International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 20s, 2025
https://theaspd.com/index.php

Role Of Patents In The Growth Of The Pharmaceutical Industry

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Abstract: *The patentization of any novel innovation is the foremost requirement for the legal protection of exclusive rights over the innovation. Patents on medicinal drugs and its effects provide safety from duplicates by competitors. Novel medicines developed through sincere research form the basis of revenue of the drug manufacturer only after acquiring patents. The patents, thus, maximize the profits of industries by enabling capitalization of the innovative ideas or discoveries. Since the growth of any industry is directly proportional to sales and revenues, patents certainly aid in the development, growth and expansion. The case of earning revenues with patents is not the same with the pharmaceutical industry. A patent on a drug means diminished availability and augmented price of the drug. The healthcare industry has recorded extraordinary success and benchmarked profits but certainly jeopardises the life of patients who can't afford the drug due to the soaring prices of patented medicine. Hence pharmaceutical industries are expected to preserve a balance between profits and humanity. In this manuscript, we have reviewed the effect on revenues and sales of twenty pharmaceutical industries caused by acquiring patents with highlights on the rate of change of growth per patent.*

Keywords: *Research, Patents, Pharmaceutical Industry, Sales, Revenue and Profits.*

1. INTRODUCTION:

A patent is an intellectual property acquired for the legal rights over the innovation, usually created in the laboratories after dedicated research. Undoubtedly, every pharmaceutical company should consistently engage its proceedings in research and developments of the drugs for noble causes. This is proved after the spread of the COVID-19 pandemic. India, Singapore, the Czech Republic, Korea, Argentina, and Brazil are among the rising countries with the most rapidly expanding pharmaceutical businesses [1][2][3]. Among these countries, India's pharmaceutical industry is often mentioned as an example of a developing nation fostering local competencies [4]. Pharmaceutical advances are highly required for the overall development of humankind. The research scholars working with the pharmaceutical industries work hard in the laboratories to develop and produce medicinal drugs to cure various diseases, infections and other life-threatening conditions. The principal objective of the research scholars is to bring out a novel compound with statistically proven and benchmarked recuperation/health improvement records. Once a novel drug is discovered, it is covered by patent protection laws if the drug's discoverer holds the patent on his/her discovery. After the patentization of the drug only the discoverer (usually the pharma company) is entitled and permitted to produce or sell the drug and eventually generate profit/revenue from the drug sales [5]. Thus, any patent creates revenue for pharmaceutical companies. Most of the time, the soaring medicine prices due to patent on the chemical formulae of the medicine becomes a cause for criticism of patents on drugs as high prices keep the drugs out of the reach of the ordinary people. Thus, ethical objection to patents is the first and significant cause of patent criticism [6][7][8]. The second cause of criticism is about the quality of patents. Patenting a drug requires a lot of background and paperwork and the patent is sometimes granted on an already-known invention [9]. The third cause of patent criticism is the cost and time required to acquire the patents [10]. In spite of the criticism faced by the patents, patents are the primary cause of revenue and profits, notwithstanding the fact that medicinal patents are provided only for a period of twenty years [11].

Innovation, creativity, and the development of the latest drugs/products are a must for industries, especially new ones. Strategic use of the patents and other intellectual properties protects the inventions, attracts customers and provides a competitive edge over the competitors. It has also been claimed in the literature that patents contribute to 80% of the revenue of any pharma company [12] [13]. In the 1950s, the Indian pharmaceutical industry lacked the technical ability to create new treatments domestically. By the 1990s, however, it had become the most technologically advanced sector of the Indian economy. It has expanded its size and technological capacity to produce modern drugs domestically and costeffectively, positioning itself as a leading rising country competitor worldwide [14]. This research article explores the nitty-gritties associated with pharmaceutical patents and its effects on the revenue of the pharmaceutical company. To fulfil the objective, this article is organized as follows: section 2 presents the association of

RnD with pharmaceutical companies. In section 3, the types of patents available for pharmaceutical companies are discussed. Current scenario of Indian and global pharmaceutical industries is described in section 4 and 5, respectively. Finally, section 6, presents the role of patents in the revenue of the reviewed pharmaceutical company.

2. RnD in Pharmaceutical Domain

Every pharma organization must carry out research and development (R&D) activities for the improvement of the health conditions of humanity. This process is crucial and critical for innovation and novelty in the areas of drug development. The R&D activities are initiated in two ways. The first is the "bottom-up" process, where researchers all around the globe tries to find out an effective medication for the treatment of a well-known disease. This happens in the case of COVID-19 vaccine design. In the "bottom-up" process, the physical and biological properties of the disease and its effects are well-known in advance.

The second type of R&D process is the "top-down" approach, where the novel chemical compound is viewed as a potential cure for some set of diseases. The suitability of a chemical compound is considered in the prospects for its effects on human biology or metabolism. The chemical compound and the to-be-cured disease are then matched for trials. In both types of research, an initial candidate solution is recognized the researchers try to acknowledge its efficacy through trials. The research trials include rigorous and precise research tests that determine its therapeutic suitability through keen observations [15]. As a usual practice for research, the biological organisation ties up with research organisations to develop prolific medicines. For performing "top-down" and "bottom-up" research, there are many disciplines. The main biology/pharma sector-related disciplines encompass two types of drug testing: (i) in vitro and (ii) in vivo testing of candidate drugs are pharmacology, biotechnology, immunology, molecular biology, bio-informatics, virology, DNA sequencing, microbiology, cell biology and neuroscience. The compounds forming the candidate drugs are also tested for toxicity by researchers who work in the Drug Metabolism and Pharmacokinetics (DMPK) teams [16].

3. Types of Pharmaceutical Patents

Similar to the other industries, the pharmaceutical industry maintains three Ps: People, product and process. These Ps are the key elements to be focused for the improvement in the industry's overall performance [17]. Based on these three tiers, pharmaceutical patents can be categorized into the following three parts:

A. Product Patent

Product patent is one of the vital types of pharmaceutical patents. A product patent grants a higher level of rights and protection to the inventor over his/her invention. With this protection in place, no other competitor/manufacturer can produce or develop or manufacture or create the same product through a similar or any other process.

B. Process Patent

Protection is granted, usually to the inventor, on the specific manufacturing process of a drug. Since a product can be manufactured by different process, multiple process patents may exist for a single product. The competitors can create the exact product by adopting different processes.

C. Formulation Patent

Most of the pharmaceutical drugs are some soft of chemical compound or a molecular formula. A formulation patent provides exclusive rights on the composition (chemical formulae) of the drug. Most of the formulation patents are taken on an altered composition of a previously known drug.

4. Current Scenario of the Indian Pharmaceutical Industry

Across the globe, India is the largest provider of generic medicines. India fulfils more than half of the world's demand for vaccines. 40 per cent and 20 per cent of the generic drugs in United States and United Kingdom respectively are supplied from India. India is the world's third-largest pharmaceutical manufacturer by volume and fourteenth-largest by value. There are around 10,000 manufacturing units and 3,000 pharmaceutical companies in the domestic pharmaceutical industry. It maintains a key place in the pharmaceutical industry worldwide [18]. Additionally, there is a good number of well-educated researchers, scientists, and engineers capable of propelling the business to new heights. Over 80 per cent of antiretroviral medications for the treatment of AIDS are now manufactured by Indian pharmaceutical firms. In the 2019-2020 fiscal year, pharmaceuticals had total annual revenue of Rs. 2,89,998 crore.

During the 2019-20 fiscal year, total medicinal exports and imports were valued at Rs. 1.46 lakh crore and Rs. 43 Thousand crores, respectively. Several sectors comprise the pharmaceutical industry: generic pharmaceuticals, OTC medications, API/bulk drugs, vaccines, well-known salts, contract research and production, biosimilars, and biologics [19].

India possesses the second-most FDA-approved pharmaceutical factories outside of the United States. India is the world's largest provider of DPT, BCG, and measles vaccinations. India produces 60 per cent of the world's vaccinations, satisfying forty to 70 per cent of WHO demand for DPT and BCG vaccines and ninety per cent of WHO demand for measles vaccine. It is the largest provider of generic drugs in the world. India's provision of inexpensive HIV medicines is one of medicine's most outstanding achievements. India is a leading global source of inexpensive and affordable vaccinations. Because of the cheap cost and good quality of Indian medications, the nation has earned the title "World Pharmacy".

Currently, Indian pharmaceutical firms generate 1.72 per cent of the nation's gross domestic product.

The pharmaceutical business primarily contributes to the nation's foreign commerce, offering attractive investment prospects and channels. India provides affordable generic pharmaceuticals to millions of people worldwide. It maintains a large number of GMPcompliant facilities for the US Food and Drug Administration (USFDA) and the World Health Organization (WHO). India is one of the world's major producers of pharmaceuticals. India is the third biggest market for APIs in the world, with an 8 per cent share of the global API business, more than 500 APIs in existence, and 57 per cent of APIs on the WHO's prequalified list [20].

5. Pharmaceutical Companies in Global Perspective

The international pharmaceutical trade market was valued at USD 405.52 billion in 2020, and is expected to expand at a rate of 11.34 per cent from 2021 to 2028 [21]. The adoption of latest technology and more cost-effective and effective production methods have significantly transformed the pharmaceutical environment. In addition, greater investment in this area has contributed to market expansion. A reduction in product waste and drop-in floor downtime is achieved via the use of robotic technology, machine learning dialects and artificial intelligence. Additionally, single-use and throwaway solutions have gained favour in this industry, substantially replacing open transfer production procedures. Furthermore, the transition to unified, intelligent, automated, data-rich and paperless processes has led to the generation of correct proportion, error-free and accurate medicines. The development of medications has been accelerated as a consequence of these continual changes.

A rise in medicine approvals by regulatory authorities is anticipated to stimulate the growth of medication manufacturing processes. For instance, the FDA approved 59 medicines in 2018, 49 pharmaceuticals in 2019, and 15 medications until April 2020. In addition, a large number of ongoing clinical investigations have shown several market expansion opportunities [22]. In recent years, there has been an increase in mergers and acquisitions in the pharmaceutical industry. In this atmosphere of intense competition, the majority of established companies are merging to boost their market position. Small and medium-sized pharmaceutical companies are acquired due of their inventiveness.

Despite recent slowdowns in major global economies, it is anticipated that the global pharmaceutical industry will expand in the future years. The causes are straightforward: a growing and ageing population, increased incomes, and the advent of new medical ailments and diseases. Various criteria, including marketplace drivers, existing and future trends, current growth patterns, and market obstacles, are used to anticipate market growth. This development is driven by the growing and ageing population in leading marketplaces. According to the World Population Prospects of the United Nations, the world population is expected to reach 9.3 billion by 2050, with around 21 per cent of that population aged 60 or older [23]. In addition to population growth and ageing, enhancements in purchasing power and access to excellent health-care and medications by weaker sections of society and middle-income families throughout the world are driving the global pharmaceutical industry ahead. Another factor contributing to this evolution is the growing focus of pharmaceutical companies on markets for rare and specialised diseases. Non-pharmaceutical companies such as Facebook, Qualcomm, and others have invested in the ongoing researches on biotechnology, biologics, nuclear medicines, cell treatments, and bioinformatics & implantables, therefore contributing to the expansion of the pharmaceuticals industry internationally.

On the other hand, governments in key nations are anticipated to tighten regulations and undertake cost-cutting programme, impacting the development prospects of the global pharmaceuticals business. Due to a downturn in growth in recent years, pharmaceutical companies have been forced to curtail R&D spending, which is expected to limit global pharma market growth because new drug income accounts for a significant amount of pharma firms' revenue due to exclusivity [24]. In addition, due to price erosion

in key countries, the generics pharmaceutical business is seeing declining returns on investment, many compelling firms to seek out new channels and markets to sustain growth.

6. Effects of Patents on the Growth of the Pharmaceutical Industry

Perception of the Intellectual Property gained through patents and licensing is different for different manufacturers. It is never a mandatory chore to apply for a patent on an innovative medicine. Many of the life-saving drugs like the Polio Vaccine by Jonas Salk [25], Insulin by Frederick Banting [26] and Penicillin by Fleming [27] are some of the unpatented, vital and most demanded drugs which saved the life of millions of people. The inventors of these drugs dedicate their findings to humanity for noble causes. On the other hand, Nusinersen by Biogen [28], Zokinvy by Eiger BioPharmaceuticals [29], Sputnik by NFGRCEM, Russia [30] are some of the vital medicines with price tags. Hence, it is totally dependent on the manufacturer of the medicine whether to dedicate it freely to the humankind or to make profit out of the discovery. Nonetheless most of the producers these days are trying to hold patents on the discovered drugs to attain an edge in the current era of sales, marketing, profits and competition.

Licensing innovative products is undoubtedly the source of the major revenue of inventors. It is typically a payback on the expenses incurred on the maintenance of laboratory, equipment's and staffs. To study the effect of patents on the revenue of pharmaceutical company, we have studied the financial market trends (revenue generated by the pharmaceutical company) vs the cumulative number of patents earned by nine major pharmaceutical companies (details provided in table 1) over a data of past eleven years, ranging from 2011 to 2021.

The cumulative number of patents and the revenue of the companies detailed in table 1 is provided in table 2. From the analyzed data of table 2, it is clear that the revenue of the pharmaceutical companies under study has increased with the number of patents held by the company. This data is graphically represented in figures 1, 2 and 3. Each of these figures contains two lines per company. One for the number of cumulative patents, plotted on right y-axis, and other is for revenue plotted in million dollars, plotted on the left y-axis. In all the graphs, all the lines are moving up from left to right, which clearly indicates that the revenue of all the pharmaceutical companies has increased with the number of patents. This increase is shown with the help of a bar graph, in figure 4, by plotting the correlation coefficients between the revenue and total cumulative patents. It is worth noting that there is a positive correlation between revenue and the number of patents despite the market bulge which happened during the outbreak of Covid-19 in the years 2020-2021. The outlier in this category is PFE, with a negative correlation value. Even for this outlier the endpoints of line graph in figure 1 show a positive gradient. The trendline in figure 4, moves between 0.5 and
0.7 with 66% of the companies having a positive correlation value 0.5 or greater. The companies reporting a correlation near to 1 are ROG, JNJ, AMGN and BHGR. Thus, it can be claimed with confidence that revenue and the number of patents correlate positively.

Table 1: List of Studied Pharmaceutical Companies.

S. no.	Name	Symbol	Origin	Website
1.	Johnson & Johnson	JNJ	USA	www.jnj.com
2.	Pfizer	PFE	USA	www.pfizer.com
3.	Roche	ROG	Switzerland	www.roche.com
4.	Abbott Laboratories	ABT	USA	www.abbott.com
5.	Galaxo Smith Kline	GSK	England	www.gsk.com
6.	Takeda	TAK	Japan	www.takeda.com
7.	Eli Lilly	LLY	USA	www.lilly.com
8.	Amgen	AMGN	USA	www.amgen.com
9.	Boehringer Ingelheim	BHGR	Germany	www.boehringer-ingelheim.com

Table 2: Cumulative number of patents and pharmaceutical companie's revenue (in million dollars).

Company		2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021

JNJ	Patents	3755	7611	10959	14607	18593	22563	27312	32428	37506	42475	48123
	Revenue	65,030	67,224	71,312	74,331	70,074	71,890	76,450	81,581	82,059	82,584	93,775
PFE	Patents	2157	4194	5975	7760	9492	11158	12950	14457	15853	17156	18528
	Revenue	61,035	54,657	51,584	49,605	48,851	52,824	52,546	40,825	40,905	41,651	81,288
ROG	Patents	2,518	4,862	7,042	9,348	11,928	14,658	17,627	20,693	23,414	26,383	29,334
	Revenue	49,949	50,627	52,477	54,568	52,454	53,441	56,655	60,830	64,165	64,362	72,046
ABT	Patents	1344	2955	4683	6518	8284	10105	11761	13150	14268	15294	16121
	Revenue	21,407	19,050	19,657	20,247	20,405	20,853	27,390	30,578	31,904	34,608	43,075
GSK	Patents	696	1338	1879	2467	3040	3625	4249	4840	5415	5866	6335
	Revenue	43,940	41,896	41,475	37,916	36,578	37,798	38,904	41,140	43,100	43,783	46,910
TAK	Patents	856	1827	2842	3869	4775	5709	6725	7720	8724	9589	10290
	Revenue	17,101	19,163	18,843	16,917	16,178	15,001	16,108	15,935	18,875	30,279	30,059
LLY	Patents	102	208	302	397	476	536	598	630	666	722	731
	Revenue	24,287	22,603	23,113	19,616	19,959	21,222	19,974	21,493	22,320	24,540	28,318
AMGN	Patents	545	1135	1805	2539	3066	3672	4330	4943	5580	6334	7120
	Revenue	15,582	17,265	18,676	20,063	21,662	22,991	22,849	23,747	23,362	25,424	25,979
BHGR	Patents	723	1367	2122	2907	3697	4334	4900	5352	5833	6226	6624
	Revenue	13,171	14,691	14,065	13,317	14,798	15,850	18,056	17,498	18,997	19,566	20,618

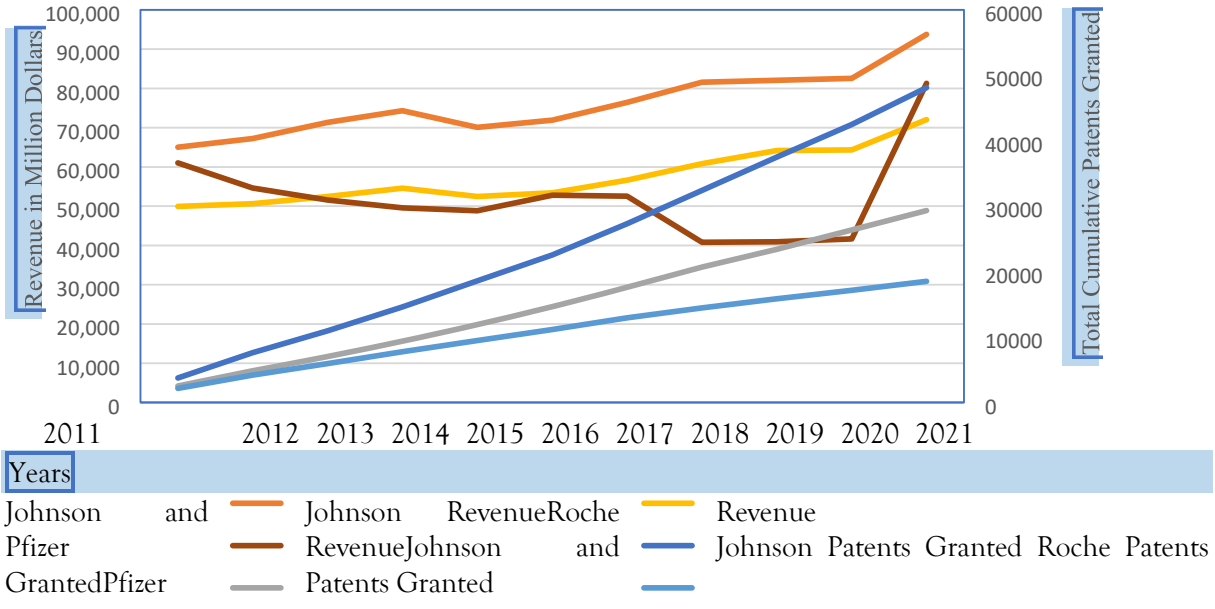

Figure 1: Revenue vs Total Cumulative Patents of JNJ, PFE and ROG.

International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 20s, 2025
https://theaspd.com/index.php

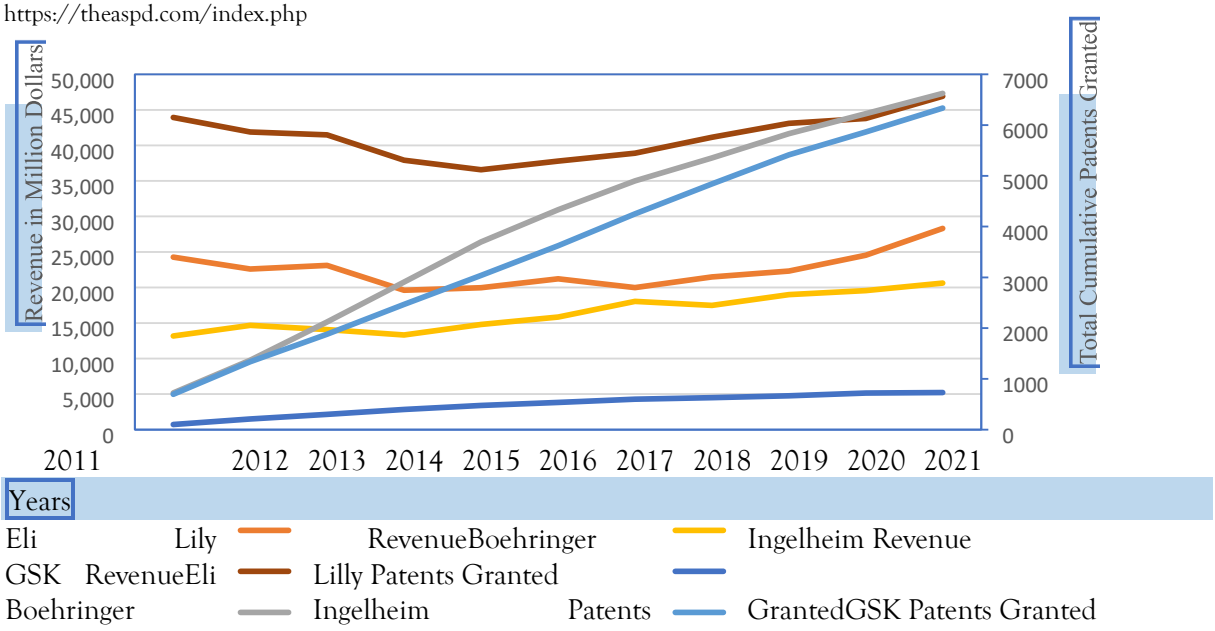

Figure 2: Revenue vs Total Cumulative Patents of LLY, GSK and BHGR.

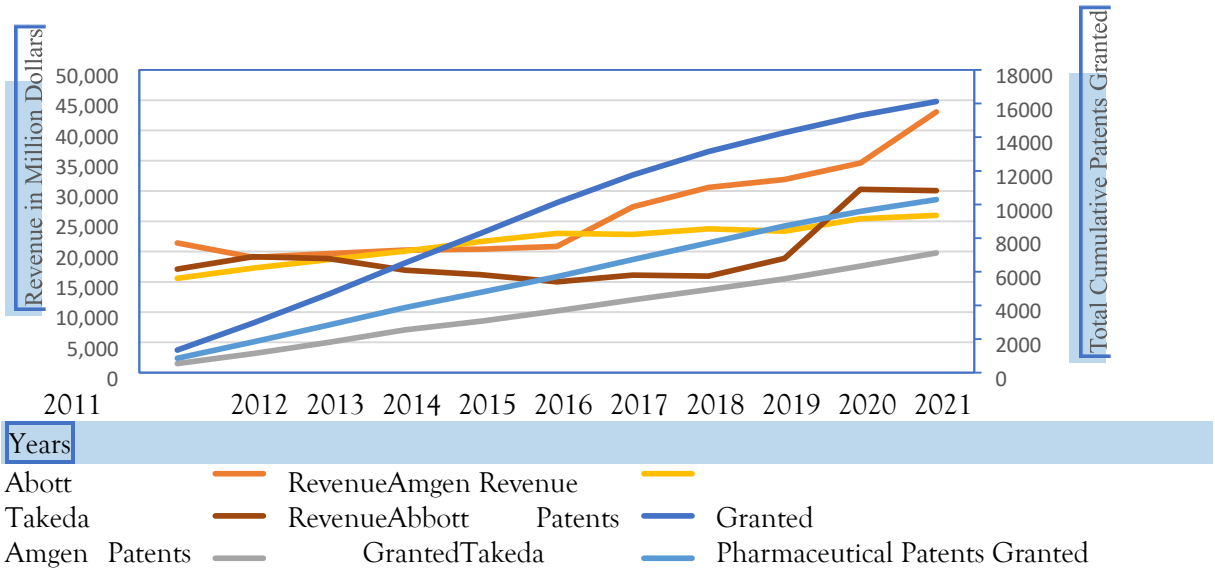

Figure 3: Revenue vs Total Cumulative Patents of ABT, TAK and AMGN.

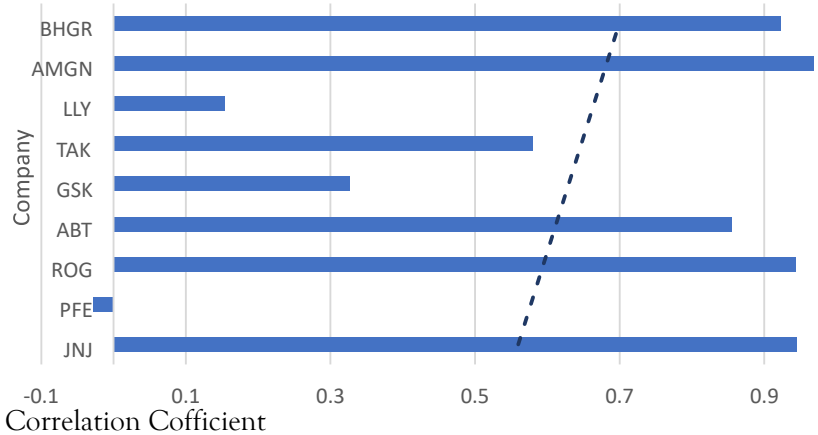

Figure 4: Correlation Coefficient Between Revenue and Total Cumulative Patents.

7. CONCLUSION

Patents and licensing have been used by manufacturers since a long for two major purposes, the first is to protect innovations and the second is to earn profits from the sale of newly discovered products. This manuscript is an attempt to bring out the details of the pharmaceutical industries and their research and

development (RnD) proceedings in a global perspective. The apparent results from the RnD activities for any pharmaceutical company is some novel findings or drugs. The sale of the drugs aid into the generated revenue. The novel findings, thus contribute to the overall growth of the company. To safeguard the newly developed drugs against copies from competitors, holding a patent on the newly discovered drug or process is the most common and customary way. Thus, having a patent implicitly implies that the revenue of the company shall increase. This proposition is validated by finding the correlation between the revenue and number of cumulative patents of nine major pharmaceutical companies during the year: 2011-2021. In the experiments, a significant positive correlation is noticed for almost all pharmaceutical companies under study.

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