IMPACT OF TRIPS AGREEMENT ON PHARMACEUTICAL INDUSTRY IN INDIA

KM Surraj, B.COM LLB (Hons.), Sastra Deemed To Be University

Sai Jawahar V Mallady, B.COM LLB (Hons.), Sastra Deemed To Be University

ABSTRACT:

The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) calls for the harmonization of intellectual property rights (IPRs) regulations across all WTO member countries. The TRIPS Agreement requires all WTO member countries to adopt and enforce minimum standards of intellectual property. It was assumed that the introduction of pharmaceutical product patents would hamper the Indian pharmaceutical industry's growth. Contrary to expectations, however, the Indian pharmaceutical industry has been growing in the post-TRIPS period. The TRIPS Agreement changed the research and development (R&D) orientation of Indian pharmaceutical companies, which have increased their R&D investments. Since the TRIPS Agreement was signed, the pharmaceutical global value chain (GVC) has been re-structured and has now expanded to emerging countries like India. Indian pharmaceutical firms have thus been participating in the pharmaceutical GVC in the post-TRIPS period. This participation is conducive to technological upgrading and technology transfers. While operating in the GVC, Indian pharmaceutical firms are upgrading by adopting state-of-the-art technologies. This study explores how the TRIPS Agreement is influencing the Indian pharmaceutical industry and discusses the industry's growth factors in the post-TRIPS period within the GVC framework.

Keywords: Indian pharmaceutical industry, TRIPS Agreement, global value chain

INTRODUCTION:

The Indian pharmaceutical industry has achieved production self-sufficiency and has been one of the largest drug exporters in the world since the late-1980s. It has also shown promising global competitiveness. The Indian pharmaceutical industry continues to expand across the world.

This success has been attributed to the industry's ability to conduct research and development (R&D) and to develop generic drugs acquired and improved under the weak patent protection regime enabled by the Patent Act, 1970 from the 1970s to the 1990s. The Patent Act, which recognized process patents but not product patents, paved the way for advances in indigenous Indian R&D.

In March 2005, India amended the Patent Act to comply with the World Trade Organization's (WTO's) agreement on TRIPS, which set global minimum standards for the protection of intellectual property. The TRIPS Agreement deals not only with patents but also with other forms of IPRs, such as copyright, trademarks, industrial designs, geographical indications, and confidential information. WTO members must comply with the provisions of the TRIPS Agreement. The TRIPS Agreement required the introduction of both product patents for pharmaceuticals and a patent- protection period of at least 20 years.

The Indian pharmaceutical industry faced new challenges due to this agreement. It was assumed that the introduction of pharmaceutical product patents would hamper the Indian pharmaceutical industry's growth. Under the product patent regime, the Indian pharmaceutical industry can no longer manufacture by reverse-engineering or export drugs with product patents in effect.

Contrary to expectations, however, the Indian pharmaceutical industry has been growing in the post-TRIPS period. This study explores how the TRIPS Agreement has influenced the Indian pharmaceutical industry and discusses the industry's growth factors in the post-TRIPS period within the global value chain (GVC) framework. Under the TRIPS Agreement, the pharmaceutical industry became globalized. The pharmaceutical GVC has been re-structured and has now expanded to emerging countries like India. Indian pharmaceutical firms have been participating in the pharmaceutical GVC through strategic alliances with multinational pharmaceutical companies in the post-TRIPS period. GVC participation is conducive to

technology transfers and technological upgrading. Indian pharmaceutical firms are upgrading while operating in the GVC by adopting state-of-the-art technologies. This study explores the relationship between this upgrading and firm development through case studies on Zydus Cadila, India's fourth largest pharmaceutical company, and Biocon, India's largest bio pharmaceutical company. These companies have achieved rapid growth and technological innovation by utilizing numerous alliances with global pharmaceutical companies.

The rest of this article is organized as follows. Section 'Overview of Indian Pharmaceutical Industry in Pre-TRIPS Period' provides an overview of the Indian pharmaceutical industry in the pre-TRIPS period. The next section describes the TRIPS Agreement and its impacts on the Indian pharmaceutical industry. In 'Participation of Indian Pharmaceutical Companies in GVC', case studies on Zydus Cadila and Biocon, two representative Indian companies, are presented.

The next section describes the upgrading of the Indian pharmaceutical industry. Finally, some concluding remarks are given in the last section.

Overview of Indian Pharmaceutical Industry in Pre-TRIPS Period:

The Indian pharmaceutical industry has shown steady growth over the last four decades and has emerged as one of the leading global players in generics. India has become a major drug-producing country. The Indian pharmaceutical industry, which had little technological capacity to manufacture drugs ingenuously in the 1950s, achieved production self-sufficiency and became one of the largest drug exporters in the world in the late 1980s.

Driving the development of the industry was the weak patent regime of the Patent Act, 1970 and the Drug Policy, 1978. After India's independence, the Indian government appointed two committees, the Tek Chand Patents Enquiry Committee (1948 to 1950) and the Ayyangar Committee (1959), tasked with improving the accessibility and affordability of essential drugs in India. These committees recommended amending the Designs and Patents Act, 1911, which recognized product patents for pharmaceuticals. This act was indeed replaced by the Patent Act, 1970 (Ramannna, 2002, pp. 2065–2066).

The Patent Act, 1970 recognized only process patents and reduced the patent period from 16

to 7 years. Automatic licenses of right could be issued three years after the patent was granted. The act allowed Indian pharmaceutical companies to produce alternative processes for drugs that were not patented in India. From the 1970s to the 1980s, Indian companies began to take up R&D work on their own. The weak intellectual property protection regime provided under the Patent Act, 1970 was a turning point in the development of indigenous pharmaceutical R&D in India. The act encouraged reverse-engineering and the development of alternative processes for products patented in other countries.

The Drug Policy, 1978 was India's first comprehensive drug policy. The basic framework of the policy remained largely in effect up to the 1990s. The basic objective of the policy was to achieve self-sufficiency in drug production. The policy emphasized the role of R&D and technology and enhanced the technological capability of the Indian pharmaceutical industry by providing R&D-promotion measures. Several measures for guiding and controlling foreign companies with a 75 per cent share of the domestic market were implemented to be consistent with the basic objective of the policy and to promote the production of bulk drugs and intermediates.

The Patent Act, 1970 and the Drug Policy, 1978 were key to advances in indigenous R&D. India's ability to develop generic drugs was acquired and improved between the mid-1970s and 1990s.

In addition, other industrial policy measures, such as the Foreign Exchange Regulation Act, 1973 (FERA) and the Drug Price Control Order, 1970 (DPCO 1970), intended as disincentives to foreign companies, also played important roles in the development of the industry. Moreover, the DPCO, introduced in 1970 with the aim of supplying drugs to the poor at affordable prices, gave the Indian pharmaceutical industry the incentive to export rather than sell to the domestic market because drugs could be sold at higher prices in overseas markets.

The Indian pharmaceutical industry, which worked on the basis of reverse- engineering and process innovation, achieved technological self-sufficiency and has been strengthening its export orientation amid the contemporary tide of economic liberalization since the early 1980s. The industry has shown promising potential for global competitiveness and is continuing to expand its presence worldwide. The trade surplus of pharmaceutical products has been increasing since 1987.

Good manufacturing practice (GMP), a system for ensuring that products are consistently produced and controlled according to quality standards, increased the reliability of Indian drugs in the global market. India decided to introduce GMP via the Drug Policy, 1986. GMP was laid down in Schedule M of the Drugs Cosmetics Act, 1940 and Rules, 1945 and came into force in 1987. The introduction of GMP helped enhance consumers' trust in Indian products in the global market. In addition, complying with the GMP standards in the United States and Europe has increased Indian exports to Western countries and has expanded opportunities for contract manufacturing. Generally speaking, the DPCO provides incentives to adopt an export orientation, and GMP provides an institutional basis for supporting the export orientation of the Indian pharmaceutical industry.

Economic reforms in 1991 changed India's strategies of import substitution. During this period, the Indian pharmaceutical industry competed with foreign companies in the field of generic drugs, which were easily imitated. The Indian pharmaceutical industry gradually accumulated R&D capabilities and had achieved trade surpluses with nations all over the world by the late 1990s.

In summary, from the 1970s to the late 1990s, the Indian pharmaceutical industry successfully shifted from import substitution to export orientation and from comparative disadvantage to comparative advantage through economies of scale, technology, and learning effects on productivity.

Impacts on TRIPS Agreement on Indian Pharmaceutical Industry

The Indian pharmaceutical industry has faced several new challenges because of the TRIPS Agreement. An amendment to the Patent Act, 1970 to introduce product patents changed the institutional factors that had supported the industry's growth.

It was assumed that the amendment would have a negative impact on India and that it would hamper the growth of its pharmaceutical industry because it would no longer be able to manufacture by reverse-engineering or export drugs whose product patents were in effect.

In view of the TRIPS Agreement and impending changes to the Patent Act, 1970, the Indian pharmaceutical industry is pursuing a new business strategy. While pharmaceutical companies are increasing their investment in R&D, they have been participating in the

pharmaceutical GVC through international strategic alliances with global pharmaceutical companies in the post-TRIPS period.

Change in R&D Orientation of Indian Pharmaceutical Companies:

Until the mid-1990s, R&D in the Indian pharmaceutical industry focused on R&D for the development of new drug manufacturing processes. The TRIPS Agreement changed this. The TRIPS Agreement has not only increased R&D expenditures in the Indian pharmaceutical industry but also changed its R&D orientation. Indian pharmaceutical companies are increasing their investment in R&D for product innovation. The pharmaceutical industry is a highly R&D- oriented sector. Under the pro-patent regime of the TRIPS Agreement, sustainable growth in the pharmaceutical sector depends on continuous R&D for the development of new drugs and technologies. Indian companies have increased investment in R&D in order to overcome stiff competition in the global pharmaceutical market.

The companies are becoming more R&D-oriented. The new R&D focus is on novel drug delivery systems (NDDS), new drug development research (NDDR), and R&D for bio-pharmaceuticals.

Novel Drug Delivery Systems:

Indian pharmaceutical companies are increasingly focusing on R&D for NDDS. Most of India's top companies are increasing investment in this area. Companies not engaged in NDDR have instead been involved in R&D for NDDS. Commercially, the most successful example is the NDDS developed by Ranbaxy Laboratories for ciprofloxacin, whereby patients are required to take the drug once a day rather than the previous twice-a-day dosage. Ranbaxy licenced its once-a-day ciprofloxacin formulations to Bayer in 1999 (Bhandari, 2005, pp. 212–214). It is highly likely that they will continue to invest in R&D for NDDS to move up the value chain. Indian pharmaceutical companies are not only licensing their NDDS technology to global pharmaceutical companies but are also introducing new technology from global pharmaceutical companies to develop NDDS via the licensing agreements.

New Drug Development Research

Supporters of the TRIPS Agreement once argued that the introduction of pharmaceutical product patenting would encourage R&D for new drug development. Indian pharmaceutical companies began investing in R&D for NDDR in the mid- 1990s. Several leading Indian pharmaceutical companies are now engaged in R&D for new chemical entities (NCEs) and have set up their own NDDR research centres. Some Indian companies, like Zydus Cadila and Glenmark, have reported successes in NDDR.

These companies have strong pipelines of novel molecules in various stages of pre clinical and clinical development.

Zydus Cadila announced a breakthrough in the anti-diabetic drug Lipaglyn (Saroglilazar) in 2013. Lipaglyn is the world's first drug for treating diabetic dys- lipidaemia; it combines lipid- and glucose-lowering effects in a single molecule. The drug is expected to be a blockbuster and clock over $1 billion sales a year when it will be sold globally. At present, several NCEs, which are at different stages of clinical trials, have been developed by Zydus Cadila.

However, NDDR is time-consuming, and huge costs are involved in discovering a molecule and launching a product into the market. Moreover, the failure rate is relatively high. Typically, out of 10,000 compounds synthesized, only about 20 reach the animal testing stage, of which only about 10 compounds reach the clinical stage, and only one may obtain the approval of drug regulatory authorities. Moreover, only about three out of every 10 drugs recover their R&D costs.

The average length of time required is estimated to be between 10 and 18 years, with the clinical stage accounting for about half the total NDDR time (ICRA Limited, 1999). The cost of developing and launching a drug into the market is about US$ 800 million in other countries (DiMasi, Hansen, & Grabowski, 2003). Though Indian pharmaceutical companies have increased their R&D spending, most cannot afford the R&D costs associated with developing and launching a product because they are small relative to most global pharmaceutical companies and are operating at the lower end of the value chain.

For all these financial and technological reasons, some Indian companies have adopted a strategy of developing new molecules and licensing them out to large global pharmaceutical companies in the early stage of clinical development. Collaborative research with global

pharmaceutical companies is increasing. For example, Glenmark has a robust pipeline of 14 molecules in various stages of preclinical and clinical development. Glenmark is actively engaged in the development of NCEs and new biological entities (NBEs).

Simultaneously, Glenmark has followed the strategy of out-licensing its molecules in clinical development to large global pharmaceutical organizations. This strategy has been successful. Glenmark has off-licence seven molecules to five companies and has received a total of US$217 million in cumulative up-front and milestone payments. Glenmark is the only company from an emerging market to have executed multiple deals on novel molecules.

R&D for Bio pharmaceuticals

The Indian pharmaceutical industry began to invest in R&D for bio pharmaceuticals in the late 1990s. The bio pharmaceutical segment accounted for the largest revenue share in India's biotech industry (64 per cent) in 2016. Bio pharmaceuticals constitute the largest segment of the industry in terms of both domestic and export revenue (India Brand Equity Foundation (IBEF), 2016). The major segments of the biopharma industry in India are vaccines, bio pharmaceuticals, and diagnostics.

The patents on blockbuster biologists began to expire around 2015, a phenom- enon referred to as the 'second wave of the patent cliff'. This patent expiry is driving demand for bio similars. A bio similar is a biological product that is very similar to a reference biologic and for which there are no clinically meaningful differences in terms of safety, purity, or potency. With patents on originator biological expiring, biosimilars are expected to take an increasing share of the biopharmaceutical market. India was the first country to start R&D for biosimilars. Bio-similars have been available in India since the early 2000s, well before their arrival in Europe in 2006 and the recent introduction of a regulatory pathway in the United States. Indian companies are aiming to receive marketing approval of bio-similars in regulated markets.

As described above, Indian pharmaceutical companies have not only increased R&D expenditures but have also become highly R&D-oriented and -intensive in the post- TRIPS period. The technological level of Indian pharmaceutical companies has been steadily improving as their R&D experience accumulates. Indian pharmaceutical companies are

growing their presence in the global pharmaceutical market via strong R&D technology. India's pharmaceutical industry is moving up the value chain in the post-TRIPS period.

Participation of Indian Pharmaceutical Companies in GVC

Typically, a pharmaceutical company conducts all activities internally, from R&D to marketing. As the patents of many blockbuster drugs generating more than US$1 billion in revenue each year are drawing near their expiry dates and given the increasing R&D costs, it is hard for global pharmaceutical companies to keep their bottom line. While global pharmaceutical companies are under pressure to enhance their R&D productivity, many developed countries are trying to cut their healthcare expenditures. They have begun to outsource some of their research and manufacturing activities in order to save costs.

Expansion of Outsourcing Business in India

The TRIPS Agreement calls for the harmonization of IPR regulations across all WTO member countries. This reduces the risks of IPR infringement in emerging economies like India. It has led to a division of labour within the pharmaceutical industry. Due to the TRIPS Agreement, the pharmaceutical industry became globalized. The pharmaceutical GVC has now expanded to emerging countries like India. The TRIPS Agreement has opened new business opportunities for the Indian pharmaceutical industry.

Companies have been participating in the pharmaceutical GVC through international strategic alliances with global pharmaceutical companies.

The pharmaceutical outsourcing business has been increasing in India through- out the 2000s. In the past, global pharmaceutical companies tended to hesitate to manufacture new drugs in India because of the Patent Act, which did not recognize product patents on pharmaceutical products. However, they are now increasingly outsourcing the manufacture of new drugs. The introduction of product patenting through the amendment of the Patent Act, 1970 made it impossible for unlicensed Indian companies to manufacture patented drugs. The incentive for Indian companies to misappropriate the know-how gained from contractors (global pharmaceutical companies) was reduced. On the other hand, the amendment's introduction of a product patent system in India reduced the risk to foreign companies of outsourcing to Indian companies.

The contract research and manufacturing services (CRAMS) business, a kind of outsourcing business, has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies have entered CRAMS, and the number of specialized CRAMS companies has increased. In the post-TRIPS period, India has become a preferred outsourcing destination for global pharmaceutical companies and is becoming a global manufacturing and R&D hub.

According to Care Ratings Limited (2015), Indian CRAMS players are expected to register strong growth rates, at a compound annual growth rate (CAGR) of 18 per cent to 20 per cent by 2018. The Indian CRAMS industry is expected to increase to approximately US$18 billion in 2018 from about US$7.6 to 7.8 billion in 2013. CRAMS in India are moving up the value chain. Research and manufacturing activities for value-added products like bio pharmaceuticals are being outsourced to Indian CRAMS players.

Company Development through Strategic Alliances

Indian pharmaceutical companies are pursuing strategic collaborations with global pharmaceutical companies. The collaboration strategy has become a preferred way to leverage GVC participation for company development. Table 2 shows examples of strategic alliances involving Zydus Cadila and Biocon. These companies use strategic alliances with global pharmaceutical companies as an instrument for rapid growth. Case studies of Zydus Cadila and Biocon are presented in the following sections.

Zydus Cadila

Zydus Cadila is the fourth largest pharmaceutical company in India. The company has achieved rapid growth and technological innovation through numerous alliances with global pharmaceutical firms. Cadila Laboratories, Zydus Cadila's predecessor firm, was founded in 1952 by Ramanbhai Patel, formerly a lecturer at the

L.M. College of Pharmacy, and his business partner Indravadan Modi. In 1995, the Patel and Modi families split, and the Modi family's share was moved into a new company, Cadila Pharmaceuticals. Cadila Healthcare (Zydus Cadila) became the Patel family's holding company. At the time of the split, Zydus Cadila was a `2 billion company, whereas staff expenses totalled `4 billion. It was difficult to make ends meet (Trivedy, n.d.). Then, Zydus

Cadila decided to adopt a strategic alliance at a global level to supplement its scarce internal resources with external resources.

Since then, Zydus Cadila has signed numerous strategic alliances with global pharmaceutical companies in multiple areas, ranging from contract manufacturing to collaborative research.

Zydus absorbed technologies and scientific knowledge through these alliances and applied them to innovations. Zydus Cadila has grown a global pharmaceutical company with the ability to develop a wide range of innovations.

Zydus Cadila was the first Indian pharmaceutical company to launch the H1N1 flu vaccine in 2010 (Cadila Healthcare Limited, 2011, p. 2). In 2013, the company developed the new anti-diabetic drug Lipaglyn (Saroglilazar), the world's first drug for treating diabetic dyslipidaemia, combining lipid-and glucose-lowering effects in a single molecule (Cadila Healthcare Limited, 2014, pp. 3, 6, 13).

The company also developed the first biosimilar of Adalimumab in 2014 (Cadila Healthcare Limited, 2015, pp. 10, 15). These innovative products were developed through these strategic alliances.

The sales of Zydus Cadila grew at a CAGR of around 17 per cent between 2001 and 2016 (see Figure 3). It can be said that Zydus Cadila uses strategic alliances as an instrument for rapid growth.

Biocon

Biocon was established in 1978 as a joint venture between Kiran Mazumdar-Shaw and Biocon Biochemicals Limited, an Ireland-based global biotechnology company. In 1979, Biocon began to manufacture and export Papain, a plant enzyme, and Isinglass, a marine hydro colloid, which are key products in the brewing industry. The company developed proprietary fermentation technologies for manufacturing enzymes and entered the bio pharmaceutical industry by applying them. Biocon has followed a strategic collaborative model at a global level. Biocon signed numerous strategic alliances with global pharmaceutical companies to acquire the new technologies required to develop bio pharmaceuticals like insulin and monoclonal antibodies.

Biocon developed human insulin on a Pichia expression system for the first time in the world (Biocon Limited, 2004, p. 14). In 2004, Biocon started to develop oral insulin in a technology alliance with Nobex and announced a joint development agreement with Bristol Myers Squibb in 2012 (Biocon Limited, 2005, p. 23; 2013, p. 39).

In 2003, Biocon established Bio con Bio pharmaceuticals Private Limited (BBPL) as a 51:49 joint venture with the Cuban Centre of Molecular Immunology (CIMAB) (Biocon Limited, 2005, pp. 31–33). Biocon absorbed technologies and scientific knowledge through its joint venture with CIMAB and applied them to innovations. Biocon developed novel biologic Itolizumab, an anti-CD6 molecule, for the treatment of chronic plaque Psoriasis in 2013 (Biocon Limited, 2014, pp. 20–21, 28– 29). Itolizumab was the first new monoclonal antibody developed by an Indian pharmaceutical company through indigenous R&D, an important R&D milestone for India.

Patents on many blockbuster biologics began to expire in 2015; thus, the global biosimilar market will expand significantly. In 2006, Biocon started planning the development of biosimilars to seize this opportunity. Biocon announced a strategic collaboration with Mylan to enter the global biosimilar market in 2009 and enhanced this partnership through a strategic collaboration for insulin products in 2013 (Biocon Limited, 2010, p. 34; 2014, p. 48).

In 2016, Biocon received regulatory approval for the biosimilar Insulin Glargine in Japan, a first for an Indian company (Biocon Limited, 2017, p. 47). In 2017, Biocon and Mylan received regulatory approval for trastuzumab, a drug for treating breast cancer, in the United States (Biocon Limited, 2018, p. 47). Biocon is the first Indian company to obtain approval for a biosimilar in the United States.

In January 2018, Biocon announced an exclusive global collaboration with Sandoz, a generic subsidiary of Novartis and the global leader in biosimilars and next- generation biosimilars. Under the terms of the agreement, both companies will share

responsibility for end-to-end development, manufacturing, and global regulatory approvals for a number of products and will have a global cost-and-profit-share arrangement. Worldwide commercialization responsibilities will be divided, and each company's strengths will be leveraged within specific geographies. Sandoz will lead commercialization

in North America and the EU, while Biocon will lead commercialization in rest of the world.2 The collaboration with Sandoz is expected to build upon Biocon's success in its existing global biosimilar

programme. Biocon has now entered a new stage. In 2013, Biocon announced an R&D collaboration with Quark Pharmaceuticals, a leader in the discovery and development of novel RNA interference (RNAi)-based therapeutics. Nucleic acid drugs directly target disease-causing genes and show promise against rare diseases that are difficult to treat. Biocon will have access to Quark's innovative and proprietary siRNA technology platform, which can be leveraged to develop novel therapeutics for various rare diseases.3

Biocon's R&D capabilities are being formed through these strategic alliances. Biocon has grown into a global bio pharmaceutical company with the ability to develop a wide range of innovations. The operating revenue of Biocon grew at a CAGR of around 24 per cent between 2001 and 2016 (see Figure 4). Biocon has achieved this drastic growth through strategic alliances. Overall, the growth of Indian pharmaceutical companies has been driven by strategic alliances.

Upgrading of Indian Pharmaceutical Industry

GVC participation is conducive to technological upgrading and technology transfer.

Indian pharmaceutical companies are upgrading in the GVC by adopting state-of-the-art technologies. The GVC approach analyses the global economy from two contrasting viewpoints: top-down and bottom-up. The key concept of the top-down view is the 'governance' of the GVC, which focusses on leading firms and the organization of international industries.

The main concept of the bottom-up perspective is 'upgrading', which focusses on the strategies used by countries, regions, and other economic stakeholders to maintain or improve their GVC positions (Gereffi & Fernandez-Stark, 2011, p. 12). Upgrading is the major benefit local enterprises in developing countries obtain from participation in the GVC. Participation in the GVC is conducive to technological upgrading and technology transfer (Gereffi, 1999; Gereffi, Humphrey, & Sturgeon, 2005; Sturgeon & Linden, 2011).

The TRIPS Agreement has made the Indian pharmaceutical industry more R&D- oriented

and -intensive, pushing it up to the higher end of the GVC. Moving up the value chain implies a continuous process of change, innovation, and productivity growth.

When India's pharmaceutical industry began to participate in the GVC, it was an API supplier. It has grown into a finished dosages supplier. India is now supplying generic drugs as well as patented drugs. Indian export items are becoming more value-added. The main exports were once antibiotics and analgesics; now, India is exporting more high-value added products, like anti-hypertensive and anti-cancer drugs. These achievements represent product upgrading.

Process development is the strong point of Indian pharmaceutical companies. India is focusing on the development of NDDSs. India offers high value-added services using new process technologies like NDDS. This reflects process upgrading.

Regarding functional upgrading, India used to be engaged mainly in contract manufacturing. Now, Indian firms are also undertaking contract research. India's position in the GVC has changed from that of contractor to that of partner.

The value chain for generics is different from that for patented drugs. Conducting R&D for new drug development requires inter-sector upgrading. In addition, leading Indian pharmaceutical companies have entered the bio pharmaceutical field. This phenomenon reflects inter-sector upgrading. However, upgrading does not occur automatically for firms in developing countries (Sturgeon & Linden, 2011). We link the upgrading process to corporate capability. Thus, the occurrence and quality of upgrading depend on the firm's corporate capability. Transfer necessarily requires learning because technologies are tacit, and their underlying principles are not always clearly understood. A company must first grasp current trends in policies, technologies, and markets, and then transform this information into commercial activities and achieve new business value creation through organizational and technical innovation.

Conclusion:

Due to the TRIPS Agreement, the pharmaceutical industry became globalized. The pharmaceutical GVC has been restructured and has expanded to emerging countries like India. Indian pharmaceutical companies adopted new business strategies to counter new challenges

posed by the TRIPS Agreement. They have not only increased their R&D expenditures but have also changed their R&D orientation. They are introducing globally competitive products based on new molecules and NDDSs. Indian pharmaceutical companies are enhancing their presence in the global pharmaceutical market through strong R&D capabilities.

They have followed a strategy of collaborating with global pharmaceutical companies since the late 1990s. Indian pharmaceutical firms have been participating in the pharmaceutical GVC through international strategic alliances with global pharmaceutical companies in this post-TRIPS period.

The TRIPS Agreement opened new growth opportunities for Indian pharmaceutical companies, and GVC participation has been conducive to technological upgrading and technology transfers. Indian pharmaceutical firms are upgrading in the GVC by adopting state-of-the-art technologies and leveraging their strong R&D capabilities. This upgrading has driven the growth and development of the Indian pharmaceutical industry in the post-TRIPS period.

Declaration of Conflicting Interests

The author declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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