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COMPETITION LAW ISSUES IN THE PHARMACEUTICAL SECTOR IN INDIA AND ITS IMPACT ON IPRS

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Abstract

The pharmaceutical sector in India is pivotal to the country's healthcare system and economy. However, it faces several competition law challenges that can impede innovation, access, and affordability of medicines. This paper explores the landscape of competition law issues within the Indian pharmaceutical sector, focusing on antitrust concerns, regulatory bottlenecks, and the impact on intellectual property rights. These issues have recently been dealt with by the Indian Antitrust Regulatory Authority which is the Competition Commission of India. Through an analysis of relevant case laws, policies, and regulatory frameworks, this research highlights the need for a balanced approach to competition enforcement that ensures consumer welfare while fostering innovation and industry growth.

Keywords: Competition Law, Patent law, Pharmaceutical sector, Compulsory licensing.

1. Introduction

The Indian pharmaceutical industry is one of the largest in the world, renowned for its generic drug manufacturing. While the sector contributes significantly to global healthcare, it also encounters numerous competition law issues. These issues range from anti-competitive practices, such as cartelization and abuse of dominance, to complex interactions between patent laws and competition regulations. Understanding these dynamics is crucial for policymakers, industry stakeholders, and legal practitioners aiming to enhance the sector's competitive environment.

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2. Overview of Competition Law in India

2.1 Historical Context and Evolution

India's competition law framework has evolved significantly over the years, transitioning from the Monopolies and Restrictive Trade Practices Act, 1969 (MRTP Act) to the more robust Competition Act, 2002. The Competition Commission of India (CCI), established under the 2002 Act, is tasked with preventing practices that have an adverse effect on competition, with the object of promoting and sustaining competition in markets, and protecting consumer interests.

2.2 Key Provisions of the Competition Act, 2002

The Competition Act, 2002, encompasses various provisions addressing anti-competitive agreements, abuse of dominant position, and regulation of combinations (mergers and acquisitions). Sections 3 and 4 of the Act are particularly pertinent to the pharmaceutical sector:

- **Section 3**[2] prohibits anti-competitive agreements that cause or are likely to cause an appreciable adverse effect on competition (AAEC) within India.
- **Section 4**[3] addresses the abuse of dominant position by enterprises, preventing practices that exploit market power to the detriment of consumers and competitors.

3. Competition Law Issues in the Pharmaceutical Sector

3.1 Anti-Competitive Agreements

Anti-competitive agreements in the pharmaceutical sector can significantly impact market dynamics, innovation, and public health. These agreements can take various forms, including price-fixing, market allocation, and bid-rigging. The primary legislation governing anti-competitive practices varies by jurisdiction but generally includes strict regulations to ensure fair competition and protect consumer interests.

Types of Anti-Competitive Agreements

1. Price-Fixing: Agreements between competitors to fix prices at a certain level, thereby eliminating price competition. This can lead to higher prices for consumers and reduced access to essential medications.
2. Market Allocation: Competitors divide markets among themselves, agreeing not to compete in each other's designated areas or customer segments. This practice can limit consumer choices and stifle market competition.

[2] Sec-3 of the Competition Act, 2002.
[3] Sec-4 of the Competition Act, 2002.

3. Bid-Rigging: Collusion between firms to manipulate the outcome of a bidding process, often leading to inflated prices and reduced competition in the procurement of pharmaceuticals.
4. Cartelization: One of the major issues in the pharmaceutical sector is cartelization, where firms collude to fix prices, control production, or divide markets. Such practices can lead to inflated drug prices, reduced availability of essential medicines, and diminished incentives for innovation.

Impact on the Pharmaceutical Sector

1. Increased Prices: Anti-competitive agreements can lead to artificially high prices for medications, placing a financial burden on consumers and healthcare systems.
2. Reduced Innovation: When competition is stifled, pharmaceutical companies may have less incentive to invest in research and development, leading to fewer innovative treatments being brought to market.
3. Market Entry Barriers: New entrants may find it difficult to penetrate the market due to established anti-competitive practices by dominant firms, further reducing competition and innovation.

Case Study: Chemists and Druggists Association of Baroda[4]

In a landmark decision, the CCI imposed penalties on the Chemists and Druggists Association of Baroda for engaging in anti-competitive practices by mandating NOC (No Objection Certificate) requirements, which restricted the entry of new pharmaceutical distributors. This decision highlighted the anti-competitive nature of association-led practices that limit market entry and stifle competition.

This case exemplifies how competitive markets and fair distribution of drugs and medicines are being undermined by the ongoing anti-competitive behaviour of chemist and druggist associations at both the regional and state levels. It is a serious issue that, despite multiple orders by the Commission in similar cases and specific directives through a press notice, these associations have not changed their ways and continue to engage in such conduct. Given the significant public interest in the distribution of drugs and medicines, the Commission condemns this behaviour and its perpetuation in any form by those involved, whether they are associations, stockists,

[4] Case No, C-87/2009/DGIR available at http://164.100.58.95/sites/default/files/c872009GG.pdf (last visited 27th June 2024).

distributors, wholesalers, retailers, or pharmaceutical companies.

3.2 Abuse of Dominance

Excessive Pricing and Refusal to Supply

Dominant firms may engage in practices such as excessive pricing or refusal to supply critical drugs. Such behaviour can severely restrict access to essential medicines, especially in a country like India, where affordability is a significant concern.

Case Study: F. Hoffmann-La Roche Ltd.[5]

The CCI examined allegations against Roche for abusing its dominant position by engaging in exclusionary practices related to its breast cancer drug, Trastuzumab. The case underscored the fine line between legitimate business strategies and anti-competitive conduct in the pharmaceutical industry. The CCI recognized in this case that "there is a special responsibility of a dominant entity i.e. not to allow its conduct to impair undistorted competition in the relevant market and not to conduct its business in any manner, which is prohibited under Section 4(2) of the Act. The focus on non-economic factors and conduct related to governmental and legal processes makes this a unique and intriguing case study in competition law."[6]

Predatory Pricing and Margin Squeezing

Predatory pricing, where dominant firms set prices below cost to eliminate competition, and margin squeezing, where firms manipulate prices to squeeze the margins of competitors, are other forms of abuse of dominance that can distort market dynamics. Though the Indian Competition Act refrains from such practices the market players adopt various strategies to safeguard themselves from the competition agencies. The enterprises maintain fake account records to get away from the allegations of predatory pricing and market squeezing.

Patent Linkage and Evergreening

Patent Linkage

Patent linkage, the practice of linking drug approval to the patent status of the originator product, poses significant competition law challenges. It can delay the entry of generic medicines into the market, thereby affecting drug affordability and accessibility.

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[5] Case No. 68 of 2016 available at https://www.cci.gov.in/antitrust/orders/details/180/0 (last visited 27th June 2024).

[6] CUTS International, '*Analysis of Competition Cases in India'* October-December 2017 available at https://cuts-ccier.org/pdf/Edition-8-Analysis_of_Competition_Cases_in_India.pdf (last visited 27th June 2024).

Evergreening

Pharmaceutical companies often engage in 'evergreening' strategies, extending the patent life of a drug through minor modifications that do not necessarily enhance therapeutic value. This practice can hinder the availability of cheaper generic versions and maintain monopolistic pricing for extended periods.

Case Study: Novartis AG v. Union of India[7]

The Supreme Court of India's decision in the Novartis case marked a pivotal moment in the balance between patent protection and public health. The Court denied a patent for Novartis' cancer drug Glivec, ruling that the modifications did not meet the requirements of enhanced efficacy under Section 3(d) of the Patents Act, 1970. This decision has significant implications for competition in the pharmaceutical sector, promoting the availability of affordable generics.

The Novartis case brought the pharmaceutical industry under the scope of patent law and set a crucial precedent for medication access. The Supreme Court's ruling may serve as a model for other developing nations in the future concerning the interpretation and implementation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. This case illustrates how India balances its international intellectual property obligations with local needs by interpreting its legal responsibilities to align with national priorities. The decision supports India's domestic industries and emphasizes social equity over commercial interests.

4. Compulsory Licensing

Mechanism and Impact

Section 84[8] of the Patents Act outlines various grounds for issuing compulsory licenses for patented products. It states that a compulsory license can be granted three years after the patent is issued on the following grounds: firstly, the public's reasonable needs for the patented invention are not being met; secondly, the patented product is not being made available to the public at a reasonable price; and thirdly, the patented product is not being made available within India. Consequently, compulsory licenses may be granted to benefit the general public or to prevent the misuse of intellectual property rights under the guise of exclusive and statutory rights. The application of the conditions for granting compulsory licenses varies from case to case, as the conditions are inclusive rather than exclusive. The term "reasonable" can differ depending on the situation, so its interpretation is left to the authority.

[7] [2013] 13 S.C.R. 148.
[8] Sec-84 THE PATENT ACT, 1970.

Compulsory licensing, provided under the Indian Patents Act, allows the government to authorize the production of a patented drug without the consent of the patent holder, primarily to address public health needs. This mechanism, while promoting access to essential medicines, raises competition law issues related to innovation incentives and market competition.

Case Study: Natco Pharma Ltd. v. Bayer Corporation[9]

In a landmark decision, India granted its first compulsory license to Natco Pharma for the cancer drug Sorafenib, patented by Bayer. The CCI's involvement in this case underscored the interplay between patent law and competition policy, highlighting the need for a balanced approach to foster both innovation and accessibility. The issue in this case was that the drug sold by Bayer for patients with advanced kidney and liver cancer was very expensive. Natco, an Indian pharmaceutical company, applied for voluntary licensing to manufacture and sell the drug at a more affordable price, but this request was denied. Consequently, Natco appealed for the grant of compulsory licensing. It was found that Bayer could only provide the drug to 2 percent of the population in India and failed to transfer the necessary technology. This failure to balance exclusive patent rights with public interest led to the granting of compulsory licensing to Natco. A specific amount of compensation was decided to be paid to Bayer by Natco. While this order appears to have facilitated compulsory licensing, its consequences extend beyond India's borders. Both domestically and globally, this decision will significantly affect investments in the pharmaceutical industry, research and development expenses, trade relations, and numerous other interconnected issues.[10]

5. Intersection of Competition Law and Public Policy

Under the Patents Act,1970, compulsory licensing allows the government to permit the production of patented drugs without the consent of the patent holder, ensuring accessibility and affordability. Effective enforcement of competition law supports public policy goals by ensuring that drugs are priced fairly and that monopolistic practices do not hinder access to essential medications. The main objectives for public policies in the sector includes:

1. **Ensuring Affordable Healthcare**: Public policy aims to make essential medicines affordable and accessible to the broader population.

[9] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).
[10] M Sood, *Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India*, 6 NUJS L.Rev. 99 (2013).

2. **Encouraging Domestic Production**: Policies promote domestic pharmaceutical manufacturing to reduce dependency on imports and ensure a stable supply of medications.
3. **Balancing Innovation and Access**: Public policy seeks to strike a balance between rewarding pharmaceutical innovation and ensuring that new drugs are accessible to the public.

The intersection of competition law and public policy in India's pharmaceutical sector is essential for maintaining a balance between encouraging innovation and ensuring the accessibility and affordability of medicines. Effective regulation by bodies like the CCI, along with supportive public policies, helps achieve these objectives, fostering a competitive market that benefits both the industry and the public.

Drug Price Control Orders (DPCO)

The DPCO, issued under the Essential Commodities Act, 1955, aims to regulate the prices of essential medicines. While intended to ensure affordability, price controls can also impact competition by affecting market entry and the viability of manufacturing certain drugs. Balancing price regulation with competitive market dynamics remains a complex policy challenge.

Public Procurement and Tendering Processes

Public procurement and tendering processes in the pharmaceutical sector are critical for ensuring that governments and public health institutions can acquire essential medicines and medical supplies in a cost-effective, transparent, and efficient manner. These processes are designed to promote competition, ensure quality, and achieve the best value for public funds. The objectives of Public Procurement include:

1. **Ensuring Accessibility:** To provide timely access to essential medicines and healthcare products for the population.
2. **Promoting Fair Competition**: To create a competitive environment where multiple suppliers can bid, leading to better prices and quality.
3. **Ensuring Transparency**: To maintain transparency in the procurement process, minimizing the risk of corruption and ensuring fair treatment of all bidders.
4. **Achieving Cost-Effectiveness**: To optimize the use of public funds by procuring medicines and supplies at the best possible prices without compromising on quality.

Public procurement and tendering processes in the pharmaceutical sector are essential for ensuring the availability of quality medicines at competitive prices. By adhering to best practices and regulatory frameworks, governments can enhance transparency, promote fair competition, and achieve cost-effectiveness in public procurement, ultimately contributing to better public health outcomes.

6. International Perspectives and Comparative Analysis

United States

The U.S. pharmaceutical market, governed by the Federal Trade Commission (FTC) and the Department of Justice (DOJ), faces similar competition law issues, including antitrust enforcement against pay-for-delay agreements and scrutiny of pharmaceutical mergers. The Hatch-Waxman letters[11], facilitating the entry of generic drugs, provides a comparative framework for examining India's regulatory landscape.

Pay-for-Delay Agreements

Pay-for-delay agreements, where brand-name drug manufacturers pay generic producers to delay entering the market, have been a significant antitrust concern in the U.S. Such agreements delay the availability of cheaper generics and maintain high drug prices.

European Union

The European Commission (EC) actively addresses competition law issues in the pharmaceutical sector, focusing on patent settlements and market abuses. The EC's approach to balancing innovation and competition offers valuable insights for India's regulatory framework, emphasizing the need for robust antitrust enforcement and regulatory oversight. The EU plays a significant role in regulating competition law within the pharmaceutical sector to ensure fair competition, promote innovation, and protect consumer interests. Here are the key aspects of the EU's role:

1. Regulatory Framework

The primary legislation governing competition law in the EU is the Treaty on the Functioning of the European Union (TFEU), particularly Articles 101 and 102:

- **Article 101 TFEU** prohibits agreements between companies that restrict competition. This includes price-fixing, market-sharing, and collusion.

[11] Drug Price Competition and Patent Term Restoration Act of 1984 available at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters (last visited 27th June 2024).

- **Article 102 TFEU** addresses the abuse of a dominant market position, preventing practices such as predatory pricing, exclusive dealing, and refusal to supply.

2. Merger Control

The EU's Merger Regulation requires that large mergers and acquisitions be reviewed by the European Commission (EC) to prevent market concentration that could harm competition. The EC can approve, prohibit, or approve with conditions any merger that affects the European market.

3. Antitrust Investigations

The European Commission conducts investigations into anti-competitive practices in the pharmaceutical sector. This includes:

- **Pay-for-delay agreements**: These are settlements where a patent-holding pharmaceutical company pays a generic competitor to delay entering the market.
- **Market exclusivity abuses**: Practices like evergreening, where companies make minor changes to a drug to extend patent protection and delay generic competition.

4. Pricing and Reimbursement Policies

While pricing and reimbursement of pharmaceuticals primarily fall under the competence of individual EU Member States, the EU promotes transparency and fairness in pricing to avoid anti-competitive practices.

Patent Settlements and Market Entry

Patent settlements and market entry are crucial aspects of the pharmaceutical sector, influencing competition, drug pricing, innovation, and access to medicines. Patent settlements can either facilitate or delay market entry of generic drugs, impacting both the industry and public health. The EC scrutinizes patent settlements between originator and generic companies to prevent anti-competitive practices that delay generic entry. Such scrutiny ensures that settlement agreements do not harm consumer welfare by delaying access to affordable medicines. Patent settlements and market entry dynamics are pivotal in shaping the pharmaceutical sector. While settlements can either hinder or facilitate generic entry, regulatory frameworks aim to balance patent protection with the need for affordable medicines. Ensuring fair competition and timely entry of generics into the market is essential for promoting innovation, reducing drug prices, and improving public health.

Conclusion and Suggestions

The Indian pharmaceutical sector, while a global leader in generic drug manufacturing, faces significant competition law challenges that impact drug affordability, innovation, and market dynamics. Addressing these challenges requires a multifaceted approach, encompassing robust antitrust enforcement, balanced patent policies, and an efficient regulatory framework. By fostering a competitive environment, India can enhance its pharmaceutical industry's growth, ensuring access to affordable medicines and promoting public health.

Apart from this, enhanced enforcement of competition law is essential to address anti-competitive practices in the pharmaceutical sector. The CCI should adopt a proactive approach in investigating and penalizing cartels, abuse of dominance, and other anti-competitive behaviors. Further, investing in capacity building and developing expertise within the CCI to handle complex pharmaceutical cases is crucial. Specialized training and collaboration with international antitrust agencies can enhance the effectiveness of competition law enforcement.

A harmonized approach to patent and competition policies can ensure that intellectual property rights do not unduly hinder market competition. Policymakers should consider revising patent laws to prevent evergreening and facilitate the timely entry of generic medicines. Coordination between the CCI, the Patent Office, and the Drug Controller General of India (DCGI) is essential to address overlapping issues and ensure a coherent approach to competition and innovation. Streamlining the regulatory approval process for drugs, promoting transparency, and reducing bureaucratic hurdles can foster a competitive environment. Regulatory agencies must work in tandem with competition authorities to address market distortions and promote consumer welfare. Simplifying and expediting drug approval processes without compromising safety and efficacy standards can enhance competition by facilitating the entry of new drugs, including generics, into the market. Encouraging the entry and growth of generic drug manufacturers through supportive policies and incentives can enhance competition and reduce drug prices, improving access to medicines.

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