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Chapter 7

Innovations Through Mergers and Acquisitions in the Pharmaceutical Sector

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ABSTRACT

Pharmaceutical firms have a noteworthy contribution in SDGs (Sustainable development goals). Their unceasing innovation of low-cost medicines and discovery of lifesaving drugs can assist in achieving the SDG 3 (good health and well-being). Having gone through the M&A scenario in the global pharmaceutical industry and the amount disbursed on R&D, the authors tried to find answers to a few important questions to understand whether these activities are in line to achieve global goals i.e. first, does Merger and Acquisition M&A in pharmaceutical sector increase innovations? Second, how can companies fully utilize M&A activities to increase innovation in the pharmaceutical sector? Third, is there any association between R&D expenditures and innovation outcome? We theoretically analyze and consolidate academic research on how M&A activities support innovation in the pharmaceutical industry. The present chapter also tried to unveil the association between R&D expenditures and the firm innovation as measured by the number of patent applications by selected Indian pharmaceutical firms.

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INTRODUCTION

The United Nations Conference happened in 2012 in Rio de Janeiro, paved the way for seventeen Sustainable Development Goals (SDGs) or global goals. The primary motivation behind setting these goals are the challenges faced by our worldtoday be it political, environmental or related to economy. These goals have a verybroad scope and that's the reason they replaced Millennium Development Goals (MDGs). All the seventeen SDGs are interconnected. These goals were born not just to improve the lives of present population but also for the future generations by making our planet more sustainable, safer and prosperous¹. Global goals prioritize good health and well-being as a main sustainable development goal (goal 3), thus the pharmaceuticals come into main stream and calls to end AIDs, malaria, hepatitis, tuberculosis, water borne diseases and other communicable and non-communicable diseases by 2030². Better medicines at low costs, lifesaving drugs and vaccines for all are the priorities under this goal. According to Richard Saynor, senior Vice President GSK, pharmaceutical firms have a responsibility to provide people high quality medicines and healthcare irrespective of their nations and income (Pharma BoardRoom, 2018)³. To provide medical assistance to more patients and to ensure sustainability in the future, we have to understand that reasonable pricing is necessary. Pharmaceutical firms have a main contribution in SDGs, by continuous innovation of low cost medicines and discovery of lifesaving drugs they can assist in achieving the SDG 3 target by 2030.

Innovation has been a matter of considerable significance in almost all organizations, its prominence can never be undermined in today's aggressive competitive markets. As competition is at its utmost peak, innovation is obligatory not just for augmenting revenues but for survival, means sustainability of innovation is something the organizations are striving for (Tohidi & Jabbari, 2012). Surprisingly a little research has been reported until recently as to how merger and acquisition (M&A) undertakings by pharmaceutical firms impact their innovation trajectories, probably because R&D productivity & integration outcomes are not shared publicly and usually done privately (La Mattina, 2011). According to Yoon & Deeken, (2013) there are multiple indicators that explain a firms innovation outcome like new process, improved business models and new products. For present study we limit the definition of innovation to new drug development only as it is the easiest way to quantify innovation outcome in pharmaceutical firms (Reeb, 2017).

According to 'the pharma letter' report 2018, the number of global M&A deals in pharmaceuticals reached to 111 in numbers, which were 101 in 2017. It reported 26 deals that valued over \$1 billion. It also estimated the value of M&A in pharmaceuticals which was about \$124.7 billion⁴. Given such high number of deals

and amount spent on pharmaceutical M&A, it's imperative to know the outcome of these deals in regards to their contribution in achieving global goals. As per our knowledge and understanding there is hardly any previous study which underlined the pharmaceuticals M&A effect on achieving global goals. This prompted us to take this under-investigated topic, moreover, there are dualistic rational behind selecting pharmaceutical industry. First, this industry has been at the forefront in (M&A) activities around the world. Secondly, innovation is the central element of competition among pharmaceutical firms. Discovery and development of drugs pose unique challenges and social & ethical responsibilities. Before discussing innovation in the pharmaceutical sector, it is imperative to know that innovation to some extent is dependent on R&D activities (Achilladelis & Antonakis, 2001).

According to press reader 2018 report, the cumulative spending on R&D by top 10 Indian pharmaceutical companies was around Rs 95 billion or 9500 crores this fiscal. The report also mentioned that during January to June 2018, Indian pharmaceutical companies received "125 final Abbreviated New Drugs Applications (ANDA) approvals from US FDA out of total 323 ANDA approvals received" probably because of high expenditure on R&D by Indian pharmaceuticals⁵. After going through the M&A scenario in global pharmaceutical industry and the amount spent on R&D, the authors tried to find answers of a few important questions to understand whether these activities are in line to achieve global goals i.e. first, does M&A in pharmaceutical sector increase innovations? Second, how can companies fully utilize M&A activities to increase innovation in pharmaceutical sector? Third, is there any association between R&D expenditures and innovation outcome? The answers to question 1 and question 2 is explained through extensive review of literature, while, the answer to question 3 is explained through basic statistical analysis. The present study focuses on innovations by pharmaceutical companies especially after two firms either merge or one is acquired by another. By innovation of new drugs at low cost pharmaceutical companies can improve access and availability to affordable medicines and treatment to all sections of population. Subsequent innovations can help in prevention & treatment of diseases by providing high quality products, quantity and accessibility. As population grow old, the use of high cost medicines and treatment increases and subsequently the need of low cost drugs and treatment arise.

The rest of the study is arranged into six sections, a review of significant literature on the topic followed by the answers of research question 1 and question 2 is done in section 2, then association between R&D expenditures and innovation outcome is explained in section 3, next, result and discussion is done in section 4, subsequently, managerial and social implications are given in section 5, and at last, section 6 provides future research directions.

REVIEW OF LITERATURE

Starting with one of the important theories i.e. theory of innovation and learning proposed by (Cohen & Levinthal, 1990) explained that a firm has two ways to enhance its intellectual property. It can do it either by spending in numerous knowledge augmenting projects or by acquiring existing knowledge base through M&A's. Same views were expressed by Henderson and Cockburn, (1993) in theory of Industrial organization which says M&A's help firms to carry out numerous R&D ventures and offer opportunity to reduce the costs through scale and scope of economies. While resource-based theory explained by Barney, (1991), stresses that in times of extreme competition firms can really avoid time taking procedure of in-house innovation instead M&A is a potential tool that can really assist the firms to expand their assets base. R&D is the prominent intellectual source in the pharmaceutical industry. The innovation of a new drug is highly complex, time taking and extremely costly affair, according to Heracleous & Murray, (2001) traditionally the first step in product development cycle starts with the discovery of a new compound. This course usually takes one year to find one pharmacologically viable new chemical entity (NCE) than an NCE goes into pre-clinical testing for approximately 2 years and normally one out of 20 NCEs survive. Next step is clinical trials for that, an approval from the regulatory authority is needed, for example, the Food & Drug Administration (FDA) in the United States. Clinical testing comprises testing in three phases. Phase I is a safety assessment test on which typically, a year is devoted. In Phase II, two years are spent on evaluating effectiveness, dosage and side effects and at last in Phase III, safety in long-term is assessed by applying it on large samples of patients for three years. Out of every five new drugs entering Phase I, approximately 1.65 typically complete the last phase successfully. After completion of clinical trials, companies need to file a new drug application (NDA) or biologic license application (BLA) contingent on the category of product, which is then reviewed by a regulatory authority, for example, FDA that may require one and a half year to finalize their review. (Heracleous et al., 2001) also said that during 1990 to 1995 the total development cycle lasted 15.3 years on an average. The success rate was so minimal that only one out of almost 5000 compounds outlasted to become a newly approved drug. Over two-thirds of the total R&D cost of a successful new drug was spent on clinical trials. The study of (DiMasi et al., 2016) surveyed 10 pharmaceutical firms and randomly selected R&D costs of 106 new drugs, their study reported direct clinical period cost and capitalized clinical period cost estimate of \$965 Million & \$1460 Million for every approved new drug.

In view of above-stated significance and complexity in the innovation of new drugs, present study theoretically analyzes the significant existing literature on how M&A activities support innovation in the pharmaceutical industry. Beginning with

one of the critical studies on the topic, Barkema & Vermeulan, (1998) suggested that companies that have few technological capabilities are more likely to acquire innovative firms while companies that have strong technological abilities are less likely to acquire or merge with a foreign firm and choose new start up over acquisitions. Pharmaceutical firms depend on new drugs and in order to sustain average industry growth they need to introduce new drugs every year and mergers in the pharmaceutical sector happens as a result of failure to innovate. A study by (Koenig & Mezick, 2004) investigated the research and development activities of pharmaceutical firms to fathom the impact of M&A activity on R&D productivity. They submitted that firms which experienced M&A had more favorable R&D productivity in comparison to firms that did not indulge in M&A activities.

An important study by Higgins & Rodriguez (2006) adopted a distinctive approach to understand the complex outcome of R&D productivity, the study examined 160 pharmaceutical acquisitions and realized that on an average there is a significant enhancement in returns of acquirers, further returns were found positively correlated with acquirer's prior information of R&D activities of target firms. A unique index was also developed to know the status of internal productivity of a firm. It was suggested that when firms experience a decline in their R&D productivity they tend to choose M&A to boost their research pipelines. Similarly, Dierks *et al*, (2016) deliberated that pharmaceutical firms are under pressure in the fast moving market and the need to create innovative drugs prompts them to resort to the strategy of inorganic growth i.e. through M&A, collaborations & venture capital. Further, Shibayama et al., (2008) investigated the impact of M&A activity by taking a case study of a Japanese pharmaceutical firm, they also advocated that M&A activities have the potential to reinforce long-term research capabilities in pharmaceutical firms.

Grabowski & Kyle, (2008) expressed a different perspective on M&A activities by pharmaceutical firms, they established that pharmaceutical mergers were the result of numerous motives and conditions, particularly the mergers were driven by industry and firm-related shocks. Some firms suffered from R&D gaps and patent expirations and the mergers were helpful in cost-reduction and solving short-run problems, but no significant improvement was seen in the long-term R&D outcomes, they further deliberated that many big pharmaceutical firms deal with constant R&D outcome problems. Same results were submitted by Munos, (2009) who took a fairly large sample size comprising 1,222 new drugs that were approved bythe United States Food and Drug Administration (USFDA) during 1950 to 2008, and the study concluded that though the R&D investment during these years had increased drastically, the production of new drugs had been constant. The findings raised serious questions regarding the sustainability of R&D models of companies, further, it also raised doubts on the rationale of M&A activities as these inorganic growth routes had no discernible effect on new drugs production. Similar results

were reported by (Ornaghi, 2009) who investigated the merger effects on the long-term innovation ability of pharmaceutical firms, the study concluded that mergers did not deliver any significant efficiency gains to merged entities, it was further suggested that merged entities innovation activities were worst comparing to non-merging firms and when acquirers decide to acquire firms with related technological contents in order to limit the negative impact on their growth, may end up having less innovative incentives in the long run. Further, (La Mattina, 2011) in their study also suggested that consolidation in pharmaceutical industry might have a reasonable short run rationale, but the impact of consolidation activities was destructive on R&D productivity of organizations.

Comanor & Scherer, (2011) expressed a very important insight, they deliberated that there is always a need of innovation in the pharmaceutical sector, as per U.S antitrust policies, the evaluation of a merger is done on the basis of its impact on innovation and price levels. A study by Ringel & Choy, (2017) observed that large pharmaceutical mergers result in significant improvement of R&D productivity, measured as a total amount of innovation created. They further expounded that big mergers among pharmaceutical firms could have a multidimensional impact on competition, drug prices & employment, but the most prominent impact could be on innovation through R&D reassessment. Mergers could be a boon for a merged entity as it gives impetus to management to reevaluate existing projects, to do away with projects that are unlikely to offer any advancement in treatment and focus more on promising projects. Dierks & Reginster, (2018) deliberated that although M&A concentrate the market, but the empirical evidence suggests that they do not decrease innovation outcome, they further suggested that small firms are a major source of innovation and large pharmaceutical firms acquire them which leads to the commercialization of new drugs as large firms can bear the expenses of filing patent applications and clinical trials.

M&A ACTIVITIES AND INNOVATION

The SDGs provide a direction to governments and private sectors all over the world to work towards attaining long term sustainability and prosperity for environment and society as a whole. Mergers and acquisitions in pharmaceutical companies help them to fill gaps in their product pipelines, to expand therapeutic areas, to eliminate duplicate resources and achieve cost savings (Jung, 2002). This part of the chapter answers the second question "how can companies fully utilize M&A activities to increase innovation in pharmaceutical sector?" the answer to this question is explained by some notable studies, a few of them is reported in this section. Starting with the most important factor behind successful M&A and subsequent innovation

in high technological industries like pharmaceuticals may be the integration process. As Haspeslagh & Jemison (1991) suggested that its implementation process that has a major role in explaining whether the acquisition or merger will be successful or not. Better integration between two firms help them in aligning their common goals and actions to achieve superior outcome (Puranam & Srikanth, 2007), while inappropriate integration process may have unfavorable impact on the acquisition outcome and subsequently on innovation output. Acquirers previous experience also impact innovation outcome as Nicholls-Nixon & woo (2003) suggestedthat prior experience in acquisitions have positive impact on technical output of the combined firm and hence may have positive impact on innovation outcome, because prior experience may help in selecting appropriate partners. Makri et al. (2010) considered similarity and complementarity of technological knowledge and suggested that complementarity knowledge base of target and acquirer may have positive impact on innovation outcome. Size of knowledge base also impact innovation outcome as Ahuja and Katila (2014) explained that although high knowledge base of acquired firms improve innovation but if knowledge base of acquired firm is disproportionally larger than acquiring firm may have negative impact on innovation output of the combined firm because knowledge absorption, understanding and implementation is a time taking process. They also submitted that in technological acquisitions innovation outcome is positively affected by the relatedness of acquiring and acquired firm. Horrobin, (2000) expounded that vital post-merger decisions involve the integration of R&D, as researchers believe that full integration of R&D often leads to innovation through internal collaborations of process and technology. While limited R&D integration may make it difficult to realize innovation synergies.

R&D EXPENDITURES AND INNOVATION OUTCOME

According to Reeb, (2017) "R&D spending is arguably the most widely used measure of corporate innovation activity". He suggested that probably the most important benefit to measure innovation through R&D expenditures is that most firms report it. The study further suggested that "R&D spending, patent counts, patent citations & new product announcements" are widely used to quantify corporate innovations. According to Griliches (1981) there exist a measurable connection between R&D and the quantity of patents. Cloodt, et al. (2006) explained that organizations having low R&D expenditures experience increment in their patents if they increase their R&D expenditures. Nonetheless, organizations that already incur comparatively high R&D expenditures an additional increment of these outlays doesn't prompt any significant development in new patents.

In view of the explained association between R&D expenditures and innovation outcome, we attempted to statistically check it by using Pearson correlation analysis between R&D expenditures and number of patent applications by selected six Indian pharmaceutical firms. Table 1 reports number of patent applications by six Indian pharmaceutical firms during the years 2010 to 2018.

Table 2 reports R&D expenditures by the same pharmaceutical firms as reported in Table 1. As it is clear from the table that there is an increasing trend in the R&D expenditures in most of the selected pharmaceutical companies. Further, Table 3 reports correlation between number of patent applications and R&D expenditures. It can be seen that out of six pharmaceutical firms three firms showed a significant association between R&D expenditures and number of patent applications. Other firms also showed some degree of association though not statistically significant. So, it can be said that there is an association between R&D expenditures and innovations.

Table 1.

	Aurobindo	Ipca Laboratories	Natco Pharma	Cadila Health Care		
Years	Pharma Ltd.	Ltd.	Ltd.	Ltd	Lupin Ltd.	Wockhardt Ltd.
2010	439	192	226	530	621	1,172
2011	464	196	347	650	911	1,259
2012	500	213	370	800	1,024	1,570
2013	532	220	397	950	1,181	1,733
2014	561	224	302	1,075	1,762	2,001
2015	507	228	374	1,140	2,197	2,268
2016	581	320	399	1,190	2,525	2,579
2017	531	256	374	1,240	2,837	2,904
2018	563	277	399	1,249	3,045	3,037

Table 2.

Years	Aurobindo Pharma Ltd.	Ipca Laboratories Ltd.	Natco Pharma Ltd.	Cadila Health Care Ltd	Lupin Ltd.	Wockhardt Ltd.
2010	126.5	568.1	77.9	1,660.0	3,570.1	596.0
2011	1,411.5	412.6	110.5	2,506.0	4,834.2	694.6
2012	1,610.4	404.7	84.3	3,637.0	5,228.3	1,290.6
2013	2,366.0	539.3	146.3	4,677.0	7,098.4	8,270.7
2014	2,791.0	855.0	142.9	4,569.0	9,294.1	4,030.4
2015	3,500.4	773.3	475.1	5,613.0	10,987.8	4,887.0
2016	4,141.9	719.0	552.0	7,546.0	16,037.8	4,977.6
2017	4,988.0	1,361.0	930.0	7,548.0	23,101.0	3,971.0
2018	5,926.0	1,174.5	1,279.0	8,687.0	18,510.0	2,872.0

Table 3.

	Companies	Pearson Correlation	Significance
1	Aurobindo Pharma Ltd	.782	.013*
2	Ipca Laboratories Ltd	.533	.139
3	Natco Pharma Ltd	.502	.169
4	Cadila Health Care Ltd	.946	.000*
5	Lupin Ltd	.951	.000*
6	Wockhardt Ltd	.380	.313

RESULTS AND DISCUSSION

The importance of innovation of low-cost drugs and treatment can never be undermined mostly because of its direct benefits to all section of population. After extensive review of literature on the topic, research findings reveal that there is no universal agreement among scholars regarding M&A's impact on innovation outcomes a few researchers (Barney, 1991; Cohen & Levinthal, 1990; Henderson and Cockburn, 1993; Koenig & Mezick, 2004; Higgins et al., 2006; Shibayama et al., 2008; Dierks et al, 2016; Ringel et al., 2017) reported positive impact of M&A's on pharmaceutical firms innovation outcomes, while others (Grabowski et al., 2008; Munos, 2009; Ornaghi, 2009; La Mattina, 2011; Comanor & Scherer, 2011) reported negative impact of M&A on firms innovative outcomes. So, the answer to the first question "does M&A in pharmaceutical sector increase innovations?" has no clear conclusion and is open for future empirical study.

Secondly, the answer to our second research question "how can companies fully utilize M&A activities to increase innovation in pharmaceutical sector?" is explained by different authors and suggested that different factors like integration process, prior experience, complimentary technological knowledge, knowledge base of acquired firm and post-merger and acquisition R&D integration process may have impact on the innovation output of the firm and firm should bear those factors in mind to increase innovation post M&As.

Thirdly, the answer to the question "is there any association between R&D expenditures and innovation outcome?" there is no universal consensus among researchers regarding the measurement of innovation. Some researchers' reliance on the amount of spending on research and development or on patent applications as a means of measuring the productivity and innovation (Koenig, 2004). While others believe that the productivity and actual innovation is the discovery of quality medicines actually benefitting the patients (Ringel et al., 2017). In present study, the authors considered the measurement of innovation based on patent applications as considered by (Koenig, 2004) and after the basic statistic test, submit that there is an association between R&D expenditures and innovation outcomes in the pharmaceutical sector.

SOCIAL AND MANAGERIAL IMPLICATIONS

Considering the fast pace and skyrocketing deals in M&A in the global pharmaceutical sector, it is vital to understand their impact on the society. To achieve the global goals and focus on the broader responsibility of pharmaceutical firms towards building a sustainable low-cost preventive and curative treatment mostly for low income countries, the present study explains the link between M&A in pharmaceutical sector and their significance in achieving SDG 3. This study is probably first of its kind to explain how M&A in pharmaceutical sector may help to achieve global goals. A large amount is spent every year on the consolidation phenomenon, the top management involved in M&A decisions must take into account the impact of these inorganic activities on achieving global goals. The study highlights the importance of innovation in pharmaceutical sector especially after their M&A and it may be helpful for researchers, governments, regulatory associations, academicians and people associated with M&A strategy in pharmaceutical industry.

FUTURE RESEARCH DIRECTIONS

Our analysis of the topic discovered that cross-border mergers & acquisitions by pharmaceutical firms and their impact on their innovation upshot have not received much attention from academicians which is very striking as pharmaceutical firms are at the forefront in cross-border mergers and acquisitions, this issue can be a great research opportunity. Additionally, second research opportunity may be to explore the innovation outcome of M&A activities by pharmaceutical firms originating from emerging economies like India as there is a dearth of studies on the aforesaid topic. Future studies may take a large sample size and use sophisticated statistical tools to check M&A phenomenon and their impact on achieving SDGs.

CONCLUSION

In the last few years, a tremendous amount of attention has been delivered to improve the quality of human beings. A landmark step of setting up SDG 3 helped navigating the entire discourse in a new route. Although the existing literature runs into volumes witnessing what has been done, it still leaves an impression that the millions of miles to be covered to reach the destination safely. The present chapter is an attempt to shed light on where the discourse is halting. Given high number of M&A deals and amount spent on pharmaceutical M&A, it's imperative to know the outcome of these deals in regards to their contribution in achieving global goals.

As per our knowledge and understanding there is hardly any previous study which underlined the pharmaceuticals M&A effect on achieving global goals. The present chapter focuses on innovations by pharmaceutical companies especially after two firms either merge or one is acquired by another. By innovation of new drugs at low cost pharmaceutical companies can improve access and availability to affordable medicines and treatment to all sections of population. The authors tried addressing how M&A in pharmaceutical industry lead to innovations and subsequently, to achieve SDG 3. A few questions were raised in order to locate a discourse in an appropriate place. The answers to those questions were answered through extensive literature review and basic statistical tools.

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