
TRIPS AND ITS IMPACT ON THE COUNTERFEIT PHARMACEUTICAL MARKETS

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ABSTRACT

The pharmaceutical industry functions in a complex sector of healthcare, which brings about the need to keep a check on the regulation of the surfeit of laws. This counterfeit drug industry is booming in India because of its feeble enforcement of lawmaking and plasticity in the present legal context, India's medicine prices are greater than those of most other countries, the community in India are unaware of the counterfeit products which due to the cheap rates, they tend to buy. In the past, the regulation system being extremely lenient of the pharmaceutical business has made people get into the life of crime, making counterfeit medicines, just because the punishment for the crime isn't properly defined under the laws laid down. This paper will discuss the effects of counterfeit drug distributed in the Indian economy and the impact of TRIPS with the help of statistical analysis of the generic drug supply in the economy.

INTRODUCTION

The industry of counterfeit medications is not new to the world, and it has existed for centuries. When more members of the World Health Organization (WHO) reported counterfeit medicines in the 1980s, the issue of counterfeit drugs arose. ¹"Counterfeit drugs," according to the Black Law dictionary, are medications created by someone other than the original manufacturer by replicating and imitating an original product without authority or right, with the intent to deceive or defraud.² Substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) pharmaceuticals have been given a new term by the World Health Organization (WHO).³

GENERIC DRUGS AND COUNTERFEIT DRUGS

A generic drug is a pharmaceutical medication that is manufactured and delivered without patent protection or marketed under its chemical name without advertising. Generic drugs are marketed under a non-brand name. Generic drugs are frequently as effective as branded drugs, but much cheaper than the brand-name drugs. Generic medications are frequently as effective as brand-name drugs, but they are far less expensive. A fake medicine is one that has been purposefully and fraudulently mislabeled as to its origin or source. Counterfeit products may include those with incorrect ingredients, incorrect active substances, missing important ingredients, insufficient active ingredients, incorrectly marked, stored, or handled with phony packaging.⁴

Under Section 17-B of the Drugs and Cosmetics Act 1940, a "spurious drug" is defined as a drug that is an imitation of another drug or manufactured under a name that belongs to another drug, or if it has been replaced entirely or partially by another drug, or if it falsely claims to be the product of another manufacturer.⁵

The counterfeit products are designed in such a way people that are not able to identify the difference between the original and the duplicate medicines, which makes it harder for the consumers to get, at the end of which, they have to procure these counterfeits which are considerably cheaper and has an almost similar packaging. The global pharmaceutical market

¹ Robert Jameson *et al*, *Using IP law as a medical patient safety tool: efforts from the US and China*, 2 IJIPR, 155, (2009).

² Black's Law Dictionary, 209, (9th ed. 2009).

³ Tim K. Mackey, Gaurvika Nayyar, *A review of existing and emerging digital technologies to combat the global trade in fake medicines*, EXPERT OPINION ON DRUG SAFETY 5, 587-602, (2017).

⁴ Elene Paltrinieri Nardi, Marcos Bosi Ferraz, *Perception of the value of generic drugs in São Paulo, Brazil*, Cadernos de Saúde Pública 2, 198, (2016).

⁵ Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, (1940). CDSCO (2009)

has always been plagued by a rash of counterfeit products, which include fake, spurious, substandard, and fraudulent preparations, which, in addition to causing huge financial losses to nations, states, and corporations, have a negative impact on people's health and well-being. The distinction between the above preparations is vague; however counterfeit drugs are those produced and sold with the intent of deception, misrepresenting the origin, and sacrificing the efficacy and safety of the product.⁶

Drug counterfeiting in India is a very lucrative business. India's status as a low-cost manufacturing base has opened up the gates for counterfeiters. Counterfeiters share none of the heavy research and development costs incurred by genuine manufacturers, yet are able to earn high profits. Identifying counterfeit drugs is quite complex and costly. Customers, and sometimes even prescribing physicians, are unable to discern the difference between a genuine and a counterfeit product. There is no reason to suspect a counterfeit product if a patient drinks the fake yet recovers normally.⁷ Drug counterfeiters are growing more and more sophisticated by using the latest technology systems in their illegal business. Investigators revealed that counterfeit makers' ability to use advanced printing technology contributed to the frequency of inactive components in counterfeit artesunate (an anti-malarial), such as holograms, had improved dramatically between 2001 and 2005.⁸ In situations where demand for drugs in the pharmaceutical industry exceeds supply, criminally minded people tend to derive profit out of manufacturing and distributing counterfeit or spurious pharmaceuticals as a substitute for legitimate medicines is a form of criminality.

The liberal process patent scenario made tremendous changes in the Indian Pharmaceutical industry by making drugs easily accessible at a very cheap rate. Local Indian firms by developing their own drugs manufacturing processes started making copies by getting it patented too.⁹ Indian companies were also free at that time to export their copied products to patent system and from 1 January 2005 brought in a product patent era for the pharmaceutical industry in which Indian pharmaceutical companies can no longer manufacture or market patented drugs without license from the patent holder. The generic pharmaceutical industry in

⁶ C. Travasso, *Counterfeit and substandard drugs in India may be smaller problem than claimed, say government findings*, BMJ, 60-209, (2014).

⁷ Saurabh Verma *et al*, *The Business of Counterfeit Drugs in India: A Critical Evaluation*, 2 I.J. Man. & Int. B.S 4, 141, 145, (2014).

⁸ *BarCode: Decoding the mysterious world of counterfeit drugs*, PLEXUS MD, (Jan 16, 2022, 3:08 PM), <https://www.plexusmd.com/md/post/barcode-decoding-the-mysterious-world/57608>

⁹ *Supra*, at 4.

India that flourished on process patent was no longer allowed to do so in this new product patent era. This act imposed constraints on the Indian pharmaceutical industry's ability to manufacture generic medications while also allowing investment in innovative drug research and development. This era results in increasing trend in awareness, public participation, patenting and patent enforcement in Indian pharmaceutical sector. In India, there is about 30% share for Pharma in filing and grant of trademarks and patents.¹⁰

Counterfeit steroid-containing pharmaceuticals have sprung out as a result of the popularity of weight-loss supplements. Often these medicines are distributed through unauthorized channels or illicit markets at very high prices. Drugs made for export by the home country are not regulated by many exporting countries to the same standards as those produced for domestic use. In addition, these drugs are sometimes exported through free trade zones (FTZ) where drug control is awkward because of which repackaging and relabelling take place. Even when the system is highly regulated, counterfeiters have a better chance of introducing illicit drugs into the distribution chain in this type of negligent commerce system. Drug regulation is founded on legislation and regulations. A competent national drug regulatory authority with the necessary resources is required to control the manufacturing, import, distribution, and sale of medicines in the country. According to the WHO report, around 20% of the 191 member nations have well-developed drug regulation and legislation, 50% are implementing drug regulation at various levels, and the remaining 30% either have no drug regulation in place or have a very limited capacity that barely functions. Inadequate, or weak drug regulatory supervision encourages unregulated drug imports, production, and distribution, resulting in the spread of counterfeit medications through legitimate distribution channels.¹¹

STATISTICAL ANALYSIS OF GENERIC DRUGS SUPPLIED IN THE ECONOMY

About 4.5 percent of all generic medications on the Indian market were found to be poor in 2018, according to the Central Drug Standard Control Organization. Furthermore, only one-fourth of India's 12,000 manufacturing facilities were found to conform with the WHO's good manufacturing standards, which are necessary quality regulations for medication makers. In a parallel world, there can be a severe impact on healthcare at an overall, which in turn leads to adverse side effects and worsening the spread of diseases, all as a result of the manufacture and

¹⁰ Nair, *Impact of TRIPS on Indian Pharma industry*, J. IPR 13, 46, 67, (2008).

¹¹ Bate, Roger, *Making a Killing - The Deadly Implications of the Counterfeit Drug Trade*, THE AEI PRESS, (2008).

marketing of phony medication. Notably, there are a plethora of laboratories in India, but only 20-30 good quality labs can identify the difference between low quality and good quality medicines that are in circulation, and the rising need and demand for quality healthcare has brought this information to light. According to statistics from 2019, India only had 47 drug testing facilities that followed the National Good Laboratory Practice. To make matters even worse, we had only six central labs, testing just 8,000 samples per year.¹²

Shown below is a report of region wise counterfeit drug smuggling rackets that have been uncovered, and comparing it to the amount of laboratories available in India, a safe estimation can be put together that while the ingenuity of the criminals is increasing at an alarming rate, it isn't anywhere close to the number of labs in the country, quality of the equipment available in these laboratories, or the equipped staff to defend these cleverly adapting criminals. And considering that these drugs are seized in huge quantities, and the testing capacity of these labs aren't quite equipped for the amount seized. And this is the data, from 3 years, by a couple of major cities. The cases not reported and unmonitored are the cause for the thriving market for counterfeit drugs.¹³

Year	Region	Report
2002	New Delhi	Two arrested for running fake medicines racket: 1662 kg of the spurious/fake drugs, Avil, Betnesol, Diclowin, Erythrocin, Voveran and Zintec, forgery labelled as the product of Cipla, Ranbaxy, Cadila, Glaxo and Smithkline Beechem, were seized in New Delhi
2003	Jaipur	Spurious drugs recovered at Sriganganagar, Rajasthan: Drug Control Department, Rajasthan, seized several products
2003	New Delhi	Delhi police seized 100 kg of spurious version of nimesulide, ranitidine, and betadine drugs made in Agra, Meerut and Ghaziabad
2003	Mumbai	Maharashtra FDA raided spurious manufacturer in Palghar, and seized spurious and substandard drug amoxicillin, ampicilline and Solutone (used in multivitamins) worth around US \$60,000 (INR 30 lakh) worth of spurious drugs
2004	Faridabad	Spurious omstal Tablets recovered at Faridabad: Health Department of Haryana from a licensed drug trader seized 10,000 tablets of spurious Domstal product

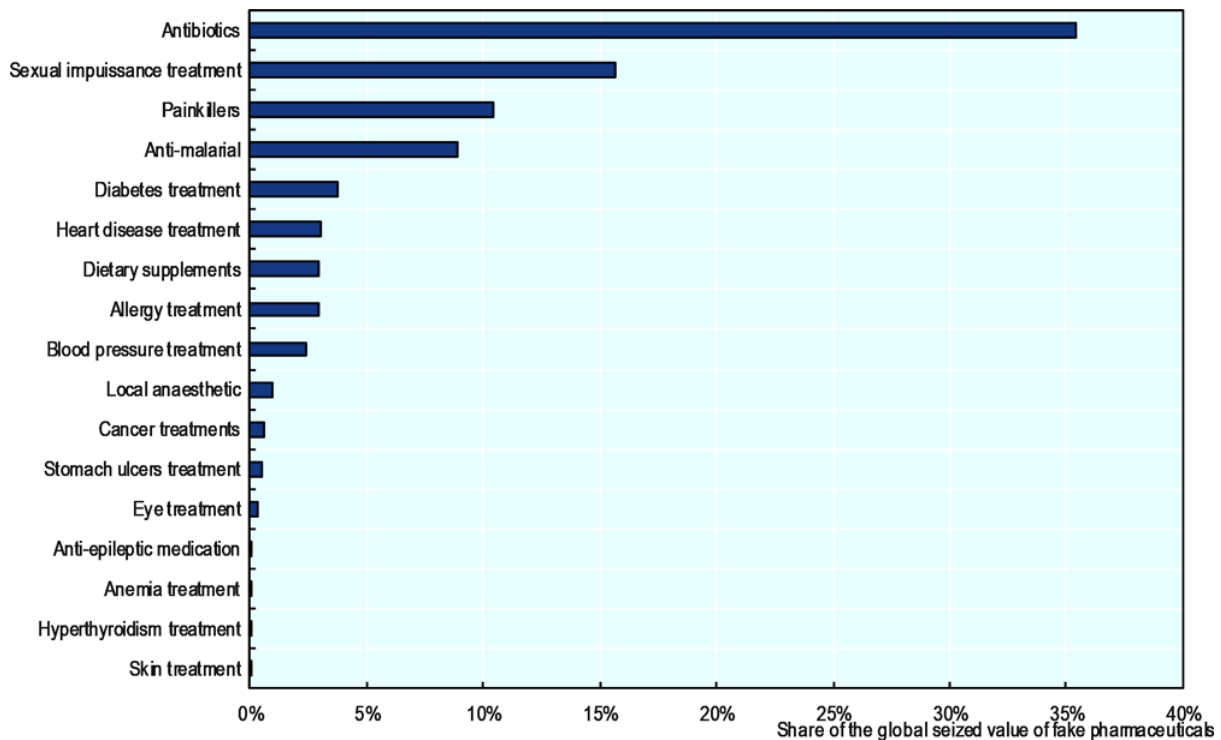
FDA: Food and drug administration

A chart depicting the many forms of counterfeit pharmaceutical items may be seen below. Medications for numerous ailments, including malaria, HIV/AIDS, and cancer, were among the counterfeits seized between 2014 and 2016. Counterfeit antibiotics, lifestyle medications, and painkillers were the most commonly targeted by counterfeiters, according to customs data. Malaria, diabetes, epilepsy, heart disease, allergy, blood pressure, cancer, and stomach ulcer medications, as well as local anaesthetics, are among the other categories of counterfeit pharmaceuticals frequently intercepted by customs authorities around the world.¹⁴

¹² Risks and Costs of Counterfeit Pharmaceuticals, PHARMA. ANTI-COFT. 21-34, (2011)

¹³ FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov>, (last visited Jan 17, 2022).

¹⁴ *Ibid.*



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The disturbing fact is that these drugs are largely consumed by the age group of 40+ adults and they belong to the lower middle class and middle-class category. Majority of them working in the employment sector, using their monthly salary to purchase these counterfeits, which they take, assuming to cure the ailments suffered by them, but in a reverse cycle, is causing their body to deteriorate due to the additives and selected chemicals involved in the making of these harmful counterfeit drugs, only for a fraction of the price off the original price marked for the branded medicines.¹⁶

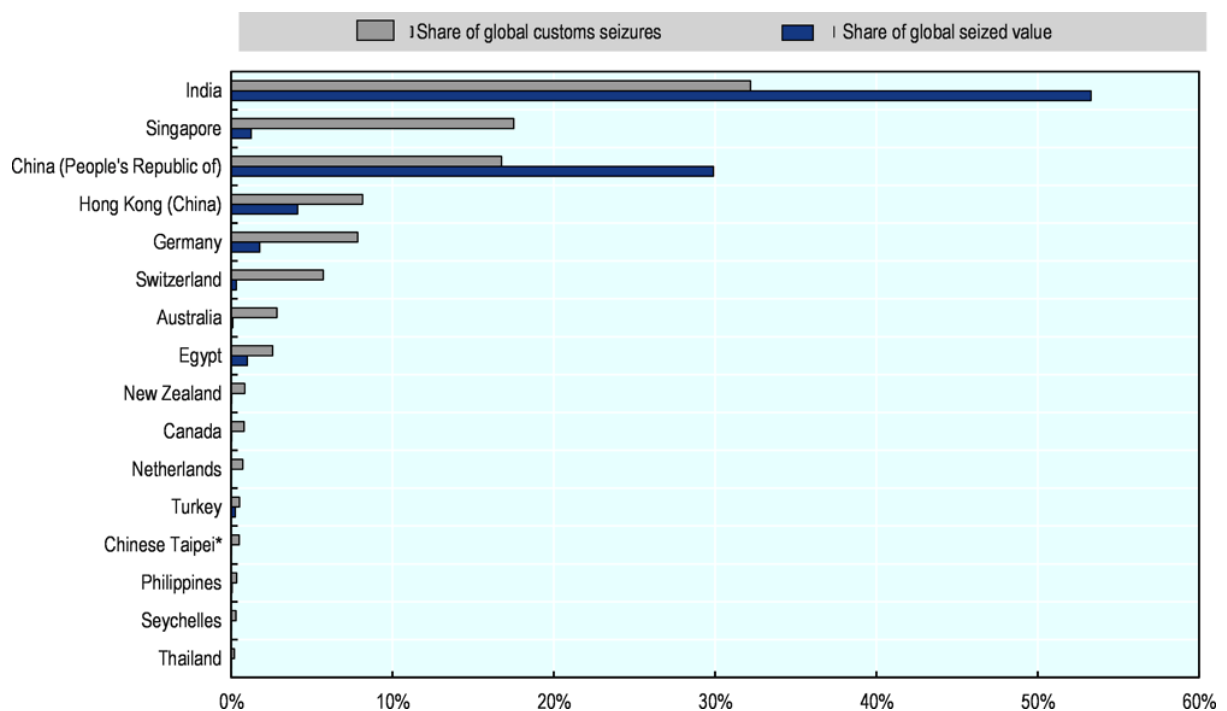
India continues to be the primary source of counterfeit pharmaceuticals, accounting for 53% of the total seized value of counterfeit pharmaceutical products and medications in 2016. It was followed by China, United Arab Emirates and Hong Kong. Singapore, Germany, Switzerland, Australia, and Egypt are also highlighted as important provenance economies in terms of the number of worldwide customs seizures. Except for Germany, the other countries were already in the top ten for counterfeit pharmaceutical products and medicines.

According to data from the OECD/EUIPO database on global customs seizures, the top four provenance economies for counterfeit pharmaceuticals traded globally in 2014 and 2016 were

¹⁵ LIVEMINT, <https://www.livemint.com>, (last visited Jan 17, 2022).

¹⁶ *Supra*, at 10.

the same as in 2011-2013. This shows that the main sources of bogus drugs in worldwide trade are very stable¹⁷.



India's pharmaceutical sector ranks among the top five in terms of bulk drug production and among the top 20 in terms of drug exports. The majority of the exports were generic items, with both developing and developed countries as target markets. At present rates, the global market for new generics is estimated to be worth roughly \$100 billion in the next years, with generics accounting for half to one third of that value. Liptor, the world's best-selling single branded medicine, with current sales of almost US \$ 14 billion, and several others will lose patent protection in 2011. If the Indian sector can capture 25% of the new generic market at that level, it will generate an additional US \$ 10 billion, which is more than the present local pharmaceutical market. In India, the "Bhagirath palace" Chandni Chowk in New Delhi is reputed to be the center for fake and counterfeit pharmaceuticals. Fake drugs form 20% of the 40,000 cr pharma market in India. What was once confirmed to exotic and costly pills like Viagra has now proliferated to cough syrups, vitamin supplements and painkillers. India, being the world's largest generic medication provider, has become a hotbed for counterfeit and fraudulent drugs. Most cases of fake and spurious drugs. In the local market were found in Bihar,

¹⁷ ORGANISATION OF ECONOMIC COOPERATION AND DEVELOPMENT, <https://www.oecd.org>, (last visited Jan 17 2022).

West Bengal, Uttar Pradesh and Gujarat. ¹⁸Since generic drugs attract low prices and margins, The high-cost economies of developed countries such as North America, Europe, and Japan are more inclined to outsource their medication needs to low-cost economies such as India, China, and Brazil.¹⁹

Fake, spurious, inferior, and fraudulent preparations have historically plagued the worldwide pharmaceutical markets, causing substantial economic losses to nations, states, and businesses while also having a negative impact on people's health and well-being. The line between the above preparations is hazy; however, counterfeit medications are those manufactured and sold with the goal of deceit, misrepresenting the origin, and jeopardizing the product's efficacy and safety.

Over 10,000 Facebook accounts or pages selling counterfeit Pfizer pharmaceuticals were found and reported by the pharmaceutical company Pfizer between 2015 and 2018. Furthermore, between April and October 2018, they reported over 1000 Instagram accounts selling counterfeit Pfizer products to Facebook, Instagram's parent firm. The company claims that it is attempting to detect and eliminate drug transactions by restricting and filtering phrases connected with them, and that it rapidly shuts down suspect accounts that are reported to it. It's also working on new technology to detect when someone is attempting to sell narcotics. In 2017, police from 49 countries recovered more than 12 million counterfeit Pfizer product dosages, according to Pfizer. On the dark web, over 5,000 dealers advertised Xanax for sale. In a trial initiative with law enforcement, the company purchased 138 Xanax samples on the dark web, examined them, and discovered only seven, or 5%, were genuine.²⁰

TRIPS, WTO AND WHO LEGAL INTERNATIONAL STANDARDS

From the production of medications to commercials and advancement, each stage of the medication development and marketing process is organised. India announced a patent safety management in 2005 to guard both progressions as well as product origination. Their own competition laws now in India address anti-trust issues which ascend in the course of daily procedures of the business, as well as owing to the abundant partnerships which the business is witnessing. In the recent past, there have been several fluctuations in the business' governing

¹⁸ *Supra*, at 7.

¹⁹ *Supra*, at 10.

²⁰ Kaur, Jaspreet, *Understanding how to Challenge the Pioneer Marketing Strategies*, CPJ GLO. REV., 367-389. (2016).

regime. All essential medicines prices on the National List of Essential Medicines, 2015 have been brought under price control under a new price control order. By applying a compulsory, a primary, secondary and tertiary requirement of barcoding in a phased manner on all its exports. For medical trial subjects, the new recompense regime specifies the fundamentals for compensation. And the government new taxing system like the GST has made a huge impact on the drug industry's making the pharma drugs rate go higher. New patent rules were passed in India in March 2005 to conform with WTO requirements and, specifically, the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). Prior to the introduction of TRIPS, global pharmaceutical companies intending to enter India were concerned about the protection of intellectual property rights (IPRs). India has well-established statutory, administrative, and judicial structures to protect IPRs in the post-TRIPS era.

A patented invention (including products) is now given 20 years of protection in India. The first amendment to India's Patent Act was in 1999 whereby Articles 70.8 and 70.9 of TRIPS were incorporated to provide for mailbox applications and exclusive marketing rights (EMRs). Patent rights for any invention in India are created only when the Patent Office grants the patent following the method outlined in the Patents Act and Rules. When it comes to patent rights, India uses a declarative method. Patents are granted on the basis of "first to file."²¹

If a patented invention is created, constructed, marketed, or imported 'solely' for the development and submission of information required under any legislation (Indian or foreign) that controls such operations, such acts do not constitute an infringement. This provision, known as the 'Bolar provision,' will gain importance in view of introduction of the product patent regime in India. A Bolar provision lets manufacturers to start the research and development process as soon as possible, ensuring that affordable generic medications can be brought to market as soon as the product patent expires.

India has historically been viewed by the global community as a 'poor patent enforcement' territory. Two provisions have been introduced that are likely to improve the patent enforcement mechanism. The first provision, compliant with Article 34 of TRIPS, is Section 104A, which is a "reversal of burden of proof" provision. Section 104A is an exception to the normal rule and requires that a person provide proof to any claims or allegations made. In 'process patent' infringement suits, the defendant will have to prove that he has used a process

²¹ M. Halliburton, Drug resistance, patent resistance: Indian pharmaceuticals and the impact of a new patent regime, GLO. PUB. HLT. 6, 515-527, (2009).

different than the 'patented process' in order to arrive at an identical product produced by a 'patented process' Second, a change to Section 108 of the Act will allow the court to order the seizure, forfeiture, or destruction of infringing items, as well as materials and implements used in the manufacture of infringing goods. Product patents granted in pursuance of black box applications have been treated differently to protect the interests of generic manufacturers. Enterprises that made significant investments and were producing and marketing the concerned product prior to January 1, 2005 and continue to manufacture the product covered by the patent on the date of grant of the patent are protected, and the patentee cannot institute infringement suits against them but is entitled to reasonable royalty payments from them. It is unclear how the reasonableness of the royalty would be established. This provision would prejudice the rights of a patentee in respect of exploitation of its patent.²²

Fortunately for India, the potential for generic markets to develop remains high due to a combination of factors such as a depleted pipeline of patented new treatments and the patent expiration of a significant number of blockbuster drugs. Indian firms will gain greatly from their supremacy in generic medications for worldwide markets. Though trade secrets and know-how are not legally protected, they are safeguarded by common law and contractual responsibilities. Confidential information and trade secrets are protected by the courts on the grounds of violation of confidentiality.

Drug counterfeiting is a criminal offense, and in recognition of the gravity of such nefarious actions leading to such goods, the WHO established the International Medical Products Anti-Counterfeiting Task Force in February 2006. (IMPACT). The 2006 Declaration of Rome stressed the necessity for every member of the WHO to take immediate actions to raise awareness and implement punitive measures to combat this threat.²³

RELATION OF COUNTERFEIT DRUGS TO GENERIC DRUGS

Attempts to link generics with counterfeit products have been the most terrible development in recent years. Issues related to the signature of the Anti-Counterfeit Trade Agreement (ACTA), WHO's IMPACT, and a slew of other accords are being considered during the Indo-EU trade talks. Currently, the right to judge what is counterfeit is left to the individual nation's customs

²² Reji K. Joseph, *Pharmaceutical Industry and Public Policy in Post-reform India*, (2015).

²³ Kaho Kwok, Lynne S. Taylor, *Raman Spectroscopy for the Analysis of Counterfeit Tablets*, *INFRARED & RAMAN SPECTROSCOPY IN FORENSIC SCI.*, 561-572, (2012).

officials as well as Interpol, which determines what is counterfeit unilaterally and seizes the relevant products even while in route to the other country. The drug counterfeiting business is booming in India for a variety of reasons, including a growing pharmaceutical industry, poor pharmaceutical regulation, high drug prices, value added tax, prescription of drugs without registration, a lack of public awareness, weak legislative enforcement, and flexibility in the current legal framework.²⁴

The Patents Act 1970 provides an impulsive growth to the generic pharmaceutical industry in India. It is incorrect to imply that generic copies of patent-expired pharmaceuticals are more likely to be counterfeit, an assertion that betrays a complete lack of understanding of the dynamics of this industry. Rather than leaving it to these agencies or IMPACT, India has appropriately demanded on the creation of an Inter Government Committee under WHO to settle out the regulations. Legitimate generic versions of patent expired drugs of the right quality as established through regulatory approvals fall strictly outside the view of counterfeiting.²⁵ In reality, a huge number of patent-protected medications are counterfeited and circulating in foreign marketplaces. If, on the other hand, the products in transit are seized on the grounds that they infringe legitimate patents, the matter can be resolved by referring to TRIPS clauses and their fair and proper interpretations. Such infringement claims have been contested by India in the World Trade Organization's Dispute Settlement Board, with Brazil as a co-plaintiff. Subsequently, Canada, Japan, Ecuador, China, and Turkey have since joined India and Brazil in this dispute.²⁶

THE TRADE MARKS ACT, 1999

In India, trademarks are protected both under statutory and common law. The Trade and Merchandise Marks Act, 1940 was India's first legislation with respect to trademarks and was later replaced by the Trade and Merchandise Marks Act, 1958 (TM Act, 1958). The TM Act was further updated in 1999 to comply with TRIPS and is now known as The Trade Marks Act, 1999 ("TM Act 1999"). Service marks and three-dimensional marks can be registered under the Trademark Act of 1999. India follows the NICE Classification of goods and services,

²⁴ Chandran, Roy *et al*, *Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities*, J. IPR 10, 380-382, (2015).

²⁵ *Ibid*.

²⁶ *Ibid*.

which is incorporated in the Schedule to the Trade Marks Rules, 2017 (“Trade Mark Rules, 2017”) under the TM Act, 1999.²⁷

Pharmaceutical products are covered under Class-5, cosmetics under Class-3 and the veterinary preparation under Class-1 and Class-5. Class 44 covers the services for medical services, veterinary services and cosmetics; Class 42 includes scientific and technology services, as well as related research and design. The TM Act of 1999 establishes a framework for conducting trademark searches.²⁸ Conducting a search for conflicting trademarks (whether registered or pending) before using or registering for any trademark is a wise practice that typically prevents potential litigation or resistance. Any registered trademark must fulfill certain conditions. The TM Act of 1999 established absolute and relative grounds for trademark registration denial. These reasons are similar to those found in the UK Trade Mark Act of 1994. The trademark can be registered even if the mark is proposed to be used in India i.e., even if prior to the date of application, no goods have been sold under the applied trademark. The registration and renewal period are ten years. Foreign companies can license trademarks in India under the proper license / Registered User Agreement.

A trademark can be used without registration and can be protected under common law but not under the statutory law by bringing a suit for passing off. Recently Indian courts have held that copying international names (even if the product is not made in India) is not permissible.²⁹

RELATED TRIPS AMENDMENTS

One of the most contentious revisions has been the one concerning compulsory licensing (“CL”). Currently, a CL can be granted if the innovation has not been ‘worked’ in India or has not been developed on a commercial scale in India because it was imported to India. New reasons for granting a CL have been added, including national emergency, exceptional urgency, and situations of public non-commercial usage, public health emergencies linked to AIDS/HIV, tuberculosis, malaria, or other epidemics. In the Compulsory License chapter, a new requirement has been included. The provision states that a license can be granted to manufacture and export a patented product to any country with insufficient or no manufacturing

²⁷ The Fourth Schedule To Trade Marks Rules, Trade Marks Act 1999, Classification of Goods and Services, (2002).

²⁸ The Trade Marks Act, No. 45 Acts of Parliament, (1999).

²⁹ *The Indian Pharmaceutical Industry: Regulatory, Legal and Tax Overview*, NISHITH DESAI, 19, (2021) http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/The-Indian-Pharmaceutical-Industry.pdf

capacity in the pharmaceutical sector in order to address public health problems, provided that such compulsory license has been granted in that country or that such country has permitted the importation of patented pharmaceutical products from India.³⁰ The amendment aims to put paragraph 6 of the Doha Declaration on TRIPS into effect while also addressing public health. The new rule would allow Indian firms to manufacture and export AIDS medications to African and Southeast Asian countries.³¹ Mr. P.H. Kurian, India's Controller General of Patents, Designs, and Trademarks, marked his last day in office on March 9, 2012, with a landmark judgment granting the first ever compulsory license to an Indian generic pharmaceutical company Natco Pharma to manufacture and sell a generic version of Bayer Corporation's patent-protected anti-cancer drug 'Sorafenib Tosyalte' (NEXAVAR). The Indian government is also contemplating mandating the licensing of cancer medications.

A CL can also ensure that no third parties take advantage of an outbreak and begin creating counterfeits in order to cause an influx in the market, where the customer would be unable to tell the difference between legitimate and phony medicine. The provision is a life saver since human health is of the utmost importance. This has the potential to assist third-world and developing nations recover from epidemics faster by utilizing technology and research similar to that accessible to affluent ones. Given the Coronavirus epidemic and the amount of foul play occurring owing to the lack of masks and fraudulent medicines on the market claiming to cure a virus that doesn't have a cure, this scenario will play out nicely for the present population.

CONCLUSION

The TRIPS controversy in India demonstrates the implications of the TRIPS in a developing country. It has resulted in substantial modifications to patent legislation. Domestic political forces are also reflected in these shifts. At the same time, the Patents Act modifications have not fully used the TRIPS provisions that would have been helpful to the country. This demonstrates that we cannot continue to blame the WTO for the evils of people committing crimes that are difficult to apprehend since it is also a concern of good domestic governance.

This makes it clear that, while India understands the need of intellectual property protection, it opposes the mercantilist use of IPRs that might harm public health or biodiversity. It also

³⁰ Juan He, *Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India, IED & IPR IN IND & CHIN. ARCIALA SER.*, 251-269, (2019).

³¹ Section 92A, *Supra*, at 5

supports the creation of a level playing field in the TRIPS agreement. However, inside India, a more comprehensive approach is necessary to guarantee appropriate utilization of TRIPS flexibilities. We must ensure that, as the amount of research and development in the pharmaceutical field increases, we can bring about a change in the provisions of law governing the sanctity of the research put into developing these medicines as well as the wellbeing of what we choose to consume in the name of medicine.