



Is Pharmaceutical R&D Proportional to The Profits Earned? / Pharmaceutical R&D And Profits in Correlation?

Introduction

For years pharmaceutical companies have featured in the list of the top profit-making companies. Even in 2016 they were predicted to have the highest profitable margin [1]. And with the increasing population, a shift towards a sedentary lifestyle has taken place and healthcare becoming more and more accessible to humankind, the scope for sales and need for new medicines is ever increasing. This fact is easily cashed in by the pharmaceutical companies, who generate large revenues by catering to this ever-growing disease market.

A higher profit margin allows them to be more flexible with their spending on various important aspects like marketing, branding and distribution etc. Which ultimately results in greater spending on research and development of new therapeutic agents, which is the most crucial investment of them. The budget analysis of leading global pharmaceutical companies reveals that out of the billion dollars revenue generated by the companies only a small percentage (around 18% on average) was devoted to their R&D departments [2][3][4][5].

R&D Investments and Revenue Comparison

It is evident that the proportion of the R&D in the major leading pharmaceutical companies is far less from their net profit. It can be seen from Fig.1, that the highest grosser in 2016 was Johnson & Johnson with a \$70 billion revenue, but only around 18% of its revenue was invested in drug development. Similarly, Bayer dedicated only 6% of their \$51.4 billion revenue to research and development budget. In fact, the trend indicates that the higher revenue generating players have been investing less rigorously in their respective R&D departments, while companies on the lower end of revenue generating spectrum shelled relatively more in that regard. Also, AstraZeneca and GlaxoSmithKline brought in just \$24.7 billion and \$23.92 billion respectively in 2016, but devoted 24% and 19% of their revenue on R&D.

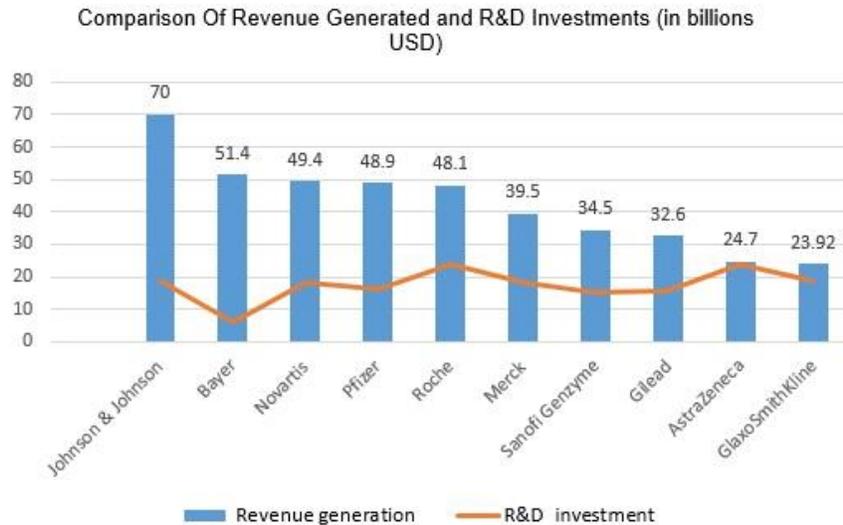


Fig.1. Shows the R&D investment and the corresponding Revenue Generation of top ten bio-pharmaceutical companies in 2016.

Therefore, one can presume such conditions do not dictate a very conducive environment for the much-needed innovation. Also, any invention needs to be well protected in the intellectual property rights domain to allow the inventor to enjoy its exclusive rights and profits. So, often patent filings can be directly correlated with new innovations and inventions in a technology sector. And, as depicted in Fig. 2 after going through the R&D budget spending [6] and the patent filing trend of these companies for 2015-2016, we found this correlation surprisingly not to be true, both for the higher revenue earning and relatively lower revenue generating drug manufacturers.

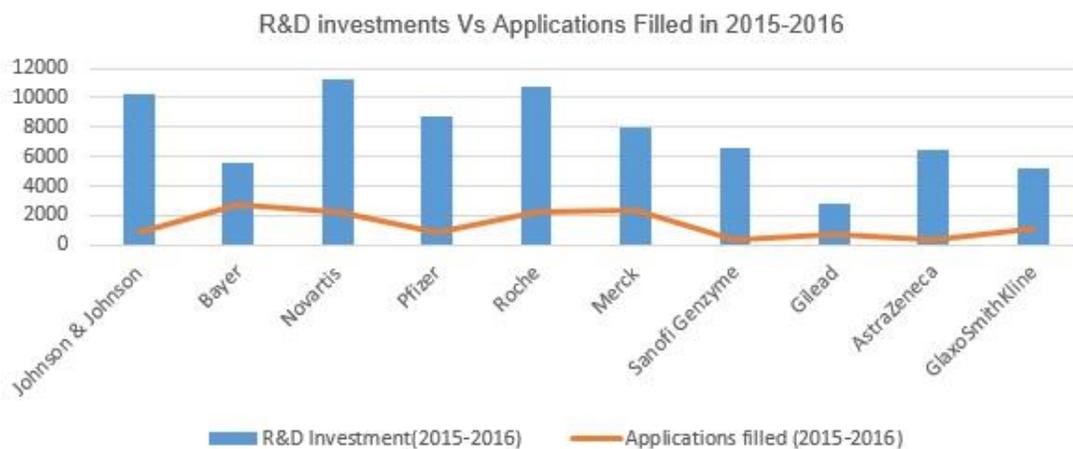


Fig.2. Depicts the R&D Investments and the applications filled by the top pharmaceutical companies and the number of applications filled by them in the year 2015-2016.

These figures beg the question why this trend of little R&D investment and deprivation of innovation from the industry?

The Era of Generics and Biosimilars

For decades most pharmaceutical giants have been able to generate their highest revenue from their respective “blockbuster” drugs. But over the last few years most of the patents of these high revenue earning drugs have expired or will expire by 2018. And in turn they have been or will be replaced by the market favorites: generic drugs and biosimilars. The generic alternatives are available at lower costs as the generic manufacturers had been spared the cost of drug development. Once a generic version of a drug is available in the market, it gives the pharmaceutical company a run for its money. Recently J&J’s patent on one of its top sellers, Remicade, expired and later that same year two biosimilars by Pfizer and Merck at a 15% and 35% discounted price respectively were available. This is pushing the drug companies to file for extensions or twisting IP laws to retain their exclusive rights for a drug.

Another way the drug companies have found to convert their investments into profits is via vigorous marketing practices. Novartis is hoping to retain the market for its highest selling drug: Gleevec, an anti-cancer drug, whose majority of the patents are set to expire in 2019, by advertising patients to switch over to its molecule other Tasigna. The market strategy is to sell it to the same pool of patients as a molecule that does a better job than Gleevec allowing the Swiss pharmaceutical giant to retain control of the market. Practices like these lead to a scenario where the marketing budget is by-passing the R&D budget.

Some giants like Pfizer were already investing in the generic drug manufacture and now other major players of drug manufacture are moving in the generic drug field as well. Merck only recently in July launched its first ever biosimilars. Generating revenues from investing in biosimilars and generic drugs, might be another reason affecting the research novelty of the drug companies. Fig 3. explains the application filling trend of the top 10 bio-pharmaceutical companies. A remarkable decrease can be seen over the years. A possible causation could be that the companies are increasingly investing in biosimilars and generic drugs to prevent decline in their profit margins. And innovative research investment is misdirected in these motives.

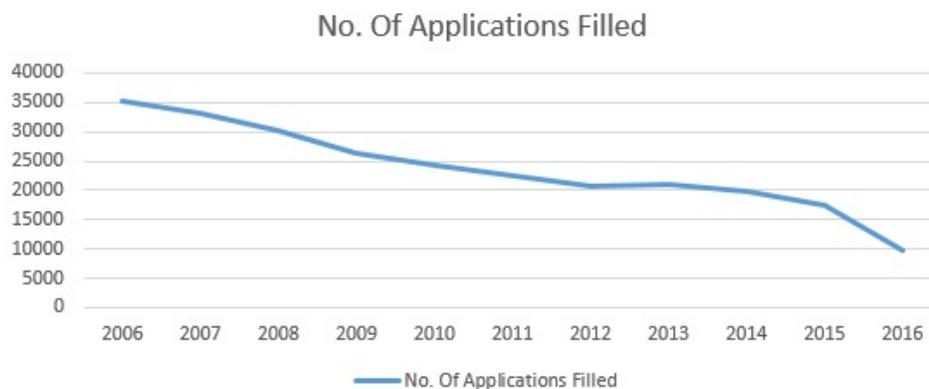


Fig.3. Number of applications filed by the top ten bio-pharmaceutical companies over the last 10 years.



But even with the big generic market for drugs, the highest grossing products still remain the original ground molecules, urging drug companies not to abandon their search for novel drug entities completely.

Indulgence In Wrongful IP Practices

There is a huge difference in the number of applications filled and the numbers to which the patents were granted. From 2011 to 2016 of thousands of applications filled, less than half of them were granted. This puts in the question the novelty standards of the new claims essential for patentability.

These facts can throw light on the inherent practice of “ever-greening” prevalent across the pharmaceutical domain. In order to enjoy the extended rights to a patent molecule whose patent is about to expire, the drug companies try to obtain another patent on a “new molecule” by bringing about minute changes in the previously patented molecule such as using a different polymorph of the previously patented molecule. And as most of these applications often fail to meet the novelty criteria, they are often rejected.

Another practice that can be a probable cause of this uneven ratio could be “portfolio development”. Often out of the many applications filled for a molecule, apart from a selected few which claim the key novelty of the molecule, most of the applications are focused on non-essential aspects allowing companies to try and obtain patents outside the scope of the genuine invention and procure all the possible rights there can be to a molecule. This helps the companies to eliminate generic competition. But the result is a high application filling number, a few granted cases, as the novelty and innovation is lost, which is an indispensable aspect for grant of a patent.

Regulatory Approvals

As such the cost of drug development is very large and coupled with the extremely low success rates, makes pharmaceutical drug development a very risky business. And to bring a drug into the market the company must pass stringent country specific markets regulatory approvals. Thus, huge amounts of funds are diverted to cope up with the legal and regulatory aspects. And to add to this, the fact that patents offer exclusivity for 20 years only and the major portion of this time often goes into getting approvals and conducting various clinical trials, eventually the pharmaceutical companies are left with a limited time to enjoy the monopoly of their novel molecule. Therefore, overcoming the time delay hurdles and generating profitable returns on investment becomes the top priorities for these companies. Practicing the above-mentioned practices therefore seems more attractive to the pharmaceutical companies, which shifts the focus from new drug discovery and research.

India Vs the World

The introduction of the product patent law was done to induce the MNCs to enhance their R&D activities in the country. Fig4. shows that despite India being one of the leading markets for the pharmaceutical MNCs, it still remains far behind in the count of novel pharmaceutical origins, with almost negligible patents being held by these MNCs in India.

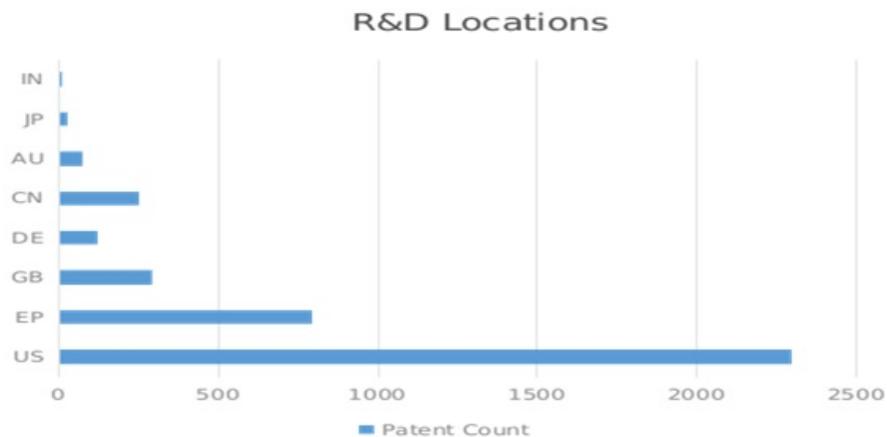


Fig.4. Patent Count of the top ten bio-pharmaceutical companies in various countries.

Over the years the investment of MNCs has gone down. MNCs rather than investing in research for new drugs in the country, manufacture them in other countries and then bring them to the big Indian market to gain high amounts of profit. The current scenario could be attributed to numerous factors.

A well IP regulated environment is very important for sharing of an invention, to allow a free flow of ideas. But due to India's flexible adherence to TRIPS the IP regulations in India have been continuously criticized at the world platform for not being good enough to allow safe investment in novel research ideas by the pharmaceutical companies.

Concepts like compulsory licensing in the Indian patent law system have helped to strike a balance between the profits earned by the pharmaceutical industries and the keeping the interest of the public safe. Bayer vs NATCO is a very good example of such, in which the pharmaceutical giant was forced by the Indian government to allow an Indian pharmaceutical company NATCO to produce and sell its patented molecule Nexavar (an anti-cancer drug). The grounds for this ruling were to provide to the public with an essential drug at a reasonable price. The law also allows a company in India on the same grounds to provide a drug at a subsidized cost to be exported to other countries as well. This stops the pharmaceutical companies from obtaining the monopoly of a drug they invested heavily on during research. This acts as a big discouragement for the drug companies from investing in R&D in India.

Under the Indian Drugs Price Control Order (DPCO) the prices of essential lifesaving drugs and their formulations are capped. This allows strict control of drugs pricing in the country. Even though the resultant aim is increased supply and cheap availability of drugs, a less profitable scenario is created for the pharmaceutical companies with options of manufacturing in other parts of the world.

There is a huge gap in the pharmaceutical sector when it comes to the capital for research investment. The Indian players are not equipped with enough resources and capital to invest as much as the global pharmaceutical giants can. Thus, for R&D to boom India, investments by the big MNCs is vital.

Key Role of The Big Pharma

Since the Big Pharma are often profit driven, their research tends to focus on the diseases of the developed nations which can afford to buy their exaggeratedly priced drugs. Thus, research invested towards diseases like TB, drug resistant bacterial strains and other communicable diseases, which are major challenges faced by third world countries, lags behind.

Restrictions of IP rights in the pharma sector have hindered drug development in the developing part of the world. It is true IP protected highly priced drugs allow drug companies to recover the costs of their R&D expenses, which is essential for their survival, but this prevents a large pool of patients with economic constraints from accessing lifesaving drugs. Research focused on development of cheap and effective drugs has been done. Expiry of the patents provides an opportunity for them to develop inexpensive versions of these drugs and cater to needs of disease stricken poorer populations. India is one of the major suppliers of generic medicines, providing up to 20% of the worlds share of generic drugs. But resources and the capital that can be pooled in by the big pharma unequivocally cannot be competed with. And they will shape the focus of pharmaceutical R&D, so it is up to these pharmaceutical giants to strike a balance between their profits and the public interest.

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