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"Analyzing law and policy along with contemporary problems relating to FDI in Brownfield Pharmaceutical Sector in India"

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Introduction

In 1991, in order to manage the IMFs loan, India endured adjustments of installments and need to promise 20 tons of gold to Union Bank of Switzerland and 47 tons of gold to Bank of England as a component of bailout from the loan. So with some encouragement from IMF, India decided to embrace the auxiliary of financial changes, which are liberalization, privatization and Globalization (LPG) in 1997.

With India being the 2nd most populous country with average growth rate of 7% having large and growing middle class population who increase the domestic consumption which makes India an important market. The stable parliamentary democracy along with skilled human resources contribute to making India a preferred country for investment both for manufacturing and trading of goods and services along with being a potential market for consumption. According to the world bank, FDI is known to be an instrument of economic growth as it facilitates transfer of technology along with capital from developed countries to the developing ones. But it is important to scrutinize as to how each sector responds to FDI as it has a different impact on each of them and the fact that in some sectors, FDI can have a negative impact with regard to the domestic producers.

Pharmaceutical Sector in India

India enjoys an important position in the Pharmaceutical sector globally with contribution of being the largest generic drug provider along with fulfilling more than 50% of the vaccine demands globally. The country has a fairly large pool of scientists and engineers who have the ability to steer even larger goals once given opportunity. Indian pharmaceutical sector is expected to grow to US$ 100 billion and medical device market expected to grow US$ 25 billion by 2025. Pharmaceuticals exports from India stood at US$ 19.14 billion in FY19 and US$ 13.69 billion in FY20 (up to January 2020). Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush & herbal products and surgicals.[1]

Why is FDI required in Pharmaceutical sector of India ?

This initial liberalization brought substantial changes to the country's pharmaceutical industry, including an end to public monopolies for the production of certain drugs and requirements that

[1] Indian Pharmaceuticals Industry Report, India Brand Equity Foundation, Ministry of Commerce & Industry, GOI, March 2020, https://www.ibef.org/industry/pharmaceutical-india.aspx#login-box

bulk drug production adhere to certain ratios.[2] Finally, the government sharply reduced its regulation of FDI in pharmaceuticals: In addition to easing approval requirements and limits on foreign equity holdings in the sector, the program removed most export requirements, technology transfer clauses, and employment and training requirements for pharmaceutical producers. Today, India has an automatic approval process for foreign pharmaceutical firms operating in the country and permits them to fully own Indian pharmaceutical companies. [3]

Pre-liberalization Era in India

In the pre-independence era, India approached a cautious and conservative approach regarding FDI in pharmaceutical sector and only collaborated with foreign companies in areas where high technology was required whereas it discouraged investments in low tech sector in order to protect the domestic industries even though before 1990, 85% of the pharma industry was controlled by the multinational corporations and after 1990, due to sectoral reservation of public sector in order to build up self-reliance, the shift of patent regime from product patent to process patent and due to FERA(Foreign Exchange Regulations Act) required the foreign holdings to reduce their shareholdings to 40% if they had to continue in India.

Post liberalization era,

- Industrial policy reforms gradually removed restrictions on investment projects and business expansion on the one hand and allowed increased access to foreign technology and funding on the other[4]. In 1995, under section 3 of Essential commodities act, a drug price control order was introduced to regulate the prices of drugs with the intention of allowing foreign investment in drug and pharmaceutical sector.
- Even though, the liberalization started in 1986 Drug policy which amended FERA and allowed the foreign entities with more than 40% holdings to conduct business in India, during the period of liberalization in 1991, only 51 % of FDI was allowed through automatic route in the manufacturing of drugs and medicines.
- In the year 2000, upto 74% FDI was allowed in case of ***bulk drugs*** under ***automatic route*** and above 74% ***Approval route*** was to be taken in case of manufacturing of ***bulk drugs***.[5]

[2] Robert J. Shapiro and Aparna Mathur, How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers, Jannuary 2014, http://admin.indiaenvironmentportal.org.in/files/file/pharmaceutical%20producers.pdf
[3] Robert J. Shapiro and Aparna Mathur, How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers, Jannuary 2014, http://admin.indiaenvironmentportal.org.in/files/file/pharmaceutical%20producers.pdf
[4] (Husain, 2011).
[5] Press Note 2 (2000 series), Government of India Ministry of Commerce & Industry Department of Industrial Policy & Promotion SIA (FC Division), https://dipp.gov.in/investors/investor-guidance/press-note-no2-2000-series

- In the year 2001, FDI was permitted up to **100%** on the ***automatic route*** for manufacture of drugs and pharmaceutical, provided the activity does not attract compulsory licensing or involve use of recombinant DNA technology, and specific cell / tissue targeted formulations, otherwise it required Govt. approval route.[6]
- In the year 2005, the government adopted a policy of minimal interference with respect to FDI in the Pharmaceutical sector. 100 % of FDI was permitted under the automatic route including the list of industries which required industrial licensing. [7]

- In 2010, on the suggestions of Arun Maira Committee report, a distinction was made between Greenfield and Brownfield Investments where 100 % FDI was permitted through automatic route in whereas in case of Brownfield investments, all the proposals will be routed through the FIBP(Foreign investment promotion board) for an interim period of 6 months which shall be reviewed later.[8] The conditions imposed by FIBP while recommending approval of brownfield investments are that for the next 5 years, the companies receiving foreign investments will have to maintain a list of medicines under the list of essential medicines with highest quantity of production for at least 3 years along with maintaining a list of expenditures and any information relating to the transfer of technology was to be provided to the administrative industry and FIBP. A quarterly compliance report was also to submitted with regard to compliance with all the conditions imposed by the FIBP and the administration. This decision of the government was largely criticized by the pharmaceutical industry as delay in approvals would decline the acquisitions in India and the major projects were on the verge of holding back.
- With respect to the unhappiness of the pharmaceutical industry, some key recommendations were made to the government by the parliamentary standing committee on Commerce in 2013 which included the suggestions of taking steps by the government to attract more investments but no changes were made by the government pertaining to these recommendations.
- In 2014, the press note 1 (2014 series) further added a condition that a non-compete clause will only be allowed by the approval of FIBP under special circumstances in case of Brownfield investments.
- Further, in 2015, the government allowed 100% FDI under automatic route for manufacturing of medical devices in both Greenfield as well as brownfield investments and

[6] Press Note 4 (2001 Series), Government of India Ministry of Commerce & Industry Department of Industrial Policy & Promotion Secretariat for Industrial Assistance, https://dipp.gov.in/sites/default/files/press4_01.pdf
[7] Press Note 4 (2006 series), Government of India Ministry of Commerce & Industry Department of Industrial Policy & Promotion (FC Section),https://dipp.gov.in/sites/default/files/pn4_2006_0.pdf
[8] Press Release dated October 10, 2011, India will continue to allow 100% FDI in Greenfield Pharma - CCI to develop necessary enabling regulations for Brownfield FDI in six months - PM chairs high level meeting, Ministry of Commerce & Industry, Press Information Bureau, Government of India.

removed the conditions imposed earlier.[9] Also in the same year, the Drugs and Cosmetics amendment bill was passed giving clarity and widening the scope of certain terms and provisions with the intention of inviting investments from foreign stakeholders.

- The major change in the brownfield investments were brought by the Modi Government in 2016 by the way of 2016 press release where the government further relaxed the FDI approval requirements bringing investments up to 74% under the automatic route and investments beyond 74% under the government route.
  The largest source of FDI in Indian pharmaceutical industry is Mauritius. Many global investors in India route their FDI through Mauritius to take advantage of the India-Mauritius bilateral tax treaty.[10]

Analysis of FDI policy during Covid-19

The Indian pharma industry has been a global leader in both domestic and international market particularly because of its quality and cost effectiveness. But recently it had been experiencing a great amount of competition from china due to its leverage in being extremely cost effective. While uncertainty lingers over the impact on greenfield investments and M&A deal activity, a Global Data report on the impact of Covid-19 as of 19 April points to a rise in venture capital deals in the pharmaceutical sector during the month of March. This sheds some light on the future after a sharp decline in deals during February, when the fall compared with 2019 was 54% in value and 90% in volume.[11]

- Nearly 70% of India’s import dependence is on China and thus, while the current international focus is on the supply chains in the pharmaceutical sector, there has been growing recognition of the need to limit the expansive exposure to China in many different sectors.[12]
- Due to the current Covid-19 outbreak, the pharmaceutical sector has emerged as a strong contender, not only in India but globally the stocks have been on rise. Most of the companies are expected to bounce back from the past 5 years of underperformance due to the increasing demand of medical supplements as well as equipments.
- The pharmaceutical industry being one of the most important sector during the pandemic has taken a hit due to the rising prices of the key ingredients which are used to make

[9] Press note 2(2015 series), GOVERNMENT OF INDIA MINISTRY OF COMMERCE & INDUSTRY DEPARTMENT OF INDUSTRIAL POLICY & PROMOTION, https://dipp.gov.in/sites/default/files/ru2261.pdf
[10] Katherine Connor Linton and Nicholas Corrado1
[11] Marina Leiva, Pharma FDI in the times of Covid-19: A challenging pill to swallow, 28 APRIL 2020, https://www.pharmaceutical-technology.com/investment/pharma-fdi-in-the-times-of-covid-19-a-challenging-pill-to-swallow/
[12] C. Raja Mohan, Coronavirus outbreak highlights China’s dominance over pharmaceutical industry, March 10 2020, Indian Express, https://indianexpress.com/article/opinion/columns/indias-drug-industry-coronavirus-scare-national-security-over-pharmaceutical-industry-india-china-relations-6307296/

essential drugs such and therefore, the prices of these drugs have also risen the most. Some of the factors of this drastic change in the prices are the lack of supply of active pharmaceutical ingredients or finished drug products from China due to the factory closures in China and the inter-state transport challenges.

As Covid-19 continues to spread, the countries worldwide are expanding their scope of FDI in order to focus on improving their healthcare and medical facilities in the view of protecting their national as well as economic interests. News reports indicate that Indian pharma companies are trading at their lowest valuations in the past 8-10 years, and the falling Rupee against the US Dollar is expected to boost pharma exports. The recent hydroxychloroquine incident underscores the importance of India retaining control over indigenous critical infrastructure and technology.[13] Given the unprecedented situation created by the Covid-19 pandemic and India's heavy reliance on private healthcare, the government will need to review the permissibility of, and security concerns relating to, FDI in healthcare.[14]

Analysis & Conclusion

Due to favorable government policies and stronger IPR laws, the Indian pharmaceuticals sector is attracting the most advanced technologies and hence, FDI policy should be formulated in a manner that would encourage the drug discovery research. But, the drug pricing policy should be in harmony with the FDI policy so that these drugs can reach the maximum people. Instead of incentivizing brownfield FDI the government should focus on incentivizing the greenfield FDI for more growth in foreign capital and new employment opportunities. The "Pharma Vision 2020" conceived by the Department of Pharmaceuticals can be considered as a positive step in this direction Also, the government should focus on stronger IPR laws along with liberal litigation so as to attract foreign investments. FDI has crucially impacted the Indian Pharmaceutical Sectors progress by stimulating domestic investment because of increase in competition and also increasing employment opportunities in India

[13] S&R Associates, Impact of Covid-19 On FDI Regimes, April 15 2020, Bloomberg Quint, https://www.bloombergquint.com/coronavirus-outbreak/impact-of-covid-19-on-fdi-regimes

[14] S&R Associates, Impact of Covid-19 On FDI Regimes, April 15 2020, Bloomberg Quint, https://www.bloombergquint.com/coronavirus-outbreak/impact-of-covid-19-on-fdi-regimes