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Counterfeiting of Medicines as a Violation of Intellectual Property Rights

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ABSTRACT

Counterfeiting of medicines and money are one of the major issues which affects economy at large. A counterfeit medicine or drug is a pharmaceutical product that is manufactured and sold with the goal of misrepresenting its origin, validity, or effectiveness by using the incorrect or non-existent active component. These are the global issues which not only affects in a direct manner but indirectly as well. counterfeiting of medicines is a growing phenomenon which has to be critically analyzed because this is the major issue which leads to numerous health problems and the area of my concern which I want to show through my research is the problems related to the trade as a violation of intellectual property rights by supporting the case laws related to medicine counterfeiting. In this research paper, I will be highlighting some initiatives taken by public and private sector to overcome such problem, the roles and functions performed by the pharmaceutical society which commonly includes pharmaceutical manufactures, wholesalers, retailers and entire chain.

Last but not the least, in this paper I will be addressing the question that why do people buy counterfeit drugs and why does intellectual property protection matter to the pharmaceutical industry.

Keywords: *Intellectual Property Rights, Counterfeiting, Drugs (Medicines), Public Awareness, Pharmaceutical Drugs.*

I. INTRODUCTION

Drug counterfeiting is not a new global phenomenon. Fake pharmaceuticals became a problem in the 1980s as more member countries of World Health Organization (WHO) began reporting them. "Counterfeit medication" is defined by the Black law dictionary as a product that has been made without authorization and with the intent to deceive or defraud by someone other than its original manufacturer[2].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 substituted wholly or partly by another

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[2] WHO (2013), "General information on counterfeit medicines", http://www.who.int/medicines/services/counterfeit/overview/en/index.html.

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drug, or if it falsely claims to be the product of another manufacture"[3]. According to the World Trade Organization (WTO), counterfeiting is the use of an illegal representation of a registered trademark on goods for which the trademark is registered in order to deceive the customer into believing that he or she is purchasing genuine goods.[4]. In the context of such problem the intellectual property protection plays a major and significant role in protecting the rights of pharmaceutical society in terms of patents, trademark and etc. Intellectual property rights represent the rights given to the people over their creations of their ideas which were developed in their minds. It aims to ensure fair competition and to protect the interest of the consumers and also to protect their innovative ideas. Another essential goal is to safeguard the results of investments in the creation of new technology. There are many measures taken by the public/private sector and Indian judiciary system to protect the rights of pharmaceutical society. There are many steps taken by the concerned authorities which helps to identify the reason for the growth of counterfeit drugs and how to overcome such problem with the help of conducting surveys and many more methods. There are many boards established by the government which helps in the restriction of such illegal practices.

II. TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS)

All WTO members signed the accord on January 1, 1995. Indian law recognises the importance of intellectual property at all levels, including legislative, administrative and judicial, however the issue arises when it is not implemented effectively. This agreement establishes the requirements for the preservation of the rights that are typically granted to creators for their ideas, primarily to defend their interests.

This agreement establishes criteria in the domains of intellectual property listed below:

1. PATENTS
    - The patents act, 1970
    - The patents (amendment) act,1999
    - The patents (amendment) act,2002
    - The patents (amendment) act,2005
    - The patent rules,2001
    - The patent (amendment) rules 2005

[3] CDSCO (2009), "Report on countrywide survey for spurious drugs", available at: http://www.cdsco.nic.in/spurious_drugs.html
[4] (WTO, 1994)

- The patent (amendment) rules 2006

2. COPYRIGHTS
    - The copyright (amendment) act, 2012
    - Copyright act,1957
    - Copyright rules,1958
    - Copyright handbook
    - Copyright piracy in India
    - International copyright order,1999
3. TRADE MARKS
    - Trade marks act
    - Trade marks act,1999
    - New elements in the trade marks act,1999
4. GEOGRAPHICAL INDICATIONS
    - Geographical indications of goods (registration and the protection) act,1999
5. INDUSTRIAL DESIGNS
    - New design act,2000

III. WHY THERE IS A SALE AND DEMAND OF COUNTERFEIT DRUGS?

There is a sale of counterfeit drugs in our society that's why demand of such medicines are there, this is how demands exceeding supply and it leads to compromise in the quality. Here, in my research I am mentioning some causes for the problem which are mentioned below as-

- Lack of public awareness
- Medicine shortage
- Increase in demand
- Increase in the cost of drugs
- Increase in health issues
- Rivalry in the business environment
- Ignorance of law and appointed authorities

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ACCORDING TO WTO, CAUSES FOR SUCH PROBLEM IS….

- Corruption
- Inefficient co-operation between the stakeholders
- Weak enforcement and penal sanctions
- Inadequate drug legislation
- Insufficient political will and commitment

IV. WHY IS PROTECTION OF INTELLECTUAL PROPERTY IMPORTANT FOR THE PHARMACEUTICAL SOCIETY?

Intellectual property in the pharmaceutical sector serves more than only to maximise revenues and maintain the market competitive. Intellectual property rights protection aids in the creation of a robust and effective public health infrastructure, but it also aids in the development and availability of new innovative products.

New pharmaceuticals require a significant amount of money to develop, and without investments to fund research, new drugs would take longer to establish a market position. Money is required to create products and ensure that they are safe for both humans and animals. Intellectual property assists in the translation of novel ideas into potential new drugs. One of the advantages of intellectual property in this industry is that patent and trademark systems assist authorities in evaluating the quality of drug items on the market. These safeguards enable authorities to take proactive steps to prevent the introduction of counterfeit medications onto the market. Without such safeguards, governments would struggle to ensure the safety of medications entering their borders. Another advantage of intellectual property is that it encourages pioneer companies to enter the market, which speeds up the introduction of new items.

We can broadly categorise the importance which are mentioned as below-

- Protection of inventions done by pharmaceutical society
- Economic growth
- Restrict monopolies
- Protection of human health and etc.

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V. CASE LAWS

- **NOVARTIS V. UNION OF INDIA-IPR LAW- (REJECTION OF A PATENT FOR A DRUG WHICH WAS NOT INVENTIVE OR HAD AN SUPERIOR EFFICACY)**[5]- Novartis filed a patent application for one of its medications, Gleevec, by claiming it as an innovation under Section 3 of the Patents Act of 1970. After a seven-year battle, the Supreme Court denied their application, citing the following reasons: To begin with, there was no new drug invented; simply discovering an existing drug would not be considered invention. Second, the Supreme Court affirmed the position that, in addition to the usual requirements of novelty, inventive step, and application, the Indian Patent Act includes a new test of enhanced therapeutic efficacy for claims that encompass incremental improvements to existing medications, which Novartis' drug did not meet. This was a historic decision because the court looked past the technicalities to the fact that such corporations were attempting to "evergreen" their patents and make them inaccessible at trivial costs.

- **BAYER CORPORATION AND ORS. V. UNION OF INDIA AND ORS.**[6] **–** In this, The Bayer corporation attempted to link the instance of patent infringement to the approval of a Cipla medicine for commercialization. The concept of a drug-patent relationship exists in the United Kingdom. The Delhi High Court ruled that there is no medicine patent linking process in India, and that only the patent controller has the right to set patent standards. It was also decided that a drug's mere approval for sale does not imply that it is infringing on a patent, and that the drug authorities do not have jurisdiction over such matters.

- CLINIQUE LABORATORIES LLC AND ANR. V. GUFIC LTD. AND ANR. - The present case involved both the plaintiff's and defendant's registered trade marks. It's worth noting that, prior to filing the suit, the plaintiff, Clinique, had filed a cancellation petition against the defendant with the Indian Register of Trade Marks, seeking cancellation of the defendant's trade mark cliniq, and that, under the trademarks act of 1999, a suit is subject to a stay until the cancellation petition is finally decided by the competent court. The court, however, has the right to issue interlocutory orders, such as those providing interim jurisdiction, keeping accounts, appointing a receiver, or attaching any property, under section 124(5) of the act. Court determined that trademark infringement might be pursued against another registered proprietor of an identical or similar trade mark in this instance. A preliminary injunction banning defendant from using the registered trade mark can be issued by the court while the litigation is stayed for a decision

[5] AIR 2013
[6] AIR 2009

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on the rectification/cancellation petition. As a result of the court's decision, the plaintiff was granted a temporary injunction.

VI. ROLE OF JUDICIARY IN THE EFFECTIVE IMPLEMENTATION OF IPR

Indian judiciary plays a very crucial role in the enforcement of the principles and standards of intellectual property rights. The judiciary's main function is to penalise those who are found guilty of counterfeiting by establishing commercial courts, commercial divisions, and commercial appellate divisions under the High Courts Act, 2016. The standard of weight and measure is a piece of legislation (packaged commodities) Rules were enacted in 1977 to govern the use of proper weighing and measuring tools in production, trade, and commerce in order to assure that the customer receives precise weight, measure, and number of commodities.. Also, there is one agreement related to the counterfeiting i.e., anticounterfeiting trade agreement (ACTA).

VII. CONCLUSION OF THE STUDY

Whether it is one problem or several, nothing is a solo effort as we all heard about idiom i.e. one hand alone cannot make the clap sound that is how counterfeiting of drugs increasing rapidly because there is a demand from consumers. Firstly, It can be eradicate slowly and slowly through the public awareness, if people are aware about their side effects they will not buy counterfeit medicines. Secondly, there are sufficient regulations enacted by the government and other concerned authorities which are continuously formulating the strategies and planning to overcome such problem but are these strategies are implementing in effective and efficient manner ? of course not, if they formulated so they also get implemented in a reasonable manner so, formulation department should be separated from the implementation department so that they can reach to the effective research about their area of research but there should be proper and balanced co-ordination between the two departments. Timely audits should be there for checking the area of concern which may be arose in the production cycle of the medicines. There is one authenticity mark at the back or bottom of the product so, it should be there in each and every medicine because it will be easier to identify the authenticity of the product for the general public for example pharmEasy is the application which is online medical supply store pharmacy, it ensures the authenticity of medicines with the help of barcode system which you can access from your mobiles. The Drug Controller General of India (DGI) is considering implementing a barcode system to verify the validity of medications imported into India as well as those made here. It has been seen that middle income countries are much more likely to engage in the production and distribution of counterfeit drugs so

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authorized companies must collect all the necessary data and information which helps to overcome such problem because the problem occurs due to unorganized supply chain especially the functions performed by the intermediaries.

If these steps properly implemented we can make our nation free from the counterfeiting of drugs and protect the intellectual property of the pharmaceutical society.

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