FDI Flows into the Indian Pharmaceutical Industry: An Analysis of Trends and Constraints

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India’s economic reforms since 1990s and World Trade Organisation’s Agreement on Trade-Related Aspects of Intellectual Property Rights have caused significant changes in the operational environment of the Indian pharmaceutical industry (IPI). In this backdrop, this study examines the Foreign Direct Investment (FDI) flows into the firms of IPI. It finds that the amount of FDI, the number of FDI recipient firms and the number of source countries of FDI are larger during the product patent regime as compared to the process patent regime. The factor analysis of primary data presents the perception of 64 sample firms of IPI as regards the main constraints of FDI inflows in the product patent regime.

Keywords: Indian pharmaceutical industry, FDI, patent regime

The operational environment of the Indian pharmaceutical industry (IPI) witnessed significant changes due to the introduction of economic reforms in the country and the emergence of WTO’s TRIPS. The liberalized industrial policy introduced during the 1990s led to the progressive, upward revision of the ceiling on Foreign Direct Investment (FDI) flows up to 100 per cent in many sectors, including IPI. Further, in conformity with the provisions of TRIPS, the Indian Patents Act was amended in 2005 to replace the process patent regime with the product patent regime. Consequently, Indian pharmaceutical producers could not manufacture generic versions of products which had been patented after 1995.

A debate between the developed and developing countries on the benefits of a stronger intellectual property rights (IPR) regime ensued with the initiation of TRIPS. While the developed nations claimed an equitable mutual benefit, developing countries observed that product patents would hike the prices of pharmaceutical products and harm their indigenous firms. A study on the relationship between intellectual property (IP) protection and the volume of FDI from 100 firms of the USA indicated that a country’s IP protection system influences FDI inflows. Moreover, research results showed that the investment behaviour of US MNCs in China are positively impacted by protection of IPR. A study on IPI observed that the protection of IPR in the form of patents was necessary to attract investment for R&D in the pharmaceutical industry. R&D units of MNCs are now usually ‘stand-alone’ units focusing on new and emerging high-tech areas, unlike in the past, when R&D units were set up to facilitate local production and marketing facilities. The change in the patent regime seems to have boosted the confidence of the MNCs.

Some scholars observed that strong IPR do not have a significant positive impact on overseas R&D investments made by MNCs. Summarizing the findings of the available literature on the determinants of FDI, a prominent study explained that market size, infrastructure quality, political/economic stability and free trade zones positively influence the flow of FDI. But fiscal incentives, labour costs, openness and business/investment climate may or may not attract FDI flows. The promotion of political and macro-economic stability facilitates FDI inflows. It has been seen that a significant positive relationship existed between structural reforms of the economy and FDI. Another study, considering different modes of MNC entry into a country, found that FDI is more sensitive to IPR than industrial licensing. Some other studies did not find enough evidence to support the positive relationship between IPR protection and FDI from developed nations into emerging economies of the developing world.

Amongst the emerging economies, China’s market size was recognized as the most important
determining factor of international pharmaceutical firms' FDI into China. Other factors guiding FDI flows into China are access to location-specific productive resources, larger domestic market, higher international trade ties with source countries, quality of infrastructure, and government policies. Another emerging economy, India, has attracted FDI because of economic reforms, cheaper labour cost, lower country risk, geographic closeness to source countries and cultural similarity with source countries.

It is well documented that the process patent regime had been a constraint in attracting FDI into IPI. Researchers found that the level of FDI into IPI was low due to bureaucratic delays, price controls and lack of IP laws. The lack of data protection is another lacuna which deters prospective investors from investing in the Indian economy. FDI inflows into the Indian economy, including IPI, decreased during financial year 2010-11, with the decline becoming more pronounced towards the latter part of the year. One of the major reasons for this decline is reportedly due to bureaucratic hurdles.

**Objectives, Scope and Research Methodology**

The objectives of this study are to analyse the FDI flows into firms of IPI by:

(i) Comparing the trend of FDI flows into IPI during the process and product patent regimes; and

(ii) Examining the constraints in FDI flows into IPI.

The reference period of the study includes the last four years of the process patent regime (2001-02 to 2004-05) and the first four years of the product patent regime (2005-06 to 2008-09). Although it is too early to gauge the impact of the change in the patent regime on FDI inflows, this study provides an analysis of the early trends of FDI inflows which are discernible as a consequence of the change in the patent regime. The study also presents the perception of IPI firms regarding the constraints which limit FDI flows into IPI. The scope of this study is limited to analysing the FDI flows into large firms of IPI. Large firms are defined as firms which have a minimum investment of Rs 10 crore on plant and machinery. There were 183 such large firms operating during 2008-09 (Prowess database of Centre for Monitoring Indian Economy (CMIE)). Out of these, 54 firms received FDI of more than Rs 5 crore during the reference period.

The secondary data was collected from the database of Government of India’s (GOI) Department of Industrial Policy and Promotion (DIPP) and Prowess database of CMIE. The primary data was collected at two levels - expert level and firm level, between September 2009 and October 2010. Interviews of experts from IPI, GOI and the academia were held for idea generation and for selection of variables. The interviews of experts were carried out in two stages; the first, an exploratory research and the second, a conclusive research. In the first stage, the opinion of the experts was obtained through unstructured personal interviews, although the topics to be covered had been decided prior to the interview. This flexibility, in the questions, which were asked, helped in getting insights from experts. This was followed by a structured interview. The discussions with the experts helped in identifying the constructs used in the study. The experts were asked to indicate their preferences on a five-point Likert scale about the suitability of a variable as a valid measure of ‘constraint’ of FDI inflows into IPI. If more than 50 per cent of the experts agreed upon suitability of a measure, it was retained. In case the experts suggested inclusion of variables other than those included initially, then these too were included and the other experts were asked to indicate their preferences regarding these new variables as well.

Based on the feedback of the experts, the firm level questionnaire was finalized. A pre-testing of the questionnaire was done on a sample of 21 pharmaceutical firms. The firms were asked to indicate whether they received FDI. They were also asked to express their perception regarding each of the five ‘constraints’ which had been identified by the experts. The perception of the firms was captured on a five point Likert scale. The final questionnaire was e-mailed to chief executive officers/chairmen/managing directors of all the large firms. A total of 64 responses were received and tested for reliability. The data was analysed using factor analysis on Statistical Package for Social Sciences software (SPSS).

**Analysis of Results and Discussion**

The FDI flows into IPI during 2001-02 to 2004-05 were to the tune of Rs 1,671.4 crore. During 2005-06 to 2008-09, the amount of FDI inflows to IPI increased by 1.8 times to Rs 3,076.9 crore. As a proportion of total inflows, the share of IPI declined to 0.7 per cent during 2005-06 to 2008-09 from 2.6 per cent during 2001-02 to 2004-05 (ref. 20).

Fifty four large firms of IPI attracted an amount of Rs 2,539.9 crore from 35 source countries during the period 2001-02 to 2008-09 (Table 1). During 2001-02
to 2004-05, 30 firms received FDI amounting to Rs 1,139.9 crore from 16 countries. Out of these FDI recipient firms, 18 firms stopped receiving FDI with the change in the patent regime in 2005. During the new patent regime, there was an addition of 24 firms to the existing FDI recipients, taking the total number of FDI recipient firms in the product patent regime to 36. The average amount of FDI per recipient firm increased from Rs 37.9 crore during 2001-02 to 2004-05 to Rs 38.9 crore during 2005-06 to 2008-09. Not only did the number of recipients increase in the product patent regime, the average amount of FDI, the number of source countries and the amount of total FDI too increased. The proportion of total FDI to the sample firms reduced from 68.2 per cent during the process patent regime to 45.5 per cent during the product patent regime, indicating that in the new patent era, larger firms have attracted a smaller portion of FDI.

During the reference period, the largest share of FDI flows into IPI was from Mauritius (52 per cent), followed by USA (17 per cent), United Kingdom (UK) (8 per cent), Cayman Islands (5 per cent) and Singapore (5 per cent) as shown in Fig. 1.

To identify and analyse the factors which act as deterrents of FDI inflows, the perception of the 64 sample firms was subjected to factor extraction process. Using varimax rotation, factor loadings were obtained and those factors which had an Eigen value greater than 1 were retained. Two underlying factors which explained 79.4 per cent of the total variance were identified. These two factors were named as ‘legal provisions’ and ‘government support’ (Table 2).

The factor ‘legal provisions’ comprising ‘weak intellectual property laws’ and ‘lack of data protection’ had a higher mean of 3.99 as compared to 3.54 of the ‘government support’ factor, comprising ‘price controls’, ‘procedural delays’ and ‘political instability’. The mean and median values of the respective variables were compared and found to be similar, thereby implying the presence of minimal or no outliers. The variable ‘weak intellectual property laws’ had the highest mean value of 4.00. The other variable, ‘lack of data protection’ too had a high mean value of 3.98. Both the variables of the underlying factor ‘legal provisions’ had high factor loadings of at least 0.87. This indicated their communality with the factor. Under the factor ‘government support’, the variables ‘price controls’ and ‘procedural delays’ had
high mean values of 3.87 and 3.83, respectively. Amongst the five variables, ‘political instability’ had the lowest mean value of 2.92. The variable ‘procedural delays’ had a high factor loading of 0.86, suggesting its communality with the factor ‘government support’.

The high mean value of the variable ‘weak intellectual property laws’, together with the secondary data findings, confirm that a stronger patent protection led to higher FDI inflows into IPI. The absence of a separate legislation protecting undisclosed test data submitted by pharmaceutical firms to the regulatory authorities results in foreign investors by-passing India. With the replacement of the process patent regime by the product patent regime, the major constraint that deters FDI flows into the country is found to be the lack of data protection. Pharmaceutical products are sensitive to price changes and the ceiling on drug prices restricts firms from reaping high profits. Similar to other studies on FDI inflows, procedural delays caused by bureaucratic hurdles were also identified by firms as being constraints to the inflow of FDI. The low mean value of ‘political instability’ as a deterrent of FDI can be ascribed to the Indian economy having become politically stable.

Conclusion

Although there has been an increase in the number of FDI recipient large firms in the product patent era, the proportion of total FDI flows to large firms has reduced vis-à-vis the process patent regime. The amount of FDI flows into larger firms of IPI has been higher in the product patent regime as compared to the process patent regime. Despite increase in the amount of FDI flows, the firms believed that the potential for FDI inflows was higher than the actual inflows. While the prevalence of weak intellectual property laws during the process patent regime was perceived to have deterred FDI, the lack of data protection, price controls and procedural delays have resulted in a low level of FDI inflow into the IPI, in the product patent regime. For IPI to be able to successfully attract FDI in the product patent regime, it is necessary that adequate infrastructure sans bureaucratic hurdles be made available. In addition to cost arbitrage, India needs to offer data protection to MNCs.

The period of coverage of the study is restricted to four years prior to the change in the patent regime and the initial four years of the new patent regime. Since the impact of the new regime is still unfolding, it is yet to be seen whether the perception of the firms regarding the constraints of FDI inflows will remain the same or will undergo a change. Additionally, two years of the study period, namely, 2008 and 2009, were years of the global crisis. Hence, the level of FDI inflows during those years may have been lower than the potential levels of FDI inflows. Once data protection is provided in India, there exists scope of further research on FDI.

References


