FDI in the Pharmaceutical Sector: Dampener or Booster?

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Abstract

The global pharmaceutical market is undergoing revolutionary changes. As western markets mature there has been a prominent shift in focus towards emerging markets like India. However, India's inward Pharmaceutical FDI regime has been a contentious issue with a spate of stakeholders ranging from Pharmaceutical companies, Finance Ministry and the Planning Commission on one hand and the Department of Industrial policy and Promotion (DIPP), Health Ministry as well as various public interest groups on the other hand. The latest decision by the state has been to continue the policy of 100% FDI in greenfield as well as brownfield ventures. The agenda of the state is to augment India's attractiveness as a favored destination for Multinationals and thereby, reap the benefits of the accompanying technology, tap innovate molecules; create fresh job prospects, among other relevant factors. However, the hope has also been to retain the pharmaceutical sector's profile as a public welfare sector and to ensure access to affordable drugs for the common man. With the fragmented Pharmaceutical sector prolifically littered with small and medium enterprises the FDI policy would amount to opening doors to the Goliath. Fears of a surge in drug prices and reduction in access to essential drugs abound. In this scenario, it is essential to investigate the overly glorified assumption of the necessity and benefits of FDI for the host country. This paper explores the impact of the surge of the recent M&A activity in this sector, and reviews the various dissenting and assenting opinions in this regard.

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Introduction

The Department of Pharmaceuticals, Govt. of India, has its vision prominently stated on its website, "To enable Indian pharmaceuticals industry to play a leading role in the global market and to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption." This very issue of ensuring affordable, high quality medicines seems to be conflicting with the need of the hour, which is to stimulate economic growth in general and in the pharmaceutical sector specifically.

The Indian pharmaceutical industry is ranked 3rd in the world in terms of production volume and 13th in domestic consumption volume; it is one of the leading drug industries of developing countries. Over a period of three decades, India's pharmaceutical industry has evolved into a world leader in the production of high quality generic drugs (DIPP, 2013). The Indian pharmaceutical industry provides a distinctive case of a late industrializing country effectively building domestic competences in a highly competitive and knowledge intensive sector (Pradhan, 2002). The Indian pharmaceutical market (IPM) is currently valued at 72,069 crore INR (PWC, 2013). Worldwide, the contribution of emerging markets in the pharmaceutical sector is expected to become twofold by 2016, as compared to 2006. This growth is projected to be led by China and India (India with a CAGR 14 per cent–17 per cent during 2012–2016). This bodes well for all the constituents of the Indian pharmaceutical industry – Indian companies and global pharmaceutical companies along with all ancillaries like CRAMS, CROs. The Indian pharmaceutical industry is expected to be among the top 10 global markets in value terms by 2020. The domestic Indian pharmaceutical (formulations) industry was valued at Rs 629.0 billion in FY12, and is expected to reach around Rs 55 billion by 2020.

Fundamentally, the domestic market progression has been driven by increased affordability (a robust middle class growing at 67 per cent from 160 million in 2011 to 267 million), enhanced reach to healthcare and alteration in the disease profile from acute to chronic (Sharma, 2013).

However, these are turbulent times, in the last one year this sector has faced a slowdown with growth going to 9.8% from 16.6% in 2012. The growth rate has declined further after November 2012 to an average of 8%. Industry experts attribute the slowdown to the National Pharmaceutical Pricing Policy (NPPP) which was announced towards the end of 2012 and the ensuing price corrections which led to a low stock uptake by the stockists. It is also attributed to regulatory ambiguities. The slowdown is more conspicuous in the MNCs than in the Indian companies. In 2012, the top five MNCs had a growth rate of 16% which plummeted down to 7% in 2013. Correspondingly, in 2012, the top five Indian companies had a growth rate of 16% that came down to 12% in 2013. The number of new products introduced has gone down from around 1900 in 2010 to approximately 1700 in 2012 (PWC, 2013).

Review of Literature

M&A Activity in the Pharma Sector

In the early 1980s, most developing countries started easing restrictions on FDI and aggressively offering tax incentives and subsidies to invite foreign capital, with the view that FDI promotes growth – but does it really? (Herzer, 2012). Most of the M&As are motivated, by the need to obtain financial synergies, to gain market control, to get access to distribution channels or to gain entry into new geographical locations, this indicates that technological reasons may not motivate all M&A. However in the current scenario there are many high-tech industries where innovation is considered a key to competitive edge (Vyas, Narayanan and

Ramanathan, 2012). In 2013 and the decade preceding it, a trend observed in the pharmaceutical market was the partnerships between the MNCs and Indian companies with the purpose of increasing reach in terms of customer volumes and geographical exposure for patented molecules. These trends culminated in the activities of co-marketing, co-promotion, licensing and joint ventures (PWC, 2013). M&A activities by Indian Pharmaceutical industries are concluded with the objective of complimenting the strengths of two entities to get market access, new technologies as well as new products. A drive to enhance the size and thereby attain higher economies of scale could be key motivations for M&A in pharmaceutical sector (Vyas et al., 2012).

On the international level, the success of the service sector has had a strong positive spillover effect on the pharmaceutical sector. Indian drugs firms undertook M&A to strengthen their position in the highly regulated overseas markets like the US, Germany and the UK (Pradhan, 2007). Domestically also the pharmaceutical sector became a major player in M&A activity. The successful espousal of M&A by software and pharmaceutical firms had all-round effects on Indian firms from sectors like chemicals, automotive, steel, etc. (Pradhan, 2007).

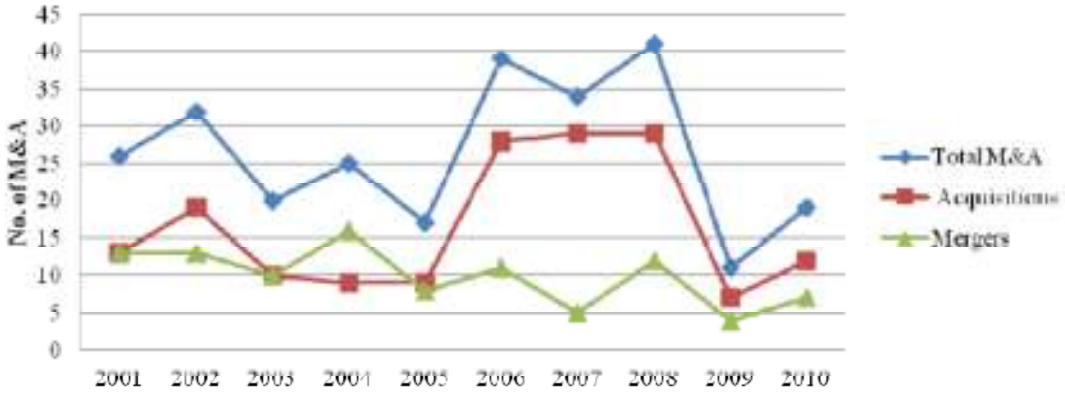

Fig 1: Mergers and Acquisitions in Indian Pharmaceutical Industry for the Period of 2001-2010, Source: Vyas et al., 2012

Vyas et al. (2012) are of the view that firms undertaking M&A activity are larger in size as compared to non M&A active firm, and in-house R&D compliments technology acquisition via M&A route. Pharmaceutical acquisitions have enabled pharmaceutical MNCs to access the infrastructure, distribution networks, and management competencies of domestic players, thus strengthening their business operations in the host country (Sharma, 2013).

Inward FDI in the Pharmaceutical Sector

Post TRIPs, Indian firms were forced to change their business strategies, focus on the generics market and devote more capital in innovative R&D and contract manufacturing as well as research. Firms started going in for more mergers and acquisitions, and forming other alliances with foreign pharmaceutical firms (Vyas et al., 2012; Rai, 2009). Pharmaceutical sector is one of the top five sectors favoured by overseas investors, with approximately Rs. 50,000 crores worth of FDI coming in since April 2000. This amounts to nearly 5% of the total foreign investment made in the country (Ghose, 2013). The FDI policy regarding Indian pharmaceutical industry has been substantially liberalized 1990 onwards as a part of the macroeconomic reforms. This liberal approach to FDI is assumed to be based on several potential benefits that FDI fetches for the host country. Apart from generating financial resources, up-to-date technologies, technical capability, access to export markets, foreign exchange, employment, expertise and management functions, FDI can cause enhanced productivity in indigenous firms when firm specific intangibles spillover to the domestic firms (Pradhan, 2002).

Given the high current account deficit, India requires FDI (PWC, 2013). A 'Press Note' issued by DIPP on January 8, 2014 put to paper the results of the inter-ministerial group deliberations held in November 2013, 100% FDI in greenfield investments as well as brownfield

investments is permitted, the former is permitted via the automatic route, while brownfield investments require Foreign Investment Promotion Board (FIPB) approval, with ensuing conditions (PWC, 2013).

The FDI policy, however, gives perplexing signals. Last year the government also decided to introduce safeguards to make certain that MNCs acquiring domestic firms did not stop manufacturing essential drugs. This included a covenant where the MNC will not reduce production of essential drugs of the acquired company for five years after acquisition. Furthermore, the target company would augment its R&D spending by 5% within three years of getting FDI approval (Ghose, 2013). However, the 'non-compete clause' will be allowed only in special circumstances with the discretionary power of the FIPB. The non-compete clause is a customary feature in M&As, it functions to restrict the target companies from attempting into the same line of business for a stated period of time. For instance, in the Daiichi Sankyo-Ranbaxy deal, a two-year non-compete agreement was signed with Ranbaxy's promoters. Likewise, in US-based Abbott Laboratories takeover of Piramal Healthcare's domestic formulations business in 2010, an eight-year non-compete agreement was signed. This implies that Piramal Healthcare's promoters cannot go into an analogous business for eight years ("Pharma FDI", 2014). Multinationals would seek further clarity on this issue.

Impact of FDI on Host Country's Economy

According to (Herzer, 2012) even in the case of greenfield investments, FDI may not add to the domestic capital stock, as foreign FDI crowds out domestic investment when multinationals fund investment projects that would else be taken on by local firms. This especially occurs when multinationals compete with domestic companies for scarce resources, or

when foreign firms finance their investment via borrowings in the host country, thereby increasing the host country's interest rate. The most credible justification for the negative effects is that foreign firms diminish the efficiency of domestic firms through competition effects. Moreover, Kuntluru, Muppani, and Khan (2012) are of the view that presence of foreign firms in isolation may not be important for productivity development in the domestic sector. FDI spillovers work when domestic firms have already grown large or are involved in innovative activities or have built sufficient domestic capabilities including technological one. Mere encouragement and openness to FDI doesn't ensure benefits. Unlike in other industries, it is observed that in pharmaceutical industry foreign owned firms export less and focus more on domestic demand and host country specific benefits.

Regardless of these concerns, most macroeconomic studies posit that inward FDI has a positive effect on the economic prospects of developing countries. Especially, countries with higher levels of per-capita income, well educated workers, greater degree of openness, and a progressive financial system (OECD, 2002).

Whenever the activities of foreign firms affect the domestic firms, in the same industry, with regard to their objective functions like profit, productivity or costs, it is called 'horizontal spillover' and if in the externalities affect forward or backward linkages of production it is called 'vertical spillover' (Bergman, 2006). Though, the existence of spillovers is well established the nature and magnitude of spillovers is debatable (Pradhan, 2002). Tripathy, Yadav and Sharma (2011) studied a sample of 64 firms from the Indian pharmaceutical industry and analysed the constraints to FDI inflows as evinced by these firms. The authors assert that lack of data protection, procedural delays and price controls hinder FDI inflows into the country.

The heterogeneity in the economic growth effects of FDI can be explained mainly by cross-country differences in private sector autonomy from government intervention, business regulation, FDI volatility, as well as primary-exports dependency. Openness, per-capita income, human capital, intellectual property rights and lack of corruption play an important indirect role in the FDI–growth relationship (Herzer, 2012).

Recent Issues and Constrains in the Indian pharmaceutical market

India has become an attractive destination for carrying out clinical trials. This is essentially due to India's genetic diversity; varied and increasing disease incidence rates; availability of qualified medical, pharmacy and pure science graduates, clinical infrastructure and a comparative low cost advantage. However, regulatory delays in clinical trials are adversely affecting the growth prospects of this sphere of FDI. Unproductive regulatory oversight, need for safeguards for informed consent for vulnerable populations and compensation guidelines for patients and for clinical trial associated deaths are the main concerns (Imran, Najmi, Rashid, Tabrez and Shah, 2013).

Additionally, through the National Pharmaceutical Pricing Policy 2012, the government has enhanced the scope of the Drugs Price Control Order (DPCO) to include all the drugs in the National List of Essential Medicines. Combination drugs in which one of the drugs is already a part of the list have also been brought under the ambit of DPCO. The government has also changed the formula to arrive at the ceiling price from an erstwhile cost based method to a market based method. The price controls associated with NPPP will have a negative impact on the topline of the companies in short term. The industry feels that the government has not provided adequate time for implementing the fresh packaging and labeling with the revised

prices. Moreover, the sector is dealing with a number of issues like a uniform code for marketing and sales practices and compulsory licensing. To add to the woes and confusion the Department of Pharmaceuticals (DoP) guidelines on the sales and marketing practices, are different from the MCI guidelines. There is a greater need for clarity both from the viewpoint of the industry as well as the tax authorities. Also, companies are facing a lot of flak over lax quality standards, to continue exporting to the foreign markets they will have to improve their quality and manufacturing compliance programmes and bring in line with the US FDA and MHRA regulations (PWC, 2013).

Is there Rising MNC Dominance in Indian Pharmaceutical Sector?

Traditionally MNCs have relied for their growth on patented drugs and focused mainly on developed country markets. The high prices of patented drugs generated high returns. But recently the pharmaceutical industry has witnessed a steep fall in the number of new drugs introduced in the market. MNCs are finding it increasingly difficult to fill up the novel product gap as the patents on their blockbuster drugs are expiring and they are facing constraints on further growth in developed country markets. On the other hand, certain developing country markets are undergoing rapid growth (Chaudhuri, 2011). The emerging markets of China, Brazil, India, Russia, South Korea, Mexico and Turkey contributed to more than 50% of the growth of the global pharmaceutical market in 2009 compared to only 16 % by the developed markets of North America, Western Europe and Japan. These numbers were 7% and 79% respectively in 2001 (Tempest, 2011). MNCs are also expanding vigorously in the generic segments. They are growing not only organically but through M&As and strategic alliances with Indian companies

(Chaudhuri, 2011). Clearly, MNCs are likely to capture a 35 per cent market share of the pharmaceutical market by 2017, compared to 28 per cent in 2009 (Sharma, 2013).

The trepidations of various constituencies over permitting 100% FDI in brownfield ventures can be summarized as follows. Acquisition of large Indian pharma companies would leave behind mostly the smaller domestic companies functioning in the lower end of the pharmaceutical value chain. This may constrain India from focusing on need-based R&D and may increase dependence on MNCs for meeting the common man's drug requirements. It could restrict the use of TRIPs flexibilities such as, Compulsory Licensing (CL) and patent challenges. MNCs may effectively use the marketing and distribution network setup by domestic companies to substitute low-cost drugs with high-priced ones, including patented drugs (Rajya Sabha Report, 2013).

Market figures present a conflicting picture. For example, soon after its takeover by Daiichi Sankyo, Ranbaxy withdrew all the patent contests against Pfizer's blockbuster cholesterol lowering drug Lipitor. According to an Indian Pharmaceutical Alliance (IPA) report (2013), Abbott increased the prices of medicines produced by Piramal Healthcare immediately after its acquisition. The price of drug Haemaccel was Rs 99.02 in May 2009; by May 2011 it had gone up to Rs 215, a 117% hike in just two years. The drug Gardenal, used for treating epilepsy, showed a price increase of 121%. The aggregate market share of MNCs in the formulations market has gone up significantly with the taking over of some Indian companies. These developments may indicate that the days of product monopolies and high prices are back in India. Some MNCs have started marketing new patented drugs at exorbitant prices particularly for life threatening diseases such as cancer (Chaudhuri, 2011).

However, in an attempt to compete with domestic generic players, pharmaceutical MNCs are launching patented drugs in India at relatively low prices than those in developed markets. At the same time, they are using a differential pricing strategy to enhance their market reach by addressing affordability issues. For instance, drugs such as Diovan (Novartis), Januvia (Merck Sharp & Dohme), and Galvus (Novartis) are being sold at discounts of up to 80 per cent on global prices. Additionally, pharma MNCs are aiming to implement new and effective business models in India to improve the health of patients. Providing patient health outcomes entails getting involved in the cycle of care, rather than mere delivering of drugs (Sharma, 2013).

Moreover, the fears of reduction in availability of inexpensive essential drugs may be assuaged by the fact that sales of the top five essential drugs has continued to show compounded annual growth rates (CAGR) of 14-24% in the period 2009 and 2012, for both multinational and domestic pharmaceutical companies. For example, sales of the anti-allergic cetirizine grew by 20.15%, antibiotic amoxicillin/clavulanate 22.84% and antacid pantoprazole 23.80% (Ghose, 2013)

Data also show paracetamol, selling at a CAGR of 14.78% while cholesterol-lowering atorvastatin grew at 14.28%. Additionally, it has been neck to neck competition between MNCs and domestic firms in many drug classes. For example, in paracetamol, the top seller was Wockhardt with annual revenue of Rs. 246 crore in 2013 while Glaxo SmithKline (MNC) came a close second with sales of Rs. 200 crore during the same period. Similarly, Ranbaxy sold Rs. 146 crore worth of atorvastatin in 2013 while domestic firm Zydus Cadila has sales of Rs.145 crore. A department of pharmaceuticals (DoP) analysis also found no evidence that acquisitions led to slowdown of nationally significant drugs. No association was observed between acquisitions and price increase. The trend analysis of the total number of medicine

packets available in the market showed an increase of 5.8% between 2009 and 2011 countering the view that availability of essential medicines would decrease after takeover. The DoP also conducted a price analysis of essential drugs of seven top domestic companies (Cipla, Sun, Mankind, Alkem, Lupin, Zydus Cadila and Intas), seven top MNCs (Abbott, GSK, Pfizer, Sanofi Aventis, Novartis, MSD and Merck) and seven major Indian companies acquired by MNCs (Ranbaxy, Ranbaxy Global CHC, Orchid, Shanta, Paras, Dabur and Piramal). It concluded that the trend for all three categories is similar to date and no conclusion can be drawn to support the supposition that acquisition of Indian companies by foreign firms results in price increase (Ghose, 2013).

Conclusion and Policy Implications

This review suggests that the impact of 100% FDI in greenfield as well as brownfield ventures is contingent on government and industry efforts to enhance the attractiveness of this sector, remove the ambiguities and build infrastructure. FDI liberalization will not generate growth unless supplemented by a reduction in market-distorting policies and trade barriers. The government should facilitate consolidation of smaller firms in the industry so that firms in this industry can have opportunity to expand and compete efficiently in the generic as well as specialized drug market. It also needs to help firms in identifying upcoming areas where R&D efforts of the firms could be concentrated. This will help firms have comparative advantage in global market. This research also suggests that economic reforms aimed at improving resource allocation, minimizing the regulatory burden, increasing political and economic stability, reduction in bureaucratic hassles and removing primary export dependency by diversifying can increase the possibility that FDI will promote growth and aid in effective utilization of FDI.

References

Bergman, A. (2006) 'FDI and Spillover Effects in the Indian Pharmaceutical Industry'. *Finance Working Papers, East Asian Bureau of Economic Research*. Retrieved from http://EconPapers.repec.org/RePEc:eab:financ:22084

Chaudhuri, S. (2012) 'Multinationals and Monopolies. Pharmaceutical Industry in India after TRIPS'. *Economic and Political Weekly, 47*(12): pp. 46-54

Department of Industrial Policy and Promotion. (2013). Retrieved from http://dipp.nic.in/English/default.aspx

FDI in Pharma, Rajya Sabha Report. (2013). Retrieved from http://www.elsevierbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/August/FDI%20In%20Pharma%20%20Rajya%20Sabha%20Report%20Aug%202013.pdf

Ghose, J. (2013), Domestic drug prices immune to pharma acquisitions, *The Financial Express*, 12 June, Available from http://www.financialexpress.com/news/domestic-drug-prices-immune-to-pharma-acquisitions/1127830/2

Herzer, D. (2012). How does foreign direct investment really affect developing countries' growth? *Review of International Economics, 20* (2), 396-414.

Imran, M., Najmi, A. K., Rashid, M. F. Tabrez, S. and Shah, M. A. (2013) 'Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go'. *J Pharm Bioallied Sci.* 5(1): pp. 2-9. doi: 10.4103/0975-7406.106553.

Indian Pharmaceutical Alliance Report (2013). Retrieved from http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Commerce/110.pdf

Kuntluru, S., Muppani, V. R. and Khan, M. A. A. (2012) 'Foreign direct investment and export performance of pharmaceutical firms in India: An empirical approach'. *International Journal of Economics and Finance, 4*(5): pp. 216-26

Organisation for Economic Co-operation and Development (2002). Foreign Direct Investment for Development: Maximising benefits, minimising costs. Retrieved from http://www.oecd.org/investment/investmentfordevelopment/1959815.pdf

Pharma FDI: Non-compete clause only in special cases (2014, January 9). Financial Express. Retrieved from http://indianexpress.com/article/business/market/pharma-fdi-non-compete-clause-only-in-special-cases/

Pradhan, J. P. (2002) 'Liberalization, firm size and R&D performance: A firm level study of Indian pharmaceutical industry'. *Journal of Indian School of Political Economy 14* (4): pp. 647-666

Pradhan, J.P. (2004) 'Quality of Foreign Direct Investment, Knowledge Spillovers and Host Country Productivity: A Framework of Analysis'. *MPRA Paper No. 17080*.

PWC Report (2013). India Pharma Inc. Changing landscape of the Indian pharma industry. Retrieved from http://www.pwc.in/en_IN/in/assets/pdfs/publications/2013/changing-landscape-of-the-indian-pharma-industry.pdf

Rai, R. K. (2009). Effect of the TRIPS-Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry'. *The Journal of World Intellectual Property*, 11, (5/6): pp. 404–431

Sharma, H. (2013), 'Indian pharmaceutical industry growth intact amid current headwinds faced by industry' *Express Pharma*, 02 Jan, Available from http://pharma.financialexpress.com/

sections/market-section/1593-indian-pharmaceutical-industry-growth-intact-amid-current-headwinds-faced-by-industry

Tripathy, I. G., Yadav, S.S. and Sharma, S. (2011) 'FDI flows into the Indian pharmaceutical industry: An analysis of trends and constraints'. *Journal of Intellectual Property Rights,* 16, (4): 330-334.

Tempest, B. (2011)'The Structural Changes in the Global Pharmaceutical Marketplace and Their Possible Implications for Intellectual Property'. *UNCTAD-ICTSD Project on IPRs and Sustainable Development, Policy Brief Number 10*. http://ictsd.org/i/publications/111430/.

Vyas, V. Narayanan, K. and Ramanathan, A. (2012) 'Determinants of Mergers and Acquisitions in Indian Pharmaceutical Industry'. *Eurasian Journal of Business and Economics, 5* (9): 79-102.