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Proceed with Caution on Compulsory Licensing

Developing countries that seek to implement compulsory licensing face a crucial dilemma—between greater innovation and greater access. As long as inadequate and inequitable mechanisms to stimulate health research and development (R&D) exist, developing countries should be extremely cautious in undertaking measures, such as compulsory licensing, that could be detrimental to the development of new drugs.

Patents and Compulsory Licensing

In recent years, pharmaceutical products have attracted significant attention in terms of both patenting and compulsory licensing, primarily because of the pharmaceutical industry's unique dependence on patents and the role the industry plays in public health. Patents play a significant role in fostering R&D investment for drug innovation, which has transformed the pharmaceutical sector into one of the largest contributors to R&D spending. The significant increase in R&D expenditures in recent years and the change in the way pharmaceutical companies organize their innovative efforts has resulted in a rising number of patent applications worldwide in the biotechnology and pharmaceutical fields.

The increase in the number of patent applications has recently been accompanied by the escalating use of compulsory licensing in some parts of the world. For example, between 2006 and 2008, Thailand issued compulsory licenses for a drug for heart disease, two HIV medicines, and three cancer drugs (breast and lung cancer). Similarly, Brazil granted a license for an antiretroviral drug in 2007.

A compulsory license authorizes a third party to utilize the patented article without the consent of the patent holder. Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) authorizes compulsory licenses only "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." Both governments and the pharmaceutical originator companies agree on the basic premise of this provision. However, while developing countries view patent-weakening mechanisms like compulsory licensing as a tool to increase access to medicines, it may come as no surprise that the pharmaceutical industry often views the mechanism as seriously detracting from the purpose of the patent system. The crucial inquiry, therefore, centers on the consequences of the widespread use of compulsory licensing.

Effects of Compulsory Licensing

While compulsory licensing might be able to provide short-term and emergency solutions to public health crises faced by developing countries by maximizing access to essential medicines, governments should think twice about implementing compulsory licensing, as it may generate undesirable long-term effects.

First, a country's decision to issue compulsory licenses often provokes considerable trade friction with the countries that manufacture the patented drugs. In 2007, for example, the United States Trade Representative elevated Thailand to its Priority Watch List, largely due to Thailand's compulsory licensing policies for pharmaceuticals in late 2006 and early 2007. The threat of trade sanctions or actual retaliation from the manufacturing countries can harm the granting nation's exports and economy.

Second, the issuance of compulsory licenses can lead to the loss of foreign direct investment (FDI), including pharmaceutical operations and related ventures such as clinical trials. Most developing countries rely heavily on foreign capital, which is accompanied by technology and innovation that bolsters economic development. In order to attract foreign investors, it is necessary for the host country to establish a suitable investment climate. Favorable investment climates cannot be created solely by the mere promulgation of investment promotion policy and various incentives. Legal and economic factors, including TRIPS-compliant policies and procedures for compulsory licensing, are no doubt significant factors that impact pharmaceutical companies' FDI decisions. The issuance of compulsory licenses by a country can trigger the loss of considerable FDI to that country. For example, pharmaceutical companies may find a different venue for their clinical trials in order to protect their products from compulsory licensing.

Third, compulsory license schemes reduce R&D activities. Research conducted by economists as far back as the 1970s suggests that the use of compulsory licensing can harm innovation and limit the ability of the patent system to deliver on its goal of incentivizing R&D. Although R&D expenditure in some developing economies (i.e., China and India) has grown considerably in recent years, developing countries account for only 4 percent of global R&D spending. R&D for new medicines is still highly concentrated in a small number of developed countries, like the big five (France, Germany, Switzerland, the United Kingdom, and the United States). Note that health R&D is largely a global joint cost, and this economic burden should not be solely borne by specific countries.

The combination of trade friction, loss of FDI, reduction of R&D, and a weak intellectual property regime—all possible effects of compulsory licensing—cause emerging markets to lose their competitive edge. As countries become less competitive vis-à-vis their neighbors and globally, it becomes more difficult for such countries to retain human capital, as evident in the case of India, whose talented scientists and researchers have left the country in search of opportunity elsewhere.

Maintaining a Favorable Investment Climate

In order to avoid the long-term effects of compulsory licensing and maintain a favorable investment climate, the government of a developing country may action the following initiatives:

1. Engage in more constructive consultation and negotiation on licenses with pharmaceutical patent holders;
2. Promote collaboration in pharmaceutical research between domestic research institutions and the pharmaceutical industry, in order to strengthen the country's research capabilities; and
3. Lower tariff barriers that affect the prices of medicines imported into the country.

When the developing country is successful in implementing these measures to promote greater access to medicines, it might find compulsory licensing to be extreme and unnecessary.