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COUNTERFEITING OF PHARMA PRODUCTS IN INDIA: WHY THERE IS A NEED FOR IPR?

AUTHORED BY - VAISHNAVI BANDHAKAVI

Abstract:

The Pharmaceutical industry is one of the evergreen industries in today's high paced world and a prime source of medical innovation. In a pharmaceutical or biotech company, Intellectual property (IP) is indeed the most valuable resource, which contributes significantly to the company's future success.IP is the bedrock on which the advancement of new medications and cures take place[1]. People buy counterfeit products for a variety of reasons, but nearly always because they cost less than the real thing. Unfortunately, these deals are too good to be true and there is always a victim.

INTRODUCTION:

Brief overview of Pharmaceutical Industry In India :

The Indian Pharma Area set out on a momentous excursion by presenting the Patent Demonstration in 1970. This act permitted Indian drug organizations to create reasonable nonexclusive adaptations of protected drugs, making medical services more open.

The industry has made significant progress in research and development beyond the production of generic drugs. Different examination foundations and organizations add to development in drugs.[2]

The Indian drug industry is viewed as one of the country's most beneficial areas, driven by expanded deals, higher Research and development spending, and government medical services use. Benefit relies upon different components, including organization execution, market interest, worldwide patterns, and guidelines.[3]

The absolute greatest players in the Indian drug industry incorporate Cipla, Deluge, and Zydus.

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[1] ***Sana Singh***, ***Bhawna Sharma*** *[Pharmaceutical Industry and Intellectual Property Rights – An Indian Perspective]* *21-Jun-2021*, *https://singhania.in/blog/pharmaceutical-industry-and-intellectual-property-rights-an-indian-perspective*

[2] An Overview of the Pharma Industry in India, *07 July 2023*, *https://groww.in/blog/overview-of-pharma-industry-in-india*

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DEFINATION AND IMPAC OF COUNTERFEIT PHARMACEUTICAL PRODUCTS:

According to the definition given by the World Health Organisation (WHO), fake medications are the "One which is purposely and deceitfully mislabeled concerning personality or potentially source, i.e., a fake medication is one which is dishonestly and eagerly mislabeled in understanding to the true items or in straightforward words[4],[5]

The deceitful or improper impersonation of valid and notable items that isn't authentic in nature and offered to individuals with the fake goal of misdirecting them is known as duplicating.

Item forging is a typical type of purchaser misrepresentation wherein an item is sold in pretense of something it isn't. The duplicating of the item generally occurs through altering, replicating or adjustment in the bundling of the item.

With regards to Forging drugs India and robbery, an enormous worldwide issue impacts basically every industry area in the world. India is the same, with broad falsifying and robbery having serious wellbeing and security repercussions in the country. Individual customer's wellbeing and security are endangered when they are followed into buying defective vehicle parts or dangerous drugs.

Quite possibly of the most weak region and most impacted area due to duplicating is the drug business. The drug items and their bundling are incredibly inclined to forging and are perhaps of the most weak market. Because of their high offer in market. Assembling and request on the lookout, falsifying is exceptionally normal.

Counterfeiting is a high-volume, high-profit business that violates Intellectual Property Rights (IPR), medicine laws, and other areas of the criminal law. Because they both involve making exact copies of the original goods, counterfeiting and piracy are synonymous[6].

Supposed way of life prescriptions are the most successive fake medications in Industrialized or created nations. These medications are frequently purchased online or from unlicensed pharmacies. Fake drugs are a main source of dreariness, mortality and makes doubt in the medical services framework.

FACTORS CONTRIBUTING TO COUNTERFEITING IN INDIA

[5] *Counterfeit medicine, European Medicinesl Agency, https://www.ema.europa.eu/en/glossary/counterfeit-medicine#:~:text=A%20medicine%20made%20by%20someone,Counterfeit%20medicines%20infringe%20trademark%20law.*

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Falsifying exercises have expanded in India by 24% beginning around 2019, causing loss of Rs. 1 lakh crore to the Indian Economy. The areas that detailed most instances of falsifying from 2018 and 2019 included quick purchaser products (FMCG), liquor, way of life, clothing, and Drug.

In addition, the pandemic has increased consumer demand and caused turmoil in the pharmaceutical industry regarding organized supply chains.[7]

A few Notable and viable associations, spreading over essentially every industry, surrender to copying and falsifying genuine things; be that as it may, they are not exact duplicates and may have differentiating and additionally faulty elements to a great extent.

- Challenges in Pharmaceutical supply chain
- -Absence of administrative oversight

Predicting Demand and Managing Inventory

It very well may be difficult to precisely foresee the amount of each medication will be required at some random time. Changes in quiet interest, economic situations, and startling occasions influence the interest.

Adjusting stock levels to forestall deficiencies while staying away from abundance stock requires cautious guaging. It additionally requires productive stock administration rehearses.

-Following rules and regulations:

The greatest test is understanding and agreeing with the mind boggling rules and guidelines. These principles and guidelines administer the pharma inventory network.

Various nations have various prerequisites for making, putting away, and shipping medications.

-Dealing with fake or poor quality medicines:-

Fake and unsatisfactory meds are a serious worry in the pharma store network. These phony or low quality drugs can endanger patients. They likewise harm the standing of a pharma

[7] Dr. Gajendra Singh, *Counterfeit Drugs: Threat to India's reputation of Indian Self-reliant Model*, Mar 5, 2021, https://health.economictimes.indiatimes.com/news/pharma/counterfeit-drugs-threat-to-indias-reputation-of-indian-self-reliant-model/81342614

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organization and the medical services framework.[8]

Forestalling and distinguishing these fake meds requires carrying out measures. Product serialization, authentication technologies, and increased visibility of the supply chain are some examples.

PUBLIC HEALTH IMPLICATIONS:

Fake goods have the potential to not only lead to an increase in morbidity and mortality but also to an increase in drug resistance and treatment failure. Counterfeit meds place the client's wellbeing at grave gamble; however, they likewise antagonistically hit the whole pharma industry's standing, tasks, and funds. In addition, the World Health Organization (WHO) estimates that counterfeit and substandard drugs cause over a million deaths annually.

It is in the bigger general wellbeing interest that all partners, including shoppers, need to remain careful of unsatisfactory and fake medications. India's pharma industry ought to zero in on making compelling correspondence pledges to foster a cautiousness outlook among customers. [9]Concerned government bodies ought to likewise effectively advance projects zeroing in on persistent wellbeing and mindfulness through the essential utilization of media.

At manufacturing facilities, anti-counterfeiting measures are essential. Utilizing the technologies that are currently available, it is necessary to place a greater emphasis on strengthening supply-chain controls and production quality. Makers ought to consider the reception of blockchain-based pharma answers for guarantee greater control across the worth chain - merchants, wholesalers, packaging and bundling and retailing. Pharma makers ought to hold back nothing, recognizable, long-lasting sequential numbering process for each thing of medication. Reception of measures, for example, track-and-follow advances, mass serialization with QR codes, and so on can assist with confining unacceptable or fake drugs from arriving at homegrown item retires and worldwide boundaries.

LEGAL AND REGULATORY FRAMEWORKM GOVERNING COUNTERFEITING

[8] *Vivek Sehgal* , ***Counterfeit drugs: A major public health threat,*** **February 24, 2023,** **https://timesofindia.indiatimes.com/blogs/voices/counterfeit-drugs-a-major-public-health-threat/**

[9] Lucy Rana and Nihit Nagpal, The Counterfeit conundrum: Civil and criminal remedies for spurious mediines in India, October 14, 2021, https://ssrana.in/articles/counterfeit-medicines-civil-criminal-remedies/

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Indian guideline doesn't have a specific game plan of guidelines focused on dealing with the duplicating of items. Regardless, there are sure regulations that go about as the solution for brand owners.

India has arrangements under licensed innovation regulation (The brand name act, 1999) and The licenses Act, 1970 and criminal regulations (The Indian Corrective Code, 1860) and criminal regulations (The Indian Correctional Code, 1860 and Medications and beauty care products Act,1940) to rebuff the medication forgers.

Basically, any brand can look for cure against falsifying under the Brand name Act, 1999 (The brand name Act). despite the fact that the term "counterfeit" is neither defined nor included in the trademark Act; the equivalent can be brought under the ambit of brand name encroachment.

As counted in segment 29 of the brand name Act, on the off chance that any imprint on an item or administration is confusingly comparative or considerably unclear from an imprint enlisted under the Brand name Act, such imprint will be viewed as encroaching on the enrolled mark under the brand name Act.

The Purchaser Security Act,2019 characterizes "misleading products" as firmly connected with past definations of fake merchandise as "Such products which are dishonestly professed to be geuine". The Buyer insurance Act,2019 endorses discipline for assembling available to be purchased or putting away or selling or dispersing or bringing in fake merchandise under segment 91.

Segment 79 of the data Innovation Act, 2000 comes as a salvage to veritable go-betweens which expresses that a delegate will be safeguarded and will be secured and will not be expected to take responsibility for the outsider substance on its foundation given that the said middle person noticed "A reasonable level of effort " as endorsed by the focal government.

Solutions for counterfeiting:

•Brief Order: Transitory directive or an in-between time order is a break cure which controls a specific party from briefly doing a predefined act.

•John Doe Request: A John Doe request is a pre-encroachment directive used to safeguard the maker's licensed innovation (IPR). Such orders are typically given in copyright encroachment

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cases.

ROLE OF PHARMACISTS AND CONSUMERS

Drug specialists as well as end shoppers are fundamental players in the conflict against drug falsifying. They are the people who are in constant communication with drug suppliers. It in this manner becomes fundamental to guarantee that drug specialists and patients know about the issue of falsifying and the ways of recognizing authentic meds from forging medications.
The medicines must be purchased by the patient from a reputable and trusted source.
[10]

Since the majority of counterfeit products are sold through unreliable online pharmacies, a patient must purchase the medications from a reliable source and avoid using shady ones. The patient must quickly contact the drug specialist or the specialist in the event that he/she sees any disparity in the appearance, taste or impact of the consumed drug.

Pharmacists must ensure that they purchase their medications from a reputable vendor that has been approved by the relevant drug regulatory agencies. To determine, pharmacists should keep product records.

Counterfeiting in the virtual world

The Information Technology Act, 2000 (the IT Act) looks to check unlawful encroaching exercises led using PCs and other innovation. The IT Act has stringent provisions and provides for both civil and criminal remedies. Online counterfeiting by way of illegal domain ***can be tackled through arbitration proceedings under in domain name dispute resolution policy (INDRP) or the Uniform domain name dispute resolution policy (UDRP[11])*** by laying out dishonesty with respect to the registrant. In situations where the enrolled space name includes an indistinguishable or confusingly comparative brand name, the bothered party can likewise look for a break directive or a long-lasting evacuation r move of the area name through a common claim by adding the area enlistment center as a co-litigant.

[10]

[11] SS Rana & Co, Intellectual Property and Combating Counterfeiting and Piracy in Digital Environment, ***October 28 2022, https://www.lexology.com/library/detail.aspx?g=70718ff3-682c-476b-8f73-36eac8f2c40c***

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Factors that lead to counterfeiting and Piracy:

a)Lure of high overall revenues: Pilfered and fake merchandise and administration are modest to create on the grounds that

i) No charges are paid
ii) Labor utilized is modest
iii) Sometimes kid work are utilized with no consistence with work guidelines.
iv) The purchaser and end-client set aside to 20 to 60% on the cost of marked products.
v) Occasionally, consumers purchase counterfeit goods knowingly and purposefully due to their low cost and non-harmful nature. One would eagerly purchase a phony piece of clothing however may not buy a phony medication.

Challenges confronted as a result of Drug Brand name Encroachment

Drug brand name encroachment presents importance challenges in India. First, it's hard to effectively monitor and control infringement activities because of the market's size and the number of small manufacturers and distributors. Second, the issue is exacerbated by consumers' lack of awareness of the dangers posed by counterfeit medicines.

A few significant central issues to consider are:

1 **Global Nature:** It is challenging to enforce trademark rights across diverse jurisdictions with varying frameworks and regulations because pharmaceutical products are frequently sold internationally.

2. **Counterfeit products** :Fake pharmaceutical products pose a particular threat to the pharmaceutical industry because they can be harmful to patients' health and damage legitimate pharmaceutical companies' reputations.

3 **Complex supply chains:** the intricacy of the drug store network makes it hard to follow the beginning of fake items and recognize the gatherings engaged with brand name encroachment.

4. **Generic substitution**: Conventional medication makers might attempt to utilize brand names or bundling that looks like the brand items to use their standing and piece of the pie, prompting potential brand name encroachment.

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Intellectual property Rights (IPR) in pharmaceutical industry

Licensed innovation Freedoms assists with safeguarding the organization's development. It assists with advancing solid rivalry in the market that ends up being helpful for the economy of a country. It is also a crucial tool for safeguarding the time, money, and effort they have invested, thereby supporting industrial growth and economic expansion.[12]

How does the pharmaceutical industry get protected by intellectual property rights (IPR)? There are many ways that intellectual property protects the pharmaceutical industry, as shown below:

- It provides fair and effective incentives for innovative processes
- It assists with safeguarding any organization against possible encroachment.
- It provides a strong enforcement mechanism for defending infringement in the case of patented drugs.

Patent regulation in the Indian Pharmaceutical industry

The law that manages licenses in India is given under the Patent Demonstration, 1970. India is a signatory to both the Paris Show of 1883 and the Patent Collaboration Deal (PCT) of 1970. The Licenses Act subtleties out the essentials of a patent which are important to be fulfilled for it to be conceded insurance:

- It should be new
- It should not be obvious
- It should be useful which can be the subject matter of a patent.
  There are some non-patentable inventions under the Act which includes[13]:
- Methods of agriculture or horticulture

[12] **Renu Bala and Johny Solomon Raj,** India: Patents And The Indian Pharmaceutical Industry, 23 January 2023, **S.S. Rana & Co. Advocates,** https://www.mondaq.com/india/patent/1273580/patents-and-the-indian-pharmaceutical-industry#:~:text=India's%20patent%20legislation%20must%20now,process%20that%20fulfils%20established%20criteria.

[13] *Renu Bala and Johny Solomon Raj*, **India: Patents And The Indian Pharmaceutical Industry, 23 January 2023, https://www.mondaq.com/india/patent/1273580/patents-and-the-indian-pharmaceutical-industry#:~:text=Through%20this%20amendment%2C%2020%20years,intensely%20%22knowledge%20driven%22%20sector.**

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- Processes for the medicinal,
- Processes of surgical, curative, or prophylactic Or other treatment of human beings, animals or plants or substances which are just due to mere admixture which results in the aggregation of the properties of the components

As to drugs in India, the substances which are expected to be utilized or equipped for being utilized as food compounds, drugs mixtures, or even meds or items which are created via synthetic cycles and such cycles are conceded security.

What is the term of patent granted to an Indian pharmaceutical company

Processes of Manufacturing of a drug in the Indian market are protected for the period of seven years from the date of filing or five years from the date of sealing the patent whichever shall be less. This is different from the other inventions which are granted a period of 14 years from the date of filing unless the patent is shown to be invalid. The method and processes of manufacture of a substance shall be used as food, drug, or medicine.

Even though, the Patent Act is under the process of the amendment as it has been recommended by the International Conventions of IPR which India is a party to, the two criteria of terms are

- Period of 7 years from the filing of the patent
- Period of 5 years from the date of sealing the patent
- Whichever shall be less.

Product patent or process patent? Which process is India following?

According to the Demonstration, there are two sorts of Licenses that can be gained in India, specifically, product patent and process patent[14]. The Indian governing body carried out these patent systems as a piece of the Patent Amendment 2005.

In short, the Patents Act of 1970 grants the inventor a statutory right for a predetermined time.

[14] ***Aishwarya Parameshwaran,*** Difference between product patent and process patent, **November 10, 2021,** **https://blog.ipleaders.in/difference-between-product-patent-and-process-patent/**

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The government grants this right. When this patent assurance is procured by the creator, he is conceded the option to prevent others from making, utilizing, selling his protected interaction or item.

Product patent versus process patent

The Indian Licenses Act, 1970 accommodates two sorts of licenses, they are process and product licenses.

This kind of patent safeguards the item. It offers the innovator higher security for his creation by diminishing the degree of rivalry of a similar item. Then again, a process patent safeguards the assembling system of an item yet not the product. The product patent boosts the degree of syndication and limits the opposition. In this way, we can reason that an item patent has the accompanying elements that ultimately helps the creator or the patent proprietor:

1. It gives a more elevated level of restraining infrastructure privileges to the designer of the patent proprietor.

2. Such an award keeps others from assembling a similar item utilizing a similar interaction or an alternate cycle.

3. Since the finished result is given assurance, the degree of security is viewed as higher in correlation with process licenses.

Process patent

In this kind, patent security is conceded exclusively to a specific process utilized in assembling an item yet not the finished result[15]. An interaction patent is frequently considered to give restricted security. The explanation is, it doesn't ban or keep others from assembling or making a

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similar item by utilizing a particular interaction. Subsequently, it is conceivable that there are numerous cycle licenses conceded for a solitary item. This in the long run diminishes the syndication that the designer appreciates, accordingly expanding the degree of rivalry.

Positions of developed and developing nations on product and process patents It has been demonstrated that developed and developing nations hold divergent viewpoints regarding product and process patents. In contrast to developed nations, developing nations have not yet recognized the significance of product patents as comprehensive protection. This division has prompted impediment in item security on a worldwide level as both item and cycle assurance gives insurance to licenses at various levels.

Since India is a piece of WTO, it has consented to bound itself and to follow the Excursions Understanding which happened in the year 1999. Through the Indian Patents Act Amendment of 2005, India adopted the product patent concept.

This Revision made in 2005 got two significant segments the Indian Licenses Act, specifically, Area 2 and 3. Indeed, even the meaning of 'Licenses' under Segment 2(j) of the Demonstration changed to an innovation implies another item or cycle including an imaginative step and fit for modern applications.

From Denying to Perceiving Patent Insurance for Drug Items

During the drafting of the Patent Law of 1984, patentable topic was a vital issue.

At that point, there were two altogether different perspectives with respect to the patent insurance of drug items. The contention that no patent right ought to be conceded to drug items was for the most part founded on the way that prescriptions are connected with individuals' actual wellbeing and ought not be hoarded by few individuals and that giving patent assurance would upset homegrown organizations which were falling a long ways behind their unfamiliar rivals in drug innovation.

The legislators came to the conclusion, after many discussions, that patent holders should not have a monopoly over pharmaceutical products for two reasons: to begin with, restorative inventory is firmly connected with individuals' wellbeing and life. Second, patent would have adverse impact on the homegrown drug industry, on the grounds that a large portion of the drug innovations were made and possessed by organizations of created nations. Footnote48 Under

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Thing 5 of Article 25 of the Patent Law of 1984, no patent right will be conceded for drug items and substances got through a synthetic interaction. As a matter of fact, all through the regulative cycle, in each form of the draft, including the last one, drug items were not recorded in that frame of mind of patent security.

However, on September 4, 1992, the Decision on Amending the Patent Law was adopted by the Standing Committee of the National People's Congress. This decision ended the Patent Law of 1984's policy of denying pharmaceutical products patent protection. This intends that, from January 1, 1993, when the change produced results, drug items and substances got through a compound process could be conceded patent right, given that they have the qualities of novelty, inventiveness, and industrial usefulness.[16]

Analysis of product vs process patents :

Clearly, a severe uniqueness seems to exist among item and interaction licenses systems. Created nations are leaned towards the item patent framework while the non-industrial nation favors the process patent framework. Since the interaction patent is conceded for a specific cycle and not for the actual item, some other individual can deliver a similar item utilizing an alternate process by modifying the parameters used . Multiple producers would be able to make the same product, thanks to this. It is a hindrance for the creator in light of the fact that the variety of makers in the market will give him less security for his licensed right

Nonetheless, a process patent is an advantage to the buyer of such an item on the grounds that the client can get elective choices and can select an item that has every one of the details accessible at a reasonable cost.[17] The non-presence of syndication over an item even compresses the innovator to showcase the item at a cheaper which makes it savvy to the purchaser of such item.

On account of an product patent, the right is given to the first creator of the product. Once a patent of this kind is issued, no one else can use, manufacture, or make the same product. Since there would be a syndication over the item, the designer would remain to benefit since he can

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showcase the item at the cost he wants. In any case, it would be a burden for the purchaser since the value of such an item would be high and the customer who has no other elective choice will presently be compelled to purchase the item at the rate chose by the creator as his restrictive right.

Case Laws:

In ***Cartier International AG vs. Gaurav Bhatia,*** *the* Delhi court granted damages totaling 10 million rupees, for infringement of trademarks and the selling of the counterfeit luxury brands online, which remains the highest punitive damages awarded by the court in a case of trademark infringement in India.

Novartis V. Union of India(Civil Appeal No. 2706-2716 of 2013)

Novartis filed a patent application for Gleevec, one of its drugs, under Section 3 of the Patents Act of 1970, citing it as an innovation. The Supreme Court refused their plea after a seven-year fight, citing the following reasons: To begin with, no new drug was created; simply discovering an existing drug would not qualify as creation. Second, the Supreme Court affirmed that, in addition to the usual requirements of novelty, inventive step, and application, the Indian Patent Act includes a new enhanced therapeutic efficacy test for claims that include incremental improvements to existing medications, which Novartis' drug did not meet. This was a landmark ruling because the court saw through the technicalities to the fact that these companies were attempting to "evergreen" their patents and make them unavailable for a small fee.

Bayer Corporation and Ors. V. Union of India and Ors. (2014 SCC Online Bom 963)

The Bayer Corporation attempted to link the infringement of a patent with the approval of a Cipla drug for commercialization in this case. In the United Kingdom, the concept of a drug-patent link exists. In India, the Delhi High Court found that there is no method for linking medicinal patents,

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and that only the patent controller has the authority to define patent standards. It was also decided that a drug's approval for sale does not imply that it infringes on a patent, and that the FDA has no jurisdiction over such problems.

CONCLUSION:

Maybe developing countries have not yet completely shifted to product patents because this will eventually affect their nation and consumers who aren't financially strong on a global level yet. Granting process patents would help such countries to increase innovation in their economy, and would promote healthy and effective pricing of the product. India, being a developing nation is also in favour of granting both process and product patents and is not inclined towards product patents. The reason is, the government at the end of the day needs to implement laws only after analysing and understanding the plight of the country .[18]

And Audits should be conducted on a regular basis to check for any areas of concern that may arise throughout the manufacturing process of pharmaceuticals. There is one authenticity mark on the back or bottom of the product, and it should be present in every medicine because it will be easier for the general public to identify the authenticity of the product.

For example, PharmEasy is an online medical supply store pharmacy that ensures the authenticity of medicines using a barcode system that you can access from your mobile phone. The Drug Controller General of India (DGI) is considering using a barcode system to verify the legitimacy of both imported and domestically manufactured drugs. Middle-income countries have been shown to be much more likely to engage in the production and distribution of counterfeit drugs, so authorized companies must collect all necessary data and information to aid in the resolution of such a problem, as the problem arises from an unorganized supply chain, particularly the functions performed by intermediaries.

[18] ***Aishwarya Parameshwaran,*** Difference between product patent and process patent November 10, 2021, https://blog.ipleaders.in/difference-between-product-patent-and-process-patent/

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