

Patent policy and public health in developing countries: lessons from Japan

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Introduction

The relevance of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to developing countries has been widely discussed at international fora, particularly regarding the impact of pharmaceutical product patents. Product patents restrict the ability of local firms to manufacture copies of new drugs, possibly leading to less competition, higher drug prices, and lower welfare in developing countries. These are the unintended public health consequences of what is primarily an industrial policy tool.

In this context, we examine the Japanese experience of introducing product patents in 1976 which also attracted heated discussion at that time. The anticipated price increase and product shortage were largely avoided, while the number of available products increased.¹ Negative consequences of product patents were largely averted through a series of well-coordinated policy instruments, the examination of which may provide suggestions for developing countries.

Japan's pharmaceutical patent policy

Japan's peculiar patent and utility model systems are said to have encouraged technology diffusion and incremental innovation in the overall economy.² The pharmaceutical patent system after 1976 was designed with the similar intention of streamlining the transition to the product patent regime. Two components of this system merit attention from the viewpoint of developing countries. One is the narrow interpretation of patent breadth, and the other is the system of "dependent-patent arbitration", a lesser known patent policy effective for promoting cross-licensing by threat of compulsory licensing. We examine these

policy tools in turn, before discussing their effects on the R&D activities of Japanese pharmaceutical firms.

Narrow patents

Breadth, or scope, is an important measure of the degree of patent protection. Broad patents provide stronger protection to patentees against competition from similar innovations. In contrast, narrow patents provide weaker protection to patentees, but create wider freedom to operate for subsequent innovators. In practice, patent breadth derives from the scope of claims allowed by the patent office, the application by courts of the "doctrine of equivalents," and other parameters of patent policy. When product patents were introduced, the Japanese patent system favoured narrow patents. Firstly, examiners at the Japan Patent Office were encouraged to literally interpret patent claims, which are verbal descriptions of the invention. In other words, only those claims supported by working examples were permissible — a practice that persisted until 1995.³ Secondly, the "doctrine of equivalents", a liberal interpretation of patent claims used in the US, was not applied expressly in Japan until a Supreme Court ruling first endorsed it in 1998.⁴ Thirdly, until 1988, the Japanese practice of allowing only one claim per patent created "holes" in the technology space, which were exploited by Japanese firms.⁵

Dependent-patent arbitration

The Japanese patent system provides for a wide range of grounds for compulsory licensing: (1) local working, (2) working of "dependent patents", and (3) public interest.⁶ A dependent patent is one that must be used in conjunction with another patent in order to produce commercial value. When Japan introduced product patents, the dependent-patent arbitration scheme became part of the

government's effort to appease concerns about the adverse impact of product patents on downstream innovations such as novel manufacturing processes and new uses for existing pharmaceuticals. Under this scheme, the patent holder on a downstream invention (e.g. novel process) could request that the Japanese Patent Office (JPO) conduct binding arbitration over a cross-licensing contract with the holder of the upstream patent (e.g. product patent on new drug), if the parties fail to reach a voluntary licensing agreement. Downstream inventors were thus assured of a means of avoiding foreclosure from the upstream technology.

Effects on the Japanese pharmaceutical industry

The working example requirement indeed forced pioneering pharmaceutical patents to have narrow claims, and helped Japanese firms with underdeveloped R&D programmes to patent new chemical entities (NCEs).³

Many Japanese drugs are structurally similar to existing ones (so-called "me-too" drugs) and not sold in other countries. Narrow patent scope has contributed to this tendency, in combination with other factors such as the price premium for new drugs under the National Health Insurance pricing scheme, and the leniency of the new drug approval system with respect to effectiveness.⁷

The common argument against promoting structurally similar drugs is that it results in wasted resources from duplicative research. However the major effect of the Japanese product patent regime that encouraged the development of structurally similar drugs was to ease the change in direction of R&D. Product patents, whether or not they promote me-too drugs, eliminate the need for innovators to protect their products through process patents. Under

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the process patent regime before 1976, Japanese firms doing research on NCEs had to patent multiple processes to preempt rivals.⁸ After the introduction of product patents, Japanese firms doing NCE research were released from the need to “build fences” with process patents. The aggregate number of process patents dropped dramatically after 1976 even though the total number of pharmaceutical patents was increasing.¹ As process R&D decreased, scientific resources were redirected to other areas, including research on new chemical entities. Because patent scope was narrow, firms that were accustomed to R&D of processes found it relatively easy to shift into R&D of products. A large part of this research may have been on structurally similar drugs, but even such research often leads to safety and/or effectiveness improvements.⁹

The dependent-patent arbitration scheme also promoted R&D by Japanese firms. By 2004, there had been a cumulative total of 14 cases involving dependent patents brought to the JPO for arbitration, all of which were withdrawn by the requestor prior to arbitration.⁶ Despite the small number of cases, the mere possibility of arbitration would have altered the cross-license bargaining process in favour of downstream patent holders, similar to the threat of compulsory licensing. Indeed, major US firms claimed that the Japanese patent system during the 1970s and 80s forced them to enter into cross-licensing contracts with infringing Japanese firms, rather than to litigate.¹⁰

Although the narrow-scope patent system, in combination with the dependent-patent arbitration scheme, may have excessively rewarded minor inventions including structurally similar drugs, it was a transitional phase under which domestic firms acclimated to the product patent regime.³ Indeed, Japan's narrow patent and dependent-patent arbitration policies were repealed in the

1990s, albeit under pressure from the US. By then, several important pharmaceutical inventions had come from Japanese pharmaceutical firms, such as the statins group of cholesterol-lowering drugs.

Implications for developing countries

The Japanese experience presents one model that may be considered by developing countries that are in the process of adopting a product patent regime. Narrow patents may encourage more firms to compete in product R&D. In addition to benefiting innovating domestic firms, the increased competition between pioneer drugs and structurally similar drugs will lower pharmaceutical prices without relying on generic competition or price control.⁹ Linking compulsory licensing to R&D by domestic firms would be a reasonable way to stimulate innovation and encourage voluntary cross-licensing.

Prerequisites to the socially meaningful use of a narrow patent regime are: (a) some level of domestic R&D capability; and (b) a well-functioning drug approval system. These are indispensable in ensuring the safety and effectiveness of structurally similar drugs developed by firms.

An alternative model is given by the Indian product patent system under the Patents Act, 2005. This system enables Indian firms to manufacture copies of new drugs somewhat earlier than rivals in other countries, thereby preserving some advantage in the generic pharmaceutical markets of developed countries. The system is supported by: (a) strict patentability requirements which preclude certain classes of pharmaceutical inventions from being patented, thereby preventing the originators from extending the exclusivity of new drugs through patenting incremental inventions, and reinforced by: (b) the absence of patent-

term restoration; and (c) the Bolar provision which allows early working of patents by generics manufacturers.

In addition to giving Indian firms an early-mover advantage in the generics markets of developed countries, the Indian patent system may benefit domestic consumers — as well as the consumers of other developing countries — through the early development of generic products.

However, it should be noted that strict patentability requirements, although not incompatible with narrow scope, may lower the incentive for incremental R&D by domestic firms. This is because while narrow scope rewards new products at the cost of existing ones, strict patentability requirement rewards incumbents at the cost of new products.

Conclusion

Japan's experience in using its patent system to promote incremental innovation demonstrates the possibility of attaining the dual goals of introducing product patents and maintaining reasonable drug prices, without discouraging innovation by domestic firms. In this context, a series of coordinated policy instruments, i.e. narrow patent scope, adequate patentability, and cross-licensing provisions, has been shown to be effective. On the other hand, India's new patent policy demonstrates that developing countries may want to shorten the exclusivity period on new drugs by, *inter alia*, raising the hurdle on patentability. Such a policy will strengthen the competitiveness of domestic firms in global generics markets, but may reduce their incentives to invest in incremental innovation in domestic markets. This trade-off should be recognized by the policy-makers of developing countries when they design patent systems. ■

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(References prefixed “W” appear in the web version only, available from www.who.int/bulletin)

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