MERGER CONTROL IN PHARMACEUTICAL SECTOR: OVERVIEW, TRENDS AND EU LAW

By *Aastha Mehta*[1]

ABSTRACT

In the research presented, author has taken up EU law as a starting point, and has analyzed it from competition law and mergers perspective. The pharmaceutical sector, one of the sectors linked intrinsically to our daily lives, it becomes pertinent to see how these companies strategize to keep themselves at the top of their game. The essence of the paper is, analyzing the merger and acquisition strategies through case studies, through EU regulations and legislations, and trying to understand the nitty-gritties that are quintessential to this sector. Competition law has a key role in mergers, and EU law is one such comprehensive framework, which the author has used to give a result that there seems to be a strong rearrangement of business tendencies in pharmaceutical companies to achieve different ends. Author has used a normative approach of using the existing literature and drawing up on it.

Keywords: EU law, Pharmaceutical sector, mergers and acquisitions, economics, competition law

INTRODUCTION

Merger and acquisition have often been associated with competition law and, it is not an understatement that, competition law policy often plays a pivotal role in making mergers and acquisitions successful. In this paper, the literature taken up, is European law (hereinafter referred as EU Law), and the entire theme focuses on competition law and mergers in pharmaceutical sector from EU perspective. The primary reason for choosing EU law is that it is well developed, codified and streamlined, which makes it easier to analyze.

Health care industry is one of the most important industries in the world, catering to lives of millions of people across the globe. This increases the duty of care on the regulatory authorities

[1] 4th Year Student, Amity Law School, Noida

to ensure that merger or acquisition of pharmaceutical or health care company does not result into anti-competitive situation in the sector. *The pharmaceutical industry is an important source of health care for billions of population globally and in India, which makes it highly regulated by various agencies and forums. The pharmaceutical industry is influenced by number of practices which may primarily relate to price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation polices, biotechnology and safety policies, drug regulation, data protection, trademarks and use of international non- proprietary names, drug promotion regulation, drug advertising regulation etc. Hence competition law has to work in tandem with all such diverse set of laws, polices and regulation governing the pharmaceutical sector.*[2] The inter-relation of mergers and competition law will be emphasized more clearly in the upcoming chapters. Our main focus will be to see how mergers work in pharmaceutical sector, and then see how EU law assesses the pharmaceutical firm mergers/ arrangements.

Pharmaceutical sector is not a constant industry, and rapid development in R&D is one of the main reasons, which requires pharmaceutical industries to keep abreast newer technology and to address the constant influx of challenges. Therefore, as a part of continuing business strategies, mergers and acquisitions are more preferred form of growth. However, one must see be aware, that in this paper we are essentially looking at horizontal mergers, since they are the typical form of mergers that have a crippling effect on competition balance, as compared to vertical or conglomerate mergers. [3]

REASONS FOR MERGERS AND ACQUISITIONS IN PHARMACEUTICAL SECTOR

Economies of Scale: In simple terms, economies of scale refers to the concept that with increase in production, the per unit cost fixed decreases, since cost of production is spread out over large numbers. Therefore, if a batch of 1000 drugs costs Company $300, then by merging with Company Y, the cost of producing the same 1000 drugs can be brought down to $30, which means average cost was earlier $30, and now it has come down to $3. The literature on this shows that especially for pharmaceutical industry the term used is "economies of scale and

[2] Centre for Trade and Development (CENTAD), 'Competition Law and Indian Pharmaceutical Sector' (*Competition Commission of India,* 2010) <http://www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf> accessed 1 April, 2016

[3] Richard Whish and David Bailey, *Competition law*, (Oxford University Press 2015) 865

scope"[4] which gives an indication on R&D scope and upward movement of the firms. This term of scale and scope further means that mergers are often used as a way of the two firms to increase the number of therapeutic areas in their R&D program.[5] Firms also prefer mergers and acquisitions to bring new technologies and research tools into the firm, so as to enhance the capability of the firm to enter into various areas of research and at the same time, cut costs on production by mass producing at a larger level.

Avoid situations of Patent cliff: Patent cliff is a metaphor used for a situation where major pharmaceutical companies are about to see expiration of their blockbuster drugs. Since evergreening of patents is not allowed in most jurisdictions, therefore mergers and acquisitions are seen as a means to ensure that a firm has a stable patent portfolio. The numbers aren't really favoring the big pharmaceutical companies. A study from 2011 shows as follows, "The 'patent cliff' started in 2011 when Pfizer's biggest anti-cholesterol blockbuster, Lipitor, went off patent. It was soon followed by Sanofi's best-seller anticoagulant Plavix in 2012. This phenomenon led to a $135 billion loss for the pharmaceutical industry in 2013 which represents nearly 20% of its turnover. In 2014, many pharmaceuticals lost their patents[6], which highly threaten their revenues, since blockbuster drugs lose 80% of their turnover when going off-patent.[7] To avoid this situation, restructuring is the only possible way, to ensure the firm's competitive existence and future potential in the market. This also increases the brand value of merging companies, thereby increasing market share. The example of Pfizer purchasing Wyeth for $68 billion is one example oft quoted in this area. [8] This strategy is often called filing the company's pipeline for newer drugs.

Other ancillary reasons: Speed of entering the market is one such reason whereby market place pressures are compelling the companies to design new methodologies of bringing promising

[4] Patricia M. Danzon, Andrew Epstein and Sean Nicholson, *Mergers and Acquisitions in Pharmaceutical and Biotech industries,* (Working paper series, 10536, 2004) p.2
[5] Henry Grabrowski and Margaret Kyle, 'Chapter 11: Mergers and alliances in pharmaceuticals: Effects on innovation and R&D productivity'in Kluas Gugler and B.Burcin Yurtuoglu (eds.) *The economics of corporate governance and mergers* (Edward Elgar 2006)
[6] --'Ten Top blockbuster drugs that lost patent in 2014' Drug Development Technology, <http://www.drugdevelopment-technology.com/features/featureten-blockbuster-drugs-that-lost-patent-in-2014-4445799/ > (2nd April 2016)
[7] Pauline Ollier, 'Patent cliff: Pharmaceutical industry is undergoing major changes' (*ERS innovation,* 2 March 2015) <http://www.ersinnovation.com/management-pharmaceutique/the-patent-cliff-pharmaceutical-industry-is-undergoing-major-changes/ > accessed on 2nd April 2016
[8] Duff Wilson, 'For Pfizer, A big deal and a test'(*New York Times,* 29 January 2009) <http://www.nytimes.com/2009/01/27/business/27chief.html?_r=0> accessed on 2nd April 2016

compounds to the global market as early as possible.[9] Some authors have also stated that mergers and acquisitions in pharmaceutical sector occurs due to the industry shockwaves [10] (a shockwave can be understood as a drastic change in technology, or change in policy/law which changes the entire economic situation) as well other have quoted that the motive behind restructuring of businesses in pharmaceutical sectors is to cope with the advent of strong generic markets in developing countries like India, which has substantially eaten up the market share of the innovation driven companies. [11]

These are some of the basic and most prevalent reasons, which are completely sector specific. In this section I have only taken up general reasons, and the next section I will deal with specific details.

MERGERS IN PHARMACEUTICAL SECTOR: AN OVERVIEW OF WORLD PRACTICE

In this section, author deals with the different examples of mergers and acquisitions across the globe. The trend of restructuring is increasing in the field of pharmaceutical, with companies focusing on diversification as well as slimming down of the company.[12] It is also seen, that top 20 pharmaceutical firms have retained their position because of their successful merger and acquisitions activity as well as even strategic alliances. [13] Author would include a word of caution here, that all the material focusing on pharmaceutical sector is essentially using different terms for combinations. Some have been calling these deals between firms as mergers, some call it takeover and some call it acquisition. However, the personal conclusion is that whatever be the terminology, no one specific kind of restructuring is being followed, and therefore such deals are a combination of different kinds of arrangements.

[9] Divya Christopher and Miss Arshima,'Pharmaceutical Mergers and Acquisitions'(2013) 1 IJAR 119, 120
[10] David J Ravencraft and William F. Long 'Paths to create value in pharmaceutical mergers' in Steven N. Kaplan (ed.) *Mergers and Productivity,* (Chicago University Press 2000)
[11] Vidhisha Vyas, Krishnan Narayanan and A. Ramanathan, 'Determinants of mergers and acquisitions in Indian Pharmaceutical industry' (2012) 5(9) Eurasian J. Bus. & Eco. 79-102.
[12] Amy Nordrum, 'Pfizer-Allergen Merger: Why are pharmaceuticals so eager to make deals?' (*IB Times,* 30 October 2015) <http://www.ibtimes.com/pfizer-pfe-allergan-plc-agn-merger-why-are-pharmaceutical-companies-so-eager-make-2162555> accessed on 2nd April 2016
[13] Myoung Cha and Theresa Lorriman, 'Why Pharma megamergers work'(*Mckinsey* February 2014) <http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/why-pharma-megamergers-work> accessed on 2nd April 2016

There are three types of combinations that have been studied here, and this primary analysis has been taken from available literature on the subject.[14] Here are a few examples that global market has seen in restructuring.

CASE STUDIES

1. Buy Growth companies: A classic example of merger turned profitable

Buy Growth companies typically have their target on achieving growth in the business, there basic essence is to have a merger to increase sales and overall profit generation.

Roche and Genentech Example

Switzerland (Basel) based company Hoffman Roche, announced its friendly merger in 2009 with California based Genentech. The terms or provisions of this agreement were as follows, *Roche intends to acquire all outstanding shares of Genentech for US$95.00 per share in cash. Research and early development to operate as an independent center; South San Francisco site to become headquarters of combined U.S. commercial operations; Genentech's unique culture to be maintained. Innovation will be enhanced through a diversity of research approaches and sharing of IP, technologies, partnerships and other key assets.*[15]

There were apprehensions that the work cultures of both these companies being drastically opposite, the merger might not be able to sustain itself. Roche being a traditional, disciplinarian kind of work setting, and Genentech a more youthful, relaxed, innovative style of working. Culture clash are often deal breakers in cases of merger.[16] However, a major part of the success of this merger was the autonomy of the Genentech, and the separate work culture of both these merging companies, which Roche very well retained. There is consensus in all the policy reviewers and consultants that the reason behind the success of this combination is the attention given to people or the researchers as the balance sheet assets, or to put it differently the human value generated by scientists and researchers being the utmost focus of this integration. The deal proved beneficial, since Genentech could focus on its core competency i.e. innovation, and Roche got an array of new anti cancer drugs from the efforts of Genentech like, **Rituxan**

[14] K. Sreekanth Reddy and others, 'Merger and Acquisition perspective in Pharmaceutical industry ' [2014] 6(2) International pharmaceutical industry 10

[15] --'Media Release' Roche website, <http://www.roche.com/media/store/releases/med-cor-2009-03-12.htm> accessed on 2nd April 2016

[16] Liz Fealy & Dave Kompare, 'When the worlds collide: culture clash' (2003) 24 (4) Journal of Business strategy 9-13.

(anti-cancer drug treating chronic lymphatic leukemia), **Avastin** (anti-cancer drug which treats brain tumor and kidney cancer), **Herceptin** (anti cancer drug used for breast cancer and stomach cancer) used to create and **Lucentis** (used for treating age related mascular degeneration), which proved to be major revenue generating drugs for Roche.

However, there are not many examples of such success stories. Unfortunately for pharmaceutical executives, the success of the Roche-Genentech deal is generally the exception to the rule. Numerous studies show that alliances in most industries have a failure rate exceeding 50 percent. [17]

2. Buy Scale Companies: An apt case for seeing the economics behind mergers in this sector. These are companies which intend to increase economies of scale and bolster the R&D and patent portfolio of the company.

Merck-Schering plough acquisition

Merger of Merck and Schering Plough at $41.1 billion was termed as the second largest tie-up and restructuring arrangement in the pharmaceutical sector after Pfizer-Wyeth which merged at above $60 billion. Though a merger agreement was signed, it was essentially an acquisition, since Schering Plough was renamed Merck, 68% of the new company's shares were to be held in favor of Merck. This arrangement was specifically approved under European Merger regulations as not being anti-competitive in nature, and detailed analysis of its European market was undertaken to ensure it does not damage the European drug market.[18]

There were multiple reasons for mergers but the major reason was to increase the innovation of new drugs, to streamline the company, and to capitalize on Schering's resources. *Merck executives said the companies were a good match because Schering-Plough would complement Merck's lineup of prescription drugs, double the number of drugs in late stages of development to 18 and expand its push into cancer and brain therapies. Merck predicted $3.5 billion in yearly savings after 2011, including a 15% cut in the combined company's 106,200 jobs*. [19] It is also an important case study with respect to what happens to existing drugs which are marketed in joint collaboration, if the one of the company is acquired by another company. Drugs Remicade and Simponi, were distributed and marketed between Johnson and Johnson

[17] Jeff Cohen, William Gangi and others, 'Strategic Alternatives in Pharmaceutical Industry' (*Kellogg School of Management*)
<https://www.kellogg.northwestern.edu/research/biotech/faculty/articles/strategic_alternatives.pdf> accessed on 2nd April 2016

[18] Case No. COMP/M.5502/Merck-Schering Plough, Regulation (EC) No. 139/2004 Merger Procedure para 117

[19] Johnathan Rockoff, 'Merck to buy rival for $41 Billion' (*Wall Street Journal*, March 10, 2009)
<http://www.wsj.com/articles/SB123659326420569463> accessed on 2nd April 2016

and Schering Plough, by way of an agreement, and Johnson and Johnson did raise concerns over the acquisition of Schering by Merck. If Johnson and Johnson revokes its obligations under distribution agreement then it results into a lot of loss for Merck, since it has to do away with potential revenue from such blockbuster widely selling drugs and drug asset for itself. However, in 2011, an agreement was reached between Johnson & Johnson and Merck, which saw a conclusion of arbitration proceedings initiated by Johnson and Johnson. The **division of distribution** is as follows,

Under the terms of the amended distribution agreement, Merck's subsidiary, Schering-Plough (Ireland) will relinquish exclusive marketing rights for REMICADE and SIMPONI to Johnson & Johnson's Janssen pharmaceutical companies in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific ("relinquished territories"), effective July 1, 2011.* ***Merck will retain exclusive marketing rights throughout Europe, Russia and Turkey ("retained territories").*** *The retained territories represent approximately 70 percent of Merck's 2010 revenue of approximately $2.8 billion from REMICADE and SIMPONI, while the relinquished territories represent approximately 30 percent.*[20]

3. Using Different strategies: An example of concoction of strategies used according to situation and market scenario. There are certain mergers/arrangements which do not have one core line of thought, but it undertakes multiple methods and agreements for integration

Pfizer-Wyeth case

It can be said Pfizer is on an acquisition spree, with three major acquisitions after 2000, i.e. Warner Lambert in 2000, Pharmacia in 2003, and now Wyeth in 2009 at $68 billion. Pfizer has adopted major cuts in R&D in its own laboratories, and is now investing hugely in merger agreements[21], shifting all its research bases into the companies which it is acquiring. The strategy adopted is getting hold of strong companies with varied pharmaceutical assets, newer drugs, and cutting down on its own employee number and research institutes. Along with being touted as the biggest merger in pharmaceutical sector, it has numerous benefits like **resources complementarities**.[22] When a company with expertise in one area merges with other company with different expertise area, the combined company will have multiple areas of expertise, and it will result into diversification, leading to higher consumer base. Pfizer's example is quoted

[20] --'Merck and Johnson & Johnson reach agreement on distribution rights of Remicade and Simponi' <http://www.investor.jnj.com/releasedetail.cfm?releaseid=569376 > accessed on 2nd April 2016

[21] John L. LaMattina, 'The impact of mergers on pharmaceutical R&D' (2011) 10 Nature Review Drug Discovery 559-560.

[22] John Graham and others, *Corporate Finance: Linking theory to what companies do* (Cenage Learning 2009) 817

in this aspect since Wyeth has a strong hold over biotheraupetics and Pfizer has strong organizational, financially sound and secure environment for innovation to further grow. This merger has also been passed and cleared under EU law, ensuring that competition is not stifled in European market. [23]

The conclusion of these case studies prove two things, firstly the trend of mergers and acquisitions in pharmaceutical industries is here to stay, and its future seems bright with more companies opting for it. Secondly, the reason for major drive in mergers in this sector, is the inherent nature of growth required for survival, with new diseases coming, new and profitable research is required by companies, and mergers provide an easy way of accumulating forces and resources of two companies to grow.

A LOOK AT EU LAW AND ITS RELATION TO PHARMACEUTICALS

In this section, author now focuses on competition law provision under the EU law, which are referred as merger control provisions. Firstly, jurisdiction, procedure and then issues under EU law will be discussed. Then author will discuss pharmaceutical sector and the effect of merger control provisions under EU law. European Commission has emphasized on the role of EU law to protect consumer welfare from the effects of monopolistic market. [24]

EU Law on merger control

What does one mean by merger control? It refers to competition law, and reviewing mergers and other arrangements from the perspective of competition in the market, and thereby ensuring firms do not undertake something indirectly which would directly be prohibited under competition laws. The main law in EU for merger control is EC Merger Regulations and Implementation regulation, Council Regulation EC No.139/2004. [25] Further implementation of merger control and detailed provisions are governed under EC No. 802/3004.[26]

Threshold

[23] Case No. COMP/M.5476-Pfizer/Wyeth, Regulation (EC) No 139/2004 Merger Procedure, para. 474
[24] European Commission, *XXXIst Report on Competition Policy* (General Reports on Activities of European Union 2001, 2002) para 252
[25] Council Regulation (EC) 139/2004 on the control of concentrations between undertakings (EC Merger Regulation) [2004] OJ L24/1
[26] Council Regulation (EC) 802/2004 implementing Council Regulation (EC) 139/2004 on control of concentrations between undertakings [2004] OJ L133/4

There is dual regulation for competition assessment on merger, one which occurs under the national law of the EU member states, and the other which is done European Commission for those concentrations which have a "community dimension". The former are those concentrations (which is another term for arrangements) which do not qualify to the threshold prescribed under EU Law. The latter fall within the jurisdiction of European Commission, and are assessed as per its impact on "community dimension". What constitutes as a concentration is defined under Article 3(1)(b) of the Regulations.

In order to decide whether a merger is subject to review under EU law or National competition law, one needs to see the threshold the combination crosses. A transaction is said to have a community dimension, if

The primary thresholds are satisfied if both:

1. The combined aggregate worldwide turnover (in the preceding financial year) of all the undertakings concerned exceeds EUR5 billion (about US$6.6 billion).

2. The aggregate Community-wide turnover of each of at least two of the undertakings concerned exceeds EUR250 million (about US$332 million).[27]

Where these thresholds are not met, the secondary thresholds apply and are satisfied if all of the following criteria are fulfilled:

1. The combined aggregate worldwide turnover of all the undertakings concerned exceeds EUR2.5 billion (about US$3.3 billion).

2. In each of at least three member states, the combined aggregate turnover of all the undertakings concerned exceeds EUR100 million (about US$133 million).

3. In each of those three member states, the aggregate turnover of each of at least two of the undertakings concerned exceeds EUR25 million (about US$33.2 million).

4. The aggregate Community-wide turnover of each of at least two of the undertakings concerned exceeds EUR100 million (about US$133 million).

However, even where the primary or secondary thresholds are met, there is no Community dimension if each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same member state (the "two-thirds" exception).[28] However even if these criteria are not met, national authorities still have jurisdiction to assess the arrangement in question.

Procedure

[27] European Commission, *XXXIst Report on Competition Policy* (General Reports on Activities of European Union 2001, 2002) Article 46(2)

[28] *Ibid* Article 46(3)

There needs to be a notification given to EC on a proposed merger, or any arrangement. If the merger/arrangement is within threshold, no elaborate check is required, but if it is above threshold, full investigation is required. In phase I, Commission will gather full information, give questionnaires to competitors and consumers, and after this in the end there will be state of play meeting, in which the concentration can be cleared with or without remedies. Second option will be that if competition concerns are seen, then Commission will proceed to Phase II. In case of remedies being given, Commission will suggest certain modification which would guarantee competition. In phase II, an in-depth analysis is undertaken, and company's internal documents are seen, extensive economic data is taken. If positive effect of efficiency of merger is more than the negative effects of merger than merger will be allowed. If even after Phase II, competition is affected, a Statement of Objects (SO) is sent to parties as to the commissions preliminary objections. In phase II within 90 days, decisions need to be taken. In final decision, there are three options. One is merger is unconditionally accepted, secondly it is approved subject to remedies and thirdly merger is completely prohibited. [29]

Analysis of EU Merger Control law in pharmaceutical sector

Here lies the crux of the paper, where the author now focuses the research on EU merger control and drug industry. Any classical competitive analysis starts with differentiating the relevant product market and the relevant geographical market.

Relevant product market

There are two drug classification system which are used for understanding the relevant pharmaceutical market. [30]

1. **Anatomical Therapeutic Chemical Classification System** of WHO (known as ATC): Drugs are divided into 5 levels, according to organ or system on which it shows its effects and their chemical, therapeutic and pharmacological properties are also given in it.

2. **European Pharmaceutical Market Research Association** (EphMRA): It is an organization whose purpose is representing the huge pharmaceutical industry and its research backbone. They have a similar pattern of drug classification, and has 4 levels.

In both the systems, the narrowest level is the molecule level. EU Commission traditionally has been using ATC 3 i.e. ATC third level system as a starting point for its study on relevant

[29] *Ibid* article 4-10

[30] World Health Organization, *Introduction to Drug Utilization research* (Norway 2003)

market, for originator companies.[31] This third level indicates the different drug actions that will address the disease in question. For generic drug company mergers, it it is the ATC4 that is the analytical starting point for EU commission. [32]

A simple question arises however that what if an originator company acquires or merges with a generic drug manufacturer, and thereby restricts competition in both the originator and the generic field. Can one say that the product markets are the same for both of them? Firstly, when a patent of originator company expires, the manufacturing of generic drugs starts at a cheaper price, unless and until it has not been given for compulsory licensing earlier. It is fairly easy to understand that generic drugs are a substitute of the original patented drugs, and therefore Commission has many times used a ATC3 analysis also since both pharmaceuticals are based on same molecule. [33] Under EU law, relevant product market is defined in Article 7 of the Commission Notice on definition of relevant market in community law, which reads as follows, 'A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use'. [34] This shows how EU law focuses on substitutability of the products, as well the intended use. Generic drugs are economically more viable, have the same effect on the affected area of the patient as the original drug, and is legally marketed after regulatory authorities's permission. Further reasons for taking generic drugs and originator drugs as same market is the fact that for generic drugs to enter into market, they need to be bioequivalent of the original drugs, which indicates that without undertaking the clinical trial and R&D costs, the generic firm has made a copy of the original patented drug, without their being any difference in molecular structure, dosage, effect, treatment etc. further allowing generic drug companies to give a tough competition to originator companies after patent expiration, since generic drug companies offer the same medicine at a much lower price. [35]

Now, we analyze a layman distinction of OTC drugs and prescription drugs, and whether they have the same relevant market or different market. OTC drug is one which is sold without prescription, can be bought off the counter by a consumer based on his/her knowledge of the medical problem he/she is suffering from whereas prescription drug is sold with a doctor's prescription specifying the dosage, symptoms etc. and is given to consumer only after he/she

[31] Case No. COMP/M.5253 *Sanofi-Aventis/Zentiva* Regulation (EC) No. 139/2004 Merger Procedure, para 12; Case No. COMP/M.5295 *Teva-Barr* Regulation (EC) No. 139/2004 Merger Procedure, para 10.
[32] Case No. COMP/M. 6613 *Watson/Actavis* Regulation (EC) No. 139/2004 Merger Procedure para 7
[33] Case No. COMP/M.5253 *Sanofi-Aventis/Zentiva* Regulation (EC) No. 139/2004 Merger Procedure ,para 349
[34] Notice on the definition of relevant market for the purpose of EU competition law, OJ C372/6, art 7
[35] Case No. COMP/M.5476 *Pfizer/Wyeth* Regulation (EC) 139/2004 Merger Procedure, para 19

produces a doctor's prescription. EU Commission also realizes the difference between OTC and prescription drugs, and in Sanofi-Aventis as well as Tevv-Baar cases OTC and prescription drug segment were separately analyzed. *This is due to the fact that seriousness of disease (i.e., medical indications or dosage, or both, in some cases), strength of products (including possible side effects and harmfulness if misused), legal framework, marketing, distribution the medical indications (including their possible side effects), legal framework, marketing, distribution and rules on reimbursement of drugs all tend to differ between the two categories of medicines, even when the active ingredients are identical.* [36] Therefore, a merger between a company selling OTC drugs, and a company dealing with prescription drugs will not be a part of same relevant product market. Competition concern will arise if the merged entity's drugs are OTC and the drugs of the competitors are prescription bound, giving an edge to the merged company to market share over others, since for routine health issues, consumer prefer to get treated themselves, and do not consult a doctor. In one of the case, EU did not undertake OTC-Prescription drug analysis due to the fact that the companies entering into an arrangement and its competitors both had drugs which required a prescription. [37]

Relevant geographical market

EU law defines relevant geographic market as 'The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and Remand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighboring areas because the conditions of competition are appreciably different in those area'. [38] Assessing new geographic markets[39], gaining entries into generic drugs[40], developing markets in emerging economies[41] are one of the most sought after reasons in mergers and acquisitions in pharmaceutical sector. For assessing the markets, one needs to find the type of drugs that are sold by the companies. It often happens that an originator company merges with a biotech company which is small scale but has a potential for good products in future, to expand the base and geographical reach. This might raise competition

[36] Pablo Figueroa and Alejandro Guerrero, "EU merger control in pharmaceutical sector" in Ilene Knable Gotts (eds.) *The Merger Control Review* (Law Business Research Ltd., 2015)
[37] Case No. COMP/M.5778 *Novartis/Alcon* Regulation (EC) No. 139/2004 Merger Procedure, para 70
[38] Notice on the definition of relevant market for the purpose of EU competition law, OJ C372/6, art 8
[39] American Bar Association, *Pharmaceutical Industry Antitrust Handbook* (American Bar Association 2009)
[40] David Harding, 'Gaining Market Share in the generic drug industry through acquisitions and partnership' (*Thomas Reuters* December 2010) <http://thomsonreuters.com/content/dam/openweb/documents/pdf/pharma-life-sciences/white-paper/newport-deals.pdf> accessed on 3rd April 2016
[41] Michael A. Hitt, Jeffrey S. Harrison and R. Duane Ireland, *Mergers and Acquisitions: A guide to creating value for stakeholders* (Oxford University Press 2001)

concerns since the more the geographical area an entity covers after any arrangement, the more chances of abuse and dominance can be felt.

Commission has made a difference between finished products and products which in pipeline and which are not developed yet completely to be marketed. So for finished pharmaceutical products the market is seen to be national i.e. the member country's geography, whereas the presence of a firm in future with respect to its innovation like R&D, pipeline products etc. are seen to be European Economic Area (EEA) wide, extending upto entire EU region, since R&D has a global scale, and can occur in any corner, and give competition to a firm.[42] So merger which tend to have an effect on a broader geographic market are more prone to higher scrutiny by EU, as the effect of merger will be felt far and wide. Therefore, we see a double regulation, whereby national regimes have a equal say in pharmaceutical sector.

The main consequence of this double regulation dimension, in the object of our study, is the fragmentation of the market, which supposes that the relevant geographic market, in the Merger Control, will be restricted to national level, because of the national price systems. Nevertheless, that delimitation only touches the medicines/pharmaceutical specialties. In the case of active substances and "Innovation Market", the antitrust authorities consider that the relevant geographic market is worldwide, because the pharmaceutical undertakings compete at international level.[43]

Therefore, in the end concluding this section, author has given a comprehensive overview over the merger control in pharmaceutical industry, especially under EU law.

CONCLUSION

Concluding, the trend in pharmaceutical sector towards mergers and acquisitions is worth seeing in future, with advancement of science. Business, science and pharmaceuticals have become an integrated whole, and not only R&D, or science can help companies achieve profits, it is the newer innovative business strategies and restructuring like mergers, acquisitions, arrangements which are being taken for keeping the companies a profit making venture. In the

[42] Pablo Figueroa and Alejandro Guerrero, "EU merger control in pharmaceutical sector" in Ilene Knable Gotts (eds.) *The Merger Control Review* (Law Business Research Ltd. 2015)
[43] Teresa Lores Morales, 'Merger Control in Pharmaceutical sector & the Innovation Market assessment: European analysis in practice and differences with American Approach' (Master Thesis, University San Paola, 2008)

paper, author gives the readers a primary idea on different types of mergers in pharmaceutical sector, and how competition law plays a pivotal role for successes of these mergers. The conclusion that can be found is, pharmaceutical industry is an innovation driven industry with myriad reasons for entering into arrangements, and a sector specific approach has been used.