NAVIGATING THE INTERSECTION OF COMPETITION LAW AND HEALTHCARE: A REVIEW OF THE KEY CHALLENGES

Mrunmai Pradeep Pimparkar, ILS College, Pune

Background of Competition Law

Competition law, also known as antitrust law in some jurisdictions, is a set of legal rules and regulations designed to promote fair competition among businesses in order to prevent anti-competitive practices that could harm consumers, competitors, or the overall market. It is a branch of law that aims to ensure that companies compete on a level playing field, without engaging in unfair practices such as monopolization, price fixing, collusion, or abuse of dominance. The primary goal of competition law is to promote efficiency, innovation, and consumer welfare by fostering competitive markets that provide consumers with a wide range of choices and products at affordable prices. It is enforced by government agencies and courts, and violations can result in fines, injunctions, or other penalties.[1]

Competition Law: Story so far

Competition law is the primary weapon for promoting competition, and its scope, applicability, and execution vary greatly among jurisdictions.

Worldwide

According to some scholars, the earliest anti-competitive regulations date back to medieval times, when cartels were found in most European towns. The Sherman Act of 1890[2] and the Clayton Act of 1914[3] established the first modern body of competition law in the United States. In the second part of the nineteenth century, railroads and steamships broadened numerous markets, while agricultural prices declined due to the gold standard's monetary restrictions.

[1] UNCTAD Intergovernmental Group of Experts on Competition Law and Policy Fourteenth session Geneva, 8–10 July 2014.
[2] Sherman Act of 1890, § 2,3, 26 Stat. 209, 15 U.S.C. §§ 1–7.
[3] Clayton Act of 1914, § 7, 15 U.S.C. §§ 12–27.

Farmers and small business owners advocated for laws to curb the trusts' influence, which resulted in the passage of competition legislation in Canada (1889)[4] and the United States (1890).

Following WWII, the Allies tightened control of cartels and monopolies in occupied Germany and Japan. In Germany, a few huge cartels dominated the industry, and business in Japan was arranged along family and nepotistic lines. Following the end of World War II, several countries enacted stricter competition regulations modelled on US legislation. However, further improvements in competition legislation have been eclipsed by the trend toward nationalization and industry-wide planning. Commonwealth nations have hesitated to establish legislative competition law protections, but emerging nations have recently implemented competition legislation.

Argentina and Mexico were among the first emerging countries to implement competition legislation in 1923 and 1917. Chile, Brazil, and Colombia have also enacted competition legislation. There were only about 35 developing countries with competition laws in place in the early 1990s, but with rapid industrialization and integration into the global market, several other developing countries have taken steps to introduce competition laws.

India

India passed its first competition legislation, the Monopolies and Restrictive Trade Practices Act, in 1969.[5] The MRTP Act of 1969 was founded on the socioeconomic philosophy stated in the Directive Principles of State Policy incorporated in the Indian Constitution.[6] It was amended in 1974, 1980, 1982, 1984, 1986, 1988, and 1991. The revisions enacted in 1982 and 1984 were based on the recommendations of the Sachar Committee, which stated that statements to consumers through such advertisements should not become false and that fictional bargaining was a prevalent kind of deceit. The Government of India established a High-Level Committee in 1999 to advise the country on modern competition law in line with international developments.

In May 2000, the Raghavan Committee delivered its findings to the government. The Indian Parliament passed the Competition Act in 2002 to regulate corporations' anti-competitive

[4] Anti-Combines Act, 1889, [Repealed].
[5] Monopolies and Restrictive Trade Practices Act, 1969, Act 54 of 1969 [Repealed]
[6] Constitution of India, Art. 39(b), 39(c)

activities in the Indian market.[7] It was implemented to avoid practices that have a Significant Adverse Effect on Competition (AAEC).[8] The Competition Act of 2002 aims to create and maintain an open, fair, competitive, and innovative environment that protects consumers' interests and fosters long-term economic success.

Evolution of Healthcare in India

The COVID-19 pandemic has profoundly impacted healthcare systems globally, with India being no exception. The situation in India has been particularly dire, with the country experiencing a catastrophic second wave of infections that overwhelmed the healthcare system, resulting in a severe shortage of hospital beds, oxygen, and critical medications. The situation was further compounded by the emergence of new variants of the virus, which were more infectious and deadly than previous strains.

The first wave of COVID-19 in India had a relatively mild impact, with the country implementing strict lockdown measures that helped to limit the spread of the virus. However, the second wave, which began in early 2021, quickly spiraled out of control, with infections rising at an exponential rate. By April 2021, India was reporting over 400,000 new cases per day, and the healthcare system was stretched to its limits.[9]

The Epidemic Diseases Act, 1897[10] is a colonial-era law that empowers state governments to take measures to control the spread of infectious diseases. It provides the state governments with wide-ranging powers to make rules, appoint staff, and detain individuals suspected of carrying an infectious disease.

The Disaster Management Act, 2005[11] provides a legal framework for the management of disasters in India, including epidemics. In response to the COVID-19 pandemic, the Indian government invoked the Disaster Management Act to impose nationwide lockdowns and other restrictions on movement and gatherings.

The Indian Penal Code[12] also provides a legal framework for the management of disasters in India. The Indian Penal Code (IPC) is the primary criminal code of India and contains

[7] Competition Act in 2002, Act 12 of 2003 as amended by Act 9 of 2023.
[8] *Id* at § 3
[9] https://www.cnbc.com/2021/05/07/india-covid-crisis-daily-cases-rise-above-400000-again.html
[10] Epidemic Diseases Act, 1897, Act 3 of 1897 as amended up to Act 34 of 2020.
[11] Disaster Management Act, 2005, Act 53 of 2005] [Updated as on 30-10-2022.
[12] Penal Code, 1860, Act 45 of 1860 as amended upto Act 34 of 2019]1 [Updated as on 30-10-2022]

provisions that can be used to punish individuals who violate public health measures put in place to control the spread of infectious diseases. In the wake of the COVID-19 pandemic, several individuals have been arrested and charged under these provisions of the IPC.

The Contagious Diseases (CD) Act, 1897[13] is another colonial-era law that empowers state governments to take measures to control the spread of infectious diseases. It provides for the compulsory examination and treatment of individuals suspected of carrying an infectious disease and the detention of individuals who refuse to undergo examination or treatment. In the wake of the COVID-19 pandemic, some state governments in India have invoked the CD Act to impose mandatory quarantines and other restrictions on movement and gatherings. However, it has been criticized for its lack of clarity on what constitutes an infectious disease and for its potential to be misused to detain individuals without due process.

The Public Health Act[14] is a state-level law that regulates and controls public health in India. The act provides for establishing public health boards and appointing public health officers to oversee public health measures.

In response to the COVID-19 pandemic, several state governments in India have invoked the Public Health Act to impose restrictions on movement and gatherings and to mandate the use of face masks in public places. The act has been criticized for its lack.

A significant case related to healthcare and law in India during Covid-19 was the case of ***Alakh Alok Srivastava v. Union of India***.[15] The case was filed in the Supreme Court in April 2020 and dealt with the issue of the provision of medical equipment and facilities to healthcare workers treating Covid-19 patients. The Court directed the Union of India to ensure that adequate personal protective equipment (PPE) and other necessary medical equipment were provided to healthcare workers. The Court also directed the Union of India to ensure that healthcare workers were paid their salaries on time and that they were given appropriate insurance coverage.

In February 2021, the Supreme Court heard a case related to the distribution of Covid-19 vaccines in India. The case of ***Tehseen Poonawalla v. Union of India***[16] dealt with the issue of the equitable distribution of vaccines to all sections of the population. The Court directed the

[13] Contagious Diseases Act, 1868 [Repealed]
[14] The Kerala Public Health Bill, 2021
[15] Alakh Alok Srivastava v. Union of India, 2020 SCC OnLine SC 345
[16] Tehseen Poonawalla v. Union of India, (2021) 6 SCC 72

Union of India to ensure that vaccines were distributed fairly, and that the most vulnerable sections of the population, including healthcare workers and the elderly, were given.

Essential Commodities Act, 1955[17]

The hoarding, adulteration and black marketing of essential commodities has mostly affected the lives of people from weak economic backgrounds. Such people have died without professional hospital aid because of the severe shortage of oxygen cylinders, the unaffordable high prices of medical drugs and other necessities There have been grievous violations to the right to life and health, as mentioned under Article 21 of the Indian Constitution.[18] A Public Interest Litigation (PIL) has filed before the Hon'ble Supreme Court which has highlighted the failings of our health infrastructure and stated that the mechanism on which the healthcare system is functioning is inadequate and incapable of curbing the hoarding, adulteration, and black marketing of basic medical necessities.[19] It is because of such ineffective and outdated laws that the government has failed to control the public health crisis, resulting in the tragic exploitation of people's lives, particularly those from financially insecure backgrounds.

It would be worthwhile to make a brief note here of the recommendations suggested in the PIL:

1. Offences related to hoarding, black marketing must be non-bailable, non-compoundable.
2. Fast-track courts should be designated with the power to deal with such matters.
3. The prices of medical drugs/medical devices should be regulated under the Essential Commodities Act.

It is also significant to mention that the Hon'ble Telangana High Court division bench, comprising of Chief Justice Hima Kohli and Justice B. Vijaysen Reddy, recently asked the Telangana state government to explain why the prices of critical drugs and medical devices have not yet been included under the ECA and why was the ECA not been invoked and amended when the situation was out of control.[20] They focused on the issue that the average citizen cannot afford the unjust prices of such critical commodities. They also pointed out that lives have been needlessly lost both because of this major legislative failure to regulate the

[17] Essential Commodities Act, 1955, [Act 10 of 1955 as amended up to Act 40 of 2021 and Noti. S.O. 5369(E), dt. 23-12-2021] [Updated as on 30-10-2022].
[18] Constitution of India, Art. 21
[19] Amit Dwivedi v. UOI, 2020, https://www.livelaw.in/pdf_upload/pdf_upload-372895.pdf
[20] https://www.thehindu.com/news/national/telangana/telangana-high-court-hits-out-at-state-over-response-to-pleas-on-covid-19-situation/article34356396.ece

(grossly unethical, but not illegal) practices of hoarding and black marketing as well as severe shortages caused by the poor production and distribution of supplies arising out of deeply flawed healthcare infrastructure. Such failings need to be urgently addressed under the ECA by introducing changes such as fixed pricing, defining hoarding as a punishable offense, etc.

"Competition law has an important role to play in promoting innovation in healthcare by encouraging the development of new and better treatments and technologies." - Johannes Laitenberger

Intersection between healthcare and competition law

Competition law and healthcare are two distinct areas of law that intersect in various ways, with important implications for the provision of healthcare services and the promotion of competition in the market.

"The goal of competition law in healthcare is not to eliminate competition, but rather to ensure that it is fair, transparent, and benefits patients." - Joaquin Almunia

Healthcare is a critical sector in India that is subject to competition law regulations. The Indian healthcare sector is diverse, comprising of public and private hospitals, clinics, and other healthcare providers. Public sector health services in India are organized as a three-tier hierarchical system, comprising primary (subcentres and PHCs), secondary (CHCs, taluka and district hospitals) and tertiary (medical colleges and teaching hospitals) health-care facilities (Figure 2.1 and 2.2). Since health is a state subject, each state operates its own health facilities. The Central Government oversees policy-making, planning, guiding, assisting, evaluating and coordinating the work of state health authorities. The sector is also characterized by a high level of government intervention, including regulation of prices and licensing requirements.

Healthcare sector is often characterised by the presence of significant market power, information asymmetry, and regulatory challenges. Competition law, on the other hand, seeks to promote competition and prevent anti-competitive practices in the market, which can have adverse effects on consumers, including patients. It encompasses 2 discrete bodies of doctrine: antitrust and consumer protection.

The intersection between competition law and healthcare is particularly relevant in the context of pharmaceuticals and medical devices, where the competition can be restricted by factors such as intellectual property rights, regulatory barriers, and market concentration. The use of

patents and exclusivity rights can prevent competition and lead to higher prices for medicines and devices, potentially limiting access to healthcare for patients.

US SC in ***Goldfarb v Virginia State Bar***[21] introduced a principle of competition to national health policy debate, the professions were subject to the same rules of competition

Furthermore, healthcare providers, such as hospitals and clinics, may engage in anti-competitive practices, such as price fixing, bid-rigging, or market allocation, which can harm patients and increase healthcare costs. Competition law enforcement can help to prevent and deter such practices and promote access to affordable healthcare services. It promotes competition and innovation, which can lead to improved quality and affordability of healthcare services. It also helps to ensure that patients have access to a wide range of healthcare options, which can improve patient outcomes.

In 2019, **Teva Pharmaceuticals** and several other generic drug makers were accused of engaging in price-fixing and market allocation schemes. The companies ultimately agreed to pay $260 million to settle the case.[22]

However, the application of competition law in the healthcare sector can be challenging, as it requires balancing the need to promote competition with the need to ensure the provision of high-quality healthcare services. In this regard, regulatory agencies and courts must consider the specific characteristics of the healthcare sector, such as the complexity of medical innovation, the role of public procurement, and the importance of patients safety.

In 2016, Mylan, the manufacturer of the EpiPen, was accused of engaging in anticompetitive practices by raising the price of the life-saving device by more than 500%. Mylan settled with the Department of Justice for $465 million.[23]

Overall, the intersection between competition law and healthcare presents significant challenges and opportunities for policymakers, regulators, and healthcare providers, who must

[21] Goldfarb v. Va. State Bar, 421 U.S. 773, 95 S. Ct. 2004, 44 L. Ed. 2d 572, 1975 U.S. LEXIS 13, 1975-1 Trade Cas. (CCH) P60,355 (U.S. June 16, 1975)

[22]https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation

[23] In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., 507 F. Supp. 3d 1289 (D. Kan. 2020); https://sevenpillarsinstitute.org/mylans-epipen-pricing-scandal/

work together to ensure that competition and innovation in the healthcare sector are balanced with the need to protect patients and ensure access to affordable healthcare services.

United States v. Carolinas Healthcare System (2016)[24]: In this case, the Department of Justice accused the Carolinas Healthcare System of using its market power to force insurers to pay higher rates, which ultimately led to higher healthcare costs for patients. The case was settled for $6.5 million.

"We need to strike a balance between promoting competition and ensuring access to affordable healthcare for all, especially the most vulnerable and marginalized populations." - Tedros Adhanom Ghebreyesus

In the healthcare sector, the CCI has been actively involved in investigating and penalizing anti-competitive practices. For example, in 2018, the CCI fined a major hospital chain for abusing its dominant position by charging exorbitant prices for medical equipment and consumables. The CCI has also investigated cases of price-fixing and cartelization among pharmaceutical companies and hospitals.[25]

Another area where healthcare and competition law intersect is with regard to intellectual property rights. Patents, for example, can be used by pharmaceutical companies to monopolize the market for a particular drug, resulting in higher prices and reduced access for patients. However, patents are also necessary to incentivize innovation in the pharmaceutical industry.

However, competition law enforcement in India faces some challenges, including a lack of resources, capacity, and expertise. The complexity of the healthcare sector, including the role of government regulations, also poses challenges for competition law enforcement. Despite these challenges, the CCI remains committed to promoting competition in the healthcare sector and ensuring that patients have access to high-quality, affordable healthcare services.

United States v. GSK (2011)[26]: In this case, the Department of Justice accused pharmaceutical company GlaxoSmithKline (GSK) of engaging in anticompetitive practices by offering illegal

[24] United States v. Charlotte-Mecklenburg Hosp. Auth., 248 F. Supp. 3d 720, 2017 U.S. Dist. LEXIS 47951, 2017-1 Trade Cas. (CCH) P79,941 (W.D.N.C. March 30, 2017)
[25] House of Diagnostics LLP Informant And. Esaote S.p. Opposite Party No. 1,. Esaote Asia Pacific Diagnostic Pvt. Ltd. Opposite Party No. 2; https://www.cci.gov.in/images/antitrustorder/en/0920161652434633.pdf
[26] United States ex rel. Moore v. GlaxoSmithKline, LLC, 2013 U.S. Dist. LEXIS 165205, 2013 WL 6085125 (E.D.N.Y. October 16, 2013)

kickbacks to doctors and engaging in other marketing tactics to promote off-label uses of its drugs. GSK ultimately agreed to pay $3 billion to settle the case.

Physicians asserted that the lay public could not reliably distinguish appropriate from substandard services, and many commentators believed that there was a "learned professions" exception to the antitrust laws. The Supreme Court dispelled this impression in **Goldfarb v. Virginia State Bar**, a case involving "ethical" prohibitions on discounted attorneys' fees for title searches.[27] The Supreme Court made it clear that professional conduct that interfered with normal market processes would face a heavy burden of justification and might even be unlawful per se.[28]

Policy analysts are used to thinking of a "three-legged stool" of health care resting on separate and distinct components: cost, quality, and access.[29] But these legs are interconnected, and lower costs can enhance quality. When costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions. Competition law prevents providers from collectively increasing prices above their competitive level or blocking the development of cheaper forms of healthcare delivery

Way forward

1. **Promote Transparency-**

Currently, many healthcare providers and insurers are not transparent in their pricing, quality of care, and other critical information. Patients often have no way of knowing the costs of their medical procedures or the quality of care they will receive. This lack of transparency creates a significant barrier to entry for new healthcare providers who may offer better quality care at lower prices. To promote transparency, policymakers could require healthcare providers and insurers to disclose their pricing and quality of care data to the public. This would enable patients to make informed decisions about their healthcare providers and encourage competition in the industry.

[27] Supra note 21
[28] *Id*
[29] W.L. Kissick, Medicine's Dilemmas: Infinite Needs versus Finite Resources (New Haven, Conn.: Yale University Press, 1994).

2. **Improve Competition in the healthcare industry-**

In order to encourage the development of new healthcare technologies. Many healthcare technologies are currently underdeveloped or non-existent, making it difficult for new entrants to enter the market. Policymakers could encourage the development of these technologies by providing funding for research and development and offering tax incentives to companies that develop innovative healthcare technologies. This would help to lower the costs of healthcare and increase access to quality care.

3. **Encouraging the development of new healthcare technologies-**

Policymakers could also consider measures to improve competition among healthcare providers.

4. **Promote the use of Telemedicine-**

Telemedicine involves the use of technology to provide healthcare services remotely. This would enable healthcare providers to offer services to patients in rural or underserved areas, where it may be difficult to access traditional healthcare services. Policymakers could promote the use of telemedicine by offering funding and tax incentives to healthcare providers who offer these services.

5. **Eliminate certificate of need (CON) laws-**

CON laws require healthcare providers to obtain permission from state regulators before opening new facilities or offering new services. These laws limit the entry of new providers into the market, limiting competition, and driving up prices. Eliminating CON laws would enable new healthcare providers to enter the market more easily and increase competition, which would lower costs and improve access to quality care.

6. **Increase antitrust enforcement against healthcare providers and insurers**

Antitrust laws are designed to prevent companies from engaging in anti-competitive practices that harm consumers. In the healthcare industry, these practices may include price-fixing, collusion, or other anti-competitive behaviour that limits competition and drives up costs. Policymakers could increase antitrust enforcement against healthcare providers and insurers to

promote competition and lower costs.

7. **Increase scrutiny of healthcare mergers and acquisitions**- Mergers and acquisitions in the healthcare industry can limit competition and drive-up prices, particularly in local markets where there may be limited options for healthcare providers. Policymakers could increase scrutiny of healthcare mergers and acquisitions to ensure that they do not harm competition or limit access to quality care.

Conclusion

In conclusion, the paper highlights the intricate relationship between competition law and the healthcare industry. The analysis presented throughout this research paper underscores the importance of maintaining a delicate balance between promoting competition and ensuring the delivery of high-quality healthcare services.

Competition law plays a crucial role in safeguarding the interests of consumers, encouraging innovation, and fostering efficient market dynamics within the healthcare sector. It helps prevent anti-competitive practices, such as abuse of dominant market positions, collusion, and mergers that may lead to reduced competition, higher prices, and limited consumer choice.

However, the application of competition law in the healthcare industry presents unique challenges. The inherent complexities of healthcare, such as the presence of information asymmetry, regulatory frameworks, and the need to balance patient welfare with market forces, require a nuanced approach.

Effective enforcement of competition law in the healthcare sector necessitates collaboration between competition authorities, healthcare regulators, and policymakers. Cooperation among these stakeholders is essential to develop tailored solutions that address specific market dynamics and ensure optimal outcomes for both competition and patient welfare.

Moreover, it is crucial to strike a balance between competition and other policy objectives, such as the provision of affordable and accessible healthcare services, especially in markets where competition alone may not be sufficient to address systemic issues.

Further research and ongoing monitoring are needed to adapt competition law frameworks to the evolving healthcare landscape, including the integration of digital technologies, the rise of telemedicine, and the increasing influence of big data. This will require a comprehensive

understanding of the interplay between competition law, healthcare regulation, and technological advancements to promote innovation, protect consumers, and foster a competitive and sustainable healthcare market.

Overall, this research paper underscores the significance of competition law in shaping the healthcare industry. By carefully navigating the challenges and complexities inherent in this sector, competition authorities, regulators, and policymakers can foster competition that leads to improved healthcare outcomes, enhanced patient choice, and a more efficient and equitable healthcare system.