INTERPRETATION OF REVERSE PAYMENT PATENT SETTLEMENT AND ANTITRUST LAWS IN PHARMACEUTICAL INDUSTRIES

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ABSTRACT

The idea of Reverse Payment Settlement came into the limelight after the essential features of the Patent holder came into the forefront. It has recently gained prominence due to the challenges that have arisen due to the ongoing uncertainty and unfair advantage the inventor, patent holder, or the corporation has gained by participating in anti-competitive and antitrust policies. It is vital to understand the history and meaning of the reverse payment patent settlement to properly comprehend what it implies and what might comprise such agreements. It also discusses why the parties have reached such agreements and what they signify. The article mainly describes the competitive policies of the USA on Reverse payment patent settlement via the ANDA and the principle it gave rise to by implementation or suspension of the generic business from creating a specific product and engaging the entity via monetary payment. The payment will be equal to the period during which the generic company's production is hampered and the cost incurred due to the litigation. As a result, it is a reverse payment or an exception, as an infringement usually pays the patent holder. The pharmaceutical sector creates many issues due to the miscarriage of competitive policies in drugs and medicines. We are all aware that access to health care is the most important policy issue for communities. The industry's therapeutic value typically defines it and the rationality it is marketed. Due to new drugs in the market and their exclusivity period from the generic medicines sold, accessibility became one of the prime concerns in the pandemic period. As covid-19 hit the world's hard right to get healthcare, fundamental rights are being violated. So, in this article, the author will explain the need for a regulatory system in the country by way of specific guidelines to ensure that these techniques do not impede competition in the country.

With it, the economy at large, which is affected at first examination, it is evident that when it comes to the general public's healthcare, cannot to extend the exclusivity provided by patented pharmaceuticals for drug corporations' unilateral economic motivations. The article discusses the value and necessity of a policy framework and the challenges of applying and implementing these words. The impact on India and its competition is significant.

Keywords: Reverse Patent settlement, competitive policies, Competition Laws, Intellectual Property Laws, Drugs, Competitive Policies

Introduction

In the current Pandemic situation, have we wondered about the outcome if the prices of the medicines are excessively priced? Furthermore, the structure and dynamics of the pharmaceutical and innovation sectors substantially impact the variables that contribute to this outcome. Despite the immense expenses of R&D in generating new therapies, Pharma companies must guarantee that new ideas are successfully patented to offset the costs and increase earnings by retaining an exclusive license to produce, market, and sell the patented drug until the period expires.

It has offered the patent holder and the allegedly generic drug company infringing on it a competitive advantage. [1] These agreements are becoming more common, particularly in the pharmaceutical industry, when a business develops a novel treatment and seeks exclusivity for a specific period for its sale to recoup its investment in its trial or others. It has created a problem with the accessibility and availability of essential medicines hampered the economy. The pharmaceutical drug domain consists of a brand medicine, a high-priced patented real innovation of the innovator drug firm, and a generic medication, which chemically duplicates the brand drug in dose and strength but is less expensive in patent protection. A medication market contains both brand and generic medicines, mainly competing on price. The availability of generic pharmaceuticals greatly aids in delivering affordable healthcare to the general public.

Research Methodology

The research is purely Doctrinal, analytical & exploratory. In this study, the researcher is trying to evaluate the concept of Reverse Payment Patent Settlement based on various judicial precedents and legal concepts. Over here, the researcher uses the doctrinal method of research where the authors collected all the information related to the first chapter from various articles, journals, e-books, and other secondary sources.

The second part explore about Covid-19 and competition Law over the patenting in pharma sector how it affects Therefore, the researcher must establish the legislation's lacunae by providing suitable examples and judicial precedents.

[1] Neelasha Nemani & Anmol Awasthi, REVERSE PAYMENT PATENT SETTLEMENTS: NAVIGATING THE ANTITRUST LIABILITY IN THE PHARMACEUTICAL INDUSTRY, 26.

Meaning of Reverse Payment Patent Settlement

Reverse Payment Patent Settlement is not a new concept, but it has been applied in recent times to get payment from the Patent owner without causing any infringement.

It refers to an agreement between the inventor and the claimed patent infringement. They do it in a way the former compensates the latter. As a result, it is unusual that the infringing party must always pay the party who owns the patent. The parties reached this agreement because the party allegedly infringing the patent by producing the identical product is disputing or questioning the validity of the patent holder's claim. The critical problem in this respect is exclusivity, which is the information given to the public. [2]

The product's inventor has exclusivity regarding their invention in the field. Still, when another manufacturer develops the same and sells it at a significantly lower price, it infringes on their right. It takes away their exclusive right to sell their invention for a set period. Engaging in such an investment will not realize the innovator's profit if he sells at a lower price. The problem now is that if the claimed infringer is found to be infringing, the cost of suing will be much higher, considering the patent's validity. As a result, the inventor frequently favors such agreements to prevent the party from making the purported invention during exclusivity and pay the price determined by such calculations.

Historical Perspective of Reverse Payment Patent Settlement

According to the regulatory framework effective in the U.S., the Reverse Payment Patent Settlement concept has evolved from the enactment of the Drug Price Competition and Patent Term Restoration Act or Hatch-Waxman Act of 1984. This act was primarily responsible for the proliferation of generic pharmaceuticals in the pharmaceutical business, which unwittingly promotes reverse payment settlements, and will study the legislative methodology in establishing the legitimacy of settlements of this kind.

Regulatory Framework under Hatch-Waxman Act 1984

The generic company contested the FDA[3] certification of the abbreviated new drug application (ANDA) in the U.S. The patent holders had six months of exclusivity. The problem was that the generic firm might sell or produce the medicine alongside the original patent owner or the

[2] Data Exclusivity - Intellectual Property - India, https://www.mondaq.com/india/information-security-risk-management/79418/data-exclusivity (last visited Jan 21, 2022).
[3] Center for Drug Evaluation and Research, *Center for Drug Evaluation and Research | CDER*, FDA (2020), https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder (last visited May 2, 2022).

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innovator as it won the lawsuit. It resulted in the development of an agreement between the two, in which the patent holder paid the generic firm an amount equal to what it would earn over the six months. The generic business agrees not to create or manufacture the ANDA during the six-month exclusivity period in exchange for the money. [4]

In essence, the Hatch Waxman Act set up a shortened path regarding generic medicine authorization and commercialization,

It allows generic pharmaceutical companies to submit an Abbreviated New Drug Application (ANDA)[5] to the Food and Drug Administration (FDA) stating that the generic medicine provided by them was bio-equivalent to its brand-name drug counterpart and included the same active components previously authorized FDA.

It assumed the concept behind the ANDA technique to save money and avoid the time-consuming testing and approval of generic pharmaceuticals to accelerate their entrance into the market, hence ensuring drug competition and the availability of low-cost generic medications to customers[6]

Regulatory Framework of the European Union

Unlike the United States, the European Union does not have laws like the Hatch-Waxman Act. Patents are issued and enforced at the discretion of the member nations.

As a result, to enforce any patent, the originator/manufacturer would have to commence infringement procedures in each member state's courts, making patent litigation a costly experience. If the patent case is decided against the branded manufacturer, it risks losing a significant market share. The demanding nature of patent enforcement for branded medicine manufacturers is the fundamental cause of reverse patent settlements. [7]

Reverse Payment Patent Settlement current scenario in Indian Pharmaceutical Sector

[4] Do Reverse Payment Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay? - EconBiz, https://www.econbiz.de/Record/do-reverse-payment-settlements-of-brand-generic-patent-disputes-in-the-pharmaceutical-industry-constitute-an-anticompetitive-pay-for-delay-drake-keith/10012458375 (last visited Jan 21, 2022).

[5] Center for Drug Evaluation and Research, *Abbreviated New Drug Application (ANDA)*, FDA (2022), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (last visited May 2, 2022).

[6] Center for Drug Evaluation and Research, *Center for Drug Evaluation and Research | CDER*, FDA (2020), https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder (last visited Jan 21, 2022).

[7] Pharmaceutical Sector Inquiry.pdf, https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last visited May 2, 2022).

The monopoly period intends to cover the expense of the clinical data and the associated expenditure. The data exclusivity grants the inventor to manufacture the drug exclusively for a set time once a new medicine has been approved. However, if the generic firm is authorized to produce, they will depend on the data to obtain permission and begin making at a lower cost. [8] The inventor will not reap the advantages of his investments or recoup the cost of the new medicine created at this stage. This exclusivity grants to an inventor who invests time and money in testing the functionality of a product and its industrial use to get a patent.

Because it has been established that healthcare is a fundamental right, this gives birth to consumer welfare. As a result, the availability of a safe product for use is required. Clinical studies are conducted for this aim. It has been determined that if the original pharmaceutical business sued the infringing generic manufacturer, they would suffer much more significant losses. They may potentially jeopardize the patent's validity. As a result of these factors, the reverse payment patent settlement is entered into to prevent generic pharmaceutical companies from developing such new pharmaceuticals in the market by paying them a specified sum. They run the danger of infringing on the patent.

When the new medicine is related to an exceptionally prominent condition or is required immediately, the drug's accessibility becomes a concern. With the recent occurrences of the COVID-19 or the coronavirus that has spread worldwide like a worldwide epidemic jeopardizing lives, it is even more vital to access these types of settlements between the parties. Because these agreements exist, the product will have a monopoly over the vaccine due to the exclusivity term of the patent holder, and customers would be unable to profit from it. It will do more significant harm because the product was not available and accessible at the time, and they were expensive on the market.

The generic companies had already reached such an agreement. The first legal issue is the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement. India is a party and must adhere to its laws and articles. As a party to WTO and TRIPS, India is required to comply with the obligations of the WTO and TRIPS and cannot, therefore, violate them. In the case of such agreements, it did extend the patent holder's privilege from 7 to 12 years. Such treaties intend to restrict the introduction of the generic product [9] to the customer to manipulate the

[8]McKinseyPharma2020ExecutiveSummary.pdf, https://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf (last visited May 2, 2022).

[9]IEEE Xplore Full Text PDF, https://ieeexplore.ieee.org/ielx7/2/6515539/06515565.pdf?tp=&arnumber=6515565&isnumber=6515539&ref=a

whole market. As a result, reverse payment patent settlements are regularly alluded to as pay for delay settlements or treaties. The patent holder compensates the generic business for the delay in entering the market. It is also vital to make specific pharmaceutical improvements during data exclusivity and market dominance.

Reverse payment patent settlements are often known as pay for delay settlements or agreements [10]. The patent holder compensates the generic business for the delay in entering the market. It is also vital to make specific pharmaceutical improvements during data exclusivity and market dominance. As a result, there is a need for a regulatory system. The concerns are numerous and cannot be resolved by allowing patent holders and generic companies to collaborate and disrupt the market. It will undoubtedly lead to the economy's destruction and the failure to achieve the goal of people's welfare. As a result, healthcare will be unavailable at the appropriate moment, disrupting people's lives and burdening the availability of necessary new treatments.

In India, a policy framework in the form of precise rules is required since competition legislation is controlled by the Competition Act and must be maintained. It encourages healthy competition in the country and guarantees that no one has an unfair advantage or a dominant position in a particular fashion. It must strengthen the legislation in these areas since the negative impact on these medications and new developments are undeniable, and consumers suffer. Another aspect is that it tends to overshadow the patent's expiration [11] since exclusivity can continue. By forming a monopoly, they can control the situation in their favor.

As a result, the term of exclusivity, the patent period, should be established in the agreement or the patent itself. The innovative firm may recoup costs while still working alongside others to enter the market. It will maintain healthy competition and compliance with antitrust legislation by preventing dominance and halting sales exclusively by the innovative firm.

Regulatory Framework of Competition Law- Position in India

To date, no Indian court has issued an official judgment on the legitimacy of reverse payment arrangements in India. Nonetheless, given the recent sanctions levied by the European Commission on Indian generics for conducting reverse payment transactions, the Competition

HR0cHM6Ly9pZWVleHBsb3JlLmllZWUub3JnL2Fic3RyYWN0L2RvY3VtZW50LzY1MTU1NjU= (last visited Mar 26, 2022).

[10] Njideka Chukwu, Regulatory Responses Against Reverse Payment Agreements in the Pharmaceutical Industry, 28.

[11] Reverse Payments: Shadowing Patent Term Expiry! - Patent - India, https://www.mondaq.com/india/patent/893822/reverse-payments-shadowing-patent-term-expiry (last visited May 2, 2022).

Commission of India (CCI) has actively observed behavioral misuse in the Indian pharmaceutical business. [12]

In the pharmacy sector, any arrangement between innovators and generics to delay or prevent the generic medication from entering the market may be subject to the If it causes or is likely to cause an AAEC on the Indian medicine market, it is subject to the Competition Act. These types of international treaties may be declared anti-competitive under Section 3(1), India's general provision prohibiting anti-competitive contracts and requiring a rule of reason analysis to establish AAEC in the relevant market, or Section 3(3), it expressly prohibits enterprise-to-enterprise lateral collaborations. [13]

It enshrines the per se unconstitutional analysis without the need for AAEC [14] to establish. As a result, a reverse payment agreement that directly or indirectly influences medication price, or restricts or supervises drug development, supply, and markets, will be deemed anti-competitive.

Assume they have the effect of reducing effective competition in the relevant medication market. Such agreements could be investigated further under Section 4 of the Competition Act, which prohibits the abuse of a dominant position. However, given the continuous interaction between IPRs and Competition Law, the catch here is Section 3(5) of the Competition Act, which gives comprehensive protection from antitrust investigations for IPRs.

Contractually, this would imply that the innovator drug business might apply reasonable restrictions to prevent generics from infringing on its patented medication; however, if this can be extended, it must include reverse payment arrangements during the patent term questionable. Since it is widely known that Intellectual property laws cannot circumvent competitive analysis outside the amount of restriction granted, the study concludes that Section 3(5) of the Competition Act cannot be interpreted in a way that eventually supports patent evergreening. It helps the negative impact such reverse payments may have on patients and the healthcare sector. The Actavis case analysis said a valid patent does not automatically shield a reverse payment arrangement from competition analysis.

[12] Vaibhav Choukse: Sweetheart deals that hurt consumers | Business Standard Column, https://www.business-standard.com/article/opinion/vaibhav-choukse-sweetheart-deals-that-hurt-consumers-114091501332_1.html (last visited Jan 21, 2022).
[13] Promoting access to medical technologies and innovation Intersections between public health, intellectual property and trade, https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4d_trilat_web_13_e.htm (last visited Jan 21, 2022).
[14] Section 19(3) in the Competition Act, 2002, https://indiankanoon.org/doc/1671507/ (last visited Jan 21, 2022).

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Judicial Interpretation

Even though the validity of reverse payment agreements in India remains unsettled, a case that spurred the need to address the problem was a Delhi High Court judgment requiring reconciliation between two parties. [15] ***Hoffman-La Roche***, a Swiss innovator, and Cipla, an Indian generic, to settle Cipla's alleged patent infringement of Roche's Tarcevatablets by manufacturing its generic version. Surprisingly, the Court confirmed the legality of Roche's, and Cipla was deemed not to infringe on it. Although the mediation failed, if the settlement conditions had resulted in Cipla not selling its generic medication, Under the provisions mentioned above of the Competition Act, the CCI would have had the Suo Motu competence to examine the settlement conditions. An examination of pharmaceutical cases demonstrates that foreign inventors mostly employ permanent injunctions and evergreening patents (intellectual strands) to ensure the exclusive sale of their brand items in the Indian market. However, the authors predict that, when it comes up for review, the Indian judiciary would use a rule of reason approach, like ***Actavis***, rather than the European Union's per se illegal approach, in assessing the anti-competitive nature of reverse payment agreements.

Conclusion

At the outset, it can conclude that Reverse Payment Patent Settlement works as a form of settlement where an inventor and the infringer's generic companies collaborate to prevent the generic company from making the infringer's specific new product. As a result, collect the cost of investment through data exclusivity. It also avoids litigation, which would be more damaging to the innovator than entering a standstill settlement by providing a predetermined estimated sum to the infringement. The gaps occur in the form of a high product price and the formation of a monopoly when healthcare is acknowledged as humans' fundamental right. It raises how such reverse payment patent settlements entered between parties should be regulated.

[15] F. Hoffmann-La Roche Ltd. And Anr. vs Cipla Limited on 19 March, 2008, https://indiankanoon.org/doc/64813/ (last visited Jan 21, 2022).