Building Product Innovation Capability in Health

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ABSTRACT

This chapter presents a theoretical framework to explain the role of intellectual property (IP) in innovation and applies the framework to the growth of the pharmaceutical industry. Developing countries progress through stages of capability to reach the status of Innovative Developing Country (IDC). To reach the status of an IDC, countries need to give concerted attention to six components of product innovation: R&D in the public and private sectors, regulatory mechanisms for drugs and vaccines to achieve safety and efficacy, the ability to manufacture to high standards new health technology products, national distribution systems in both the public and private sectors, international distribution systems (including supply of drugs and vaccines through international organizations such as UNICEF, the operation of global funds, and trade among countries), and systems for managing IP.

An analysis of pharmaceutical innovation in Korea's vaccine industry concludes that its success in developing its impressive capabilities was achieved by paying close attention to all six components of innovation. Yet unknown is the extent to which the Agreement on Trade-Related Aspects of Intellectual Property will stimulate or thwart progress in the other innovation components when IP is quickly moved to an advanced stage.

1. INTRODUCTION

Several developing countries, including Brazil, China, India, and South Africa, are rapidly increasing funding for biotechnology. These countries and others are improving their drug regulatory agencies and are adopting modern laws and regulations for IP management, as well. Some of the pharmaceutical companies in those countries have entered the international market with both generics and self-developed products. Rapid economic development is leading to expanded domestic markets. This expansion is increasing demand for products that address domestic diseases. Countries that are developing in the ways mentioned here are referred to as Innovative Developing Countries (IDCs).[1] Because diseases of the poor disproportionately affect these and other developing countries, IDCs may become a major source of health product innovation for diseases of the poor.

The changes in IP management taking place in IDCs need to be assessed so that the international development community can understand how IDCs can best participate in and, in some instances, actually lead efforts to develop new health technologies for the poor in developing countries. Such an assessment should consider changes in biotechnology manufacture, local demand for these products, potential for export, the nature and extent of public and private sector support for biotechnology research, and the changing environment of IP, drug, and vaccine regulations. This chapter describes a framework for analyzing these factors.

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2. A FRAMEWORK FOR ANALYZING THE PHARMACEUTICAL INDUSTRY

2.1 *The six components*

The framework allows us to analyze the development of the pharmaceutical industry in developing countries through six components:

1. R&D in the public and private sectors
2. Ability to manufacture to high standards new health technology products
3. National distribution systems in both the public and private sectors
4. International distribution systems, including supply through international organizations such as UNICEF, the operation of global funds, and trade between countries
5. Systems to manage IP
6. Systems for drug and vaccine regulation to achieve safety and efficacy

The components of the framework are linked dynamically. Progress in one requires progress in most—if not all—of the other components. It is difficult to improve R&D capability without first increasing manufacturing capability or having a national or international export market (requiring a distribution system) to generate resources for investment in production facilities. It is likewise difficult to enter markets in developed countries without good IP or regulatory systems. And while developing countries can access new technologies by entering into joint ventures with sophisticated firms in developed countries, these foreign firms will decide to form joint ventures based on the value of the domestic market in the developing country, the capability of local R&D centers, and IP protection levels. The interconnectedness of the six components is clearly very strong. And IP is an important aspect in all of them.

2.2 *From knowledge access to the role of IP*

IP policy-making in developing countries seems to be driven by conflicting goals. One goal is to encourage the influx of foreign technology. This can be achieved by providing enough protection for IP rights to enable foreign IP owners to pursue profits through licensing, marketing, and investment in the recipient country. This protection is needed especially when domestic R&D is focused on imitating or modifying foreign technology. On the other hand, developing countries have been able to access foreign technology cheaply and build manufacturing capability more quickly when unfettered by IP rights. This has worked to keep IP protection levels low, especially since few domestic innovators are harmed by such a regime. Instead of viewing the goals of foreign IP owners and domestic innovators as simply opposed, however, a closer analysis leads to a dynamic perspective. In the early stage of development, conflicts with foreign IP holders are minimal, typically, because domestic capability is poor and few foreign firms are interested in bringing technologies to the country. As the country's technological capability improves, poor protection of foreign IP rights is likely to conflict with the further growth of domestic capability. In the last stage, when local firms are able to generate their own IP, local demand for greater IP protection increases, reducing conflicts with foreign IP holders.[2]

2.3 *The special role of drug and vaccine regulation*

One key difference between the pharmaceutical industry and most other industries is the role of the stringency of the regulatory system for drugs and vaccines. As a country develops, the IP system and the regulatory system often progress in tandem.[3] In the early stage, there is little need for a well-developed national regulatory system. Most drugs and vaccines are imported from other countries, and it is assumed that the regulatory agencies of the producing countries have ensured their safety and efficacy. Any local production is contracted by foreign companies, which ensure quality control in order to meet regulatory standards in their home country or other countries where the products will be sold.

However, as the local production of copied products intended for the domestic market becomes important, the need for local regulation emerges. The government now has an interest in ensuring quality products. Initially, its main activities are to check composition and review the production facilities. Later, domestic companies demand a much more developed regulatory

capability. They want greater regulation and a capable regulatory agency for two reasons: to establish an approval process for newly developed products and to support the development and sustenance of export markets.

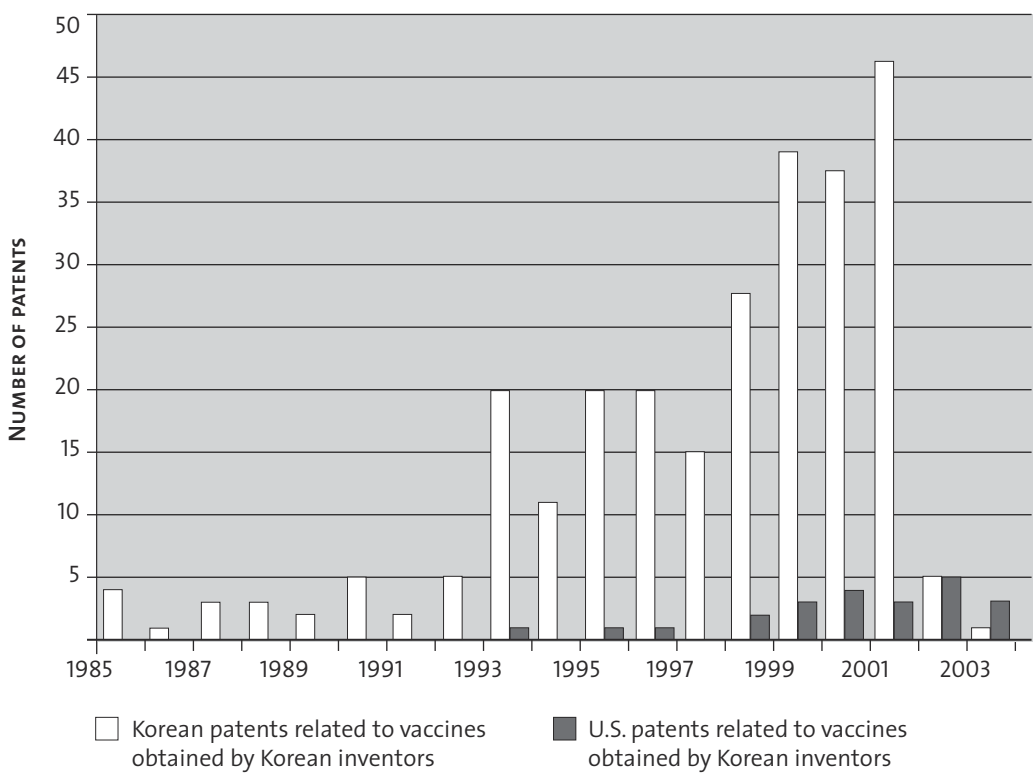
3. IP AND THE GROWTH OF BIOTECHNOLOGY IN KOREA

3.1 *A dynamic version of the framework*

The growth of biotechnology in developing countries is illustrated in Figure 1, which shows the patenting trends in Korea and the United States by Korean vaccine inventors. Korea is a good example for purposes of this chapter because of its rapid development in biotechnology. Korean vaccine biotechnology evolved rapidly, especially beginning in the mid-1990s.

The growth of the biotechnology industry in Korea can be interpreted in terms of the six framework components illustrated in Table 1. Showing the varying levels of capability with respect to each of the components of innovation at each stage, the table illustrates how developing countries can progress through four stages of capability in pharmaceuticals. The table distinguishes between national and international distribution and breaks out support for R&D into public and private sectors. The table illustrates that there are different systems of IP management at different stages of development. The table assists our thinking about one of the challenges brought about by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), namely that all developing countries that are signatories of the Agreement will have to move immediately to Stage 3. Several countries, such as

Figure 1: Vaccine-Related Patents Obtained by Koreans



Source: Based on data from the U.S. Patent and Trademark Office (PTO)[4]

Table 1: The Four Stages in the Development of Biotechnology

	Development of Manufacturing	Development of Distribution Systems		Development of R&D Capability		IP Systems	Drug and Vaccine Regulation
		National	International	Private Sector	Public Sector		
Stage 1. Establishing the foundation	Importation of finished goods or assembly of parts into finished products	Small domestic market	Very little, except as toll manufacturer	Very little	Very little	Initial development allowing patents for local inventors; no interest from foreign inventors	Very limited
Stage 2. Capacity Building	Production on license or by copy	Growing local market of increasing interest to foreign companies; import substitution	Growing companies learning how to establish export markets	R&D to understand technology either to produce on license or to copy	Development of university and independent research centers; capacity building	Interest growing among foreign inventors; local inventors starting to file more patents	Limited services but without enforcement capabilities
Stage 3. Maturation IDCs	Manufacture of domestically developed, high technology products	Rapidly growing domestic market of interest to foreign companies	Increasing exports that account for a growing share of GNP	Small-scale, advanced R&D effort capable of creating new products for domestic and export market	Vast acceleration of funding for R&D; development of major research centers; linking with private sector	Advanced IP system but with certain limitations such as lack of enforcement	Advanced capabilities but not at highest level because of lack of enforcement capabilities
Stage 4. The Most-Developed Countries, with a drug or Vaccine Industry	Highest capabilities to produce high technology drugs and vaccines	Highly profitable market in both the public and private sectors, generating profits to support, in part, advanced research	Global companies	Generous support for health research from basic to applied; large research investment by private companies, including large pharmaceutical manufacturers and biotechnology companies		Sophisticated system of IP management operating according to the requirements of the TRIPS Agreement	Sophisticated agency overseeing regulatory approvals of drugs and vaccines; government oversees clinical trials and production facilities and enforces regulations

Brazil, China, and India, have achieved this goal. Others are in the process. The major unresolved issue is whether the immediate move to Stage 3 IP systems will provide a pull effect on the other components of innovation or whether it will lead to imbalances that will adversely affect access to pharmaceutical products.

3.2 *Development of IP systems in Korea*

Korea provides a useful case study of a country that developed economically and, for the most part, independently enhanced IP protection without the requirements of TRIPS. Now in Stage 3, Korea was able to develop a vaccine industry very rapidly because it addressed each of the framework components stage-by-stage. It passed through the first two stages of the framework in roughly ten-year steps during the 1980s and 1990s. Having joined the World Intellectual Property Organization (WIPO) in 1979, Korea acceded to the Paris Convention in 1980 and the Patent Cooperation Treaty (PCT) in 1984. The country revised its laws in 1987 to allow product patents. By the end of the 1980s, Korean laws and policies largely conformed to the requirements that TRIPS would eventually impose.

As with the development of biotechnology R&D capability, Korea completed Stage 1 of its IP system in about 1990. It acceded to the TRIPS Agreement in 1995 and further revised its IP laws in 1997–98 to reach full compliance with TRIPS. The World Trade Organization (WTO) conducted a trade policy review of Korea in 2000 and concluded that "*protection of [intellectual property] rights has been strengthened by the signing of the new treaties, increased international cooperation, and stricter enforcement.*"[5]

Unlike the United States, universities and research institutes in Korea were not major sources of technology for the country's industry during the 1980s and most of the 1990s. Most companies wishing to obtain new technology had to look outside the country. In the United States, on the other hand, the Bayh-Dole legislation had gone into effect in 1980, and universities invested heavily in efforts to manage new IP that they developed. This included not only the out-licensing of patents for inventions made by research scientists, but also the creation of spin-outs, in which a professor set up a company for the specific purpose of developing an invention into a commercial product. Beginning in the late 1990s, Korea followed suit, revolutionizing its laws and regulations concerning IP management by public institutions. Public universities were allowed to retain ownership of new IP and were encouraged to set up technology transfer offices. The Technology Transfer Facilitation Law was passed, mandating the establishment of technology transfer offices and setting guidelines for sharing licensing income with a specific allotment for the inventors.

Based in part on the patent data in Table 1, Korea seems to have completed Stage 2 of its IP system in about 2000, again in tandem with its progress in biotechnology R&D capability. Thus, the country was able to develop its IP system in tandem with the growth of capability in the five other components of innovation. It will be interesting to see what happens in other developing countries that, under the TRIPS Agreement, must move immediately to Stage 3 in IP systems. A broader survey of the development of IP systems in Korea is available in Lee, et al.[6] While we lack sufficient data to make any unequivocal conclusions, it is worth noting that Korea was able to move forward by addressing all six innovation components.

4. CONCLUSION

The framework shows that IP is an important component of innovation in pharmaceutical development, but it is only one of six. As the analysis of biotechnology shows, the regulatory system is also a very important component. Above all, however, the above analysis demonstrates that developing countries will pass through the four stages of development as they increase their capabilities in biotechnology innovation. Such progress is possible only by attending to each of the six components of innovation. A key question that the framework highlights is what impact the immediate movement of IP systems to Stage 3 will have on countries that are still in Stage 1 or 2 of pharmaceutical innovative capability. Will it hin-

der or help their progress? We lack the data needed to assess the impact of this TRIPS requirement for moving from Stage 1 to Stage 3. But the case study of Korea shows that it was able to undertake a wide range of initiatives that helped it to advance in biotechnology. The country addressed all six components of innovation. In particular, it made its IP systems compatible with those of more developed countries and thus compatible with TRIPS. At least with respect to vaccines, Korea has experienced considerable success in biotechnology. We conclude that TRIPS should not inhibit efforts to enhance biotechnological capabilities. It may actually promote such efforts. Conversely, arguments that TRIPS is inimical to the interests of developing countries seem premature at best. At worst, they are counterproductive because they may lead countries to seek higher levels of biotechnology capability ineffectively: They will not be able to participate in international trade (other than as importers) because their products will not be accepted in markets that observe IP rights. ■

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1 The term *innovative developing countries* has been introduced by Dr. Charles Gardner, Associate Director, Health Equity, The Rockefeller Foundation.

2 Lee K, CS Lim and DH Park. 2003. The Role of the Industrial Property Rights in the Technological Development of Korea. World Intellectual Property Organization: Geneva.

3 Mahoney R, A Pablos-Mendez and S Ramachandran. 2003. The Introduction of New Vaccines into Developing Countries III: The Role of Intellectual Property. *Vaccine* 22 (5–6):786–792.

4 www.uspto.gov.

5 WTO. 2000. Trade Policy Review: Korea 2000. World Trade Organization: Geneva. www.wto.int/english/tratop_e/tpr_e/tp138_e.htm.

6 See *supra* note 2.