**From a revenue-based business model to a growth-based business model: The case of the Indian pharmaceutical and biomedical industry**

**Abstract**

The paper is an attempt to address the question of economic growth and development through a sectoral analysis of the Indian pharmaceutical &biomedical industry and its transition from a ‘*revenue-based business model’* to a ‘*growth-based business model’*. It critically addresses this transition, the reasons behind it and its consequences through two distinct strands in the literature vis-à-vis economic growth and development. Concomitantly, the paper provides an understanding of the role of multilateral organisations such as the World Trade Organisation (WTO) in this transformation and how such institutions act in order to benefit multinational corporations (MNCs) to expand their hegemony. With the spread of the ideology of ‘maximisation of shareholder value’ that is intrinsically linked with the ‘growth’ of the industry, there was a reorientation of global pharmaceutical industry in terms of innovation and drug manufacturing. This in turn impacted the pharmaceutical industry in India in such a way that the companies here became extension units of multinational pharmaceutical companies at the expense of the Indian population, particularly the most vulnerable sections.

**Introduction**

The pharmaceutical industry in India is a very successful and self-reliant industry and is a leading exporter of drugs to other third world nations, ensuring the accessibility of drugs at prices affordable by them. It ranks eleventh in terms of exports, third largest producer of medicines in terms of volume and the fourteenth in terms of value (1). But, all this glory of the pharmaceutical industry has to be attributed to a critical policy decision by then Government of India (GoI), which is the introduction of process patents in the name of the Patents Act, 1970. This Act has allowed the domestic industry to use reverse engineering techniques to manufacture drugs and generate revenues through free market competition. This model of business is what is termed as a ‘revenue-based business model’. The industries were generating revenues and thereby profits under the controlled conditions of free market competition. This revenue-based model, complemented by a ‘process patent regime’ resulted in a win-win situation to all the concerned domestic stakeholders. It protected the domestic producers from the multinational corporations (MNCs) and also generated profits, made drugs accessible to the country’s population at affordable prices and in fact to other third world countries. This successful trajectory of the industry was put in peril through a major policy take back by then GoI, which is the introduction of the product patent regime. This take back is a result of India being a member country of World Trade Organisation (WTO) and in accordance with the Trade Related Intellectual Property Rights (TRIPS) agreement, all the WTO member countries are obliged to introduce product patent regimes in their respective countries within a specific time frame. The introduction of product patent regime implies that the success story of the Indian industry ensured through a reverse engineering process has to be stalled. On the other hand, it is becoming increasingly evident across the developed countries like the US and other European countries, how the cost of bringing a new drug to the market has escalated and how financialisation has become an integral part of the pharmaceutical industry. A study by Tufts Centre for the Study of Drug Development estimates that, currently, out-of-pocket cost of bringing a new drug to market is around 1,395 US million dollars (2) and also only one in every five drugs that enter clinical trials is successful (3). Complementing this high cost of drug development is the innovation deficit and patent cliff that raised serious apprehensions among the industry and in turn encouraged it to diversify its strategies to mitigate risks in order to maximise shareholder value. Given this high rate of risk and uncertainty, the terrain of drug development has generated an entire value chain in itself through various processes of diversification. In a situation where the global pharma industry has to undergo excessive valuation in the financial markets in order to keep its shareholders happy, it has devised various strategies such as outsourcing research, mergers and acquisitions, out-licensing molecules from upstream biotech companies, outsourcing clinical trials etc. Ironically, the multinational pharmaceutical industry at one register looked more like an investment banker rather than an innovation agent (4). This interweaving of the global pharmaceutical industry with the financial markets concomitant with the policy changes in the Indian patent regime obliged the Indian pharmaceutical industry also to restructure itself. In this process of restructuring, several strategies have been adapted by the Indian industry in such a way that it had effect on its own population. The question of access to medicines in the light of expensive patented drugs, the recruitment of vulnerable sections in clinical trials and the disasters resulting thereof are all pertinent issues that are manifested either implicitly or explicitly through the perusal of this ‘growth-based business model’. These are the aspects that this paper deals with, situating all these micro level sectoral changes and consequences in the context of the macro level debate of ‘economic growth and development’ and delineating who and what are at stake.

**‘Revenue-based to Growth-based Business Model’ and The Reasons Behind Transition**

At the outset, it is important to explain what a revenue-based business model is and what a growth-based business model is. A revenue-based business model is one in which the value of the company is determined by profits which is, *“how much money they actually make over the amount expended*” (4: p 40) While in a growth-based business model the focus is on *‘how much potential there is for future earning over and above the present rate of earning so that it can be translated into shareholders value*’ (4: p 40).

The fundamental reason why the Indian pharmaceutical industry has to move from revenue to growth model is because of India being a signatory of WTO and in compliance with the WTO TRIPS agreement, a patent regime was introduced in India which is the regime of product patents.

“…the TRIPS obligation made it imperative for the Indian firms to start their own R&D or face the threat of being reduced to being producers of only off-patented drugs” (5: p 244).

This introduction of a product patent necessitates the industry to pursue high end research and drug development which is a very risky and high stakes enterprise. A study by the Tufts Centre for the Study of Drug Development estimates the current cost of drug development at 1,395 million dollars and capitalising out of pocket costs to the point of market approval at a real discount rate of 10.5 % is estimated at 2,258 million dollars (2). Such high costs of drug development had led to the use of emergent technologies (6) and the induction of financial actors in the drug manufacturing process whereby the ideology of ‘maximisation of shareholder’s value’ became a central mission witnessed in the case of countries like the US.

In such an endeavour, it becomes an obligation for the industry to generate capital through financial institutions and hence venture into a growth model. This venturing into a growth model comes with its own structural regulations where valuation of the companies is conducted through the highly complex mechanisms of financial institutions. It is important to note that the Indian pharmaceutical industry was a highly successful industry when this change was taking place.

**The Reorientation of Indian Pharmaceutical Industry**

After India became compliant with the TRIPS agreement, the landscape of the health care sector in general and that of the pharmaceutical industry in particular has transformed to a great extent. Compliance with the TRIPS agreement means a heavy focus on R&D and what was immediately witnessed was a drastic increase in the R&D investment. However, the success of such investments turned out be modest (7). The industry has also adapted various other strategies such as mergers and acquisitions (M&A), out-licencing and in-licencing molecules etc. On the other hand, there has also been a rise in new social forms such as contract research organisations and clinical research organisations. The following subsections will provide an account of each of these endeavours and their specific mechanisms.

***Focus Towards R&D***

With the introduction of the product patent regime, it became a compulsion for the industry to focus more on R&D. During the early 1990s, the R&D expenditures of Indian pharmaceutical industry on an average amounted to only 1.5% of its sales, but since the early 2000s, there has been a drastic increase in the percentage of R&D expenditure (8). The R&D expenditure of top Indian companies has grown at a composite annual growth rate (CAGR) of 38% during 2000-01 to 2005-06 (9). Currently, Indian companies are spending around 7% of their net sales on R and D (See Figure 1).

**Figure 1: Percentage of R &D to Sales of Indian Pharmaceutical Sector**

Source: (10).

Despite such a drastic increase in R&D expenditure, only Zydus Cadila has been successful in bringing out a new drug named Lipaglyn from lab to market through indigenous R&D (11). Though there has been a drastic increase in the R&D expenditure over the years, it still lags much beyond their global counterparts. McKinsey & Company estimates that the cost of R&D in India would be only 40-60% of what is spent in the US and the Central Drug Research Institute (CDRI) estimates that India needs to spend only 30% of what is spent in the US. But the Indian R&D expenditure falls way below even that yardstick (12) (Joseph, 2016).

“The combined R&D investment of India’s top 10 pharma R&D investors during the last 10 years amounts to only 40% of Pfizer’s investment in R&D in one year” (12: p 100).

***Mergers and Acquisitions (M&A), Out-licensing and in-licensing***

Several strategies other than increased focus on R&D such as M&A, out-licensing and in-licensing molecules have also been adapted by the the Indian pharmaceutical industry in order to gain through the advantages possessed by their global counterparts (See Table 2). The rationale behind M&As on behalf of Indian companies seems to be that of “increase market share, to gain control of a blockbuster drug existing or potential, to gain entry into a high growth therapeutic area, to enhance R&D productivity, to access new technology platform and management efficiency” (13: p 187). On the other hand, MNCs are interested in such M&As because of the rising innovation cliff as well as to access the generic market in other countries (14).

**Table 1: Snapshot of Mergers and Acquisitions (M&As) Between Indian and Foreign Pharmaceutical Firms**

|  |  |  |
| --- | --- | --- |
| **Indian Firm** | **Foreign Firm** | **Deals** |
| Primal Health Care | Abott | Acquired the domestic formulation business for 3.7 billion dollars |
| Orchid Chemicals | Ospira | Acquired generic injectable business for 400 million dollars |
| Shanta Biotech | Shanofi Aventis | Acquired for 783 million dollars |
| Ranbaxy | Daiichi-Sankyo | Acquired for 4.6 billion dollars |
| Dabur Pharma | Frsenius Kabi | Acquired for 219 million dollars |
| Matrix Laboratories | Mylan | Acquired for 736 million dollars |

Source:(13) .

The Indian pharmaceutical industry, realising the huge costs of taking a drug towards clinical trials, has been seen to be adapting widely the strategy of outsourcing lead molecules that are an outcome of their R&D efforts. They enter into such deals in exchange for upfront milestone payments, royalties etc. There are instances, though very few, where the Indian companies also in-licensed molecules to take it further towards clinical development. For example, Glenmark has struck a deal with Napo Pharmaceuticals to develop Napo’s anti-diarrhoeal molecule with Napo granting development and commercialisation rights to Glenmark in 140 countries including India (12).

***Rise of New Social Forms***

Along with the implementation of the product patent regime in 2005, the Indian government also amended ‘Schedule Y’ of India’s Drugs and Cosmetics Rules of 1945, “in order to harmonise guidelines for the conduct of clinical trials with those mandated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use” (4: p 5). These two harmonising acts were enacted in order to bring the national legislations in concurrence with the global regulatory frameworks and in turn led to the rise of new social forms such as contract research organisations and clinical research organisations (CROs). One of the direct parties involved in the rise of CROs is the Indian pharmaceutical industry itself because of the necessity of clinical trials to manufacture novel drug candidates after the enactment of TRIPS. And also since the drug companies do not have direct access to patients, a void was created that got filled by the CROs. The clinical trials industry recorded a significantly higher growth rate of 44% during 2003 and 2009 and also the Indian government allowed 100% FDI in clinical trials which attracted a large number of MNCs (15). In terms of financial turnover between 2003 and 2010, the clinical trial industry grew more than 100 times at the rate of 1414% annually (16). Several scholars arguing that India is experiencing “big pharmaceuticalisation” asserted that, “TRIPS has encouraged a concentration of capital, with large companies gaining increasing market share and using their market power to rewrite regulations and regulatory practices in their own interest” (7: p 240).

India acts as a favourite destination for clinical trials, particularly for two reasons. While cost advantage is one, the other is the availability of a large chunk of treatment naïve subjects. These two reasons have played a crucial role in outsourcing of clinical trials to India by the MNCs.

***The Impact on India and its Population***

After the enactment of TRIPS that led to restructuring of the business model of Indian pharmaceutical industry, there has been a significant effect on the landscape of the health care sector. These effects are multifaceted and have led us to witness instances where even the sovereignty of the Indian parliament was also challenged. To list out a few effects that have been witnessed,

***Non-equity Mode of Partnership***

After the mid-1990s, once the Indian pharmaceutical sector opened doors to globalisation, the Indian pharmaceutical industry became an integral part of global R&D and production networks in non-equity modes. Indian firms were able to be integrated in the first place because of the strengths it accumulated during the previous patent regime. However, once the doors were opened, the Indian industry shifted its focus from the domestic industry and reoriented themselves from being competitors of MNCs to being their subordinate collaborators (12).

***Patents Couldn’t Ensure Innovation***

While the rationale behind introducing the product patent regime is that it fosters innovation that caters to local needs, the reality in the Indian scenario provides evidence to the contrary. The MNCs took advantage of the patent system and imported drugs from their home countries by establishing their subsidiaries in India rather than domestically manufacturing them. The process of liberalisation has ensured that the restrictions that were imposed earlier mandating manufacturing and investments in the country are also withdrawn. In 2012-13, 49 MNCs sold medicines worth 1,67,733 million rupees in the Indian market and among these 49, 22 companies each with sales more than 1,000 million rupees accounted for 95% of MNC market (17). But if one were to look at the amount expended by these MNC subsidiaries on R&D, the figures would be staggering. Before the TRIPS came into effect, MNCs were spending 1% of their sales on R&D which has actually declined to 0.3% in 2012-13(17). These figures explain how the rationale behind patents that they would foster innovations catering to domestic needs hasn’t come to bear fruit, at least in the case of India. The scenario is a resemblance of the one before 1972, where MNCs resorted to importing finished products from their home countries rather than domestically manufacturing them.

***Exorbitant Prices of Drugs***

With the introduction of the product patent regime, the prices of the drugs have been hugely escalated. This has come to directly affect the Indian populace, particularly in the case of life-threatening diseases. As per the recent National Sample Survey Organisation (NSSO) report of 71st round on Health in India (2014) reveals that nearly 72% of medical expenditure in rural India and 68 % in urban India constitutes the cost of medicines (18). A significant proportion of this catastrophic health expenditure is met through the savings and borrowings or with the help of relatives and friends since 86% of the rural and 82% of the urban population are not covered by any health protection scheme (10). The monopolies granted in the form of patents has given a leverage for the MNCs to charge exorbitant prices. In India, the regulatory authority to control drug prices is the National Pharmaceutical Pricing Authority (NPPA) under the Drug Price Control Order (DPCO), 2013. Though TRIPS doesn’t forbid any country from regulating prices, the DPCO of 2013 doesn’t cover patented drugs that don’t fall under the National List of Essential Medicines in case of drugs developed outside India and for domestic companies a five-year exemption is provided from price regulation (19).

The TRIPS agreement provides the provision of compulsory licencing (CL) to member countries and doesn’t “specifically list the reasons that might be used to justify compulsory licensing” (20). However, India invoked the provision of CL only once to NATCO in 2012 to manufacture the generic version of Sorafenib, (an anti-cancer drug marketed by Bayer as Nexvar) that reduced its price to 8,800 rupees for a month’s treatment from 2,80,000 rupees (21).

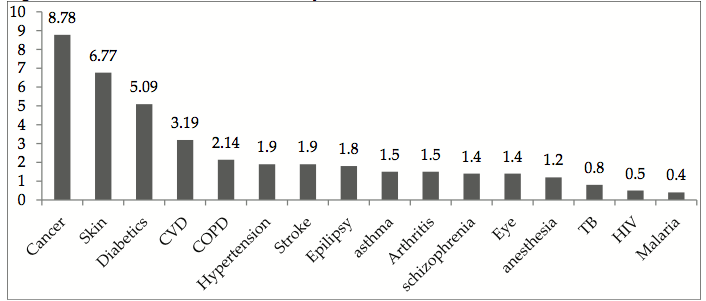
***Clinical Trials and Disasters***

With the rise of CROs, there has been a rise in the recruitment of individuals for clinical trials, particularly from the most vulnerable sections. While in developed countries like the US clinical trials through social contract ensure the accessibility of drugs that manifest out of trials, the Indian scenario is one of apathy. In India, there is no guarantee that “an experimental drug tested on the local population will necessarily be marketed there after approval - let alone be made available at an affordable cost” and interestingly, India is the only country in the world where violation of good clinical trial practice is a criminal offence rather than a civil offence (22: p 78). Several thousand deaths took place since 2005 due to clinical trials, most of the victims belonging to vulnerable sections (15, 23). Kaushik Sunder Rajan (24) provides a polemic of how disposed mill workers from Bombay textile mills are recruited as experimental subjects in clinical trials by Well Spring hospital that is operated by the pharmaceutical industry NPIL. On the other hand, the promise that clinical trials would result in a technological spillover from developed countries also didn’t bear fruit, given the fact that more than 60% of trials conducted in India are Phase-III and Phase-IV trials which are only used to test efficacy and therapeutic dose (15, 16). Issues with regard to violation of ethical practices in clinical trials is also very rampant and a regular affair. As per the estimates of the Ministry of Health and Family Welfare, during 2005-2012, 2,644 deaths were recorded across India due to clinical trials(15). However, after pressure from several civil society organisations, the Central Drugs Standard Control Organisation (CDSCO), which is the nodal body to regulate clinical trials in India, issued new guidelines in 2013 (25).

***Drugs for Markets - Not Epidemiological Concerns***

In the growth model of business, drugs get manufactured primarily for markets and epidemiological priorities take a backseat. A particular trend has been witnessed in the rise of increasing R&D efforts which is in tune with market logic rather than epidemiological concerns (10). While the Indian population is prone to both communicable and non-communicable diseases (NCDs), statistics show that the R&D efforts of the industry are primarily concentrated towards NCDs because of the huge market share they provide both in domestic and global markets (See Figure 2).

**Figure 2: Disease-wise Clinical Trial Data in Terms of Percentage from India**



Source: (15)

***Challenging the Country’s Sovereignty***

Section 3(d) of the Indian Patents Act restricts pharmaceutical companies from patenting innovations with little increments to prevent ‘ever greening’(26) (Fischer, 2013). Novartis, a Swiss-based MNC in India, in May 2006 challenged the Indian Patent Office in the Madras High Court for denial of patent based on section 3(d). The company challenged the denial of patent and also the constitutional validity of section 3(d) in the court. It was not just challenging the denial of patent to its drug by name ‘Gleevec’ but rather the provisions made by Indian Parliament and its sovereignty.

“…it was challenging sovereign legislation of the Indian Parliament in a court of law, suggesting that the nation-state sovereignty is not absolute but tempered by and subject to international agreements that the state has signed” (4: p 121)

Novartis also asserted that section 3(d) violates the government’s constitutional duty to harmonise its national legislations with its international obligations but the defence claimed that a “domestic court does not have the authority to examine TRIPS compatibility. Rather, the exclusive forum for deciding such an issue would be WTO’s Dispute Settlement Board” (27: p 63). It is only member countries that can approach the boards and in this case and the Swiss government was not doing so. Eventually, Novartis lost the case both in Madras High Court and the Supreme Court. But the point here is the extent to which MNCs go in order to assert their hegemony.

***Situating the Case in the Context of ‘Economic Growth and Development’***

The perusal of the strategy of growth in India after the liberalisation measures had a deep impact on the pharmaceutical industry and on the Indian populace in terms of their access to health care. While the perusal of growth is about the opening up of domestic markets and exploring wider global markets, in sectors such as pharmaceuticals which are technologically intensive and scientifically competitive, the perusal of growth comes with several preconditions, for instance, the change in patent regime. In such scenarios, the perusal of the growth strategy comes with certain costs and a careful scrutiny of such costs becomes essential, specifically and more so in sectors like pharmaceuticals.

In the book ‘Why Growth Matters: How Economic Growth in India Reduced Poverty and the Lessons for other Developing Countries’ (28) the authors in their course of demystifying their critics with regard to the impact of perusal of growth with regard to the health care sector, especially in comparison with respect to China and Bangladesh, adopted the strategy of elucidating the historical and comparative advantages that the two countries possess in order to explain the poor performance of India. But, if one were to adopt the same strategy and look at the historical and comparative advantages that India possessed, specifically with regard to expertise in generic manufacturing over a period of time, the available empirical data suggests that the strategy of perusal of ‘growth’ is something that contradicted the idea of inclusive development. In Uttar Pradesh (UP), a news item broke in all the popular media about the deaths of children in Gorakhpur and Faridabad district hospitals, allegedly due to lack of oxygen cylinders and concretely due to Japenese Encephalitis (29). When placed in the context of the ongoing state of affairs in the Indian pharmaceutical market and industry, it indicates two things. On the one hand, there are patented drugs that are priced around Rs one lakh and on the other, there are these kids who allegedly died due to lack of oxygen. And secondly, the encephalitis disease that is plaguing UP for more than two decades now is a neglected disease (30) and there is a huge evidence that points to the fate of neglected diseases in the current scenario. Two questions arise here in the light of the above-mentioned quote. The first being, ‘Is this kind of inequality a matter of concern?’ if so, ‘is it of any relevance’?

While there are such staunch proponents of growth who see its perusal as an end in itself, on the other side of the spectrum are scholars such as Amartya Sen and Jean Dreze who look at economic development in a broad perspective, in which both social and economic opportunities have central roles. Proponents on this side of the spectrum argue that, “If the central stage of economic development in India is understood in terms of the need to expand social opportunities, then liberalisation must be seen as occupying only one part of that large stage” (31: p 51). The scholars in fact argue that while India’s growth increases rapidly, it will potentially be handicapped “by its overwhelming illiteracy, backwardness in health care and other deprivations” (31).

**Concluding Remarks**

The perusal of growth as a principle of macro economy takes various forms when it comes to operate at the micro level, especially at the sectoral level. The micro level sectoral specificities and their nuances actually complicate the situation than it might be theoretically envisaged. The rise in the dominating role of financial institutions and the scientific advancements are several contingent factors upon which the prospects of the pharmaceutical industry are being determined and in such complex situations, the costs of perusal of growth might outweigh its benefits in several qualitative dimensions. While the process patent regime is a win-win situation for all the domestic stake holders along with other less developed countries in terms of access to cheap medicines, the perusal of ‘growth-based business’ definitely hindered such access. Before the 1970s when product patent regime was in place, MNCs used to export drugs from their home countries without manufacturing them in India and sold those drugs at exorbitant prices. While such a situation has changed after the 1970s due to the introduction of process patents, a reintroduction of the product patent regime brings in a situation that is reminiscent of the one that prevailed before the 1970s. The Indian industry became a non-equity partner to the MNCs in their perusal of growth as an end in itself at their own cost and especially at the cost of most vulnerable sections of the Indian population.

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