

CHALLENGES AND GROWTH IN THE PHARMACEUTICAL INDUSTRY OF INDIA: A THEORETICAL PERSPECTIVE

Abhishek Misra,

Research Scholar,

University Business School, Panjab University, Chandigarh

ABSTRACT

Health awareness is the essential concern of any individual and it is of most extreme significance for the administration to guarantee that it comes to over the masses at sensible and moderate cost. The Indian pharmaceutical part has progressed beyond anyone's expectations being non-existent before the year 1970 to a conspicuous supplier of human services items meeting just about 95% of the pharmaceutical needs of the nation shortly.

Harmonization of licenses administration in the year 2005 and the presentation of item patent have tossed new difficulties to the Indian pharmaceutical industry to overcome them. Thus the Indian pharmaceutical industry is at a defining moment. Drug revelation procedure has experienced a significant change. It obliges vital arranging adjusting to concentrate on new sedate disclosure and its insurance. Indian pharmaceutical organizations need to change their directions to meet these difficulties. This may require quantum bounce in quality framework, development in assembling and business skill.

Key Words: Growth, Pharmaceutical Industry, Generic manufacturing, Reverse engineering, Patents

Introduction and Review of Literature

The Pharmaceutical business is an energizing industry worldwide with development rate of 8 % and a turnover of around US\$ 650 billion. Because of the Pharmaceutical business' capital and

know-how force, the vast majority of the world's creation is spotted in the created nations, the significant ones been the United States, European Union and Japan. The Indian Pharmaceutical industry has through a scope of legislative motivators and, remote firms that have put resources into the business, which have added to the development of Pharmaceutical Industries. The outcomes have been blended.

India is one of the couple of creating nations with a substantial generation base in Pharmaceutical items. India's exchange items has expanded a considerable measure following the liberalization changes and it has near focal points in exchange with Pharmaceutical items, both mass medications and definitions. The Indian Pharmaceutical industry positions high among creating nations, regarding innovation and quality, and is today in the front rank of India's science based commercial ventures.

In the late research it has been affirmed that 80% of the medications supplied to Africa for Human Immunodeficiency Virus (HIV) and Malaria have been supplied from India through Indian pharmaceutical organizations. Subsequently, in its actual sense India has turned into the 'drug store of the world'.

The growth of the Indian Pharmaceutical industry has been remarkable in recent times. The industry is today the fourth largest globally, in terms of volume, and 13th largest in terms of value. The industry accounts for 8% of the global sales in volume but in terms of value it is barely 1%. The role of the Indian Pharmaceutical industry in the international market today is as a supplier of good quality, low cost generic bulk and formulation. The annual turnover of the Indian Pharmaceutical industry is approximately, US\$ 19 billion.

However the Indian Pharmaceutical part has made a ton of progress of being non-existent before the year 1970 to an unmistakable supplier of medicinal services items meeting right around 95% of the Pharmaceutical needs of the nation without further ado. The time of the 1995-2008 saw the strongest execution of the Indian Pharmaceutical industry on a few fronts. Not just did the business enhance its generation execution seen in the earlier decades, and that too by a noteworthy edge, the industry transformed into a net remote trade worker amid the decade being

referred to. The Indian Pharmaceutical industry, now a \$19 billion industry, has indicated huge advancement.

India ranks among the top 15 drug manufacturing countries of the world and is rated very high in the world in terms of technology, quality and range of medicines being manufactured. The country boasts of manufacturing almost every type of medicine right from simple headache pills to sophisticated antibiotics and complex cardiac compounds.

Reverse engineering has been one of the greatest boons to the Pharmaceutical industry and is a form of innovation that Indian Pharmaceutical companies have mastered, but the story of Indian Pharmaceutical companies does not end at developing and manufacturing generic versions of branded or patented drugs, in fact that is where it starts. This strength in generic manufacturing operations, gave India the confidence to challenge patents of some of the world's largest Pharmaceutical companies. India has fast become the hub of Contract Research and Manufacturing (CRAM) outsourcing.

Generic manufacturing is an area where India has been able to take a firm foothold with a total market share of 31% in the total **Abbreviated New Drug Application** (ANDA) approvals and estimated 50% in the total **Drug Master File** (DMF) filings in the year 2009, India is likely to continue holding a dominant position here.

Enough writing is not accessible on the difficulties and development of Indian Pharmaceutical industry taking numerous parameters all the while. Constrained exploration has been there covering firm astute ANDA filings and regards, DMF filings and approbations with USFDA. Whatever writing is accessible is as papers/articles distributed in Pharmaceutical magazines and studies demonstrating the difficulties and development of Indian Pharmaceutical industry by taking a couple of parameters just. Chadda (2006) in her paper has attempted to demonstrate that Indian firms are spending gigantic assets to secure non-encroaching procedure licenses in outside nations. In the wake of tapping the creating nations, they are attempting to get to created nations with medication expert filings (DMFs) for mass actives supply and condensed new tranquilize applications (ANDAs) for details. The study by Grace (2004) uncovers that the possibilities of changing licensed innovation on Pharmaceutical industry are amazingly positive for the eventual

fate of the Indian business. The study demonstrates that 33% of all FDA applications originated from India in 2003 and this number is relied upon to be one half in 2004. MNCs have been occupied with working with Indian firms for quite a while, pulled in by lower expense structure.

The study by Dhar & Gopakumar (2006) gives investigation to demonstrate the execution of the organizations in the Indian Pharmaceutical industry taking after the progressions in the patent administration required by the Agreement on TRIPS. The study demonstrates that the R&D spending of a portion of the main firms, specifically, Ranbaxy and Dr Reddy's has indicated increment in Post- TRIPS period. Therefore, R&D intensities of the organizations have enhanced altogether. Sunil (2006) in his working paper attempts a point by point mapping out of the sectoral arrangement of development of India's Pharmaceutical industry. The study demonstrates that the TRIPS agreeability of the licensed innovation right administration has not diminished the advancement limit of the residential Pharmaceutical industry which has imagined an increment in both exploration plan and licensing. In his working paper, Chaudhuri (2007) investigates that R&D use has significantly expanded for a fragment of the Indian Pharmaceutical industry after TRIPS became effective. It is not just that the measure of R&D use has expanded, yet there has been an exceptional move in the structure of R&D exercises of the Indian organizations. Prior they were basically connected with the advancement of new techniques for assembling medications, now they are likewise included in R&D for new compound elements (NCE).

As per Sheena Reddy (2006) the development in R&D for bigger Pharmaceutical is more prominent than the development for the general Pharmaceutical part. Bigger Pharmaceuticals have the assets to give more speculation for R&D and can stand to consider what's to come. Littler Pharmaceutical don't have these assets and may not have the capacity to make due in the business. Gupta (2007) feels that the Indian Pharmaceutical Industry has Exciting Opportunities in Post- TRIPS period. Indian organizations are expanding their rate of DMF filings each quarter. Indian nonexclusive players are additionally expanding their support in the propelled markets, especially the US. ANDA filings with USFDA are additionally expanding in Post- TRIPS period Sharma (2008) explores that India is now emerging as a preferred supplier of Active Pharmaceutical Ingredients (APIs) to many global companies for considerations beyond costs. It

is today the third largest API player after China and Italy. India is way ahead of its competitors in Drug Master File (DMF) filings. The proportion of DMF filings by Indian players has gone up more than three times in the last few years. India has the largest (being outside the US) US FDA approved facilities. Indian firms are able to tackle complex synthesis in relatively short periods of time with cost efficiency.

With the above background, the main objectives of this paper could thus be classified as:

- *To explore the factors which hinder the growth of Pharmaceutical Industry in India*
- *To explore the factors that fuel the growth of Pharmaceutical Industry in India*

Understanding the Factors which are responsible in fuelling of growth

India is known today for producing high quality generic medicines that are sold globally. Further India is known to be one of the fastest growing Pharmaceutical markets in the world. The following factors have fuelled its growth

Population explosion: Indian population is growing. India is the second most populous country in the world, with over 1.27 billion people (2014), more than a sixth of the world's population. Already containing 17.5% of the world's population, India is projected to be the world's most populous country by 2025, surpassing China, its population reaching 1.6 billion by 2050. Its population growth rate is 1.2%, ranking 94th in the world in 2013. The Indian population had reached the billion mark by 1998. This results in more probable people getting sick and hence demands of different kinds of drugs increase.

Growth of Indian Economy: India flourished as one of the world's fastest-growing economies for much of the last decade. This has resulted in growing incomes of members of the population. With the growing income levels, the demand for the drugs is bound to increase. Infact the demand curve for these drugs is inelastic in nature. This means, that even with the increase in the

prices of drugs, the demand doesn't fall. Hence it means higher profits for various Pharmaceutical companies and the Industry in general.

Changing Disease Patterns and Patient Demographics: Numerous districts have infections which are not completely comprehended and may have distinctive restorative needs in light of the fact that distinctions in hereditary qualities, eating routine, atmosphere or different variables which are remarkable to their surroundings. It is imperative that organizations perceive that they have to put resources into clinical trial and other investigative work before they endeavor to present their arrangement of current items to the area. This again can be seen as a colossal development potential particularly in the Indian connection. In India we have an immense white collar class. The white collar class experiences different illnesses like hypertension, diabetes and so on. The underlying driver of the issue is the more elevated amounts of anxiety confronted by the working class because of its high goals. This again will bring about appeal of medications which will bring about higher development rate.

Penetration of Health Insurance: Wellbeing is dependably a need in India. While India has made critical picks up regarding wellbeing pointers - demographic, infrastructural and epidemiological, it keeps on battling with more up to date challenges. The nation is presently amidst a double ailment weight of transmittable and Non-transferrable sicknesses. In light of the financial emergency confronting the legislature at both focal and state levels, as contracting general wellbeing plans, heightening social insurance expenses coupled with interest for medicinal services administrations, and absence of simple access of individuals from the low-salary gathering to quality health awareness, wellbeing protection is developing as an option component for financing of social insurance. This option instrument for financing makes interest for quality social insurance which thus brings about further development of Pharmaceutical organizations because of higher access of medicinal services by individuals.

Tropical Climate: India is a tropical country. Hence the presence of mosquitoes and flies can never be ruled out. These result in various kinds of water and food borne diseases. In other words in results in creation of a huge patient base in India. This too results in increase in demand of medicines, which result in growth of the Pharmaceutical Industry in India.

Understanding the Factors which are hindering of growth

The Pharmaceutical business is presently encountering the same marvel that numerous different commercial enterprises have confronted in the past where numerous organizations have been compelled to attempt and reevaluate themselves even with difficulties in their business surroundings. It happened with the PC business for instance International Business Machine Corporation (IBM) moving to an administration display, the steel business (outsourcing and expansion) and all the more as of late, the innovation area with the blasting of the dotcom bubble. One thing has ended up clear. Just the organizations that are willing to change or alter their techniques and take after that with superb execution of these procedures will have long haul achievement. The issues included are extremely mind boggling and spread a wide mixed bag of regions including innovative work, business, political and geological to give some examples. The accompanying components are seen as a test to the current Pharmaceutical organizations in India.

Limited Approval of New Chemical Entities: New Chemical Entities (NCEs) are the intensifies that rise up out of the procedure of medication revelation. Research done by IMS research (The world's biggest Pharma statistical surveying firm) demonstrates that there has been a noteworthy decrease in the quantity of NCEs propelled throughout the most recent ten years. This wonder has not been limited to simply a couple of restorative ranges or organizations and is exacerbated by the way that the estimation of the dispatches that have happened are fundamentally not as much as in the years when blockbusters medications gave huge increment in income. Despite the reasons, the organizations need to manage the truth that there are less new items being endorsed and in this manner they are neglecting to attain to their capability to give treatment to patients and business advantages to their organizations.

New medicates disclosure and improvement has not come to its maximum capacity in India. In any case, the quantity of mixes in the Indian pharmaceutical organization's pipeline and in the propelled phase of advancement is expanding. Indian pharmaceutical organizations have not got

an achievement in commercializing a New Chemical Entity (NCE). Till date, there has been no medication disclosure by an Indian pharmaceutical organization that has hit the business sector.

Increased Generic Competition: Generic drugs have always been a big challenge for the established big Pharmaceutical companies. Enormous Pharmaceutical organizations spend numerous years and a huge number of dollars from revelation to item dispatch. In 1976 the appraisal was \$137 million dollars and by 1990 it had expanded to \$445 million dollars. These organizations have the capacity to exploit their diligent work and speculations while their licenses are in actuality, however when these licenses terminate, the bland medication creators have the capacity to undercut the enormous Pharmaceutical net revenue inside 6 months by creating lower expense, and as a rule exceptionally viable options. The late monetary downturn, human services change in numerous nations and less discretionary cashflow for clients have made the bland alternative more alluring to payors, insurance agencies and customers concerned with dealing with their expenses. Subsequently the nonexclusive medication creators have been making advances in the item offers of the marked items and this alongside patent close has prompted increment in non specific deals.

Regulatory Changes and Political Impact: The recent (2006–2010) economic downturn has in many situations intensified and refocused people's attention on regulation in the Pharmaceutical industry. Some of the arguments in the fall of 2009 healthcare debate in the United States are a prime example. The debate has been driven both by the need for the improvement in the regulatory process to meet the current needs of all the stakeholders as well as the stated and in some cases implied need to ensure that the expected benefits are aligned with the cost for the insurance, products and services.

India had thrown open the sector to foreign investments up to 100% on the automatic route in 2002 under the previous NDA regime. However, the subsequent United Progressive Alliance government imposed certain restrictions after an intense debate following a spate of acquisitions of Indian companies by global drug makers including the takeover of biggest domestic company Ranbaxy by Daichi Sankyo. The government then introduced distinct norms for FDI in green field or new projects and brown field projects amid fears that consumers in India will be denied

cheap medicines if foreign multinational companies continued to buy large domestic Pharmaceutical companies. In year 2014, foreign direct investment (FDI) in Pharmaceutical sector was back in the spotlight, with the finance ministry pitching for a review of the policy that was tightened for brown field investments, or investments in existing Indian companies, following fears of large-scale takeover by multinational companies.

The government also moved medical devices sector out of the approval route even in case of brown field investments, indicating it may not be averse to dropping some restrictions. India was keen to draw investments into the sector to reduce the country's dependence on China for bulk drugs and is looking at measures to boost productivity in the sector.

Hence Regulation and Political factors have an impact on the growth of the Pharmaceutical Industry in India. Regulation also impacts many other issues and stakeholders concerned about issues like Global Warming (the effects of manufacturing plants on the environment, e.g. Ranbaxy in Mohali, Punjab) Animal Rights groups (resistance to testing in animals) and many other groups. These groups often have not only the monetary resources but also the political connections that can make it very difficult for Pharmaceutical companies to operate to their full potential in many countries and markets.

Conclusions

At the point when taking a gander at the business from a worldwide angle it is pass that there are chances to address un-addressed medicinal issue in numerous helpful ranges and areas of the world. It is additionally pass that with this extremely complex industry, rolling out the improvements important won't be simple, and it won't occur without any forethought. To be effective later on Pharmaceutical organizations will need to discover approaches to convey the prescriptions and arrangements expected to meet the ailments of today and what's to come. Organizations need to figure out how to make science and innovation work with business needs in an effective approach to profit all partners. As organizations set out on this voyage, they have to give as much time and push to plainly impart their systems to representatives, clients and different partners, anticipating change and organizing their associations for achievement.

Numerous organizations are well while in transit to changing their authoritative methods and also their operations to meet the difficulties they confront. Mergers and acquisitions and different types of associations have been an enormous piece of these progressions, and their long haul vital effect and execution is as yet being played out so it is too soon to make determinations. It is vital for individual organizations and the Pharmaceutical business to listen to their partners and invest time evaluating their choices, techniques and in particular, understanding the long haul needs of patients before they put intensely in any specific region. This will go far towards exhibiting that they are not kidding about addressing patient needs, and the partners at each level will advantage as a consequence of these activities.

Directions for further research:

Investigating the shift in the assembling base from created nations to fundamentally India and China there is a gigantic potential for the Indian pharmaceutical industry. A selective study could be possible just on the assembling capacity of Indian pharmaceutical industry as this is the quality range of the Indian organizations. Tropical maladies and its exploration in the Indian connection will likewise be a region concerning us as multinationals are not exceptionally quick to create cure for tropical infections which does not give gigantic prizes and perpetually does not fit into their procedure.

Bibliography

Andheria, Mahalaxmi 2009 “Indian Patent System and Indian Pharmaceutical Industry.”
<http://www.Pharmaceuticalinfo.net/og/pharmindia/indian-Pharmaceutical-and-new-patentregime>.

Biswajit Dhar & KM Gopakumar,2003 “ Effect of Product Patents on the Indian Pharmaceutical Industry” retrieved from <http://wtocentre.iift.ac.in/Papers/3.pdf>

Business Standard 2009 “ Pharmaceutical companies on DMF filing spree” Sept 2009

Business Line 2006 “Indian Pharmaceutical companies top DMF filings” Aug. 2006

Chadda, A. 2006 “Destination india - the right choice for the Pharmaceutical industry”, Delhi Business Review Vol. 7, No. 1 (January - June 2006) pp 1-8

Chaudhuri, S. 2007 "Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS" Working Paper Series WPS No. 614/ September 2007 retrieved from <http://www.iimcal.ac.in/res/upd/Sudip%20Wp%20614.pdf>

Chaturvedi, K. and Chataway, J., 2006, "Innovation In The Post-Trips Regime In Indian Pharmaceutical Firms: Implications For Pharmaceutical Innovation Model", International Journal of Business Innovation and Research, Volume 1, Number 1-2, pp 27-50

Dhar, B. and Gopakumar, K.M. 2006 "Post-2005 TRIPS scenario in patent protection in the Pharmaceutical sector: The case of the generic Pharmaceutical industry in India" the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development November, 2006.

Express Pharmaceutical, 2008 "The preferred API partner" 16-30 Sept.

The Financial Express 2006 "Indian firms top DMF filing with US FDA," May 2006

Grace, C. 2004 "The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines", DFID Health system resource centre: London 2004

Gupta, Desh Bandhu, 2007, "Exciting Opportunities for the Indian Pharmaceutical Industry", Indian Chemical Engineer, Vol. 49 No. 2 April-June 2007, pp. 154-157

Mata, J. and P. Portugal 2002. "The survival of new domestic and foreign-owned firms", Strategic Management Journal, 23, 323-343.

Nagesh Kumar, "Intellectual Property Rights, Technology and Economic development: Experiences of Asian countries", Study Paper 1b, Commission on Intellectual Property Rights, 25 (accessed at <http://www.iprcommission.org>)

Nilesh Zacharias and Sandeep Farias, "Patents and the Indian Pharmaceutical Industry", Business Briefing, PharmaTech 2002, accessed at <http://www.nishithdesai.com/Research-Papers/Patents-and-the-Indian-Pharmaceutical-Industry-NZ&SF>

Pharmaceutical Industry in India, Sample Report August 20, 2001, Evaluserve Business Information accessed at <http://www.rsc.org/lic/docs/pharmaceutical-india> on 29-12-2005

Praveen Raj R.S., "India moving to a Strong Patent Regime -Challenges & Concerns", Scientist - IP management, Regional Research Laboratory, Trivandrum, accessed at <http://www.patentmatics.org/pub2005/pub10b.pdf>

Reddy, S.2006 “The Costs to India of Complying with World Intellectual Property Rights: Effects on the Pharmaceutical Industry and Access to Drugs” Economics Thesis, May 2006.

Siddharth Narrain, A costly prescription, Frontline, 22 (4), Feb 12-25, 2005

Sengupta Amit, "Jeopardising the lives of millions"
<http://www.phmovement.org/India/articles/indianpatentsact.html>

Vishwas H.Devaiiah, TRIPS, patents and public policy: A pot of gold and a tale of woes!,
(accessed at <http://www.infochangeindia.org/Intellectual/Pro/Rts/08.jsp>)