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Changing Dimensions of Drug Patents of Indian Pharmaceutical Industry

Manjul Vaidya[1], Sukrit Garg[2], Charu Singh[3] and Madhur Mohit Mahajan[2†]

[1] Department of Information Technology, Sector 9-D, Chandigarh – 160 009, India

[2]Department of Economics, GGDSD College, Sector 32, Chandigarh – 160 030, India

[3] Department of Economics, Punjab University, Sector 14, Chandigarh – 160 014, India

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The Patents Act, 1970 which provided for process patenting led to pharmaceutical revolution in the country as India witnessed a spectacular increase in generic manufacturers. The Patent Act, 2005 however is considered to be a major game changer as it provides for both process and product patents and will set the tone to shift away from reverse engineering to forward engineering. The growth in Patent activity reflects the development in science and technology of the nation. With the passing of Patent Act, 2005 and increase in Intellectual Property (IP) awareness amongst the Indian companies, they seem to be taking IP protection more seriously on a global level. The paper aims to bring about trend, growth and prospects of patenting in Indian Pharmaceutical Sector. Relative Specialisation Index (RSI) for pharmaceutical patents in India *vis-à-vis* the whole world has been calculated to concur if its trend is uphill. An inter-country RSI analysis of top ten pharmaceutical markets in the world has been conducted to project India's strength at the world level.

Keywords : Relative Specialization Index, World Trade Organization, Trade Related Intellectual Property Rights Agreement, Gross Domestic Product, General Agreement on Tariffs and Trade, Bolar provision, Patent Office Journal, Economic Survey, Drug patents, Pharmaceutical sector, Patent laws, Patent trends, Pharmaceutical markets

Economic policy and law collectively govern the socio-economic development of a nation. Various economists and lawyers such as Trubek,[1] Davis & Trebilcock,[2] have examined the relationship between law and development, confirming a correlation between these practical and social sciences. It has been empirically validated that an improvement of one standard deviation of laws and governance of a country would result in an increase in income per capita of as much as 300 percent in the long run– which is true for the likes of Chile and India.[3] Development is interrelated to law partially by the elucidation that without intellectual property rights, the society would not produce scientific, cultural and technological entities at the optimum level.[4] From as early as Adam Smith,[5] to Schumpeter[6] and Ulku,[7] stress has been laid on the undeniable relationship between innovation and development. The scope of innovations has widened to a plethora of activities in the modern day, spanning through the whole supply chain from raw materials to the final product. This is why governments give incentives and benefits to inventors, all the while providing a suitable framework to protect valuable inventions from being imitated and misused.

Intellectual property (IP) states to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.[8] For all WTO member countries, the existing framework of intellectual property laws are identified by the

Trade Related Intellectual Property Rights Agreement (TRIPS) governed by WTO. This has strengthened India's capacity to invest in research and development, especially in the pharmaceutical sector. The laws governing IP in India originate from the mid-19th century. Henceforth, various laws have been implemented and modified to protect inventions (1856, 1859, 1872, 1883, 1888 and 1911). The first milestone of IP rights in independent India was The Patents Act, 1970, which came into force on 20 April 1972. The Act gave rise to reverse engineering through product patenting, resulting in a flourished Indian pharmaceutical industry. However, the Act exempted 'food or medicine or drug' from product patenting.[9] With time, global competition increased tremendously and there was a need to amend laws. With the formation of World Trade Organization

†Corresponding Author: Email: madhureco@gmail.com

(WTO) and consequential introduction of Trade Related Intellectual Property Rights (TRIPS) Agreement in 1995, all member countries were required to follow TRIPS Agreement laws. The laws included providing product patent protection within a period of 10 years. To meet its TRIPS obligations, India amended its Patent Laws on 22 March 2005, abolishing its 'process' Patents Law and introducing 'product' Patent Law.

Objective and Hypotheses

The study aims at analysing the changing trends of growth of drug patents in India and its relationship with GDP growth and R&D growth. The study further endeavours to estimate the relative specialization of drug industry of India.

Hypotheses

H_0: There is significant relation between R&D expenditure, drug patent applications and GDP growth in the country for the period under study.

H_0: The Relative Specialization Index for the Indian pharmaceutical Industry has increased during the period under study.

Methodology

The study has been conducted for the time period of 19 years from 1997-98 to 2015-16. The study is based on the secondary data which has been collected from the Patent Office Journal, Economic Survey and WIPO reports for various years. The data of R&D for all pharmaceutical firms (876 in number) has been collected form CMIE Prowess database. Growth rate comparisons in patent applications, GDP growth and R&D expenditure have been done on the basis of year on year growth computations. Correlation and regression techniques have been applied to find out the relation and degree of impact among variables. To capture the concentration in drug innovation or a higher propensity to drug patenting, relative specialization index (using Balassa)[10] has been constructed.

WTO, TRIPS and India

Intellectual property protection was not a part of General Agreement on Tariffs and Trade's (GATT) objectives. With the conception of WTO in the Uruguay Round, TRIPS Agreement was included and new Patent Act came in force from 1 January, 1995.[11] Article 65.2 of TRIPS granted a transition period of five years to execute the provisions of TRIPS for developing countries. Under Article 65.4, an additional five years were granted to the countries that did not require product patent protection in any field when TRIPS was imposed. A system of Exclusive Marketing Rights (EMRs) was introduced which remained in operation during the transition period until TRIPS requirements were fully adopted. The Patent Law in India was amended in years 1999, 2002 and 2005 to provide for TRIPS Agreement requirements and incorporate country specific changes in new Patent Law. India wholly complied with all agreements of the WTO by January 2005.[12] The pharmaceutical industry in India reached new prospects of growth with the advent of the TRIPS Agreement. Chaudhuri analysed the TRIPS Law and forecasted its socio-economic implications, keeping in view India's pre-TRIPS Patent Regime.[9] The adoption of Bolar provision by India has allowed generic producers to enter the market even before the expiry of patents. The amendment of Section 107A (a) enables pharmaceutical corporations to execute further R&D over patented products to prepare for regulatory consent. The companies utilise this exemption to generate generic version of drugs before the patent expires.

Dhar and Gopakumar investigated the performance of firms in the Indian pharmaceutical sector in wake of the TRIPS Agreement.[13] Data from both domestic firms and international regulatory authorities were utilized for this study. They concluded that generic firms have shown tremendous growth after 1995 and that emphasis has been laid on keeping the patent regime flexible contrary to exclusive rights being provided to major players so that domestic players in the pharmaceutical industry can thrive along international competition. The Indian Pharmaceutical sector has hence emerged as a global giant during post-TRIPS period.

Drug Patents Trend in India

Ghai attempted to analyze Indian patent regime with special reference to TRIPS and establish its impact on the Indian pharmaceutical sector.[14] He inferred that for the 60% of Indians who are the deprived of pharmaceuticals, demand sensitivity and price rise owing to patent introduction is trivial. Although Indian economy is witnessing a steady rate of growth, only a small part of the market would be covered under the new patent law. Nevertheless, the drugs and pharmaceutical industry has an important

place in the Indian economy due to its positive technological spill-over to other sectors of the economy.[15]

Indian Pharmaceutical industry is one of the largest in the world and ranks 3rd in terms of volume today. From its nascent stages in the 1970s, it has matured immensely over time. Presently, the industry has differentiated into myriad spheres comprising research and development (R&D), manufacturing APIs, manufacturing of branded, generic and branded generic drugs and clinical research.[16] It is expected to grow to US $45 billion by the end of 2020. The industry also attracts high FDI in India and is definitely one of the components determining progress of the nation.

Figure 1 shows that for drug patent applications as a percentage of total patent applications, an increasing trend can be observed initially up to 2004. After that, the percentage dropped significantly with the implementation of TRIPS Agreement. The Agreement replaced process patenting with product patenting. While process patenting allowed for production of the same drug through different processes, product patenting put a stop to reverse engineering causing a fall in patent applications. From 1997-98 to 2015-16, a Compound Annual Growth Rate (CAGR) of 8.39% was seen in total patent applications and of 3.72% in pharmaceutical patent applications. Total patent applications witness a roughly increasing trend post TRIPS. However, the absolute number of drug patent applications per year has remained more or less stagnant in the last decade. Yaeko Mitsumori analysed the bearing of new patent regime (post 2005) in India.[17] The study established that there could be two major reasons that might have helped shrink the negative effect of a stringent patent system- Article 3(d) in the Patent Law (2005) and secondly the transitioning business models embraced by the Indian pharmaceutical countries. At the same time, drug patent applications have not increased due to government policies. Keeping in mind that around 70% of Indians do not have health insurance, the government has made efforts to issue fewer patents in the past few years.[18] It must also be noted that a large number of drugs have price caps in India, acting as another disincentive for applicants.

Patents, R&D and GDP: A Three-way Growth Nexus

In order to materialise an innovation-friendly patent regime, its role in overall growth of the economy cannot be unheeded. One of the customary ways to measure economic growth is by measuring the growth of GDP. The comparison between innovation, GDP and increase in Patent applications project a three way nexus – increase in the number of patents is a result of technological and/or scientific advancement of the economy. As this advancement takes place, an increase in GDP is consequential. On the other hand, as an economy advances as whole, its GDP rises, resulting in greater expenditure on research and development. This results development of mind and matter, following which more patenting activity can be anticipated. Thus, patent growth and GDP growth can be said to have a cyclical pattern, where each has an effect on the other.

Shilpi Tyagi and D.K. Nauriyal applied regression using ordinary least squares method with six independent variables with profits as the dependent variable.[19] They observed that export intensity, R&D intensity and post TRIPS era have had a significantly positive impact on pharmaceutical industry profits. Michele Boldrin and David K Levine conducted a review of readings that study the macroeconomic effect of IPRs on R&D and economic growth.[20] They concluded that international cooperation is necessary for a globalized economy and that there is a positive correlation between innovation and IPR protection. In another study by Ravi Kiran and Sunita Mishra, it was established that R&D activity and pharmaceutical patents had seen higher growth in the post-TRIPS period compared to the pre-TRIPS era.[21] Their paper emphasized on how the share of Indian companies in the total drug master files (DMFs) filed with the USFDA had increased dramatically from 14% in 2000 to 50% in 2007. An attempt has been made to compare and contrast growth rates of total patent applications, drug patent applications, GDP and pharmaceutical R&D expenditure in India.

There is a consistent increase in the growth of drug patent applications as well as total patent applications initially after 1998 (Fig. 2). Year 2003-04 witnessed sharp increase owing to clarification of rules and their

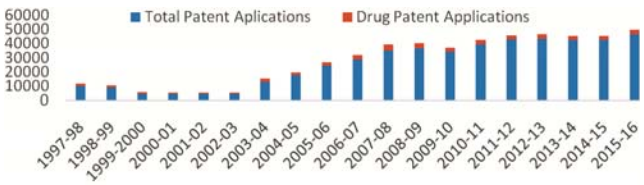

Fig. 1 — Total patent applications and drug patent applications (1997-2016)

enforcement under The Patents (Amendment) Act 2002, accompanied by a similar trend in R&D expenditure growth. However, this was followed by a parallel decline the succeeding year. Post 2003 up to 2011, there was high economic certainty in India as real GDP grew roundabout 8%. This certainty was albeit not enough to inculcate in the investors a positive attitude and R&D growth rate fell during the period, partly owing to the long wait involved between patent applications to grants. Hence, growth of total patents and drug patents (except 2006-07) also showed a negative trend for the period. Post 2010, no clear trend is observed in the growth rate of drug patents in spite of an increasing trend in R&D. Growth rate of GDP declined marginally in 2011-12 and further slowdown was seen thereafter, only to get stabilized again after 2014-15.

The potential of the patent system has been widely recognized in the context of dynamic innovation activities.[22] Hulya Ulku in an IMF working paper has plotted time series data considering per-capita patents with per-capita R&D expenditure and with per-capita GDP of various countries from 1981-97.[7] He concluded that there is a strong positive correlation between patent stock and per capita GDP. The analysis supports endogenous growth theories by confirming a significant relationship between R&D and innovation, and between innovation and per capita GDP. Another study by Albert G.Z. Hu and I.P.L Png showed that the stronger effective patent rights promoted industry growth through technical progress in the 1981-85 and 1996-2000 periods and through more rapid factor accumulation in the 1986-90 and 1991-95 periods.[23] Mahajan analysed R&D intensification of Indian pharmaceutical firms in the post-TRIPS period, to find out that the changes in Patent laws due to TRIPS reforms have acted as a catalyst in increasing innovative R&D activity in Indian firms.[24] Tables tend to analyse the three-way relationship between drug patents, R&D and GDP.

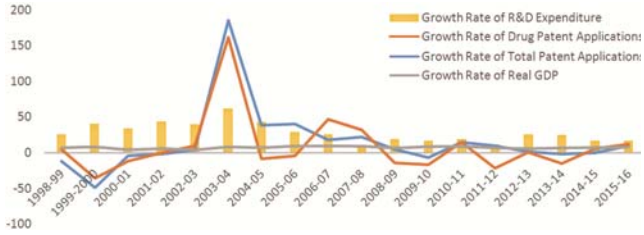

Fig. 2 — Growth rate comparisons*

A peculiar result to be noticed above is that there exists a negative relationship between growth rate of R&D expenditure and growth rate of GDP (Fig. 2). R= 0.247 signifies no relationship concerning growth rate of drug patent applications and that of GDP. It can be seen that Pearson coefficient of correlation between growth rates of drug patent applications and pharmaceutical R&D equals 0.474, which is significant at the 0.05 level for two-tailed test. It is clear from the table that $p< 0.05$, and indicates that overall, the R&D expenditure significantly predicts the drug patent application number in the country for the period 1998-99 to 2015-16 (Table 2).

Relative Specialization Index (RSI)

The concept of specialisation was first introduced in terms of trade theory – Ricardo's Comparative Advantage,[25] and Ohlin's Factor Endowment.[26] However, it was Balassa who pioneered the concept of Revealed Comparative Advantage (RCA) which later matured and developed into a function of innovation economics.[10] The Relative Specialization Index (RSI) corrects for the effects of country size and focuses on the concentration in specific technology fields; it captures whether a given country tends to have a lower or a higher propensity to file patents in certain technology fields.[8] Vollrath suggested applying logarithmic transformation to

Table 1 — Correlations

Growth Rate		Drug Patent Applications	R&D Expenditure	Real GDP
Drug Patent Applications	Pearson Correlation	1	0.474*	0.247
	Sig. (2-tailed)		0.047	0.323
	N	18	18	18
R&D Expenditure	Pearson Correlation	0.474*	1	-0.265
	Sig. (2-tailed)	0.047		0.288
	N	18	18	18
Real GDP	Pearson Correlation	0.247	-0.265	1
	Sig. (2-tailed)	0.323	0.288	
	N	18	18	18

*Correlation is significant at the 0.05 level (2-tailed).

Table 2 — Coefficients and Model Summary

Term	Coefficient	Std. Error	T	P
Constant	26.858	2.941	9.131	0.000
Growth of R&D Expenditure	0.149	0.069	2.152	0.047

*Growth rate of drug patents is the independent variable

remove the problem of asymmetry in RSI.[27] The logarithmic conversion clusters the values around zero. If a country's share in a given technological field is equal to all patents filed in all fields, then the index is equal to zero, implying no specialisation. Else, a positive index implies specialisation.

Relative indices of specialisation, according to Nicole Palan focus on the variation of a nation's industry arrangement from the mean industry arrangement of the concerned set of nations.[28] Some version of these indices have been used by various researchers such as Amiti,[29] Gilles Duranton and Diego Puga,[30] Dirk Frantzen,[31] Frank Bickenbach et al,[32] Dag W. Aksnes *et al.,*[33] etc.

D. Archibugi and M. Pianta studied the technological index (taking into account technological proximity along with patent filings) for 13 major OECD economies.[34] They found that countries like UK and USA were doing well but were far behind other nations like Japan and Germany in terms of innovation. Other economists like Malerba and Montobbio,[35] and Verspagen,[36] analysed input output relations and specialisation patterns using slightly modified versions of RCA index. Dr. Viola Peter and Nelly Bruno,[37] in their report for the European Commission calculated RSI for EU, USA, Japan and other OECD economies. They concluded that change in RSI over time, if any, occurs very gradually and is not easily observable over short periods of time. The Australian Government in its report on the Australian Pharmaceutical Industry calculated RSI values of all countries (excluding those with less than 100 patents) in the world.[38] According to their results, India stands on 2nd rank following Cuba in the pharmaceutical sector. In a WIPO Statistical Review too, India is far ahead of other developed economies like Denmark, UK and USA in terms of RSI.[8] Although RSI fell in 2005, Indian pharmaceutical companies stood at being far more efficient when compared to those in other countries. Given its comparative advantage, India specializes in pharmaceutical invention.[39] This implies that India definitely enjoys benefits owing to allowance of 100% FDI and its bio-diversity.

The RSI for Indian Pharmaceutical Industry has been calculated using the following formula: $RSI_{ij} = \text{Log}\,(F_{ij} * \sum F_{ij} / \sum F_i * \sum F_j)$

where, F_i and F_j are applications from country i and in technology field j.

India's RSI was very high during 1997-2000 wing to process patenting. With the first amendment in Indian patent laws in 1999 to accommodate the TRIPS Agreement, pharmaceutical companies held back R&D investment to assess the changing market conditions.[40] William Greene stated that around year 2000 (Fig. 3), patenting activity decreased in India as domestic drug companies relied essentially on generic and bulk production to maintain their low cost advantage.[41] This explains a falling RSI in the aforementioned period (Table 3).

While the total number of patent families depicts a comprehensive depth of the nations' R&D intensity, the RSI analyses strength of a country in a specific domain of technology. India's relative specialization in drugs never fell below zero. The falling trend does not negate growth and prospects of the industry. Analysts have found that the transition to R&D oriented growth by the generic drug manufacturers will be slow owing to the high risks involved in discovery of drugs.[42] The transition shall be classic- slowly but surely.

It can be argued that the introduction of TRIPS has had a discouraging effect on Indian pharmaceutical innovation. However, conclusions based on studying a nation in solidarity are incomplete and sometimes trivial. A comprehensive and relative position of India with the world must be analysed so as to infer the effects of TRIPS (Table 4).

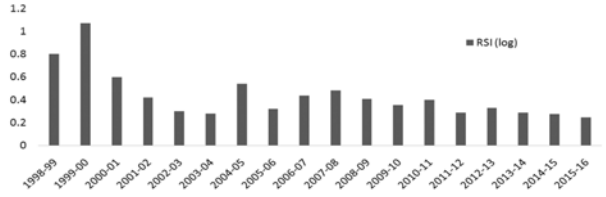

Fig. 3 — Relative Specialization Index of Indian pharmaceuticals

Table 3 — India's cumulative RSI Post-TRIPS and Pre-TRIPS

RSI Pre-TRIPS (1998-2004)	RSI Post-TRIPS (2005-2016)
0.56345	0.33813

Table 4 — Top 10 Pharmaceutical markets worldwide in 2016

S. No.	Country	Sales 2016 (billions, US $)	% Growth over 2015
1	United States	450.6	5.6
2	China	80.3	7.8
3	Japan	80.1	-1.6
4	Germany	40.7	4.1
5	France	33.1	3.2
6	Italy	28.6	6.0
7	United Kingdom	23.8	4.6
8	Brazil	21.0	13.1
9	Spain	20.9	2.1
10	Canada	19.3	3.5

Source: Quintiles IMS MIDAS, MAT December, 2016

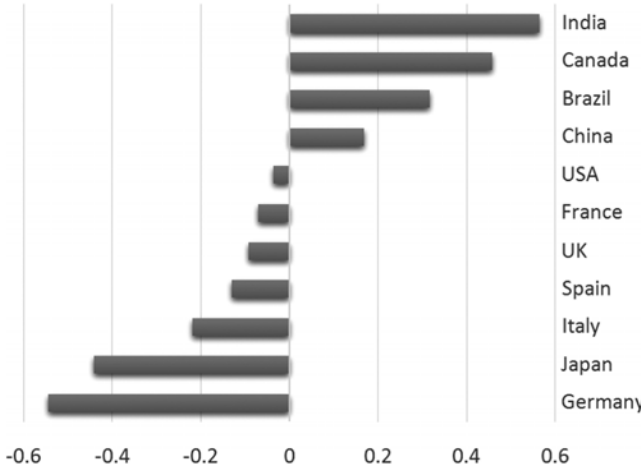

Fig. 4 — RSI Pharmaceutical Pre-TRIPS (1998-2004)

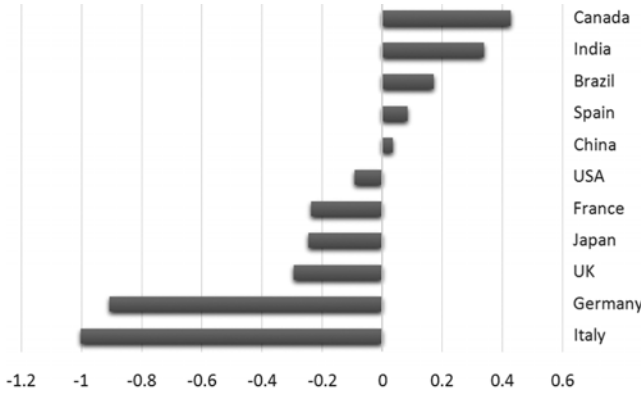

Fig. 5 — RSI Pharmaceuticals Post- TRIPS (2005-16)

Globally, the pharmaceutical RSI has seen a decrease Post 2005. Explosive growth of other sectors like IT, Biotechnology etc. are also factors contributing to the fall in pharmaceutical RSI. Our analysis harmonises in that India does hold a strong position in relative specialisation of pharmaceutical industry. Only Canada is above India with an RSI of 0.4+ (Fig. 4). This can be attributed to its specialisation in clinical research. Of the total R&D spending in Canada, 45% is directed towards clinical research.[43]

France, Germany and Italy have a highly negative RSI in pharmaceuticals, as all three countries focus on infrastructure development and transport innovation (Fig. 5).[23] As per the report, those countries which have above average concentration in a particular technology field are easily identifiable (i.e. those having a positive RSI value). Few examples of these are India in pharmaceuticals, USA and Denmark in biotechnology and Israel, Denmark and India in medical technology etc. The large pharmaceutical market of the country is one of the most cost-effective drug producers in the world, which in turn helps the leading pharmaceutical companies to focus on setting up R&D centres and on the discovery of new chemical entities.

Conclusion

Pharmaceutical industry of India is the greatest exporter of generic drugs owing to its cost effectiveness. But every industry has its own set of challenges, and those of pharmaceutical industry in India include lack of infrastructural facilities, regulatory hindrances, lack of monetary incentives, expensive research equipment, underdeveloped technical knowhow etc. The post TRIPS period witnessed a fall in patent applications as well as grants in the Indian pharmaceutical sector. There exists an internal divide in terms of pharmaceutical industry growth in this period – expansion and benefits are still restricted to large scale companies which can finance R&D activities, while the small scale manufacturers are labouring to establish themselves. Despite a decrease in pharmaceutical patent applications after the pinnacle in 2007-08, a CAGR of 3.72% is observed. The three-way nexus between GDP, Patent numbers and R&D growth rate does not hold true for India as compared to other countries. Our analysis confirms that the growth of pharmaceutical patent applications is not significantly affected by growth of GDP whereas growth in R&D expenditure is positively correlated to pharmaceutical patents. RSI for India never fell below zero implying specialisation advantage over the global pharmaceutical industry. Taking the top 10 countries with respect to pharmaceutical market value, India stands only second to Canada in our period of analysis. The post-TRIPS decline in Indian pharmaceutical RSI does not negate industry prospects and growth. The decline reflects the impact of global financial crisis and euro zone crisis. Notwithstanding the impact of crisis, the erratic growth rate of drug patents *vis-a vis* growth rate of GDP and falling RSI are areas of concern which need the policy attention. The falling trend in RSI in the recent years, however, does not negate the growth potential of this sector as the global pharmaceutical industry is changing landscape and moving towards M&A, contract manufacturing and contract R&D.

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