NATIONAL LAW SCHOOL OF INDIA UNIVERSITY, BENGALURU

DISSERTATION ON:

MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL INDUSTRY AT ITS IMPACT ON INNOVATION

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PROF. DR. T.S SOMASHEKHAR

PROFESSOR OF ECONOMICS

NLSIU, BENGALURU

SUBMITTED BY:

RAHUL SIMHA. N

(M23068)

NLSIU, BENGALURU

DECLARATION

I, Rahul Simha. N, do hereby declare that this dissertation titled Mergers and Acquisitions the Pharmaceutical Industry and Its Impact on Innovation is the outcome of bona fide research undertaken by me in partial fulfillment of the Degree of Master of Laws (LL.M.) for the academic year 2023-24, at the National Law School of India University (NLSIU), Bangalore, under the guidance and supervision of Prof. Dr. T.S Somashekar. I declare that this dissertation is my own original work and all sources used have been properly acknowledged and cited. I further declare that I have not used any generative artificial intelligence (AI) and AI-assisted technologies in the writing process. I also declare that this work has not been submitted either in part or in whole for any Degree or Diploma at any other university.

Date: 30 April 2024 **RAHUL SIMHA.N**

Bengaluru **(M23068)**

CERTIFICATE

This is to certify that this dissertation titled ‘Mergers and Acquisitions

The Pharmaceutical Industry and Its Impact on Innovation’, submitted by

Rahul Simha. N (M23068) at the National Law School of India University, Bangalore,

in partial fulfillment of the Degree of Master of Laws (LL.M.) for the academic year

2023-24, was undertaken under my supervision.

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Bengaluru **Prof. Dr. T.S Somashekhar**

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I. ABSTRACT

The Indian pharmaceutical industry has emerged as one of the best performing sectors of the Indian economy and is undergoing rapid transformation. This rapid transformation is due to the increase in merger and acquisition (M&A) activity in the pharma sector. This study investigates the influence of M&A on innovation within the Indian pharmaceutical sector, with special focus on investment on research and development (R&D) investment, technological progress, filing of patents and the introduction of novel medicines.

II. REVIEW OF LITERATURE

Beena[1] in this research paper traces the history of mergers and acquisitions in India post liberalization of the economy in 1991. The main reason for mergers and acquisitions was to increase their product profile and it was found that the companies performed well post consolidation. She has analyzed CCI's analysis of the relevant market and the modifications ordered. Agarwal M and Bhattachajea A[2] analyzed M&A activity in India prior to the enactment of the Competition Act from 1973 to 2002 and found that removal of pre notification in the MRTP Act increased M&A activity post liberalization. Regulatory shocks were also one of the reasons in the reasons in increased M&A activity according to them. Bhattachajea A & Sindhwani F[3] in their study on the Indian Pharmaceutical sector give a brief overview of the sector in 2014. Six merges in the pharma sector were approved by the CCI when their study was conducted and they observed that many mergers were going under the radar of the CCI due to

[1] Beena, Mergers and Acquisitions in the Indian Pharmaceutical Industry: Nature, Structure and Performance, 2006

[2] Agarwal M and Bhattachajea A, Mergers in India: A response to regulatory shocks, Taylor Francis Ltd, 2006

[3] Bhattachajea A & Sindhwani F, Competition Issues in the Indian Pharmaceuticals Sector, Delhi School of Economics, 2014

higher threshold limits. They recommended the merger thresholds be reduced and reviewed for the pharma sector. Innovation being an important aspect of the study also found increased spending in R&D and the number of patent grants have not increased proportionately. Innovation competition is an important part of antitrust policy and framework, Spulber[4] urges the antitrust enforcement authorities to consider innovation competition in their economic analysis. Antitrust enforcement must move away from perfect and imperfect competition and horizontal and vertical merger analysis should consider development in innovation competition. Wang[5] in this research paper written in 2022 analyses the impact of Mergers on product prices and innovation in the United States of America. This study found that post the merger of pharma companies the innovation increased only in respect of rebranding and repackaging and did not result in innovation of new drugs. The study also found that consolidation was one of the reasons for product price increase and had implications on access to affordable healthcare. Schutz[6] has conducted a similar study as above in November 2023 to analyses the impact of mergers on prices and innovation in the pharmaceutical industry. This study reveals that the patent filing by companies post the merger has decreased and larger companies supplement their research and development through the acquisition of smaller companies. The findings of this study also negate the notion that mergers and acquisitions lead to better innovation and overall efficiency. The researcher concludes her study by recommending the regulatory authorities to consider the impact of consolidation on prices and innovation. Tyagi[7] conducts research on the merger control of the Competition commission of India and the effectiveness of the merger control

[4] Spulber D, Antitrust and Innovation, Journal of Antitrust Enforcement, 2023
[5] Bonaim´e Ye (Emma) Wang, Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry
[6] Sarah Schutz, Mergers, Prices, and Innovation: Lessons from the Pharmaceutical Industry
[7] Kalpana Tyagi, Mergers Between Generics: How Competition Commission of India Promotes Innovation and Access Through Merger Control?

policy in promoting innovation. She analyses the CCI's order in the Sun & Ranbaxy's order and its role in promoting innovation. The research has not gone into the details of R&D investment and patent filing. Therefore, by reviewing the existing literature this paper will conduct an analysis of the impact of mergers and acquisitions on the innovation and will attempt to fill the gap in Tyagi's research by analyzing the Sun and Ranbaxy merger and explore the aspect of R&D investment and patent filing post the merger.

III. RESEARCH OBJECTIVE

This research aims to study the history of merger control in India and the existing regulatory framework. It aims to evaluate the influence of mergers and acquisitions (M&A) within the Indian Pharmaceutical sector and compare it with case studies in USA and India. Ultimately this study seeks to understand the relationship between M&A activities, research and development (R&D) investment, technological advancements, and the introduction of novel medicines.

IV. RESEARCH QUESTIONS

1. What is the history merger control in India and USA? How are they regulated?
2. What impact does M&A activity have on innovation in the pharmaceutical industry? What are the indicators to measure its impact?
3. What happens to R&D investments and patent filing post mergers?

V. METHODOLOGY

This research employs a mixed-methods approach to study the impact of mergers and acquisitions (M&A) on innovation within the Indian pharmaceutical industry. By integrating both quantitative and qualitative techniques, this methodological framework aims to provide a comprehensive understanding of the complex interplay between mergers and acquisitions, regulatory influences, innovation in the pharmaceutical sector.

CHAPTER 1

1.1 OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN INDIA

The pharmaceutical sector plays a pivotal role in the economy of a country. It is progressing rapidly and was successful in producing a vaccine for COVID-19 in very quick time. Prior to the 1970's the pharmaceutical market in India was relatively small and both in terms of production and capacity. When India attained independence in 1947 the India's pharmaceutical market was dominated by multi national companies and they held most of the patents for almost all the pharmaceutical products[8].

India's growth trajectory in the pharmaceutical industry has been phenomenal in over the last few decades. From being a net importer of drugs in the 1970's, India is now a global exporter of drugs and vaccines[9]. The total value of the branded generics and patented drugs in the Indian retail market amounts to a whopping 141,102 crores[10]. The pharma industry in India is valued at $50 billion currently and is expected to increase to $65 billion in 2024 according to the National Investment Promotion and Facilitation agency[11]. The Indian Pharma industry accounts for 20% of the global generics and biosimilars supply. Indian pharma caters to 50% of Africa's generics, 40% of USA's generic demand[12]. The United Kingdom's 25% of all medicine demand is met by the Indian Pharma. The Govt of India to develop the pharma infrastructure in the country has allowed 100% Foreign Direct Investment in Greenfield Pharma projects which intend to build pharma infrastructure in the country[13].

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[8] Bhattachajea A & Sindhwani F, Competition Issues in the Indian Pharmaceuticals Sector, Delhi School of Economics, 2014, p. 8

[9] Competition Commission of India, Market Study on the Pharmaceutical Sector in India, 2021, p. 4

[10] Ibid

[11] "Pharmaceutical Industry in India: Invest in Pharma Sector" (*Invest India*) <https://www.investindia.gov.in/sector/pharmaceuticals>

[12] Ibid

[13] Ibid

1.2 RECENT TRENDS IN M&A IN THE INDIAN PHARMACEUTICAL SECTOR

Along with rapid progress the pharmaceutical industry in India is also witnessing an increase in mergers and acquisitions. The 3rd quarter of the previous financial year 2023-24 witnessed hectic M&A Activity and the 3rd quarter of 2023 alone witnessed mergers and acquisition deals worth $2.7 billion according to G&T Bharath Healthcare and Pharma deal tracker report. The 1st quarter of the new financial year witnessed a dip in M&A activity and mergers and acquisition deals worth $409 million was witnessed.

1.3 HISTORY OF MERGER CONTROL IN INDIA

Mergers, Amalgamations, Acquisitions and takeovers were regulated by the MRTP Act, 1969 prior to the enactment of the Competition Act, 2002. This law aimed to prevent concentration of economic power in the hands of the few by regulating monopolistic and restrictive trade practices. It was enacted based on the recommendations made by the Monopolies Inquiry Commission set up by the Central Government in 1964. It sought to control monopolies, prohibit monopolistic trade practices and restrictive trade practices. M&A under this Act were required to be approved by the Central Government through a notification. The MRTP Act was amended several times but it failed to stand the test of time and had to be repealed ultimately. It failed to define the term concentration of economic power and aimed at curbing monopolies rather than facilitating competition. The finance minister in 1999 in his budget speech expressed the intent of enacting a new law on competition as the MRTP Act had become obsolete.

1.4 RECOMMENDATIONS OF THE RAGHAVAN COMMITTEE

The Central Government in October 1999 constituted a committee under the chairmanship of S.V.S Raghavan to propose a modern competition law for India. The Raghavan Committee submitted its report on 22 May 2000 and

recommended the enactment of the Competition Act to prohibit activities which have appreciable adverse effects on competition.

The Raghavan committee recommended that only the combinations that threshold of assets and turnover be notified and approved by the Competition Commission of India. The focus of the competition policy was primarily on horizontal mergers which created a bad outcome. The committee was of the view that a merger should be challenged only if they reduce or harm competition and adversely affected competition.

1.5 REGULATION OF COMBINATIONS UNDER THE COMPETITION ACT, 2002

The Central Government based on the recommendations of the Raghavan Committee repealed the MRTP Act and enacted the Competition Act, 2002 to suit the modern requirements. Section 5 and 6 of the Competition Act deal with the regulation of combinations. The ambit of Section 5 extends to only those combinations which are of the prescribed size in terms of assets and turnover. It prescribes the thresholds for filing the notice with the Competition Commission of India for approval. The thresholds are defined at the enterprise level and at the group level and assets and turnover in India and worldwide. The threshold limit prescribed by the Competition Act, 2002 is explained in Table 1[14].

[14] SM Dugar, Guide to Competition Law, 6th Edition, Volume 1, Pg 36

		Assets		Turnover
Enterprise Level	India	More than ₹2000 crore	or	More than ₹6000 crore
	World Wide with India Leg	More than $1 billion with at least ₹1000 crore in India		More than $3 billion with at least ₹3000 crore in India
Group Level	India	More than ₹8000 crore	or	More than ₹24000 crore
	World Wide with India Leg	More than $4 billion with at least ₹1000 crore in India		More than $12 billion with at least ₹3000 crore in India

Section 6 of the Competition Act makes it mandatory for any person or enterprise entering into a combination to give a notice to the Competition Commission. Combinations once notified under Section 6 shall come into effect only after the Competition Commission has passed an order under Section 31 or only after passing 210 days of filing a notice. The parties to the combination had to give a notice within thirty days earlier, which was later reduced to seven days under the Competition Amendment Act, 2007. The Competition Commission is empowered to levy a fine on the parties if they fail to file a notice within the time frame prescribed under Section 6. In the Jet and Etihad airways deal[15] the commission imposed a penalty of ₹1 crore on the parties for non-compliance with the provisions of Section 6. Etihad Airways acquired 24% stake in Jet Airways and filed a notice before the commission for its approval. All the binding documents such as investment agreement, Shareholder's agreement and Commercial co-

[15] Jet-Etihad Deal, Combination Registration No. C-2013/05/12 as in SM Dugar, Guide to Competition Law, 6th Edition, Volume 1, Pg 635

operation agreement were executed on 24 April 2013 and the parties filed a notice under Section 6 on 01 May 2013. The Commission found that prior to the filing of the notice certain provisions of the Commercial co-operation agreement were already operational. Hence a penalty of ₹1 crore was imposed on the parties.

1.6 COMPETITION AMENDMENT ACT, 2023

India's competition regime is still at a nascent stage compared to other regimes in the world. In its nascency shortcomings are bound to appear and a periodic review of the regime is necessary. The Ministry of Corporate Affairs (MCA) in 2018 set up the Competition Law Review Committee (CLRC) headed by Injeti Srinivas to review the Competition Act, 2002 and recommend amendments to suit the prevailing conditions. The CLRC submitted its report to the MCA and recommended several amendments to the Competition Act, 2002.

The CLRC while reviewing the provisions on combinations suggested the introduction of "Green Channel Combinations" to facilitate business growth and reduce delay in transactions. Green Channel Combinations are such combinations that are not likely to cause appreciable adverse effects on competition and are approved automatically. The CLRC recommended this type of mergers based on the data available from 2011 to 2018 where the Competition Commission had recommended changes to only 2.1% of the mergers and did not block a single merger.

The CLRC reviewed the existing thresholds for combinations and felt the need to introduce a new deal value threshold as the existing thresholds based on assets and turnover were not accurate to measure the effect on competition. A deal value threshold any deal that crosses the threshold of ₹2000 crores have to notified with the Commission. The MCA incorporated these recommendations, introduced the Competition Amendment Bill, 2020 and invited comments from the public. The Deal value threshold recommended by the CLRC was incorporated under Section

5(1)(d). Section 6 was also amended and prior to the amendment parties to the combination had to wait for 210 days after filing the notice to deem that a merger has been approved. This has been significantly reduced to 150 days.

CHAPTER 2

2.1 MEGER BETWEEN SUN PHARMA AND RANBAXY

The merger between Sun Pharma and Ranbaxy is a landmark case in the history of Indian competition law as it was a merger between two giants of the pharmaceutical industry. Sun Pharma is a pharmaceutical company established in the year 1983 and has its manufacturing facility in Vapi, Gujarat. Sun Pharma decided to go public in 1994 and is currently listed on the Bombay stock exchange. Sun Pharma specializes in the field of therapeutics, Active Pharmaceutical Ingredients (API), oncology, genealogy etc.

Ranbaxy Laboratories was established in the year 1961 and was listed on the Bombay Stock Exchange, National Stock Exchange and Luxembourg Stock Exchange. It had its ground operations in 43 countries and manufacturing facilities in 21 countries across the world. Daiichi Sankyo a Japanese pharma giant acquired a controlling stake in Ranbaxy Laboratories in 2008. After this acquisition, Ranbaxy ran into a lot of trouble and started incurring losses. The USFDA import alerts on Ranbaxy's manufacturing facilities in India and was found guilty of felony charges in 2013 for selling adulterated drugs. Ranbaxy had to pay a huge penalty of $500 million which severely damaged its reputation. Following this fiasco Sun Pharma and Ranbaxy to enter into a merger in 2014 and a notice was filed with the Competition Commission of India under Section `6(2) of the Competition Act[16].

[16] Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited, Combination Registration No. C-2014/05/170

2.1.1 CCI'S ANALYSIS OF THE MERGER

Sun Pharma and Ranbaxy are both companies involved in the manufacture of generic copies of original medicines and they also produce a small number of medicines with licensed molecules. Since generic brands of different chemical formulations can be considered substitutable the Commission defined the relevant product market at the molecule level i.e. medicines based on the same active pharmaceutical ingredients[17]. The Commission also considered the territory of India to be its geographical market as the products of both Sun Pharma and Ranbaxy were available throughout India.

The Commission further in its investigation found that there were horizontal overlaps in forty-nine relevant markets that were likely to cause appreciable adverse effect on competition[18]. The Commission also identified two such relevant markets where Sun Pharma was already marketing and selling products which are in Ranbaxy's pipeline[19]

RELEVANT MARKETS WITH ADVERSE EFFECTS ON COMPETITION

There were seven such relevant markets out of forty-nine where the Commission was of the opinion that the merger between the two parties would cause adverse effects on competition.

Tamsulosin + Tolterodine, Rosuvastatin + Ezetimibe, Leuprorelin, Terlipressin Olanzapine + Fluoxetine, Levosulpiride + Esomeprazole, Olmesartan + Amlodipine + Hydrochlorothiazide were the seven markets identified by the Commission having adverse effect on competition[20]. In all these relevant markets the Commission was of the opinion that the combination would either they would

[17] SM Dugar, Guide to Competition Law, 6th Edition, Volume 1, Pg 743
[18] CCI Order in Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited, Combination Registration No. C-2014/05/170, Pg 7
[19] Ibid
[20] CCI Order in Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited, Combination Registration No. C-2014/05/170, Pg 7

create a near monopoly or it will significantly lessen the competition where in there would be less choices to consumers.

In the relevant market of **Tamsulosin + Tolterodine, Rosuvastatin + Ezetimibe & Leuprorelin** - Ranbaxy was a market leader with 40-45% and Sun Pharma also had a significant share of 30-35%. The combination would result in a situation of a near monopoly with a market share of almost 90%. Hence the Commission was of the opinion that the combination would cause adverse effect on competition.

In the case of **Terlipressin Olanzapine + Fluoxetine, Levosulpiride + Esomeprazole, Olmesartan + Amlodipine + Hydrochlorothiazide** – Sun Pharma was a market leader with 50-55% market share and Ranbaxy had negligible market share. The combination would have resulted in a combined market share of 65-70% which is not a situation of monopoly. In these relevant markets the number of competitors along with Sun Pharma and Ranbaxy were one or two in some cases. The combination would significantly reduce competitors in market and hence Commission was of the opinion that the combination would cause adverse effect on competition.

2.1.2 MODIFICATIONS RECOMMENDED BY THE CCI

The Competition Commission of India analyzed this merger and came to the conclusion that the combination would cause appreciable adverse effects on competition. However, the Commission did not block this combination but approved it with certain modifications. The modifications were as follows[21]: -

i. Sun Pharma was directed to divest all the products containing Tamsulosin and Tolterodine marketed under the brand name Tamlet[22]

[21] CCI Order in Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited, Combination Registration No. C-2014/05/170, Pg 29
[22] Ibid

ii. All products containing Leuprorelin which are currently marketed and supplied under the Lupride brand name were to be divested by Sun Pharma

iii. Ranbaxy was asked to divest – Terlibax containing Terlipresslin, Rosuvas containing Rosuvastatin + Ezetimibe, Olanex F, Raciper L, Triolvance[23]

Along with this modification the Commission specifically mentioned in its order that the combination shall not come into effect until the divesture of the following brands take place. The parties were also not supposed to acquire whole or any part of the divested products for a period of five years.

The Commission's order overall aimed at preserving competition in the market and its modifications ensured that the combination would not result in a monopoly. The Commission correctly analyzed the AAEC in relevant market in the case of Terlipressin where the combination's market share would be about 65-70%. In this relevant market there would be only one competitor i.e. Alembic with about 20% market share left and the number of competitors would reduce from three to two. The modification also ensured consumer welfare by ordering the divesture of brands in the seven relevant markets causing adverse effects.

[23] Ibid

CHAPTER 3

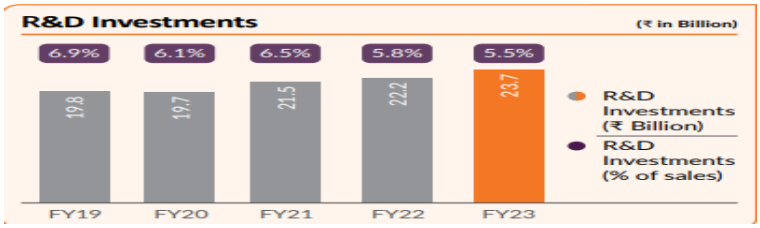
3.1 INNOVATION POST THE MERGER

A merger can have its own implications on innovation post the merger. To test the impact of the merger of Sun Pharma and Ranbaxy, two indicators have been chosen. The indicators are spending on Research and Development and the number of patent filings made by Sun Pharma post the merger. The data has been taken from the annual report published by Sun Pharma's annual report of 2022-23.

INVESTMENT IN RESEARCH AND DEVELOPMENT

Sun Pharma's investment in Research and Development for the year FY23 stood at ₹23,676 million i.e. ₹1,482 million increase in investment compared to FY22. An upward trend can be observed in Sun Pharma's investment in Research and Development. From FY14 the investment in R&D rapidly increased from ₹10, 418 million in FY14 to ₹23,138 million in FY 17[24]. From FY18 onwards a dip in R&D investment can be seen till the year FY 20. The investment decreased by ₹3402 crores to ₹19,736 million in FY 20. Investment again assumed an upward curve in FY21 and has been steadily increasing since then. The current investment of Sun Pharma stands at approximately around ₹24 billion which is roughly around 5.5% of its total sales. It is interesting to note that the amount of investment has gone up every year but the R&D investment in percentage of sales has decreased from FY 19.

[24] Annual Report 2022-23, Sun Pharmaceutical Industries Limited, Pg 3



Sun Pharma has invested significant sum of money towards Research and Development over the last ten years, however it is important to test whether it has resulted in the filing of new patents and innovation of novel drugs. In its annual report of 2022-23, Sun Pharma has filed 2,346 patents and 1,665 have been approved by the authorities. It has filed 616 Abbreviated New Drug Applications before the USFDA and 519 have been approved[25]. Merger of Sun Pharma and Ranbaxy has had a positive impact on innovation considering the data from these parameters.

[25] Ibid at Pg 32

CHAPTER 4

4.1 MERGERS CONTROL IN THE UNITED STATES OF AMERICA

The Merger control regime in the United States of America is perhaps the oldest in the entire world. The US Congress passed the first Antitrust legislation the Sherman Act in 1890, it mainly dealt with the restraint of trade and did not deal with mergers specifically. It extended to merges only when it was shown to the Supreme Court that the very purpose of the merger was to restrain trade[26]. Industries started to flourish post the civil war in the US and new challenges started emerging and the US Congress enacted the Clayton Act in 1914 to deal with these challenges. The Clayton Act prevented specific business transactions and anti-competitive acquisitions. Section 7 of the Clayton Act prohibits any acquisition of "stock or other share capital of another corporation . . . where the effect of such acquisition may be to substantially lessen competition between the corporation whose stock is so acquired and the corporation making the acquisition . . .."[27]

4.1.1 ENFORCEMENT AUTHORITIES

The Department of Justice's (DOJ) antitrust division and the Federal Trade Commission (FTC) are in charge of enforcing antitrust laws in the US. The DOJ is an agency that is an executive arm of the federal government. It is headed by the Attorney General and the Assistant Attorney General heads the antitrust division of the department of Justice[28]. The Federal Trade Commission is an independent regulatory body which has investigative, prosecutorial and adjudicative authority. It has five Commissioners who are nominated by the President with a term of seven years. The FTC has six Bureaus and the Bureau of

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[26] "The Evolution of U.S. Merger Law" (*Federal Trade Commission*, July 25, 2013) <https://www.ftc.gov/news-events/news/speeches/evolution-us-merger-law>

[27] Ibid

[28] Rowley and Baker, International Mergers – The Anti-Trust Process, Sweet and Maxwell, 1991, p. 464

Competition and Bureau of Economics handle the merger investigation and litigation[29].

4.1.2 AMENDMENTS TO THE CLAYTON ACT

The Clayton Act, 1914 did not deal with vertical mergers and conglomerate mergers and this loop hole was identified by the DOJ and the FTC and they urged the congress to amend the Clayton Act. No amendments were made to the Clayton Act as the world during the 1930's was recovering from the after effects of the First World War and in the 1940's instability increased due the Second World War. In 1950, the Celler-Kefauver amendments were introduced, making the Clayton Act applicable to asset acquisitions and to acquisitions involving firms other than direct competitors[30]. These amendments were brought in to restrict the economic concentration in the American economy. The Clayton Act was amended again in 1976 and the Hart-Scott-Rodino Act for the first time introduced the Premerger notification. Prior to 1976, parties were free to merge and the details of the merger would come out only after the deal was finalized. The Hart-Scott-Rodino Act prescribes a size of a person and size of transaction test to determine whether filing is required. The size-of-transaction test is satisfied if the acquirer would hold an aggregate total amount of voting securities and assets of the target in excess of US$101 million. Transactions in which holdings post-acquisition will be valued between US$101 million and US$403.9 million are reportable only if the size-of-person threshold is also met: either the acquiring or acquired person must have total assets or annual net sales of at least US$202 million, and at least one other person must have total assets or annual net sales of US$20.2 million[31].

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[29] Ibid

[30] "The Evolution of U.S. Merger Law" (*Federal Trade Commission*, July 25, 2013) <https://www.ftc.gov/news-events/news/speeches/evolution-us-merger-law>

[31] "Spotlight – The merger control regime in USA" (Lexology, August 6, 2022) <https://www.lexology.com/library/detail.aspx?g=216423cb-0156-4c62-97bc-81747db845b6>

The Competition Policy in the US has also undergone changes and differences can be seen in every decade of its enforcement. In the 1960's the US Supreme Court sought to prevent concentration of economic power. In the Philadelphia National Bank Case[32], the Supreme Court emphasized on the importance of market share and opined that competition will be healthy in market which has multiple players with significantly less market share. In the 1970's emphasis shifted from market shares to non-statistical factors. Competitive harm was measured based on factors such as the potential effects on the industry as a whole. This continued in the 1980's where factors such as market participants, foreign competitors and entry barriers were also considered while evaluating competition harm[33]. Consumer welfare became the center of the antitrust policy in the 1990's and a variety of other things such as quality of products, innovation, prices of products were being looked at. Protection of consumer welfare along with merger efficiencies gained prominence. The current competition policy aims at promoting societal good and goes beyond efficiency and consumer welfare to include aspects such as sustainability and privacy[34].

4.2 MERGER BETWEEN PFIZER AND WYETH

Pfizer is one of the biggest pharmaceutical companies in the world which is over 175 years old. It has under its portfolio patents for various medicines and is involved in the production of medicines in cardiology, oncology and immunology. Pfizer has made significant investments in innovation and was one of the pharmaceutical companies to develop a vaccine for Covid-19. Pfizer being a pharma giant has made 43 acquisitions and has approximately spent $332

[32] 374 U.S. 321
[33] Rowley and Baker, International Mergers – The Anti-Trust Process, Sweet and Maxwell, 1991, p. 463
[34] "Spotlight – The merger control regime in USA" (Lexology, August 6, 2022) <https://www.lexology.com/library/detail.aspx?g=216423cb-0156-4c62-97bc-81747db845b6>

billion for its acquisitions[35]. It most recently acquired pharma company Seagen a global biotech company involved in the production of cancer medicines for $43 billion[36]. One of the most prominent acquisitions of Pfizer is its acquisition of Wyeth in 2009 for $68 billion. Wyeth was a Pharmaceutical which was founded in 1860 and became a wholly owned subsidiary of Pfizer in 2009 post its acquisition.

Pfizer's huge investment in acquiring Wyeth was motivated by its lack of research and development in the biotech sector. Pfizer's strategic move aimed at boosting its revenue and increasing its product line. Wyeth had 22 products in its pipeline ranging from oncology to women's health under various phases of trail, it's acquisition would solidify Pfizer's position[37]. The deal would further help Pfizer diversify into injectable vaccines and acquire Wyeth's Prevnar vaccine which was for treating arthritis is children. This deal would have a profound effect on the financial situation of Pfizer as it had to layoff 8000 workers just after the merger[38].

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[35] "43 Acquisitions - Pfizer" <https://tracxn.com/d/acquisitions/acquisitions-by-pfizer/__xyg9oYmOnhITPLamLtTyQOduT8SRmMbg5vRv1SWpJwU>

[36] "Pfizer Completes Acquisition of Seagen | Pfizer" <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-seagen>

[37] "Pfizer Acquires Wyeth in the Industry's Largest-Ever Takeover Deal" (January 27, 2009) <https://www.spglobal.com/marketintelligence/en/mi/country-industry-forecasting.html?id=106595917#:~:text=Both%20firms%20registered%20pressures%20in,in%20the%20periods%20under%20review.&text=The%20acquisition%20of%20Wyeth%20by,in%20the%20next%20five%20years.>

[38] "Pfizer Completes Acquisition of Seagen | Pfizer" <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-seagen>

4.2.1 FTC'S REVIEW OF THE PFIZER'S ACQUISITION OF WYETH

This was the first merger to be reviewed by the FCT under President Obama's regime in the US. The Federal Trade Commission reviewed the merger after analyzing many relevant markets and approved it with modification. The FTC found horizontal overlaps in animal health supplies as both the companies were one of the largest manufacturers of animal health supplies. Fort Dodge – the animal health division of Wyeth and Pfizer would have about 60% of the market in cattle health products. The FTC ordered Pfizer to divest all its horizontal overlaps with Fort Dodge as the transaction would decrease the number of sellers in the animal product market which would increase prices and harm consumer welfare.

The FTC most importantly concentrated on the aspect of innovation and questioned the parties as to how the transaction would not decrease innovation in the entire industry[39]. The FTC also considered the potential innovation competition between the products in the pipeline. The parties were able to convince the FTC regarding innovation effects by showing the ongoing clinical trials for new molecules and the R&D spending. In 2008, both Pfizer and Wyeth had R&D investments north of $2 billion. The FTC particularly examined the innovation effects for treating Alzheimer 's as the products of both the parties overlapped. However, there were 50 pharmaceutical companies and 14 large pharmaceutical companies involved in the research and development of medicine for Alzheimer's which were undergoing various stages of clinical trials. Hence the FTC was satisfied that Pfizer's acquisition of Wyeth would not effect the competition in developing a cure for Alzheimer's[40]. The FTC also investigated whether Pfizer's acquisition of Wyeth would block the development of new

[39] Stempel S and Schiffer D, "Pfizer-Wyeth: Lessons from The First Major Merger Review Of The Obama Administration" (2010), The Threshold, Volume XI, p. 81

[40] Ibid p. 82

patents. The Commission previously in the merger between Ciba and Sandoz in 1996 and had ordered the companies to divest their IP rights in gene therapy products as there were only few companies in the market with the technology and intellectual property to produce gene therapy products. It was found that the patent positions held by the Pfizer and Wyeth were not complementary and would not foreclose specific innovation of others. The combined portfolio would not foreclose innovation was the conclusion reached by the FTC[41].

4.2.3 INNOVATION POST THE ACQUISITION

Pfizer over the years has acquired several pharmaceutical companies and it is important to test the effect of these acquisitions on innovation. Prior to the acquisition of Wyeth in 2008 the R&D expenditure of Pfizer was $7.9 billion in 2008 and $8.1 billion in 2007. In 2009 the investment again saw a slight dip to $7.8 billion[42]. There are multitude of factors that are to be considered in this particular situation to analyze the investment in R&D. In 2008, the recession in the US economy and Pfizer's acquisition of Wyeth in 2009 could have impacted the slight reduction in the investment in research and development. The investment figures indicate only a slight drop in investment and not a massive one. The investment in R&D have remained stable despite the influence of various external factors.

Pfizer as of January 2010 had 500 projects in development and out of which 133 were under Phase 1 of the trail. In the same time line 30 compounds in oncology, 11 in inflammation, 10 in Alzheimer's and six vaccines were under development and were yet to undergo regulatory scrutiny[43]. Pfizer's portfolio included 34 projects which were under Phase III trial[44].These figures also indicate a positive

[41] Ibid p.83
[42] Form 10k, Pfizer Inc, United States Securities and Exchange Commission, 2010, p. 5
[43] Ibid
[44] Ibid

outcome for innovation as immediately post the merger both investment and filing and development of medicines are happening simultaneously.

Pfizer has also invested massively in developing its facilities and has constructed a 70 Acre research and development facility in Andover, Massachusetts with state-of-the-art facilities. It contains laboratories, manufacturing units and purifiers. It has also constructed an API manufacturing facility in Franklin, Ohio which spans over 48,000 square feet. This facility manufactures herpin API which is helpful in clotting blood.

4.2.4 CURRENT INVESTMENT IN INNOVATION & R&D PIPELINE

In 2023, Pfizer acquired Seagun and improved its innovation potential in oncology. It performed a late phase clinical development for a new technology in end-to-end technology in oncology. Pfizer currently holds a strong innovation portfolio with a total of 112 projects out of which 41 projects are under phase 1 trial, 34 under phase 2, 32 under phase 3 and 6 intellectual property registrations in 2023[45].

In 2022, Pfizer had in it's R&D pipeline with a total of 110 projects out of which 34 projects were under Phase 1 trial, 37 under Phase 2, 23 under Phase 3 and 16 intellectual property registrations were made[46]. In 2021, Pfizer had in its R&D pipeline with a total of 89 projects out of which 27 projects were under Phase 1 trial, 25 under Phase 2, 27 under Phase 3 and 10 intellectual property registrations were made[47].

The Data over the past three years indicate that Pfizer has a total of 311 projects under various phases of development and 32 registrations were made over the same period of time.

[45] Form 10k, Pfizer Inc, United States Securities and Exchange Commission, 2023, p. 5
[46] Form 10k, Pfizer Inc, United States Securities and Exchange Commission, 2022, p. 5
[47] Form 10k, Pfizer Inc, United States Securities and Exchange Commission, 2021, p. 6

R&D INVESTMENT[48]

Costs and Expenses

Costs and expenses follow:

(MILLIONS)	Year Ended December 31, 2023	2022	2021	% Change 23/22	22/21
Cost of sales	$ 24,954	$ 34,344	$ 30,821	(27)	11
Percentage of *Total revenues*	42.7 %	34.2 %	37.9 %		
Selling, informational and administrative expenses	14,771	13,677	12,703	8	8
Research and development expenses	10,679	11,428	10,360	(7)	10
Acquired in-process research and development expenses	194	953	3,469	(80)	(73)
Amortization of intangible assets	4,733	3,609	3,700	31	(2)
Restructuring charges and certain acquisition-related costs	2,943	1,375	802	*	71
Other (income)/deductions—net[a]	(835)	217	(4,878)	*	*

The R&D investment for 2023 stood at $10,679 million, it declined from $11,428 million in 2022 and 2021 the investment in R&D stood at $10,360 million. The figures indicate stability in R&D investment during the pandemic and post the pandemic. The Covid-19 pandemic caused an economic crisis around the world and despite this the investment has remained quiet stable despite slight dip last year. These figures also indicate that post the acquisition of Seagun in 2023 there is only a small decrease in the R&D investment which may not have a great impact on innovation.

[48] Form 10k, Pfizer Inc, United States Securities and Exchange Commission, 2023, p. 39

CONCLUSION

Innovation is a critical part of the pharmaceutical industry and novel medicines have to invented from time to time to tackle the diseases like cancer. The Covid-19 pandemic emphasized the importance of innovation in the pharmaceutical sector. Indian companies were able to develop a vaccine only because of their investment in manufacturing facilities and research laboratories. Indian Pharmaceutical sector will play a major role in India's journey in becoming a developed nation. Encouraging competition in the pharmaceutical sector will play a key role in this regard.

As seen from the two case studies above M&A activity has boosted innovation, R&D investment, product development and patent filing. Innovation can be boosted if the M&A activity is regulated efficiently in the pharmaceutical sector. The Competition Commission of India till date has not blocked a single merger and has approved all the mergers with or without modification. The Competition Commission's analysis of the Sun Pharma Ranbaxy merger focused more on preventing adverse effects on competition and rightly ordered the parties to divest certain products in seven relevant markets. But the analysis did not go deeper into the aspect of innovation and the potential effects the merger could have on innovation. The Federal Trade Commission's analysis of the Pfizer's acquisition of Wyeth included both these aspects.

The new amendment to the Competition Act gives emphasis on the speed at which mergers are approved. Regulatory authorities have to be given sufficient time to assess the relevant markets as they are extremely complex. Emphasis needs to be on the correct assessment only then positive outcomes are possible.

Authors try to draw a correlation between R&D investments going up every year but patent filing and registration not going up in the same proportion. R&D investments not only go into discovery of new medicines but also into

developing laboratories and manufacturing facilities. Sun Pharma has 43 such facilities in India and Pfizer has ten manufacturing facilities all over the US. Patent filing cannot go up in the same proportion as the R&D investment as clinical trials in various stages take a lot of time to be completed. In case of Sun Pharma, the data indicates that over 70% of their filings have seen approvals and 32 registrations were seen in the case of Pfizer over the last three years. Hence, it is not correct to correlate the patent registration/filing and R&D investment as multitude of factors are to be considered. Overall, the impact of mergers and acquisitions have had a positive impact on innovation in the pharmaceutical sector.

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