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Impact of Patent (Amendment) Act, 2005 on Indian Pharmaceutical Industry

Keerti Singh[†]

Department of Commerce, Aligarh Muslim University, Aligarh — 202 002, Uttar Pradesh, India

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Since 1901, the Indian pharmaceutical industries have expanded and strengthened to become a significant supplier of healthcare items, meeting around 90% of the nation's need for bulk pharmaceuticals, drugs intermediates, chemicals for the medicinal base, pharmaceutical compounds, medicinal formulas, drugs, tablets, orals, respules/capsules, and injectables. Indian pharmaceutical industry has embarked not only on national markets but it has an esteemed and illustrious position in international markets also. India is the world's third-largest pharmaceutical manufacturer by volume and fourteenth-largest by value. The growth and empowerment of the pharmaceutical industry is totally attributed to the rules and principles governing the operations and evolution of the pharmaceutical industry in India. These rules are the controlling guidelines mandated by the Government of India, through the Acts and amendments made in the acts at various times. One of the major and most influential amendment is the Patent (Amendment) Act, 2005. This act has provided new dimensions and horizons to the Indian pharmaceutical industry and a good number or rational researches have been performed on this subject. It has thus been a fascination to dig the researcher's points of views about how The Patent (Amendment) Act, 2005 after TRIPS has impacted the Indian pharmaceutical industry since this act has been passed. This survey paper is an attempt to bring out the deviations and modifications, Indian pharmaceutical industry has been gone through, since year 2005.

Keywords: Indian Pharmaceutical Industry, TRIPS, The Patent (Amendment) Act, 2005, Trade, Exports, Profitability

With around more than ten thousand manufacturing units of three pharmaceutical companies, the Indian pharmaceutical segment is contributing to the overall world's humanity through the supply the quality medicinal drugs. After 1 January 2005, when international patent regulations are applied, the Indian pharmaceutical company will undergo unprecedented changes. India's domestic pharmaceutical industries saw substantial growth in R&D expenditure to make the world market competitive. In Marrakech, Morocco is following the signing in April 1994 of the General Agreement on Tariffs and Trade (GATT). Instead of an agreement like the GATT, the WTO is an institution. It sets trade rules between its 132 Member States. Member States have made necessary revisions until 1 January 2005 before they are compelled to comply with WTO standards. It concerns the influence on Indian pharmaceutical companies of the modified Laws of Intellectual Property and Patents, 2005. The Patent (Amendment) Act, 2005,[1] thus, modifies the Indian Pharmaceutical Company's research and development landscape. [2] There are a lot of books and journals available for reading from both abroad and Indian authors, for all fields such as research and development activity in Pharmaceutical, Patent Act and Indian Pharmaceutical Companies. Several papers dealing with different elements of the issue is also published. The literature review is a sort of appraisal or assessment report of information found in the body of literature gone through by the researcher related to one's area of study. It should abstract and recapitulate the vast literature in a short and precise one. It forms a theoretical framework or base for the further analysis of the topic. It provides a sense of authenticity to the work of the researcher. The researchers have been able to examine many materials from various fields and to review the following books and periodicals to assess the results of the research studies that have been published so far, director indirectly. The advocates of a strict patent regime suggest that product patents will result in a metamorphosis of the industry. It would increase the international technology transfer to India by encouraging foreign firms to relocate their R&D units into this country because of its sizable pool of low cost and technically skilled labour.[3] A few more studies have supported this view. However, the empirical results of a few other studies appear not to support this view. This paper presents a systematic and comprehensive review of the literature with highlights of the conclusion, literature and the

[†]Email:keertisingh173@gmail.com

research methodology adopted with regards to Interest and Corporate Social Responsibility by other previous researchers.

History of the Changes in Indian Patent Laws and Acts

Technology and innovations know no boundaries. Further, the globalization of markets has broken the barriers to trade and commerce of goods, services, thoughts, ideas, knowledge, and inventions. With the exchange of original products/goods or ideas, there lies a possibility of the duplicity of originals. Thus, it is vital for every business to protect their intellectual properties as the competitors might infringe the original ideas to take away the market share. Therefore, to safeguard the arguments or intellectual properties against illegal and duplicate usage, a business may exercise its rights through the laws and rules laid down to protect copyrights, trademarks and patents. These laws stop your competitors from making, selling, purchasing or even using your intellectual properties without your permission. TRIPS or Trade- Related Aspects of Intellectual Property Agreement[4] is a formal international-miltilateral agreement between all the member nations of World Trade Organisaion, for the protection of intellectual properties. Although there is a lucent system for the protection of intellectual properties in various countries across the globe, the TRIPS Agreement further strengthens and fortifies the international trade order. This agreement provides a framework for standardization, enforcement and dispute settlement related to trade-related aspects of intellectual properties.[5,6] This manuscript presents a comprehensive review of the studies on the impacts of TRIPS Agreement on Export/Sales/R&D/Profit of Indian pharmaceutical industry. Though, every pharmaceutical company performs some sort of research and development activities, the creation of TRIPS created pressure for pulling out innovation and novel ideas through the adoption of technical procedures, methodological process, scientific skills, practical's and trials. This pressure was due to the fact that the laws prior to TRIPS agreement were somewhat flexible. Many acts with different amendments and changes were enacted since independence (Table 1).[7] In India, a developing country, the pharmaceutical industry witnessed a massive turnover of USD 24.4 billion in 2020-21, with an 18.1 per cent year over year growth.[8] Thus, presently there is an enormous scope of capital investment for research and development activities. As an icing on the cake, the technical and scientific persons with good domain knowledge are available in abundance.

Importance of IPR in the Pharma Industry

The pharmaceutical sector is one of the most promising industries in today's globe, with enormous earnings, growth, expertise, and potential. A product's success or failure is quite likely in the pharmaceutical industry at every stage of development. In addition to these difficulties, a significant amount of money is spent on research and development before a product can be released into the market. To get medication from conception to production, intellectual property rights (IPRs) are critical (Fig. 1). All major and Multinational Companies throughout the globe now rely on intellectual property rights to maintain their worldwide market domination, economic strength, and profitability. In today's global marketplace, intellectual property rights are commodities and assets that may be traded via licensing agreements, joint R&D/Production ventures, and so on. In pharmaceutical IPR, there are a number of areas where IP may have a significant influence. IPR's, exclusion of rivals, the availability and cost of new drugs are all linked to the problem of pricing and access in the first place. First and foremost, there is the problem of incentives for drug discovery and development, as well as how intellectual property rights (IPR) affect R&D spending.[9] There are several hurdles to overcome in the Indian pharmaceutical industry when it comes to intellectual property, not only at the beginning but throughout the life of medicine and throughout the life of industry. There is a strong correlation between the growth of pharmaceutical industries in developed countries and the success of the patent system, which has been criticised on many grounds, including drug design and molecule formation, litigation, patent laws, and anti-competitive monopolies, the neglect of opportunistic innovation. It is also common knowledge that patent and trademark rights have little value unless they are fully used. A growing number of Indian pharmaceutical businesses are contributing to this worldwide expansion via both organic and organic

Table 1 — Changes in Indian Patent Laws and Acts

S. No.	Year	Description of Change
1	1950	With an aim to strengthen Indian Patent and Designs Act 1911 after independence, a committee under the chairmanship of Justice (Dr.) Bakshi Tek Chand suggested recommendations for the prevention of patent infringements. The committee stressed upon a balanced tradeoff between honours for patentee and the availability of medicines for common man at a fair price.[13, 14]
2	1952	An amendment regarding issue of compulsory license for health related Intellectual Properties like medicines and surgical devices.[15]
3	1970	The Government of India passes "The Patents Act, 1970" which governs the legislature regarding Intellectual Properties while promoting innovations in India till date.[16]
4	1972	Most of the provisions of The Patent Act- 1970 came into force in April 1972 with the emergence, and subsequent enforcement of Patent Rules as the Central Government was empowered to make rules via The Patents Act, 1970.[17]
5	1999	To meet India's obligation to WTO's TRIPS while being a member country of WTO, The Patent Act, 1970 was amended to provide the Exclusive Market Rights (EMRs) for the trade-related issues of drugs patented in other countries.[18, 19]
6	2002	As a consequence of Doha ministerial conference of November 2001, to overcome the hurdles of TRIPS several changes were made in The Patent Act, 1970. These changes were mainly regarding the definitions of inventions, term date of patents, application formats of patents and compulsory licensing.[20]
7	2004	In line with the TRIPS guidelines regarding provisions for patenting a process along with the product, The Patent Act, 1970 was modified along with the clarification on the international date of patent filing and slight changes in EMRs.[21]
8	2005	For the prevention of ever-greening of patents by preventing the patentability of a new form of known substance unless it further optimizes a past benchmark, The Patent Act, 1970 is modified along with the firmness in the procedures of obtaining patents.[1]
9	2006	The Government of India notified The Patents (Amendment) Rules, 2006 for the delegation of responsibilities among the various patent offices and for bringing up necessary transparencies for the timely action on the patent applications.[22]
10	2016	To promote the Make in India and startups The Government of India notified The Patents (Amendment) Rules, 2016 for felicitating the patents on the innovation for startups with reduction in fee and provisions for expedition of patent examination.[23]
11	2019	The Patents (Amendment) Rules, 2019 makes it compulsory to file patents in electronic forms only with an objective to expedite the patent examination process.[24]
12	2020	To encourage small entities to ideate and innovate, a significant reduction in the patent fee is provided through The Patents (Amendment) Rules, 2020.[25]
13	2021	The Patents (Amendment) Rules, 2021 support the patents on novel ideas which originate in academic and educational institutions for encouraging the smooth commercialization of novel technologies at reduced cost.[26]

activities since India is becoming a significant link in the global pharmaceutical value chain.[10] A large number of foreign pharmaceutical businesses are making forays into India's market. Furthermore, the Indian pharmaceutical market is one of the most important rising markets for the global pharmaceutical sector since it is expected to rank among the world's top ten sales markets by 2020.[11] Since the advent of globalisation, national policymaking has narrowed due to external limitations and the rise of Transnational Corporations (TNCs) as national actors. There are two trends in current economic globalisation that are critical in determining the impact that the TRIPS Agreement has on national intellectual property protection in the context of economic development: internationalisation in production and the development of a global knowledge-based economy.[12] Global industry and politics and governments in developed and developing nations are becoming more concerned about intellectual property legislation in general and intellectual property protection in particular.

In light of the globalisation process, the TRIPS Agreement and its impact on poor nations are inextricably related to the globalisation movement.[27] Brand names and drug names for pharmaceutical products are often derived from the therapy they conduct, the salt composition of their medicine, and other medical terms that do not have an inherent

uniqueness, yet "distinctiveness" is a requirement for a trademark to be valid.[28] A trademark cannot be confusingly similar to a previous trademark, as stipulated in Section 11 of the Trade Marks Act, 1999. Customers should be able to quickly distinguish various pharmaceutical items or pharmaceuticals based on their brand name or drug name and trade dress in order to minimize or eliminate mistakes during procurement. This complicates the process of securing trademark protection for a brand name or medicine name since proof of the secondary meaning or newly acquired unique character must be considered. Including from patents and trademarks, various other entities ensuring the intellectual property are: copyright, industrial design rights, plant variety rights, trade dress, trade secret, and geographical indications. Figure 1 provides a bird eye view of these intellectual property entities.

The Patents Act of 2005: Its Implications on Pharmaceutical Industry

There are around 24,000 firms in the Indian Pharmaceutical Industry (IPI), making it very fragmented (330 in the organised sector). More over a third of the market belongs to the top 10 corporations. Most of the market is controlled by branded generics, which account for around 70-80 per cent of sales. For the year ending March 2014, the IPM was valued at Rs 750 billion.[29] In 2014, growth was just 6 per cent, compared to 13 per cent in 2013. After 348 medications were put on a price-control list by the Drug Price Control Order, growth slowed. Indian pharmaceutical sales continue to be one of the fastest-growing industries worldwide; despite this The IPM is now the third-largest volume producer and the thirteenth-largest value producer in the world. Pharmaceutical R&D and manufacturing R&D and

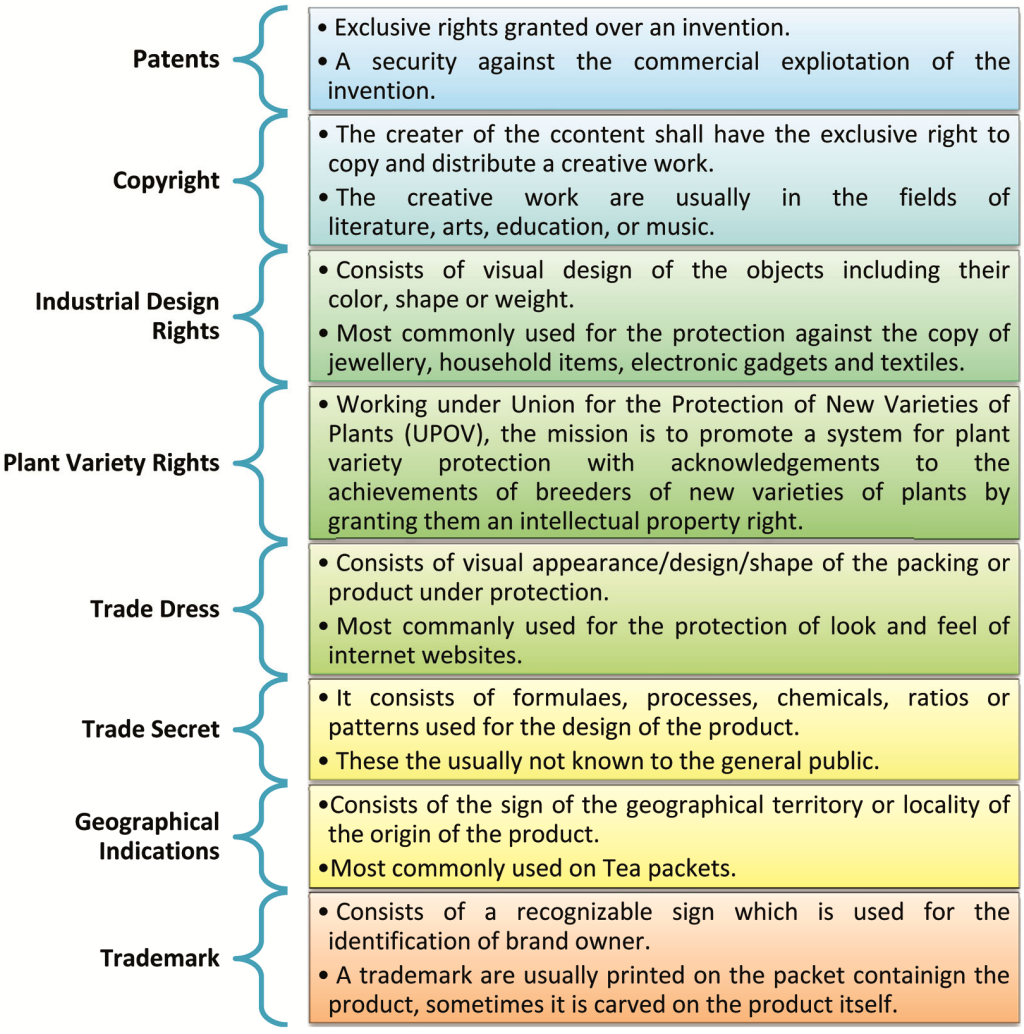

Fig. 1 — The IPR entities

manufacturing are two sectors where several international pharmaceutical corporations are focused on growing FDI in India. The short-term impact of product patents in India, on the other hand, may be less severe. However, in the future, it may be more severe due to the fact that the Indian customer has access to numerous non-patented therapeutic counterparts, and just around 3 per cent of the pharmaceuticals sold in India are patentable.[30] Big Pharma in India typically showed a near-complete reluctance to knowledge transfer in bulk drug manufacture before the TRIPS era.

When it came to establishing bulk medication manufacturing, the Indian Government had to provide incentives. The effects of technology transfer by multinational corporations (MNCs) in India are less positive in the high-tech industries, according to studies. Global pharmaceutical MNCs spent much of their money before 2005 expanding their formulation activities. In addition, research shows that after 2005, their propensity for forming new businesses as totally owned subsidiaries was also reinforced. According to the majority of commentators, the TRIPS Agreement has failed to persuade multinational corporations to do more offshore R&D in poor nations. The availability of robust patent protection may be overtaken by technology. It's difficult to assess whether strong patent regimes promote intellectual transfer, but research done after TRIPS shows that they do. Many studies have looked at how patent protection affects foreign R&D and international licensing. A lack of buyer bargaining power in developing countries makes it more likely that the prices of technology transfer will rise as a result of strong patent systems. This is because of the high direct and indirect costs associated with strong patent systems, as well as the poor buyer bargaining power. Exports account for a significant portion of the income generated by Indian pharmaceutical businesses in addition to sales inside the country (Fig. 2). In the US, Europe, and semi-regulated countries where generics are widely available, several businesses are focused on bespoke production for innovators. Because of the difficulty in producing biopharmaceuticals and the fact that there is little competition, this field is becoming more popular. As a result of the lack of health insurance coverage in countries like India, they believe that any shift in the demand structure might have a substantial effect on the poor, and hence welfare via increased medicine costs would be counterproductive.

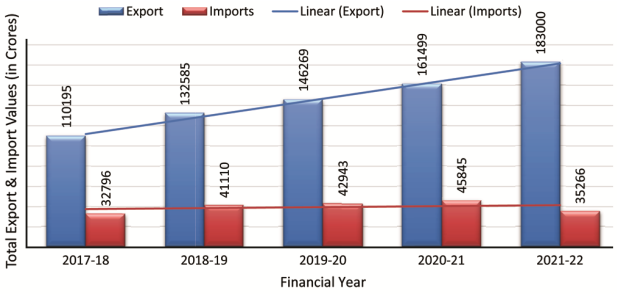

Fig. 2 — Pharmaceutical sectors' import and export values during FY 2017 – FY20 21
Source: IBEF[32]

Immediately after the TRIPS Agreement came into effect, it was stated that there were enough TRIPS flexibilities to ensure that inexpensive medications could be produced.

A variety of options are available in terms of breadth of subject matter for product protection, reasons for issuing a compulsory licence, exceptions to patent allowing provisions for parallel import, and protection of test data, amongst other things. This flexibility is important. The Government should launch additional public R&D programmes that take use of the industry's capabilities. The Government has set out Rs. 150 crores for research and development. At least Rs 2,000 crores is needed to make this a reality.[31] Particularly, throughout the product patent term, the pharmaceutical industry's R&D is critical to its success. More than $30 billion was spent on research and development in the pharmaceutical business in 2001. Comparatively, Intellectual Property Industry R&D expenditures are modest (1.9 per cent) compared to worldwide giants (10.16 per cent). Many Indian businesses are increasing their R&D spending in preparation for the new regime's arrival. Pharmaceutical businesses were given a 10-year tax break by the Government of India (GOI) to boost R&D. Further, additional $34 million has been set aside for the tenth plan's pharma sector R&D promotion fund. Currently, only a few Indian pharmaceutical companies make significant investments in research and development (R&D). As a research boutique or contract research company, domestic universities and academic institutions may provide the necessary technological know- how and labour. The share and proportion of different categories of imports and exports from the Indian pharmaceutical industry during FY 2020 are shown in Figs. 3 & 4.

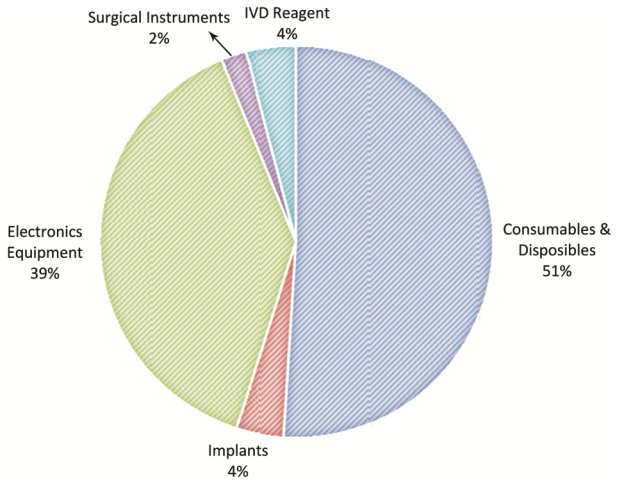

Fig. 3 — Share of different categories of export items
Source: Annual Report, Department of Pharmaceuticals[33]

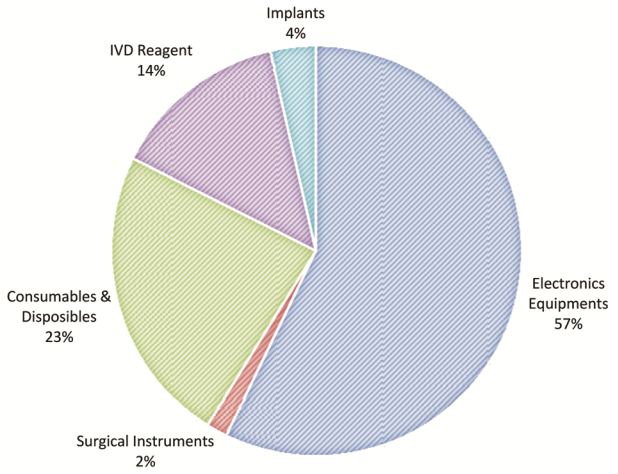

Fig.4 — Share of different categories of import items
Source: Annual Report, Department of Pharmaceuticals[33]

TRIPS in the Pharmaceutical Industry

Varun M[34] aims to experimentally explore, using non-parametric data envelopment analysis, the influence of a Product patent system on the productivity of multiple categories, including property, R&D, size and product-related products in Indian pharmaceutical companies. This study has used Ray and Desli's Malmquist productivity indices and their decomposition to measure the change in the overall factor productivity factor for 141 Indian pharmacist companies between 2000–01 and 2014–15. The study is based on the purely technical difference in effectiveness, scale change in efficiency, and technological changes under the assumption of variable returns on scale (VRS) technology. The study concluded that the product patent system had modest impacts on productivity. Technology development has positively influenced productivity growth, although the change in technical efficiency shows the prudent use of resources for performance improvement.

The results show that R&D-intensive firms are more stable than non-R&D companies in the total factor productivity (TFP). Compared to the previous patent regime, both small and large companies have exhibited good growth in the current regime. By upgrading technology by improving access to better foreign technology, these small organisations can compete with larger businesses. The results show that the Indian Pharmaceutical Industry (IPI) needs to increase network productivity and support cost excellence through operational excellence and digital efforts. In India, pharmaceutical industries have undergone recent patent-law reforms regarding innovation in low-income markets and societal welfare.[35] The authors further stated that the Indian pharmaceutical sector has grown to be the fourth-largest globally between 1972 and 2004 under its process patent system. In the context of generic and clinical testing, Indian companies became globally competitive and moved to R&D. The effects of the new product-patent laws in India on these trends were discussed by researchers. The writers address the internal characteristics of India's pharmaceutical sector and worldwide competitiveness. In the process-patent regime in India, they contrast data (from 2001 to 2004) on patents with preliminary information about patents in the new product-patent system in the country (from 2005 to 2008). Their argument is that Indian pharmaceutical businesses have shifted their decision-making by transitioning from process to product research as a result of revised patent restrictions. However, these modifications may have damaged domestic innovation, according to the preliminary results. In conclusion, they emphasised the necessity for research and government policies to provide the best possible social return of product-patent regimes for the Indian pharmaceutical sector.

Some of the researchers state how the Patents Act of 1970, which provides for the patenting of processes, led to the pharmaceutical revolution in India, whereas generic manufacturers increased spectacularly.[36] The authors claimed that the Patent Act 2005 is seen as a fundamental changeover since it covers both method and product patents and sets the tone for backward engineering to forward engineering. The increase in patent activity reflects

the nation's scientific and technological advancement. As the Patent Act was passed in 2005 and the awareness among Indian enterprises of intellectual property increased, IP protection seemed to be taken more seriously on a worldwide basis. Authors have also showed that the market performance of companies depends positively on technological advancements.[37] Their study examines the market dominance of 168 Indian pharmaceutical enterprises from 2000 to 2013 as a result of product and process innovation. To capture business-level innovation activity, they produced products and processed patent stock. Results from this study indicate that both product and process innovation have a favourable impact on the market power of companies. Results also show that the Indian pharmaceutical industry has stronger market power over Multinational Enterprises. In addition, this study shows that the product group of companies has a varied impact on market power. This study concludes that patenting in the Indian pharmaceutical business is a good cause of company performance.

In a study[38] authors have claimed that the Indian pharmaceutical industry has proliferated, becoming the world's largest supplier of generic medications based on the innovation of products and processes. Dynamic changes have taken place in recent decades and have operated in a fast-developing domestic and global policy context; the TRIPS Agreement is a prime illustration of this. In the context of intellectual property, authors have shown how changes in the innovation ecosystem have influenced the worldwide activity strategy of enterprises in the transition eras (1995–2004 and 2005–2014) and acquiring knowledge both from the internal and external knowledge sources. By combining arguments on intellectual property with contextual characteristics of an innovation ecosystem, the authors assumed that, during the post-TRIPS period, external knowledge is more significant than domestic knowledge for the worldwide business activities of Indian pharmaceutical companies. The authors seek to capture the latest market structure developments, comparative benefit indices, R&D, trading, M&A and ownership, particularly under the new IPR system.

There are numerous studies that provide extensive analysis of the comparative advantage of India compared to other major pharmaceutical exporters worldwide. The paper is of relevance to practitioners and scholars interested in structural modifications of the IPI, particularly in the system of product patents. The conclusions have substantial repercussions for the future policies of management and government. While describing patenting trends, authors Gokhale *et al.* have stated that patents are growing internationally and the trend towards growth is not consistent.[39] In comparison to industrialised countries, China and South Korea saw a large increase in the patent filing. Growth is low in regard to India. In the case of formulations, dosage form, drug combination and mode of distribution, the trend shows that more patents are filed in India. The discovery of new drugs has shifted from chemical entities to biological entities. Although India is known for its important contribution through generic medications to the pharmaceutical business, it still has a vital role in the patent environment.

Racherla[40] described the evolution of the Indian Patent Regime in a chronological manner. He has stated that The Indian Constitution under Article 21 provides the right to life and the right to personal freedom to every individual and citizen of India. Moreover, the indigenous government's duty and commitment to improve public health are declared in Article 47 of the Indian Constitution. Moreover, Article 12 of India's International Covenant on Economic, Social and Cultural Rights (ICESCR) states that governments have a duty to promote their rights to health. The Indian Government, therefore, predicts that medicines that are vital to India's population's crucial health demands must be both accessible and inexpensive. In fact, this paradigm provides the cornerstone of India's notion of the right to health in accordance with Article 21 of the Indian Constitution. Indian policymakers are therefore striving to meet the constitutional requirements of India for the right to health while developing its ecosystem of innovation and defending the legitimate interests of MNCs. Indeed, since Indian independence in 1947, the era of economic liberalisation began in the 1990's, and the membership of the WTO and TRIPS Agreement in 1995, after TRIPS in 2005, and up until now, this mighty undercurrent has shaped the development in the Indian patent regime. In his famous book, "Pharmaceutical Marketing in India", Brooks, states that the country spends less than 1.9 per cent on R&D than 10 – 20 per cent on pharmaceutical businesses spend in the industrialised countries.[41] The book asserts that low profitability has given rise to such low funding for R&D by Indian

corporations. In addition, the author has remarked that the drug discovery records in India are abysmally poor; the public sector was also the earliest drug to be found in India. He has raised a question on the Indian pharmaceutical sector: why in 40 years the Indian pharmaceutical sector has not been able to introduce a few commercially successful new drugs. Author have described the overall benefits of TRIPS, but he claimed that the presidential compelled order aligning Indian laws with TRIPS was not natural adoption in the parliament, thus showing hostility to the patent in India.[42] It is believed that the patent is only beneficial for an inventor company, such to the high cost of medicines for AIDS (USD 10,000 per year). Still, that following due involvement by corporations, such as Cipla (India), the price later fell to USD 350 to USD 201/year only. His research also looks at the provision of compulsory licencing that strikes a balance between patent rights and the socio-economic needs and goals of its citizens. Its understanding, however, is so vague that patentees can use litigation as a means of preventing others from obtaining such licences. In the same line of this research, Nair,[43] expressed his opinion on the impact on the Indian pharmaceutical business of the TRIPS Agreement. He emphasized that India has benefited from the reintroduction of product patents *via* TRIPS. The TRIPS agreement offers the Indian pharmaceutical industry a specific orientation and urgency for the creation of world-class research facilities, the launching of new medication delivery systems and the introduction of new molecular research across the country. The TRIPS agreement gives the Indian industry a clear advantage. He also believes that the industry would bring fresh investments in research and development into novel molecules, not just from Indian but from multinationals as well, with the implementation of strong intellectual property rights. The author is of the view that there is considerable knowledge of intellectual property rights by Indian pharmaceutical enterprises, helping to consolidate their technical and scientific workforce, and also, to some extent. The IPR awareness developed in the country several par excellence educational and educational institutions. Indian pharmaceutical businesses also boosted their USFDA patent application with relation to the DMF and new drug application shortened (ANDA). In addition, the scientist feels that India will fully adopt TRIPS and that India's pharmaceutical industry is in the lead in the research and development of novel pharmaceutical compounds in the near future[44]. It is also clearly indicated in the research that pharmaceutical exports to the least developed countries, developed countries like the USA and the European continent, were greatly increased during the post-TRIPS era.

Some of the authors have very well described the changes in Indian pharma companies after TRIPS[45,46]. The authors highlighted the fact that many Indian pharmaceutical businesses acknowledged the importance of R&D and the development of new chemical entity investments with the return of product patents. This caused many companies to expand their R&D, which has seen a 5.07 per cent increase over the pre-TRIPS era of 3.88 per cent. The study shows that the company's growth in size leads to an increase in R&D activity and R&D performance. It clearly indicates that the active R&D in India only involves larger companies with financial resources. They also demonstrate that even giant corporations that invest in research and development are not in the development of novel compounds, which again confirms that Indian companies lack the financial and scientific capacity to create new therapeutic molecules from design to delivery. The survey also showed that better technology has changed whether in India it is major, medium-sized or smaller businesses that are in line with shifting global patterns, which have led to higher sales and exports for Indian pharma. In line with these findings, authors have provided a thorough report on the Indian pharmaceutical industry's pre TRIPS and post-TRIPS scenario.[47] Their analysis demonstrates that Indian pharmaceutical businesses simply produced or copied copyrighted medicine blockbusters worldwide until the TRIPS agreement was signed by India, which did not incite domestic enterprises to focus on original pharmaceutical studies. They are of the view that, without knowing many of the imminent difficulties affecting the pharmaceutical business of that nation, the Indian Government has exhibited unduly haste in signing the TRIPS Agreement. In the neglected illness and region-specific diseases, the TRIPS Agreement also failed to implement R&D. Some of the authors have expressed that a favourable response from capital-exporting countries was received in the liberalisation of India's foreign investment policy in 1991.[48] However, this did not involve global pharmaceutical companies. The primary basis for the ruling was the

absence of patents on pharmaceuticals in India. Obviously, the environment of intellectual property affects the flow of foreign investment in a country, especially in businesses highly reliant upon the protection of intellectual property. India is unique among developing countries since it boasts a prosperous pharmaceutical industry that offers low-cost healthcare. However, India's increasing pharmaceutical sector is not built on innovative research and is reliant on reverse engineering current pharmaceuticals. A study by Smith discloses the preparations made by companies for 2005 and beyond.[49] The analysis by the author indicates that while the new patent framework may be capable of awarding international companies to Indian businesses, even then, local companies will probably profit from more stringent legislation. The researcher predicts that India and MNCs will become important in the future of the medicinal product sector, although in a slightly different form when he evaluates different strategies like technology strengthening, re-defining new discoveries, and focusing on export by the 12 major companies (four MNCs and eight Indians). Some Indian pharmaceutical companies will be given world-class status under the law of 2005. Lalitha has carried out a SWOT analysis on the patent rules.[50] She highlighted that the main strength of the industrial sector is in the growth of the process fostered by the Patent Act of 1970. Based on this capacity, India could also benefit from multinational businesses' initiatives in the WTO environment. At the same time, though, efforts should also be directed at enhancing domestic research and development and increasing research and development FDIs. Care should be taken in the handling of the FDI cases so that such investments do not increase the FDI by themselves but also improve technology. Most critically, the Indian Pharmaceutical industry must ensure that people's access to medicinal products and consumer interests are not adversely affected by globalisation and the quest for new medication discoveries. According to Kubo, after 1995, the intensity of R&D and the R&D patent ratio increased in India.[51] His studies were centric on underlying R&D and patenting trends observed by Indian pharmaceutical undertakings following the adoption of a 1995 TRIPS agreement. His research was based on the period 1988-2002, on a sample of 242 Indian domestic pharmaceutical companies. The author also stated his observation that the majority of product patent applications and a large percentage of process patents than companies with specialist products alone are submitted by vertically integrated enterprises, i.e., companies which make bulk medications and formulations. The fact that product patents were introduced could give the formulant makers and bulk medication producers the possibility of opportunistic behaviour. In a study, by Chaturvedi *et al.,* about the response to changing IPR circumstances by Indian companies, authors acknowledged the post-TRIPS scenario, R&D as a "survival kit".[52] Researchers have observed that Indian companies not only engage in R&D for the new discovery of drugs but also to strengthen the capacity to absorb and use externally available knowledge. They also position themselves as a partner of choice for technology-savvy national and multinational firms. In a study, by Basant in 2007,[53] contrasting patent issues in India v patent issues in Pakistan, the author explains that higher prices in Pakistan for pharmaceutical products v India were not due to the disparities between both nations in the intellectual property rights scheme. This occurred because a weak patent system in India was linked with measures for reducing market concentration, curbing monopolies and boosting bulk medication manufacture through initial investment in the public sector. Furthermore, the Indian market size might have led to the development of the ability for indigenous processes. In the meantime, in Pakistan, the same patent policy has not been combined with policies that have been enacted in India. Gupta in his paper[54] has opines that the Indian Pharmaceutical Industry has availed exciting opportunities in the post-TRIPS period. Indian corporations increase their DMF (Drug Master File) charges each quarter. Indian generic businesses, in particular in US, are also strengthening their involvement in advanced markets. Consequently, in the post-TRIPS period, USFDA filings are also growing with the ANDA (Abbreviated New Drug Application).

Concerns Over Strong Adherence to TRIPS

ANDA Forming laws and passing them in both houses of parliaments, in line with TRIPS, was a typical issue for the Indian Government. Secondly, the check over the adherence to these laws was another milestone to be achieved. Authors, Banerji *et al.,* outlined the issues posed by India's TRIPS agreement after it was signed.[55] The study addresses the application of modified patent legislation for

patent rights versus human rights to obtain medicines. The authors raised their concern: will the compulsory licensing balance the patent holder's right against his billion- plus people's fundamental health rights according to Indian Constitution? They further apprehended the serious reality of weak research and development in India even after the TRIPS regulation had been established in 1995. Chatterjee[56] in his research, provides details on the laws on the pre and post-2005 pharmaceutical patents, including the patent laws practised in countries other than the United States, Europe and Japan. The study strongly argues that the patent should be consistent with public health policy. It should not distort competition leading to lower access and access for the impoverished bulk of the country to medications. The article further confirms its ideas by analysing Novartis Glivec's case regarding the logic of patenting and the price of medications. If India wants to resolve the problem of accessibility and affordability, India's drug businesses must take action on path-breaking research and development.

Kalaskar *et al.*[57] discussed various solutions to address emerging problems of the product patent system by Indian pharmaceutical companies to maintain their competitiveness and profitability. The benefit of reverse chemical process engineering of the patented molecule will no longer be available to Indian enterprises to create and sell their generic version on the Indian and international markets. Highlighting the issues with the cases against patents, Boldrin *et al.*[58], revealed that there are no actual facts to demonstrate, other than to profit the company which patented the invention, that the strengthening of the patents regime gave the broader public additional social good. On the other hand, they say in their paper that weak patent systems have enhanced innovation with few side effects, as historical and international facts suggest, whereas powerful patent systems have delayed innovation with numerous bad side consequences.

Analyzing the patents as a challenge in a new dimension, Sampath *et al.*[59] state that Indian pharmaceutical enterprises are strengthened to face up to the challenge of patents for their ultimate survival. Noticing the implementation of the TRIPS Agreement, the non- viability of compulsory licencing as a supply mechanism will not only directly involve India but also large numbers of least developed countries in the access and affordability of medicines, which makes little sense in economic terms to Indian generic suppliers. The study also analyses the drivers of the innovative strategies of the Indian company to focus on global illnesses rather than Indian disorders: Authors highlighted that demand for export medications that guarantee the maximum return increases profit, and Indian companies entirely pay for their own research efforts with little or no government support, through their earnings. Sharma *et al.*[60] in their report, has shown that implementation of the product patent system will considerably enhance the Indian pharmaceutical industry because the global pharmaceutical giants look forward to entering Indian markets through various contracts and co-operations with Indian pharmaceutical companies, and in his opinion, the author certifies that India has the necessary infrastructure, demonstrated capacity, capabilities, and adequate resources to carry out big tasks at inexpensive costs to meet the world's need for excellent medication. The author also claims that the USFDA is ready to provide its knowledge and skills to Indian industry to translate the country into a worldwide centre for research and production. The author concludes his investigation on the lack of conviction to attract MNCs in the Indian legal environment by citing one case of the patent protection lawsuit Novartis Gleevec has lost at the Indian Supreme Court.

Chaudhuri *et al.*[61] have highlighted Indian potential not just in a single country but throughout the whole developing globe, which under the new patent regime is proficient in preserving high-quality generic medicines at low prices. While Indian pharmaceutical companies' intact capacity to produce generic versions of patented drugs is still intact, research shows that TRIPS implementation has adversely affected the possibility of leveraging new drug patent manufacture, resulting in the unstoppable utilisation of the capacity. This has made drugs worldwide less accessible and more costly. Their analysis also concerns the knowledge and rationale of developing countries' product protection for pharmaceutical products. Joseph[62], has provided an in-depth review of R&D expenditure and I&D plans for some of India's biggest pharmaceutical businesses once TRIPS in India has been implemented. It was intended to invest in R&D, boost collaborations in technology and enhance skill training for diseases which are widespread not only worldwide but specific to India and other tropical nations. The author also argues that,

because of Indian companies' lack of capacity, both science and technology and financial resources, the development of new pharmaceuticals has not succeeded. As the private sector remains away, the Author argues that India must resurrect its leading public-sector enterprises for indigenous innovations, notably for the neglected ailments, under the former policy regime.

Juma C in his research[63] raises calls on the developed nation to take account of the relevant points relating to technical cooperation and to include them in the Treaty on TRIPS. The authors also pointed out that the implementation of strong intellectual property rights must lead to the spontaneous promotion of technological innovation, technology transfer, and diffusion in the context of economic and social welfare in society around the globe for the benefit of manufacturers and users. At the same time, a balance between rights and obligations should be created. The study also explores how the global stock of knowledge might be mobilised to solve the technological innovation and global financial flows of the emerging nation. The author shows how to fix the problem through collaborations and realistic programmes which address developing countries' concerns. Thus public interest issues, such as health, nutrition and conservation of the environment, which must be handled in compliance with the TRIPS agreement through scientific and technical collaboration, were mentioned clearly. Bruche[64] while discussing Indian Pharmaceutical Companies (IPC), explores opportunities for the participation of global research-based pharmaceutical businesses to gain a natural ability and internationalization as IPC, which are labelled as newly rising multinationals of the developing world. The study found that IPCs have an unusual worldwide competitive position in the aforesaid circumstances. The report claims that IPCs do not pose a significant threat to bigger global organisations and that Indian firms' competitive position remains essentially inferior. The author feels that many enterprises have a great potential to become players in the worldwide arena. But their task, primarily family-owned, is to break the inflexible mentality of making short-term benefits into an innovation-based, capacity-building strategic business model to become part of the integrated, globally-research-based pharmaceutical organisation. Although a large number of IPCs develop into research-based players, their associated capacity building procedures are still far away. In contrast to the research by Bruche[64], Amit Shovon Ray acclaimed India's great pharmaceutical and production record while critically mentioning that companies in India are far from reaching the world's frontiers in cutting-edge research into drug innovation[65].

Since the establishment of TRIPS Agreement, pharmaceutical businesses have found it exceedingly difficult to cope with their issues; as the author says, the Indian pharmaceutical industry has developed strong process chemistry capabilities under the process patent regime since 1970. The author is confident that India will face the challenge of growing its pharmaceutical industry and entering the range of medication development. In a brief report by Gopakumar *et al.*[23] authors have investigated post-TRIPS behaviour in India in MNC's reporting that a powerful IPR system has failed, either with FDI in the field of Research and Development, Technology Transfer or product innovation for local needs, as envisaged. The report also deals with the much bigger issue of acquisitions and strategic alliances by MNCs with Indian companies of a high level of technological capability, which, according to the authors, has not only eliminated the access to affordable drugs in India but forced Indian companies for dependency on MNCs for meeting the country's drug needs in the long run. When, for example, Daiichi took over Ranbaxy, Pfizer's blockbuster cholesterol medication Lipitor quickly dropped all the patent disputes. This kind of development would have meant that all vital medicines were out of the reach of the common man by MNCs in the pre-1970 period. Mahajan while discussing the evolution of R&D paradigms in the Indian pharmaceutical industry after TRIPS, analyses several aspects of domestic pharmaceutical companies' post-TRIPS behaviours regarding the R&D intensification, new drug molecules development and increased Drug Master Filings[66]. The researcher found that Indian companies actually made a lot more R&D after India accepted the TRIPS agreement sponsored by World Trade Organization (WTO). Companies have used better process technology and production capacity to stay competitive in the industry. While pointing out the growth and competency issues resulting from the patent system, Janodia *et al.* have sought to determine how Indian pharmaceutical businesses are examining the product patent regime, its impact on

pharmaceutical industries' growth and the country's motivation for research and development[67]. The authors have commented that they are sure that India will have a large part in the future pharmaceutical industry, especially those who work in the intellectual property area of pharmaceutical businesses. The authors also observed that Indian scientists could develop and safeguard intellectual property rights. In addition, it is noted that TRIPS is a commitment to enterprises in India but that they cannot invest heavy sums in the development of new medicinal compounds.

Ramanna[68] explored the inability to enforce compliance with the TRIPS of external trading pressures. This is evident since India did not amend its patent laws as required by TRIPS between 1995 and 1998. Only industry organisations' changing interests in 1998-99 forced the government to comply with TRIPS fully and evolved a pro-IPR electoral division in India. The recent (third) amendment to the Patent Act, 1970, brings India into full compliance with its obligations under the TRIPS Agreement. The amendment was distinguished by a comparatively silent language and an unprecedented degree of accord among activists and critics. In a study by Rangnekar[69], the author examines an agenda for patent reform while focusing primarily on domestic compulsions. His analysis shows that the restrictions for TRIPS implementation are also based on the Government's ambivalence regarding intellectual property and the changing interest of the Indian pharmaceutical business. The patent reform was thus doubly restricted by the narrow goal and internal considerations in India, despite a favourable international intellectual property climate. Thus, the author presented a brief criticism regarding the law implementation policies of the government.

Lanjouw[70] expresses concerns over adherence to strong IPRs. While it is crucial to international companies to decide where to locate R&D facilities for strong IPR, even after product patents have been introduced, there seems to be no convincing justification for them to locate in India. While robust intellectual property rights could make the Indian environment more attractive for MNCs as an R&D venue, it is unlikely that their options will change dramatically. It is simply because, given the centralised nature of R&D and the fact that costs are not the primary concern, substantial intellectual property rights do seem to be important in deciding where to find their R&D facilities. However, there is no compelling reason for them to locate their R&D faculties in India even after product patents exist. Lanjouw[71] again emphasises that there is little question that global and clearly defined patent rights may improve the public funding of pharmaceutical research to the developing world, but that the reason for extending patents to poorer countries is unclear for key global diseases. The paper examines typical intellectual property and regulatory procedures for differentiating protection, but it also determines that these systems have severe inconveniences. To prevent these difficulties, the new mechanisms with structures are revealed in the paper. It would enable the establishment of a worldwide patent scheme that would not only be sensitive to countries' development levels and but to specific drug markets' features also.

Glasgow[72] examines the role that antitrust law should play in evaluating and implementing pharma corporations' possibly unwanted behaviour. The paper analyses how pharmaceutical corporations seek to extend the patent life of their brand-name pharmaceuticals by alleging several loopholes of Hatch-Waxman Act 1984 through empirical examples. The researchers are concerned about the fact that the protection of the intellectual property is not exploited to stimulate innovation through analysis of different approaches employed by big corporations specialised in brand-name medications. Rather than being the most profitable, not always the most promising pharmaceuticals, intellectual property rights are utilised to achieve and preserve exclusive market share. It also says that anti-trust law should take action to correctly curb those violations of intellectual property rights which have gone beyond their reach, apart from ways like legislative improvements. In a multinational study[73], about the implementations of TRIPS, the author raised the argument on the relevance of this TRIPS agreement for developing countries and its specific requirements that is the subject of discussion inside the WTO has persisted. The author worries that the debate is still taking place instead of settling down fast. The research shows that arguments remain for or against the utility and acceptability of TRIPS in developing nations, even after five years of entering the TRIPS Agreement. TRIPS and patent protection can definitely not be advantageous for developing countries, and patenting in poor countries is evidently undesirable. Their preservation is primarily the

responsibility of western multinationals, which allows them to establish monopolies, drive away from the local competition, distract research and development from the demands of poor states and raise prices for all, from seeds to software. Patents in the process restrict the poor from obtaining lifesaving drugs and prohibit interference with ancient agriculture traditions. Without authorisation or recompense, foreign pirates are allowed to raid local resources like therapeutic plants. A similar study[74] addresses patent protection's environmental and developmental impacts by focusing on the global agreement on trade-related aspects of intellectual property rights (TRIPS). While the TRIPS treaty is a crucial step forward in harmonising the international IP system, public and private interests, particularly the gap between wealthy and poor, are currently not appropriately balanced. The investigator argues that TRIPS does not help establish "innovation, ethical and sustainable societies" directly. In contrast to the study by Adede[73], Lall[75] performed research on the data of four groups containing 87 countries for the year 1997-98. The researchers have calculated the Industrial Performance Index (IPI) and Technology Effort Index (TEI). The results reveal that IPRs, IPI and TEI correlate well. Though the results are similar to observations by Adede[73]regarding beneficiaries, the results show that higher IPRs are likely to benefit high-performance countries. Thus, TRIPS is unlikely to assist countries with a low and shallow performance index. The application of stronger IPRs throughout the developing world appears not to be the case. The economic concerns call for a diversified TRIPS strategy according to the degrees of industrial and technological capacities as the results are likely to be context- specific. The author further advises that it may be premature to draw general conclusions regarding the net benefits of TRIPS without further inquiry.

In another study, Zuniga *et al.*[76], from Mexico, the economic impact of pharmaceutical patent protection on the Mexican business is focused. The researchers have sought to do a short evaluation and compare them to those predicted by economic literature on the dynamic and static consequences of introducing patent protection for pharmaceuticals in Mexico. The author claimed that additional elements in addition to patent protection must be considered before a rise of R&D in the Mexican pharmaceutical sector is expected. The study by Niar[77] explores that although patent rights often lead to the monopoly pricing of drugs that make them unaffordable to large numbers of populations in developing countries, especially those economically back-up, nevertheless, when interpreted and properly implemented, the TRIPS provisions are not likely to be a major obstacle to making drugs available at an affordable price even under patent protection. While focusing on the TRIPS created tradeoff between profit v humanity, Lalitha has written that IPR laws reflect business interests mostly on a one-sided basis and do not reflect the needs for health or responses to economic health challenges.[50] She believed that TRIPS implementation would be a hotchpotch of measures without addressing numerous problems typical of the Indian drug sector, which has generated concerns. She further raises her concerns that TRIPS can badly impact the industry in the long term if not implemented with concerns for the health of poor people. In an another similar study by Lanoszka,[78] author emphasizes that, due to the persistence of asymmetry in the degree of development and investigational capacities between developed and developing countries, WTO regulations on intellectual property rights are controversial. The author points out the ways in which TRIPS may cause monopolies, tolerance, exploitation and economic tactics. The author further claims that many poor nations do not have the financial means to address the difficulties posed by the TRIPS treaty and have still not adopted sufficient competition regulations to address them successfully. To modify their mindset, the leading industrialised countries must take care of the social and economic needs of the emerging countries. The idea of fairness as one of the principles controlling the discourse between developed and developing countries should begin. By fairness, the author means to be sensitive to developing countries' specific demands and acknowledgement human needs, for instance, health and care.

The relationship between firms' R&D activities and TRIPS is also dealt in available research. Pradhan[79] focused on foreign and Indian enterprises' R&D activity. Pradhan shows that, in terms of R&D intensity, external enterprises are significantly behind domestic firms, based on a survey carried out by the pharmaceutical industry on R&D. The intensity of research and development in local companies observed is 2.6 per cent and three-and-a-half times that of overseas companies, which is 0.74 per cent.

The study reveals that the R&D intensity of foreign enterprises is constantly below the average sample and has decreased since 1997. Although competitive pressure has been effective in driving Indian pharmaceutical companies towards R&D with the implementation of TRIPS, its impact is probably limited to a few large and medium-sized enterprises since large segment of small companies lack the huge resources needed for their product development. In a similar study[80] by the same author, Pradhan expresses doubts over the benefits of signing TRIPS by small pharmaceutical companies in India. The author claimed that the regulatory regime of small companies had seen substantial changes during the 1990s, with most favourable policies removed and rules such as the long-term product patent system implemented, price control exemption abolished, good manufacturing practices applied, and so on. The new guidelines have several consequences for small pharmaceutical companies' survival and development. The researcher attempted to resolve static discrepancies between small and large pharmaceutical units' inefficiency and other performance metrics by gathering unit data from the 2000-01 annual industry survey. While commenting on the mandatory licensing provisions, the author in Chaudhuri[40] states that The Patent Act's amendments to respect TRIPS have exploded the provisions and flexibilities that TRIPS promised to balance patentee private rights with the socio-economic needs and objectives of the society and have attempted to examine the question as to whether they have taken advantage of these flexibilities. India was not able to make full use of the mandatory licencing provisions, according to him. In a separate study, Aggarwal,[81] based on primary survey analysis and focuses on the competitiveness of exports of pharma corporations, the author finds the factors determining the competitiveness of companies' exports. The results indicate that the competitiveness of enterprises depend not just on individual corporate benefits but also fiscal incentives from the government. One of the key elements that influenced export competitiveness has been its R&D initiatives. On the other hand, technology imports have not played a significant export- enhancing impact. The study also found that export competitiveness variables differ between enterprises of different sizes and ownership. There are substantial obstacles facing Indian exporters on high transactions and cost of production. The study identifies beneficial policy consequences such as the government's role in export promotion and the development and marketing of brands on foreign markets to enhance industry export competitiveness. According to Brahmi *et al.*[82], the TRIPS Agreement has introduced a new worldwide intellectual property protection system. But this could be beneficial, but only in the long term, for developing countries only. In the medium term, the main winners are probably the industrialised countries. The authors advise that including fields such as drug goods, agricultural inputs, biotechnology, and environmental and electronic databases of international intellectual property rights would have serious development repercussions that should be considered carefully. In a study by Sampath,[83] the author has empirically analyzed the close link between the intensity of export and investment in R&D for the Indian pharmaceutical. The study also supports Indian enterprises' opinion that, because of rigid global competitiveness, they will confront significant challenges in order to adjust to the evolving patent regime while working in an industrial or regulatory atmosphere that is yet not fully tailored. The analysis of Sampath was based on data from 103 pharmaceutical companies. The author argues that since most of the Indian company fully finances their own research efforts with their profits, the main goal is to invest in the research of pharmaceuticals that would provide the greatest returns. This means that R&D expenditure on global diseases will only be emphasized as a consequence of TRIPS. In another similar study by Reddy,[84] author has claimed that R&D is higher than growth for the generic pharmaceutical industry for major pharmaceuticals such as Ranbaxy. More prominent drugs have the means to invest more in R&D and can bear in mind the future. These resources are not available to smaller pharmaceuticals and could not thrive on the market. More market strengthening and more extensive medicines are likely to continue to expand and take over the market in the future since more giant pharmaceuticals are already partnering with MNCs and licensing items for them. In a balanced favour of TRIPS, Raju[85] demonstrates that the TRIPS agreement does not provide for a single law. Yet, the maximum requirements that significantly increase the degree of intellectual property harmonisation are prescribed. Even universal protection leaves considerable scope for national legislation to determine specific key issues. The idea

of patents was formed to safeguard their intellectual creations by industrialised countries. The developing countries have always been in receipt. The researchers are looking in this study at significant and procedural levels at the modifications to the Indian patent system due to TRIPS and Indian reactions. The report further analyses the consequences of the transition period to identify additional alternatives for India and makes some ideas for improving the patent system across the country. In her study, Bhaduri,[86] the author considered many of the reasons favouring a TRIPS imposition in India to be unfounded and inconsistent. The Commission has sought to stress specific rhetorics concerning TRIPS. Given that research and development costs are increasing, the IPR regime is perceived as a threat for innovators for a week to reimburse the innovator. By presenting several actual examples, she has critically analysed the reality of these claims. Finally, she finds that extending monopoly rights for up to 20 years could lead to a fall in research and development expenditure since the monopoly impact of a secure market could not be an incentive to seek more efficient processes of the same product during a patent lifetime. Consumer use of novel drug procedures under the TRIPS, which is strongly opposed to the goals expressed by the WTO, can, therefore, pay higher prices.

A few studies have tried to highlight the problems small pharmaceutical units face in the post- TRIPS period. According to the Cygnus Report,[87] during the post-TRIPS period, the issues caused by shutters of small pharmaceutical facilities were: compliance with goods and manufacturing practices of schedule M of the Drugs Act, excise duties on MRP rather than ex-factory costs; and the migration of drug production units to duty-free zones. The minimal cost of up-gradation for one pharmaceuticals company was calculated at Rs. 15 million in order to meet the standards of Schedule M. Since most SSI units didn't have the necessary financial strength to achieve this upgrade, their operations had to be shut down. In addition, with the 40 per cent cut in excise tax on MRP, effective on January 07, 2005, the situation of the businesses of these SSI units, who in any case were successful in upgrading their production planning to the M standards, was still unpleasant. According to Chaudhuri,[88] R&D expenses in the Indian Pharmaceutical Industry segment have surged considerably since the entry of TRIPS. The results of this research suggest that the R&D intensity of the big spenders has improved from 1.78 per cent in 1992-2013

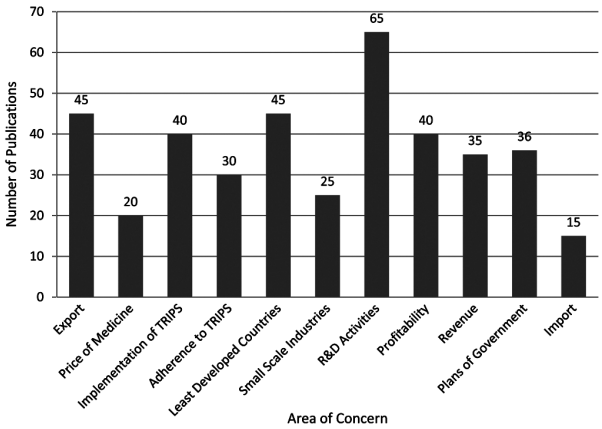

Fig. 5 — Distribution of different areas of concern related to the Patent Amendment Act, 2005 and TRIPS

to 8.79 per cent in 2005-2006, based on the R&D spending of 109 companies (of whom 28 were significant R&D spenders). However, if the results of R&D are targeted, the studies show that even after TRIPS, the expertise of India remains in the development of processes and in the development of new goods, as no new chemical entity has yet been generated. In the absence of TRIPS-compliant protection, R&D impacts are unlikely to be detrimental for developing country companies because developed nations are protected and can boast the possession of the largest markets for new pharmaceuticals.

Author in Jayakumar[89] has claimed that in the past two years, more than half the smaller pharmaceutical units operating in India have either closed or discontinued their business operations indefinitely, impacted by unfavourable government policy and unable to compete in a new environment with big businesses. Good production techniques obliged them to make significant investments in modernization in order to comply. A detailed study by Khader[90] discussed the obstacles drugs face in pursuing a patent application in India under the post- TRIPS patent system. As it turned out that Section 3(d) of the Indian Patent Act 1970 was a contentious issue, the current study analyses the issues of the application of the Patent Cooperation Treaty (PCT) patent and the effect of exclusion from patentability and the way in which a patent can be used before the grant or the opposition pre-granting procedure. While conducting the literature review, the findings of one hundred twenty-five papers were thoroughly observed. The authors of different papers have shown diverse and critical concerns over different issues related to the Patent Amendment Act, 2005[10] and TRIPS[16] (Fig. 5).

Conclusion

There are various studies whose focus spans over TRIPS and Indian pharmaceutical organizations. Most of the research has emphasised the formulation of government policies for the best possible social return from IPR rules and patent laws. It has been outlined that the enforcement of patent laws will result in better performance, global business activities, exports and increased R&D. TRIPS regulations will cause the development of educational institutions in the country in the fields of chemical synthesis, cheap production of medicines, production of generics. It has also been acclaimed that the industries have focused on producing medicines for all diseases instead of focusing on rare diseases only. As an interesting review finding, most of the studies stated that R&D as the path to adherence to TRIPS. Most of the studies have disapprovingly raised their worries on the adverse societal impact of TRIPS, which is stated as the monopolization of medicinal drugs by the big multinational organisations. Thus, it is unanimously proposed that the patent system should be well-designed to foster innovation and societal benefit. It has also been urged that government should put efforts in R&D investments for the overall benefit of the society in India as well as in the other developing and less developed countries. Thus, it is well observed from the literature review that Patent Amendment Act, 2005 and TRIPS has created a profound impact on the Indian pharmaceutical industries in the dimensions of export, import of raw material, profitability and R&D activities.

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