

The Strategy of Cooperation and Competition Based on Comparative Analyses of Pharmaceutical Industries of Korea and India

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1. Background

The Korean pharmaceutical industry has recently experienced difficulties because of the rebate issue and the Korean government's continued policy to lower drug prices. In addition, the adoption of the drug approval-patent linkage system,¹ following the implementation of the Korea-US and Korea-EU FTAs, could lead to

the deterioration of the profitability in Korean pharmaceutical companies.

Of the many risks that Korea's pharmaceutical industry is facing, this study began out of the concerns over the possibility of the entrance into the Korean market by the Indian pharmaceutical firms. With the Korea-India CEPA, which became effective as of 2010, the possibility of the influx of cheap Indian pharmaceutical products into Korea is a potential risk factor to Korea's pharmaceutical industry with a high level of dependence on the domestic market and generic drugs.

¹ Drug approval-patent linkage system is a system that the approval procedure for generic drugs is automatically stopped if a patent infringement lawsuit occurs when an application for a sale permit for a generic drug is provided to the patent holder.

2. Indian Pharmaceutical Industry

India's pharmaceutical industry is a 16 billion-dollar industry (with 1.5% of the world's market share) and as of 2011, it is the world's 12th largest in terms of sales. In particular, it has been showing a remarkable double-digit growth rate since the start of the new millennium. Such growth rate far surpasses India's overall economic growth rate and it has been demonstrating sustainable growth despite the recent economic downturn. When compared to Korea's pharmaceutical industry (ranked 13th in 2011, with 1.4% of the world's market share), the Indian market was smaller than Korea in terms of size. However, as of 2009, India's pharmaceutical industry has surpassed that of Korea, and the gap continues to grow. Notably, in terms of production quantity of generic drugs, India has about a 20% share of the world's market. India has the most number of FDA-approved production facilities outside of the U.S., and its pharmaceutical industry has a substantially superior competitive edge as compared to its other industries. Four of the country's pharmaceutical companies are ranked among the top 100 in the world. When this is considered in light of the fact that none of Korea's pharmaceutical companies are among the world's top 100, one can gauge the level of competitiveness of India's pharmaceutical industry.

The Indian pharmaceutical industry is comprised largely of pharmaceutical raw materials and generic drugs, and is export-oriented. India's pharmaceutical industry has many strengths, such as cheap production and research costs, plentiful expert human resources, many production facilities approved, including the U.S. FDA. Accordingly, multinational pharmaceutical firms are entering the Indian market to utilize India's resources as a base

for consignment manufacturing, and research and development. Foreign investment in India's pharmaceutical market has been on a rapid rise recently, with majority of them taking the form of M&A of Indian pharmaceutical firms by multinational pharmaceutical enterprises. Currently, the Indian government has set the scope of drug price regulations on 348 drugs based on the list of essential drugs, which applies only to manufactured drugs and not to pharmaceutical raw materials. The standard for price regulation is based on the market price.

Recent important issues in the Indian pharmaceutical market are the implementation of compulsory licensing and the ruling of the Supreme Court of India against the patents rights for Gleevec, a leukemia treatment drug. As for the compulsory licensing, by applying the exception clauses pertaining to patents under TRIPs, India's Natco was permitted to manufacture and sell Germany's Bayer's Nexavar, a cancer treatment drug. Because of the late development despite Nexavar's patent, which is still effective, multinational corporations are expected to experience losses in the Indian market. On April 1, the Supreme Court of India dismissed the patent lawsuit filed by Novartis in relation to Gleevec, a leukemia treatment drug. The reason for the dismissal was that Gleevec had no sufficient improvement over the previous products. The ruling could be viewed as an effort to put a check on the evergreening strategies adopted by multinational pharmaceutical firms wherein they extend the patent terms by making slight changes to the existing drugs. When a leukemia patient takes Novartis's Gleevec, a patient will have to spend KRW 4.5 million per month, whereas if he takes the Indian generic, it would only cost KRW 90,000. The multinational pharmaceutical companies in India will be unable to avoid losses in the Indian market because of this late ruling. Of course, some

expressed concern over the compulsory licensing and the patent lawsuits and the possibility of it leading to reduced investments in India by developed countries. However, as already discussed, the foreign investments in India are linked to the local consignment production in India, as well as to research and development, so the actual decline in foreign investment is likely to be minimal.

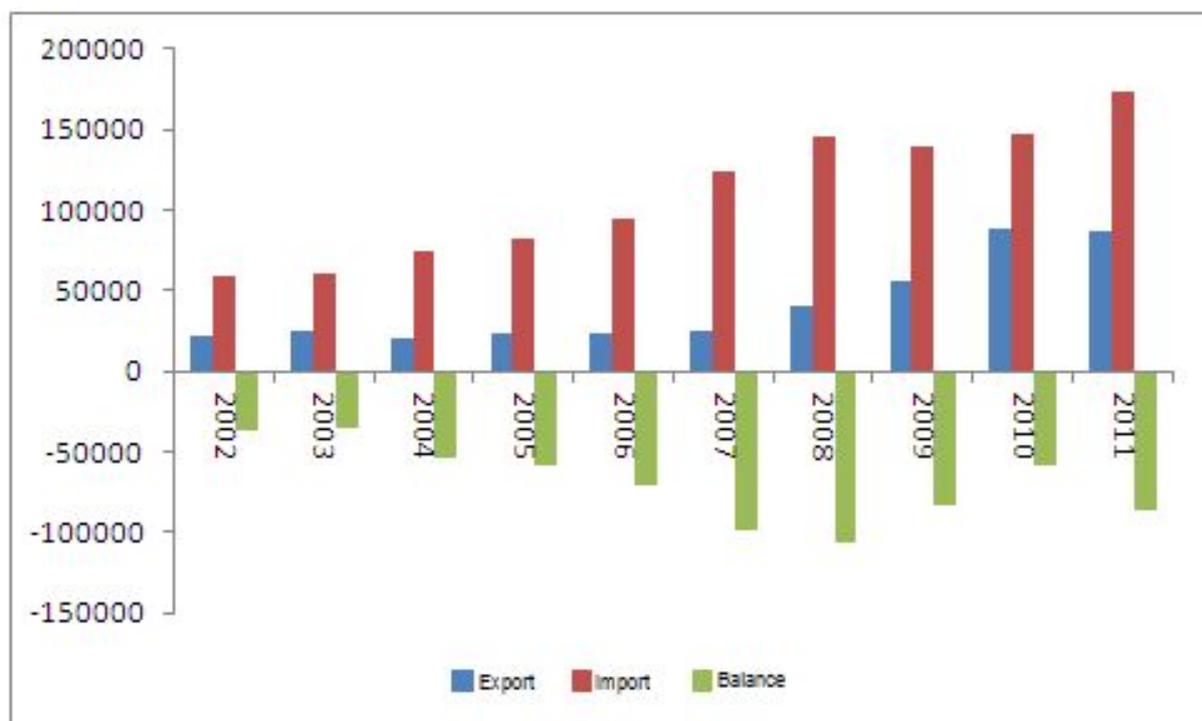
3. Korea-India CEPA and the Pharmaceutical Industry in the Two Countries

India has a trade deficit with Korea in most categories, especially in manufacturing. However, it has been showing a steady trade surplus in the pharmaceuticals industry. In

2011, India recorded a trade surplus with Korea in terms of pharmaceutical products (SIC 283: Drugs) in the amount of USD 86 million. For these reasons, the Korean pharmaceutical companies had raised objections during the Korea-India CEPA negotiations over concessions. The Japan-India CEPA had also been delayed mostly for the same reason.

Korea's trade deficit with India in pharmaceuticals has continued since 2000, and it amounts to almost USD 100 million every year. Korea mainly imports pharmaceutical raw materials and the trade deficit with India is continually increasing. Korea intends to almost completely (with the exception of one product) open the pharmaceutical market by 2018 through the Korea-India CEPA. India will also open a substantial amount (with the exclusion of 14 products).

Table 1. Trend of Korea's Pharmaceutical Trade with India



Note: 1) Unit used is USD 1,000.

2) Based on SIC code 283 (Drugs).

Source: UN Comtrade Database.

Korea has immediately abolished customs taxes for 371 products out of 429 products based on HS 10 unit with the CEPA taking effect in 2010. However, India postponed the abolishment for all products for five to eight years. Although Korea has immediately abolished customs tax for almost all products, it postponed the abolishment of customs tax for products that are mass produced in Korea, such as antibiotic raw materials for eight years, which was to protect the Korean pharmaceutical industry.

When the Korea-India CEPA is compared with the Japan-India CEPA, the latter appears to show a substantially higher degree of market opening than that of the former. In particular, the Japan-India counterpart provides guarantees for national treatment, including the right to exclusivity over drug products materials. Whereas the Korea-India CEPA only defines the pharmaceutical industry as one of the areas of cooperation under Article 13 (Cooperation between parties). The Japan-India CEPA provides for generic drugs in Article 54, establishing more detailed and specific cooperation plans.

4. Comparison/Analysis of Korean and Indian Pharmaceutical Industries

The comparison of competitiveness of the pharmaceutical industries in each country using trade-related competitiveness index (share of pharmaceutical products in total exports, trade specification index, revealed comparative advantage index, market comparative advantage index, export specification index, etc.) demonstrated that the international

competitiveness of India's pharmaceutical industry is substantially higher than that of Korea's. What is especially noteworthy is that the trade intensity index between Korea and India is higher than the global market's average trade intensity index.² In particular, Korea's trade intensity towards India is higher than India's trade intensity towards Korea, which indicates that Korea's exports of pharmaceutical products to India is more mutually beneficial. In other words, the mutually supplementary effect is more pronounced when the Korean pharmaceutical products are exported to the Indian market than when it is the other way around. Thus, the increase in the exports of Korean pharmaceutical products to India will hurt India's market less and will even supplement it.

² Trade Intensity Index (TII) is an index that measures the level of supplementing for specific products among countries. If the TII is greater than 1, it means that the ratio of the trading partner country's total income as against the total income of the entire world is less than the ratio of the relevant country's exports to the trading partner country. This signifies that the TII between the two countries is higher than the world market average. Therefore, if the TII is greater than 1, it means that the mutual degree of supplementing for relevant products between the two countries is higher than the world average, and if the TII is less than 1, then it signifies that the mutual degree of supplementing between the two countries is less than the average.

Table 2. Competition/Supplementary Index Related to the Korea-India Trade

Year	SPE		TSI		RCA	
	Korea	India	Korea	India	Korea	India
2003	0.4%	3.8%	-0.50	0.40	0.10	0.88
2004	0.4%	3.4%	-0.51	0.40	0.09	0.80
2005	0.4%	3.1%	-0.50	0.33	0.09	0.77
2006	0.4%	3.3%	-0.54	0.35	0.09	0.84
2007	0.3%	3.5%	-0.57	0.35	0.09	0.89
2008	0.4%	3.7%	-0.53	0.36	0.10	0.99
2009	0.5%	4.1%	-0.49	0.36	0.10	0.81
2010	0.4%	3.8%	-0.49	0.35	0.10	0.89
2011	0.4%	3.8%	-0.49	0.42	0.10	0.92

Year	MCA		ES		TII	
	Korea	India	Korea	India	Korea	India
2003	0.51	3.68	0.33	2.83	6.11	3.27
2004	0.47	3.21	0.37	2.65	5.87	3.55
2005	0.51	3.11	0.33	2.49	5.57	3.06
2006	0.27	2.07	0.35	2.59	2.70	2.62
2007	0.30	2.05	0.31	2.67	2.94	2.60
2008	0.38	1.87	0.34	3.11	3.32	2.34
2009	0.43	2.12	0.30	2.55	4.08	2.20
2010	0.56	1.90	0.41	2.81	4.62	1.80
2011	0.80	1.79	0.43	3.11	5.60	1.46

Note: 1) Share of pharmaceutical products in total exports (SPE), Trade Specification Index (TSI), Revealed Comparative Advantage Index (RCA), Market Comparative Advantage Index (MCA), Export Specification Index (ES), Trade Intensity Index (TII)

2) RCA was prepared using the World Bank's WITS, and SIC code 283 (Drugs) was used.

Source: Prepared by author using UN Comtrade data.

A simulation of the effects of the abolishment of customs taxes following the implementation of CEPA (World Bank WITS' SMART) indicated that it would help both countries, a win-win situation for Korea and India. That is to say, while the abolishment of customs taxes between the two countries following the Korea-India CEPA does not have special effects on their total imports of pharmaceutical products, they do have the effect of increasing the volume of trade between them. Accordingly, it appears that during the

negotiation for the upgrading of CEPA, an amendment that pushes up the schedule for the abolishment of customs taxes may be necessary.

The positive attribute shared by the two countries based on the SWOT analysis of their pharmaceutical industries is the consumption market, which shows consistent growth and solid manufacturing fundamentals centered on generic pharmaceutical products. The excessive government intervention in the

markets and the inadequate patent laws that lag behind those of developed countries are some of the common negative attributes shared by both countries. India's positive attributes that sets it apart from Korea is their English-speaking, but low-cost, labor force and the market potentials based on the demographic dividend effect. Korea's positive attributes include its capability for new drug development, which is based on R&D and an all-out government support for bio-pharmaceutical products. Therefore, if Korea and India could join forces to jointly produce high-value added pharmaceutical products, such as improved new drugs, by utilizing Korea's technology-intensive elements, such as new drugs and bio-pharmaceuticals, and India's globally competitive manufacturing foundations, to aim on the U.S., EU, as well as the Korean and Indian markets, it could prove to be a win-win situation for both countries.

5. Case Analysis of Korea-India Pharmaceutical Industries

Although the Indian pharmaceutical companies are interested in the Korean market, it is not highly likely that they will enter the Korean market sooner because of the recent continued price lowering by the Korean government and the difficulties in securing the distribution network in Korea. Rather, the Korean pharmaceutical companies should be more proactive in looking into cooperation with, and entry into, India. Recently, the Korean pharmaceutical companies are experiencing deterioration in profitability because of the lowering of drug prices. However, through exploring India's cheap but high quality raw pharmaceutical materials, they may be able to realize costs and make up for the profitability

losses. What is more important is the entry into India by Korean pharmaceutical companies. The Korean pharmaceutical companies need to enter the Indian pharmaceuticals market and proactively utilize India's world-class drug manufacturing infrastructures, thereby, cutting research and development costs and targeting the Indian domestic market. For example, India is a country that has the most number of diabetic patients. It also shows signs of a marked continued growth in its domestic market. Therefore, it is possible for the Korean pharmaceutical companies to target the Indian market through its diabetes-related high-value added drugs.

As a means of entering the Indian market, a joint venture appears more desirable compared to solo ventures by Korean companies at this time. The cooperation between LG Life Sciences' Indian subsidiary, with its distribution network, and company Daewoong Pharmaceuticals' R&D office, could be an alternative.

In conclusion, while Korea has 19 (Korean-type) new drugs, it lacks world-class manufacturing facilities, while India has the most number of U.S. FDA-approved manufacturing facilities outside of the U.S., although each does not have any notable results in relation to new drugs that require high-level creativity and technology. Accordingly, Korea needs to proactively seek ways to jointly enter the markets in the developed countries by aggressively utilizing Korea's technology and creativity as well as India's advanced manufacturing foundations. This means that the Korean and Indian pharmaceutical industries could explore a successful case of a "win-win" situation for both through the so-called "copetition" where, instead of mere competition, cooperation exists alongside it. **KIEP**