countries/asia/india-cdsco/> (last visited on Jan. 15, 2022).
7. Ethical Issues in Pharmaceutical Market In India - docshare.tips, http://docshare.tips/ethical-issues-in-pharmaceutical-market-in-india_59c7f92ddc0d604214a25eea.html (last visited on Jan. 15, 2022).
8. Sanjeev Kumar & Kumar Akhilesh, Detail study on Indian Pharma companies Vs. European Pharma Companies, Scribd, (2010), <https://www.scribd.com/document/33631014/Original-Final-Project>.
9. Regulatory Issues In the Indian Pharmaceutical Industry - docpalyer.net, <http://docplayer.net/48284428-5-regulatory-issues-in-the-indian-pharmaceutical-industry.html> (last visited on Jan. 15, 2022).
10. Compulsory licensing: law, challenges and strategies - Lexology, <https://www.lexology.com/library/detail.aspx?g=8efb1c00-65cd-4d66-8925-5ece8f8f2551> (last visited on Jan. 15, 2022).

Commission Report

1. 7th Pay Commission - docshare.tips, http://docshare.tips/7th-pay-commission_58a71931b6d87fde488b4c2f.html (last visited on Jan. 15, 2022).
2. National Consumer Helpline(NCH), <https://consumerhelpline.gov.in/faq-details.php?fid=GENERIC+DRUGS> (last visited on Jan. 15, 2022).