*Page 131 - 146* **DOI:** *https://doij.org/10.10000/IJLMH.116096*

# INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

**Volume 6 | Issue 6**

**2023**

# Shaping the Future of Biomedical Research and Healthcare: A Critical Analysis on the Application of Competition Law in Biomedical Technologies and its Relationship with Intellectual Property Rights and Consumer Welfare

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## ABSTRACT

*Biomedical research has demonstrated its capacity to question and reshape our established concepts of life and mortality. Biomedical technology and its associated products are an evolving field crucial for extending the lives of patients receiving treatment. In this context, it is imperative to examine the implications of competition law. Primary challenges in this domain encompass preventing anti-competitive behaviors, addressing the abuse of dominant market positions, and regulating mergers and collaborations among enterprises that could negatively impact competition, all aimed at safeguarding the welfare of patients and consumers. The application of competition law in healthcare serves to curtail monopolistic practices and fosters equitable competition within the market. Equitable competition entails engaging in competition based on merit, free from the influence of anti-competitive agreements. It prohibits the imposition of barriers that hinder entry into markets and ensures the viability of emerging and smaller businesses. Moreover, it promotes wealth distribution and prevents the concentration of economic power, while also safeguarding the freedom of trade for other enterprises. Competition plays a role in eradicating inefficiencies that often result in high prices, as it prevents predatory pricing and upholds product quality through the promotion of fair competition, ultimately safeguarding consumer well-being.*

*Additionally, it is essential to consider the interplay between competition law and intellectual property rights within the biomedical technology sector, as well as devising remedies for combating anti-competitive practices. The study is based on a comparative perspective of the USA, UK, and Indian Laws for a better understanding of the subject.*

***Keywords:*** *Biomedical Technology, anti-competitive practices, unfair trade practices, healthcare, abuse of dominant position.*

## I. INTRODUCTION

*"Even within a particular national system, the goals of competition law may evolve and*

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*transmogrify, often depending upon the state of industrialization of the economy, the strength of the political democracy, the power of the judiciary and the bureaucrats, and the exposure of the domestic firms to global competition."*

-Fox Eleanor M.

The healthcare sector has undergone dynamic transitions due to technological advancements. The fundamental objective of every advancement is to balance the interests of the stakeholders. Biomedical research has been proven to be an effective mechanism that challenges the pre-existing notions of life and death. Biomedical technology undergoes transitions through biomedical research. The biomedical technology and its products are a developing area, and essential for prolonging the lives of those undergoing the treatment. In this regard it is necessary to look into competition law's implications in this area. The major challenges in this aspect include prevention of anti-competitive practices and abuse of dominant position and regulation such combinations of enterprises having adverse effect on competition to protect the interests of patients and other consumers. Here it is also necessary to consider interaction between competition law and intellectual property rights in biomedical technology as well as the remedies to anti-competitive practices.

Biomedical research and its products have transformed the health care sector. The 20$^{th}$ Century has witnessed several medical advancements including discovery of blood types, identification and isolation of insulin, discovery of penicillin, ECG, Chemotherapy, Polio Vaccines, etc. Due to its future value, biomedical research and its products have been handled considerately. The laws governing biomedical devices are Medical Devices Rules, Drugs and Cosmetics Act, etc. In addition to this the biomedical products are also subject to the provisions of Competition Law.

Competition law aims to enhance fair competition to ensure consumer welfare and free trade. Application of Competition law in health care sectors helps to ensure the right to access to affordable health services by overcoming the issues of high price, and low quality. At the same time, it also encourages innovations. Therefore, it becomes inevitable to analyze the application of competition law in biomedical products.

## II. BIOMEDICAL RESEARCH AND ITS PRODUCTS

According to Redman and A.V.H Mory, it is a systematized effort to gain new knowledge. The biomedical research is the branch of science that focuses on the prevention and treatment

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of diseases that cause death and sickness in animals and human beings[2]. Here, the combination of engineering and technology is used in resolving medical complications in human beings. It is referred to as biomedical technology (hereinafter referred to as BMT). It has revolutionized the health care sector. Application of biomedical technology in human beings encompasses a range of activities from designing medical equipment or conducting clinical trials. It is a broad area of science that involves the investigation of the biological process and the causes of disease through experimentation, observation, laboratory work, analysis, and testing. Biomedical technology is used to discover ways to prevent ill-health, and to develop medications, treatment procedures, cure of diseases and conditions that cause illness and death in human beings. The invention of microscopes has been a rudimentary development in the medical field, which leads to identification and collection of information on causes of diseases. In this regard a medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination for a medical purpose[3]. Such devices and technologies are used to diagnose illness, to monitor treatments, to assist disabled people and to intervene and treat illnesses, both acute and chronic. Examples of biomedical technologies include 3D medical imaging, such as X-rays, MRIs, CT scans, Sonograms; 3D Bioprinting and surgical robots.

## III. CONCEPT OF COMPETITION LAW: A COMPARATIVE PERSPECTIVE

Competition generally means the "*struggle to win*" or "*outperform others*". It is the economic rivalry among the market players, where the ultimate aim is to gain more profit and maximum customers. The OECD definition of competition is "*it is the situation in market in which sellers independently strive for buyers' patronage to achieve business objectives*"[4]. It is equated with rivalry. It may occur between one or more market players, in terms of price, quality, service, or combinations of any of these, which has a direct effect on customers. Competition as concept marks the idea of 'free market'[5]. The notion of competition can be traced back to the works of John Locke, who propounded the unalienable right of one and all to pursue happiness[6].

Conventionally, competition law is regarded as regulation of the marketplace to ensure private conduct does not suppress free trade and competition[7]. Its aim is to preserve competition in the

[2] NHINBRE, http://www.nhinbre.org/what-is-biomedical-research/, (last visited on October 29th 2023).
[3] WORLD HEALTH ORGANIZATION, https://www.who.int/health-topics/medical-devices#tab=tab_1, (last visited on October 29th 2023)
[4] OECD, *Glossary of terms*, https://stats.oecd.org/glossary/detail.asp?ID=3163, (last visited on October 29th 2023)
[5] Introduction to competition in healthcare delivery sector, http://14.139.58.147:8080/jspui/bitstream/123456789/338/8/08_chapter%201.pdf, (last visited on October 29th 2023).
[6] *Id* at 3.
[7] Max Huffman, *Bridging the divide? Theories for integrating competition law and consumer protection*, ECJ,7-

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market and serves to optimize consumer welfare. Competition Laws maintain free trade and fair competition in the market by preventing anti- competitive and unfair trade practices[8]. Fair competition in a market enhances economic growth and the global financial system. Fair Competition pave ways to better market efficiency as it encourages innovation, technological developments, reasonable prices and better quality of products. Effective competition is one of the basic prerequisites for a market economy to work efficiently[9]. It not only introduces market efficiency but also protects the interests of consumers. To improve dynamic efficiency and encourage disclosure and commercialization of technology, the competition law also addresses Intellectual Property rights. The Competition law in context of Intellectual property rights and Consumer protection is termed as relevant in prevention of monopolies and abuse of dominant position.

In the USA 'competition law' is known by the term 'anti-trust laws. The evolution of anti-trust laws began with the introduction of the Sherman Act in 1890. Its purpose was to curb the anti-trade practices of the business giants known as "trusts". They grew into powerful monopolies and used to control the whole sections of the economy, by fixing the supply of goods and services and their prices. Due to this there was no active competition in the market and smaller businesses and consumers had no choice but to succumb to such prices. The quality did not match the price albeit the high prices. To overcome this situation, people pleaded with the then President Theodore Roosevelt to act against it resulted in enforcement of anti-trust laws. The Sherman Act prohibited contracts, combinations and such conspiracies that restrained fair trade. It also prevented monopoly. In 1914 the Clayton Act was passed which stopped mergers and acquisitions that are likely to limit competition[10]. In the following years the Federal Trade Commission Act of 1914 and Robinson-Patman Act or Anti Price Discrimination Act of 1936 were passed in this regard. The former created a new federal agency to watch out for unfair business practices. The latter prohibited anti-competitive practices, particularly price discrimination. In *United Kingdom* v *Topco Assocs*.[11], it was observed that "*anti-trust laws are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.*

The United Kingdom based on Doctrine of restraint of trade which is only a residual limitation

25.

[8] Li, Rita Yi Man, Li Yi Lut, *The Role of Competition Law: An Asian Perspective*, 47-53

[9] Chauhan BS, *Indian Competition Law: Global Context*,3, JILI, ,316-319

[10] Corporate Finance Institute, https://corporatefinanceinstitute.com/resources/knowledge/finance/clayton-antitrust-act/, (last visited on October 29th 2023)

[11] 405 US 596, (1971)

on the freedom of commercial operators[12]. The doctrine is based on the decision in *Dyers Case*[13]. According to Lord Diplock, a restraint is identified where the parties agree that one party will '*restrict his liberty in the future to carry on trade with other persons not parties to the contract in such manner as he chooses*'[14]. The Monopolies and Restrictive Practices Act enacted in the aftermath of World War II was comparatively a less stringent law. Later the Restrictive Trade Practices Act 1956 was enacted. It had several shortcomings which enabled the enterprises to enter anti-competitive practices. The decision was supposed to be made by Court based on harms and benefits[15]. The 1956 Act had been widely criticized due to such enablement. Later the UK enacted more intricate legislation such as Competition Act 1998 and Enterprises Act, 2002 to deal with the situation. It was in consonance with Articles 81 and 82 of European Community Laws. It expressly prohibits anti-competitive agreements and abuse of dominant position. The Enterprises Act had three objectives vis-à-vis, extrication of political influence from the process of merger control; instigation of procedural reform to leave the regime more open and transparent, and thirdly, the installation of an exclusively competition-based standard against which mergers would henceforth be assessed[16].

In India Competition law is based on Articles 38 and 39 of the Constitution of India[17]. Based on the Directive Principles of State policy the first legislation was enacted in 1969 known as Monopolies and Restrictive Trade Practices Act 1969(MRTP Act). It was later replaced by the Competition Act, 2002. The Competition law in India evolved through three phases beginning from 1950. During 1950-70 the nation suffered from concentration of wealth and economic. Economic power was never frontier during the British Regime, but in the post-independence era Indian begun to adopt strategy for planned economic development. It commenced with the Industrial policy of 1948. The reports of the Hazari Committee, Prof. Mahalanobis and Monopolies Inquiry Committee led to the adoption of MRTP Act. The signing of the TRIPS Agreement and occurrence of Economic Reforms and Liberalization of 1991 pointed out the shortcomings of MRTP Act. The Act was not capable of meeting the challenges posed by the WTO trade regime such as cross border business, mergers, amalgamations, which had strong impacts on Indian economy. Therefore, in 1991 the High-Level Committee on Competition Policy and Law headed by SVS Raghavan was appointed to examine the relevance of the MRTP

[12] Andrew Scott, *The Evolution of Competition Law and Policy in United Kingdom,* Working Papers, LSE, 1-20, http://eprints.lse.ac.uk/24564/1/WPS2009-09_Scott.pdf
[13] (1414) 2 Hen. V, fol 5, pl. 26.
[14] *Petrofina (Great Britain) Lrd* v *Martin*, (1996) Ch. 146,180.
[15] ANDREW SCOTT, *supra note at 9*
[16] *Id* at 24.
[17] Patil Shalaka, Chatterjee Payel, Gautam Shashank, Ananth MS, Jha Aditi, Reis Simone, Jain Prathibha, *Competition Law in India: A Report on Jurisprudential Trends and way forward,* NDA,17-19

Act and recommend a suitable legislative framework. Based on the Committee report Government of India in 2001 introduced the Competition Bill passing in both houses and receiving the assent of President in 2003. It came into force as the Competition Act, 2002.

The Competition Act aims to provide for a Competition Commission to prevent practices having adverse effect on competition, to promote and sustain competition in market, to protect their interests of consumers and to ensure freedom of trade carried on by other participants in Indian markets. In *Brahm Dutt* v *Union of India*[18], it was challenged that the Competition Commission could not combine the roles of a market regulator and an adjudicatory body. It led to a series of Amendments, where it was finally held that Competition Commission will only function as a market regulator, an expert body performing advisory and regulatory function and the establishment of Competition Appellate Tribunal which would be the quasi-judicial adjudicatory body.

## IV. RELEVANCE OF COMPETITION IN HEALTH CARE INDUSTRY

The right to affordable and good quality healthcare is an essential component of the right to health. Right to health has been recognized in both international instruments, such as Constitution of World Health Organization[19], Universal Declaration of Human Rights[20], and International Covenant on Economic, Social and Cultural Rights[21]. In India it was brought under the ambit of Article 21 that provides for right to health in *Consumer Education and Research Centre* v *Union of India*[22]. In *Kikloskar Bros Ltd* v *ESI Corpn*[23], it was observed that right to health care at affordable prices have become a universally recognized right. In this regard, fair competition in healthcare Industry is beneficial to the patients and other consumers to ensure right to healthcare. It helps to limit costs, improve quality and promote innovation[24].

Competition law seeks to overcome the above-mentioned issues. It prevents enterprises from engaging in practices that have adverse effects on competition. It restricts monopolistic activities and promotes fair competition in the market. Fair competition means competing on merit and not with the aid of anti-competitive agreements. It prohibits entry barriers to markets and ensures survival of new and small enterprises. It encourages distribution of wealth and prevents concentration of wealth. It ensures freedom of trade of other enterprises. Competition

[18] WP 490 of 2003 (Supreme Court of India)
[19] WHO CONST. art 1
[20] UDHR, art. 25
[21] ICESCR, art. 12
[22] AIR 1995 SC 922
[23] (1996) 2 SCC 682
[24] Federal Trade Commission, https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care, (last visited on October 29th 2023).

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eliminates the elements that cause inefficiency that yields to high prices. By preventing predatory prices and ensuring good quality products through fair competition it also ensures consumer welfare.

In *Competition Commission of India* v *Steel Authority of India*[25], the need for competition law were recognized. They are:

- To promote economic efficiency,
- Assisting the creating of market responsive to consumer preferences,
- Improve product quality
- Guarantee allocative efficiency, i.e., to ensure effective allocation of resources
- Guarantee productive efficiency, i.e., to ensure that costs of production are kept at a minimum and
- Guarantee dynamic efficiency, which promotes innovative practices.

The elements of competition in health care involve one or more elements such as price, quality, convenience and superior products or services and new technology and innovation[26]. The key role of competition in health care is to reduce the costs of products. It improves service quality and patient satisfaction. The most important aspect is that the competition law deters the possibilities of potential anti-competitive agreements between hospitals or medical professionals with pharmaceutical companies, diagnostic centres, health insurance, and medical equipments. In this manner, competition law optimizes consumer welfare by promoting efficient allocation of resources resulting in high outcome, low prices, high quality, varied services, innovation, production and distribution[27]. In United Kingdom and United States of America, the competition law is applicable to healthcare industry. In USA, the Federal Trade Commission by virtue of its powers under Federal Trade Commission Act may promote competition in health sector. In United Kingdom, the Health and Social Care Act 2012 has underscored the applicability of general competition law to health sector[28].

[25] (2010) 10 SCC 744

[26] Rivers Htrick, Glover Saundhara, *Healthcare Competition, Strategic mission and patient satisfaction: research model and propositions,* HOM, 627-641,(2008)

[27] Fornaciari Diego, Callens Stefaan *Competition rules and healthcare players: principles and consequences, 5* IJHCQA, 379-386, (2012)

[28] Mary Guy, *Competition Law: its applicability and application in Dutch and English HealthCare,* Competition Policy in Healthhcare: Frontiers in Insurance based and taxation-funded systems, 61-114 (2019)

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## V. COMPETITION LAW IMPLICATIONS IN BIOMEDICAL RESEARCH AND ITS PRODUCTS

Anti-competitive practices have led to concentration of wealth and deterioration of consumer welfare. There are both legal and economic implications of anti-competitive practices[29]. It restrains competition and deteriorates consumer welfare by creating entry barriers and predatory prices. It leads to efficiency and innovation concerns. Adam Smith has pointed out the adverse effects on unfair trade practices on public in context of 'cartels. However, he did not support the legal restrains upon it. His opinion is as follows[30]:

> *"people of the same trade seldom meet together, even for merriment and diversion, but their conversation ends in a conspiracy against the public, or in some contrivance to raise prices. It is impossible indeed to prevent such meetings, by any law, which either could be executed, or would be consistent with liberty and justice. But though the law cannot hinder people of the same trade from sometimes assembling together, it ought to do nothing to facilitate such assemblies; much less to render them necessary".*

The Competition law implications in biomedical research and its products are therefore discussed and analyzed based on the provisions of the Competition Act, 2002.

### (A) Prohibition of anti-competitive agreements.

The first and foremost issue is 'anti-competitive agreement'. There are horizontal and vertical agreements. Horizontal Agreement in biomedical products is an agreement between enterprises each of which at the same level in production or distribution chain engages in price fixation, output control, market sharing and big rigging. One of the most disparaging forms of anti-competitive agreements is 'cartel'. Section 2(c) of the Act defines 'cartel' as:

*"Cartel includes an association of producers, sellers, distributors, traders or service providers who, by agreement amongst themselves, limit, control or attempt to control the production, distribution, sale or price of, or trade in goods or provision of services."*

A cartel is a horizontal agreement between businesses not to compete. The agreement usually will be verbal and often informal. The cartel members may agree on prices, output levels, discounts, credit terms, which customers they will supply, which areas they will supply, who

[29] Qaqaya Hassan, Limpile George, *The effects of anti-competitive business practices on developing countries and their development prospectives,* United Nations Conference on Trade and Development, 17-19, https://unctad.org/system/files/official-document/ditcclp20082_en.pdf

[30] Adam Smith, *Wealth of Nations,* Library of Economics and Liberty, 13-38, (1776), https://www.econlib.org/library/Smith/smWN.html?chapter_num=13#book-reader

should win a contract[31]. It can occur in any industry or any level and can involve goods or services at the manufacturing, distribution, or retail level. *Organization of Petroleum Exporting Countries* is a famous cartel. Another is *The Lombard Club*[32], a banking cartel, upon which the European Commission imposed fines for their participation in a wide-ranging price fixing[33]. A Vertical Agreement is an agreement between enterprises at different levels. It includes tie-in agreements, exclusive distribution agreement, refuse to deal and fixing of resale price. Such agreements cause adverse effects on competition and restrain free trade of other enterprises.

An illustration of anti-competitive agreement in health care is found in *Arizona* v *Maricopa County Medical Society*[34]. In this case, several foundations were set up by medical professionals to promote fee-for-service medicine and to provide the community with a competitive alternative to existing health insurance plan. Based on the agreement, the maximum fees the doctors could claim in full payment for health services provided to policyholders of specified insurance plans. The US Supreme Court held that it amounts to horizontal price fixing and therefore is a direct violation of Sherman Act.

Another important decision is made in *Sarabhai Chemicals P Ltd and another, in re*[35], by MRTP Commission. In this case Sarabhai Chemicals, an Indian Company and E Mereck AG, an overseas collaborator entered into an agreement where EM agreed not to engage in manufacture, packaging, selling or distributing any pharmaceutical chemicals in Union of India but shall be free to import into Union of India any such products. MRTP Commission held that the agreement has an adverse effect on competition; therefore, shall be void.

Section 3 of the Act prohibits anti-competitive agreements. It says that no enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India. Any such agreement shall be void. Clause 1 is a general prohibition of an agreement to cause or is likely to cause appreciable adverse effects on competition. Clause 3 of Section 3 prohibits horizontal agreement between enterprises or persons or their associations, including cartels engaged in the following activities are presumed to have an appreciable

[31] OFFICE OF FAIR TRADING, GUIDE ON COMPETITION ACT, 1998, 3, (OFT, 2005)
[32] EC IP 02/844
[33] EC Press Release, https://ec.europa.eu/commission/presscorner/detail/en/IP_02_844, (last visited on October 29th 2023)
[34] 457 US 332
[35] 1979 49 CompCase 145

adverse effect on competition[36]:

- Directly or indirectly determines purchase or sale prices,
- Limits or controls production, supply, markets, technical development, investment, or provisions of services,
- Shares the market or source or production or provision of services by way of allocation of geographical area of market or type of goods or services or number of customers in the market or any other similar way,
- Directly or indirectly results in bid rigging or collusive bidding. Here, bid rigging means any agreement, between enterprises or persons referred to in sub-section (3) engaged in identical or similar production or trading of goods or provision of services, which has the effect of eliminating or reducing competition for bids or adversely affecting or manipulating the process for bidding.

Under clause 4, prohibits vertical anti-competitive agreements. It includes tie-in arrangement, exclusive supply agreement, exclusive distribution agreement, refusal to deal and resale price maintenance. The explanation to the clause defines these terms as follows:

- Tie-in arrangement includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods.
- exclusive supply agreement includes any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person
- exclusive distribution agreement includes any agreement to limit, restrict or withhold the output or supply of any goods or allocate any area or market for the disposal or sale of the goods
- refusal to deal includes any agreement which restricts, or is likely to restrict, by any method the persons or classes of persons to whom goods are sold or from whom goods are bought;
- resale price maintenance includes any agreement to sell goods on condition that the prices to be charged on the resale by the purchaser shall be the prices stipulated by the seller unless it is clearly stated that prices lower than those prices may be charged.

[36] Competition Act, 2000, Clause (3) of §3, Acts of Parliament, 2000 (India)

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In *FTC* v *Indiana Federation of Dentists*[37], the respondent association of dentists made and agreed to a policy where it compelled the members to withhold x-rays from dental insurers in connection with evaluation of patients' claims for benefits.

In *Masimo Corp.* v. *Tyco Healthcare Group, L.P*[38], it was found that Tyco Healthcare Group and Mallinckrodt, Inc entered into an exclusive dealing agreement in business of pulse oximetry products, due to which Masimo Corp was foreclosed from the market. The jury found it as an Anti-competitive practice in violation of section 3 of Clayton Act and Sections 1 and 2 of Sherman Act. In *Kinetic Concepts, Inc*. v. *Hillenbrand Industries, Inc*[39] , Hillenbrand Industries and several of its subsidiaries were engaged in exclusive dealing combinations in the manufacture and rental of specialty hospital beds. The conduct of the respondent companies was held as anti-competitive agreements.

**(B) Prohibition of abuse of dominant position**

The second issue is 'abuse of dominant position'. It is the conduct of an enterprise that enjoys a position of strength or dominance, which enables it to act independently of competitive forces prevailing in the relevant market[40]. It occurs when a dominant firm in a market or dominant group of firms, is intend to eliminate or discipline a competitor to deter future entry by new competitors, with the result that competition is prevented or lessened substantially[41].

Section 4 prohibits abuse of dominant position. As per clause (2) of Section 4, there shall be abuse of dominant position in the following situations:

- directly or indirectly, imposes unfair or discriminatory condition or price, including predatory prices, in purchase or sale of goods or service, or
- Limits or restricts production of goods or provision of services or market therefor or technical or scientific development relating to goods or services to the prejudice of consumers; or
- Indulges in practice or practices resulting in denial of market access; or

[37] 476 US 447 (1986)
[38] No. 02-CV-4770 (C.D. Cal.)
[39] No. 95-CV-0755 (W.D. Tex.)
[40] RAMAPPA, COMPETITION LAW IN INDIA: POLICY, ISSUES, AND DEVELOPMENT,161-200, (Oxford, 2013)
[41] Competition Bureau Canada, https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/h_00511.html, (last visited on October 30th 2023)

- makes conclusion of contracts subject to acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts; or
- uses its dominant position in one relevant market to enter into, or protect, other relevant market.

Explanation to section 4 says that predatory price means sale of goods or services at a price below the cost with a view to reduce or eliminate competition.

In *Hoffman-La Roche and Co,* v *Commission of European Communities in Brussels*[42], the Commission held that the Company was abusing its dominant position in respect of manufacture of certain groups of vitamins, where it concluded an agreement with twenty two purchasers, which contained an obligation upon them, or the grant of fidelity rebates offering them an incentive, to buy all or most of their requirements of vitamins exclusively, or in preference from Roche. The decision of Commission was upheld by the European Court on appeal. In this case, the Court elaborated the factors to determine 'dominant position':

§ the relationship between the market shares of the undertaking concerned and of its competitors, especially those of the next largest;

§ the technological lead of an undertaking over its competitors; the existence of a highly developed sales network, and

§ the absence of potential competition.

The Court further explained the abuse of a dominant position as:

> *"The concept of abuse is an objective concept relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."*

*In Istituto Chemioterapice Italiano S.p.A. et Commercial Solvents Corporation* v. *Commission of the European Communities*[43], Commercial Solvents Corporation (or CSC), a biotechnology Company was found to be abusing its dominant position in world market by discontinuing sale

[42] EC: 85/76
[43] EC: 6 and 7/ 73

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of raw material. The case is based on inability of *Istituto* to continue to supply aminobutanol to a company called "Zoja". Aminobutanol is a raw material for the manufacture of ethambutol, which it had been supplying for some years. Istituto was a reseller of aminobutanol and nitropropane produced by the Commercial Solvents Corporation (CSC) in the US. CSC had 51% of the voting stock in *Istituto,* making it a subsidiary of CSC. The termination of supply of raw materials by *Istituto* was based on the change in policy made by CSC. In this case, the Court held that the abuse of dominant position by CSC in raw materials market have severe effects restricting competition in the market as it affects manufacture and sale of derivative products. It results in eliminating all competition in both raw materials and its derivatives market.

In *Retractable Technologies, Inc*. v. *Becton Dickinson & Co*[44], the respondent companies abusing its dominant position illegally conspired to prevent Retractable Technologies, Inc (or RTI) from selling its retractable needle syringe products to hospitals and monopolized the needle and syringe market. In 2003 RTI reached out-of-court settlements with respondents for $100 Million.

In *Medtronic AVE Inc*. v. *Cordis Corp*[45], a suit was filed against Cordis Corp., a subsidiary of Johnson & Johnson (J&J) in 2003. It was alleged that the respondent misused its monopoly power in the drug-eluting stent market through tying and exclusive dealing arrangements. And it had foreclosed competition in the market for other angioplasty products.

In *Vivek Sharma* v *MS Becton Dickinson India*[46], discussed abuse of dominant position, resulting in higher prices of Disposable Syringes. In this case CCI held that there is violation of Section 3 and 4 of the Act.

### (C) Regulation of Combinations

In addition to this, Section 6 provides that no person or enterprise shall enter a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void. The section functions with respect to the regulation of combinations. Combinations, including mergers and acquisitions, are not perse illegal, but if it adversely affects competition, it becomes void. Section 5 defines the term combination. Combination within competition law is the merger between two or more enterprises or firms or the acquisitions in business sectors or any amalgamation. Some examples

[44] No. 01-CV-036 (E.D. Tex.)
[45] No. 03-CV-212 (ED. Tex).
[46] CCI, Case no. 77 of 2015

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include Pfizer/Warner-Lambert in 2000, Sanofi and Aventis in 2004, Takeda-Shire Merger of 2018, etc. The elements of combination as per Section 5 are:

- acquisition of one or more enterprises.
- acquisition of control, shares, voting rights, or assets,
- acquisition of control by person over an enterprise where such person has direct or indirect control over another enterprise engaged in competing business
- merger and amalgamation between or amongst enterprises when the combining parties exceeds the thresholds set in the Act. The thresholds are specified in the form of assets or turnovers in India and abroad.

As aforementioned combinations under Section 5 also include mergers and acquisitions. A merger is the voluntary fusion of two companies on equal terms into one new legal entity. It contains an agreement that unites two existing companies into one new company. Mergers help in consolidating companies or assets with the intention of stimulating growth, gaining competitive advantages, increasing market share and influencing supply chains. The purposes of mergers include attainment of financial synergy, where the combination increases the overall performance efficiency; to achieve the strategic goals such as re-inventing the company, accessing new markets etc.; it helps in diversification, and replaces leadership in market. Sometimes, such practices lead to the elimination of competition. The negative effects of mergers and acquisitions are several. It generally results in overpayment, value of synergy becoming over-estimated, and poor-post merger integration. Section 5, 6 along with the powers of Competition Commission of India under the Act could be applied to curb the effects.

**(D) Conflict with Intellectual Property Rights**

The third issue is conflict with Intellectual property rights. IPR is the bundle of rights given to persons over the creation of their minds. They usually give the creator an exclusive right over the use of her or his creation for a certain period. The notion of IPR is contradictory to the aims of Competition law as it restricts and reduces competition in the market by permitting monopoly rights. It is because when the IPR policies increase incentives to innovate in an economy, they may cause efficiency losses due to abuse of market power. It leads to trade-off between competition law and patent policy[47]. Competition law comes into play when the monopoly rights exercised by the patent holder results in anti-competitive practices.

[47] QAQAYA HASSAN, LIMPILE GEORGE, *supra note 5*

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### (E) Adverse effect on Consumers

The last issue is 'adverse effect of anti-competitive practices on consumers. The anti-competitive practices usually lead to predatory pricing and also due to abuse of dominant position the quality of the goods and services might also meet an adequate standard. Predatory means exploitation for financial purposes. Conduct amounting to an abuse of dominant position may also be such that it affects its competitors or consumers or the structure of the market in its favor. It would impair the ability of the competitors to compete as they would and consumers would, therefore, have to accept higher prices or reduced quality[48].

### (F) Remedies under the Competition Law

In matters of violation of provisions of the Act, the remedies are provided by the Competition Commission of India. Section 7 establishes the Competition Commission of India. The Commission is a body corporate by the name aforesaid having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property, both movable and immovable, and to contract and shall, by the said name, sue or be sued. It is the duty of the Commission to eliminate practices having adverse effect on competition, promote and sustain competition, protect the interests of consumers and ensure freedom of trade carried on by other participants, in markets in India. Under section 19 the CCI is empowered to inquire into any alleged contravention of the provisions contained in subsection (1) of section 3 or sub-section (1) of section 4 either on its own motion or on receipt of any information, or on a reference made to it by the Central Government or a State Government or a statutory authority. Under Section 20 it has the power to inquire into combinations having an adverse effect on competition. The procedure for inquiry is given under Section 26. Under its powers to issue order, CCI may order for discontinuance of such practices, impose penalty, direct modification, or pass any other orders.

## VI. CONCLUSION

The various aspects of competition law, and its implication in biomedical research and its products are discussed above. Biomedical products are essential to diagnose illness, to monitor treatments, to assist disabled people, etc. making it an essential element of modern health care system. Also, the right to health has been recognized as a basic human right by several international and domestic legal instruments, of which access to biomedical products also forms part.

[48] Competition Act, 2000, §18, Acts of Parliament, 2000 (India)

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Inadequate access to health services has adverse effects on the social and economic conditions of a nation. The State shall ensure that all sections of society have access to life-saving medicines. Regulations on anti-competitive practices maintain fair play in the market, which is essential for consumer welfare. Unless such activities are brought within the control of an authority it will disturb social welfare and create allocative inefficiency. It lowers productivity and lessens the quality of products. This ultimately affects the rights of patients to access affordable and good quality health care services. Application of competition law in healthcare sector ensures access to healthcare services in a better way as it prohibits every act detrimental to the interests of consumers.

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 [ISSN 2581-5369]