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Indian Patent Policy and Public Health: Implications from the Japanese Experience

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Abstract

The introduction of pharmaceutical product patents in India and other developing countries is expected to have a significant effect on public health and local pharmaceutical industries. This paper draws implications from the historical experience of Japan when it introduced product patents in 1976. In Japan, narrow patents and promotion of cross-licensing were effective tools to keep drug prices in check while ensuring the introduction of new drugs. While the global pharmaceutical market surrounding India today differs considerably from that of the 1970's, the Japanese experience offers a policy option that may profitably be considered by India today. The Indian patent system emphasizes the patentability requirement in contrast to the Japanese patent policy which relied on narrow patents and extensive licensing. R&D by local firms and the development of local products may be promoted more effectively under the Japanese model.

Keywords: public health, pharmaceutical industry, industrial policy, intellectual property rights, patent law, India, Japan

JEL classification: I11, I18, L50, L65, O10, O14, O31, O34

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Introduction

India's Patents (Amendment) Act, 2005, introduced patent protection for pharmaceutical and agricultural chemical products, in accordance with the TRIPS Agreement. Implications of the new patent law for industrial development and public health are still unclear. Many observers worry about the consequences of product patent protection, on drug prices in particular. It is also apprehended that patents would hurt domestic firms, and promote only R&D on those drugs which are suited mainly for developed country diseases *(1)*.

This paper contends that the negative consequences of product patents can be averted through a choice of policy instruments. Our argument is based on the Japanese experience of introducing product patents in 1976, amidst heated discussions as to the possible rise in drugs prices. However, the anticipated price increases and shortages were largely avoided, while the number of available products increased. Furthermore, Japanese pharmaceutical firms are known today for their competitive edge in several therapeutic areas, especially those in which a disproportionate number of Japanese people are affected, such as gerontology[1].

The Japanese experience has not received much attention in international discussions because the country already had a high level of income by the time it introduced product patents, and its national health insurance (NHI) scheme attenuated the impact on drug prices. A close look at Japan's patent policies during the introduction of product patents, however, reveals rich implications for developing countries, India in particular.

The new Indian patent law reflects the view that patents on incremental innovations will be used by multinational pharmaceutical firms to "evergreen" the monopoly period of their products. Consequently, Section 3(d) of the 2005 Patents Act does not recognize the patentability of new uses of known substances, on the grounds that they do not fulfill the "inventive step" requirement. New forms of known pharmaceutical substances are also subjected to a strict requirement of "utility" *(2)*. Patentability requirements, in contrast, were not used in Japan as policy instruments. Instead, patent breadth and compulsory cross-licensing provisions were employed to spur innovation and

[1] Interview with Mr. Kazuyoshi Hirai, Japan Pharmaceutical Manufacturers' Association (January 2005).

competition in the domestic pharmaceutical industry. India may profitably consider the Japanese experience with a view to allowing for the protection of local inventions and building local R&D capabilities.

1. 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 *(3)*. The pharmaceutical patent system after 1976 was designed with similar intentions, and it streamlined 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". These are described in turn, before discussing their effect on the R&D activities of Japanese pharmaceutical firms.

(1) Narrow patents

Breadth, or scope, is an important measure of the degree of patent protection. 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 *(4)*. The Japanese patent system at the time of product patent introduction created narrow patents. Firstly, examiners at the Japan Patent Office (JPO) were encouraged to interpret patent claims literally, i.e. only those claims supported by working examples were permissible *(5)*. This practice persisted until 1995, when patent examination guidelines were revised to widen the interpretation of claims *(6, 7)*. Secondly, the doctrine of equivalents was not applied expressly in Japan until a Supreme Court ruling first endorsed it in 1998 *(8, 9)*. Finally, the Japanese practice until 1988 of allowing only one claim per patent created "holes" in the technology space which could be exploited by Japanese firms *(10)*.

Broad patents, which are created by liberal interpretation of claims and the use of the doctrine of equivalents, provide stronger protection to patentees. In contrast, narrow patents provide weaker protection to patentees, but create wider freedom to operate for subsequent innovators.

(2) Dependent-patent arbitration

The Japanese patent system provides for the following grounds on which compulsory licensing can be utilized: (i) local working, (ii) working of dependent patents, and (iii) public interest *(11)*. When Japan introduced product patents, the "dependent patent" rationale, which already existed as Article 92 of the Patent Law, received renewed attention. Japanese policy makers and

manufacturers at the time were concerned about the adverse impact of product patents on downstream innovations such as novel manufacturing processes and new uses for existing pharmaceuticals. The dependent-patent arbitration scheme became part of Government's effort to appease those concerns *(12)*. Under this scheme, the holder of a patent on a downstream invention (e.g. novel process) would first enter into voluntary cross-licensing negotiations with the holder of the upstream patent (e.g. product patent on new drug). If those negotiations fail, then the downstream patent holder could request the JPO to conduct a binding arbitration over the cross-licensing terms. In this way, downstream inventors would avoid being foreclosed from using the upstream technology.

It is unclear how well this compulsory cross-licensing scheme attained its objectives. As of 2004, there had been a total of 14 cases involving dependent patents brought to the JPO for arbitration. All of them were withdrawn by the requestor prior to arbitration *(11)*. Despite the small number of cases actually brought before the JPO, the mere possibility of arbitration may have altered the cross-license bargaining process in favor of downstream patent holders. Indeed, US firms in the chemical, pharmaceutical, and biotechnology industries have claimed that the Japanese patent system during the 1970s and 80s forced them to enter into cross-licensing contracts with infringing Japanese firms *(13)*. Responding to the complaints by the US Trade Representative, the JPO, in 1994, agreed to restrict the use of dependent-patent arbitration to cases with legitimate antitrust concerns *(11, 14)*.

(3) Effect on the Japanese pharmaceutical industry

In 1992, the US General Accounting Office conducted a survey of 300 large US-based firms – a quarter of which were in the pharmaceutical or biotechnology industries – regarding their experience with the Japanese patent system. 71% of the responding firms viewed Japanese patent protection as being too narrow, while those who thought so with regard to US and European patents were only 12% and 25%, respectively *(13)*.

The working example requirement indeed forced pioneering pharmaceutical patents to have narrow claims, and helped Japanese firms with underdeveloped R&D programs to patent new chemical entities (NCEs) that were structurally similar to existing ones *(5)*. Without waiting for patent expiration on existing drugs, many Japanese firms started to conduct their own research on NCEs. Figure 1 appears to support Saiki's claim. The number of domestic drugs that are sold only in the home country is remarkably high in Japan, along with Italy and France.

Many Japanese drugs are structurally similar to existing ones – which are sometimes termed "me-too drugs" – and not approved in other countries. Narrow patent scope largely explains this, but there are other reasons. The National Health Insurance (NHI) pricing scheme created a price premium for new drugs which was independent of therapeutic value *(15 – 17)*. Moreover, the

Japanese new drug approval system during the 1970s and 80s, which was lenient about effectiveness, may have encouraged the proliferation of me-too drugs *(17, 18)*.

Structurally similar drugs have often been criticized by practitioners and economists. Glennerster and Kremer opine that the pursuit of "me-too research" not only involves a "use of scientific talent [that is] socially wasteful," but it also "reduces incentives for developers to undertake original research" *(19)*.

However, introducing a product patent system that encourages the development of structurally similar NCEs may not necessarily lower the social returns to R&D. A significant effect of the Japanese product patent regime was to change the 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 the process patent regime before 1976, Japanese firms doing research on NCEs had to patent multiple processes to preempt rivals *(12)*. Many of the processes developed at the time were inferior to existing ones, implying low social returns to R&D. After the introduction of product patents, Japanese firms doing NCE research were released from the need to "build fences" with process patents. As can be seen from Figure 2, the aggregate number of process patents dropped dramatically after 1976.

As process R&D decreased, scientific resources were redirected to other areas, including NCE research (Figure 2). Because patent scope was narrow, firms that were accustomed to process R&D found it relatively easy to shift into product R&D. A significant part of this research may have been on structurally similar drugs, but such research often leads to safety and/or effectiveness improvements *(20)*. A shift in the direction of R&D from new processes to new products may raise or lower social welfare, depending on the existing technological opportunities. Contemporary accounts suggest that technological opportunities in products were greater than those in processes in 1970s Japan *(12)*.

Although the narrow-scope patent system may have excessively rewarded R&D on structurally similar NCEs, it was a transitional phase under which domestic firms acclimated to the product patent regime *(5)*. Indeed, Japan's narrow patent and dependent-patent arbitration policies were repealed in the 1990s, albeit under US pressure. By then, several important innovative drugs had been developed by Japanese pharmaceutical firms *(21)*.

2. India's pharmaceutical patent policy after 2005

Indian pharmaceutical firms have flourished under the Patents Act, 1970. It was not an infringement to produce copies of new drugs using unpatented processes, selling them in India and other markets where product patents do not exist. Commercial experience thus gained allowed

Indian firms to become competitive entrants in generic markets of developed countries, through early capacity buildup and learning effects *(22)*.

The TRIPS Agreement, which introduced product patents in India for drugs patented in 1995 and beyond, will gradually weaken the first mover advantage of Indian firms in the generics markets of developed countries *(23)*. Indian firms can still develop drugs patented after 1995 without an *ex ante* license. However, selling those drugs without a license would be deemed an infringement, and *ex post* licensing to sell patented drugs is unprofitable for the licensee. In general, TRIPS would make it costlier for Indian firms to achieve early mover status.

In contrast to the bleak outlook for the generics business, product patents have benefited some other segments of the Indian pharmaceutical industry. It is important not to overlook the international competitiveness of Indian firms in innovative research, which will benefit Indian public health in the long run. Under the new patent system, Indian firms developing NCEs are receiving stronger patent protection, and an early indication is the number of drug candidates that are emerging from the laboratories of Indian pharmaceutical manufacturers. As of 2004, 33 drug candidates developed by 10 Indian firms were in the clinical or pre-clinical stages of development, with 1 product having completed clinical trials *(1)*. In another development, "custom synthesis contracts," involving the discovery of "routes of synthesis" for newly invented pharmaceutical compounds, are increasingly being awarded to Indian firms. Multinational originator firms have become more comfortable in giving custom synthesis assignments to India due to the security afforded by product patents[2]. Product patents contribute to the efficiency of outsourcing by facilitating the transfer of know-how, rather than protecting the patented compound *per se*. The introduction of product patents improves the licensor's incentive to share know-how with the licensee, because the licensor will have less to lose in the event of contractual breakdown *(24)*.

Still, as of 2005, NCE discovery and custom synthesis are being pursued by only a handful of Indian firms, and generics markets are likely to remain the main revenue source for some time. The Indian government understands this, and has designed a product patent system that preserves, as much as possible, the competitiveness of Indian firms in the global generic pharmaceutical industry. First of all, India's new patent law does not provide for patent term restoration, so that an Indian product patent is likely to expire a few years before the same patent expires in the main generics markets. Also, a Roche-Bolar provision was introduced in 2002, which facilitates R&D and lab scale production before patent expiration (Section 107A of the Patents Act) *(25)*. Finally, the strict patentability requirement introduced in the 2005 Act may be used to reject some patent applications on incremental innovations, such as new uses for existing drugs and new forms of a known

[2] Interview with Mr. Venkat Jasti, Managing Director of Suven Life Sciences, Hyderabad, India (February 2004).

compound (Section 3(d) of the Patents Act) *(2)*. These aspects of the patent legislation are expected to shorten the exclusivity period of drug products, allow early entry by Indian firms, and maintain the competitiveness of Indian firms in the global generics industry.

3. Implications for India

(1) Comparison of Indian and Japanese patent policies

Indian patent policy after the 2005 amendments is quite different from Japan's circa 1976. While the Japanese system used patent breadth as the main policy instrument to counter stronger protection, India is utilizing the patentability requirement.

Patent breadth and patentability have very different implications for technological development. The strict patentability requirement in India's new law is intended to shorten the exclusivity period for new drugs. Shorter exclusivity will indeed allow earlier entry of domestic firms. There is a side effect, however, that Indian firms will generally have a low incentive to innovate, because their inventions are less likely to satisfy the patentability criterion.

In contrast, the Japanese patent system after 1976 had a patentability requirement similar to other developed countries, but patent scope was extraordinarily narrow. Although product patent holders could extend exclusivity by patenting incremental innovations, narrow patent scope made it easier for Japanese firms with fewer R&D resources to enter with their own products, rather than wait until patent expiration. Because patentability was not strict, Japanese firms had high incentive to innovate.

(2) Policy suggestions

In view of the global environment in which Indian pharmaceutical firms are competing, it is understandable that Indian patent policy places higher weight on giving Indian firms a first mover advantage in the global generics market. Moreover, today's Indian pharmaceutical market is smaller as a proportion of the world market, in value terms, than Japan's was in 1976. Therefore, the collective profits of Indian firms may well be maximized under the short-exclusivity strict-patentability regime that India has today, given the constraints imposed by TRIPS.

However, the performance of Indian firms in overseas generics markets brings little direct benefits to Indian consumers. There are alternative policy options that may increase overall welfare. First of all, a more narrow interpretation of patent scope combined with "normal" patentability requirements may encourage more Indian firms to compete in product R&D. In addition to benefiting innovating domestic firms, the increased competition between pioneer drugs and structurally similar drugs in the Indian market will lower pharmaceutical prices without relying

on generic competition or price control. Even in the US, structurally similar NCEs have been known to create price-lowering competition in markets with price-sensitive buyers *(20)*.

Secondly, linking compulsory licensing to R&D by domestic firms would be a reasonable way to stimulate innovation and encourage voluntary cross-licensing. Currently, the issuance of compulsory licensing in India is independent of R&D effort by Indian firms. Cross-licensing can also be an effective tool for guaranteeing returns to innovation under weak patentability requirement, or short leading breadth *(4)*.

A prerequisite to allowing narrow patents and structurally similar NCEs is to establish and manage a functioning drug approval apparatus. Such a system is necessary to ensure the safety and effectiveness of structurally similar drugs developed by Indian firms. Currently, drug quality is being taken up as the most pressing issue within Indian drug regulatory policy *(26)*. After the quality issue has been taken care of, it is hoped that domestic drug approvals becomes the focus of policy discussion.

Price control is sometimes claimed to be an effective antidote to monopolistic pricing under product patents *(27)*. However, India's experience shows that it is difficult to implement effective price control without a single-payer national health insurance scheme. Japan's NHI, which attained universal coverage in 1961, negotiates the reimbursement prices of drugs with pharmaceutical firms. In contrast, Indian consumers are not covered by a national health insurance scheme that negotiates drug prices on their behalf. India has a complex system of price control that dates back to 1963. Under the Drug Price (Control) Order currently in force, 74 "scheduled" bulk drugs whose prices are regulated on a cost-plus basis, using a pre-specified rate of return on capital. Enforcement of such price control is not simple. Even in cases where there is clear violation, remedial actions by the National Pharmaceutical Pricing Authority are often held up in litigation, and many violators have avoided paying fines *(1)*.

Concluding remarks

At present, it may seem that the only way for governments of developing countries such as India to keep pharmaceutical prices low, while ensuring that new drugs are introduced, is to use the threat of price control and compulsory licensing. These measures are not only difficult to implement, but create regulatory uncertainty which diminishes the returns to innovation. This defeats the purpose of introducing product patents, and has an adverse effect on the R&D capability of the domestic pharmaceutical industry.

Japan's experience in using its patent system to promote incremental innovation demonstrates the possibility of attaining the dual goals of product introduction and drug price attenuation without

discouraging innovation by domestic firms. In particular, narrow patent scope, adequate patentability, and cross-licensing provisions have been shown to be effective policies. This may provide broader options also for India.

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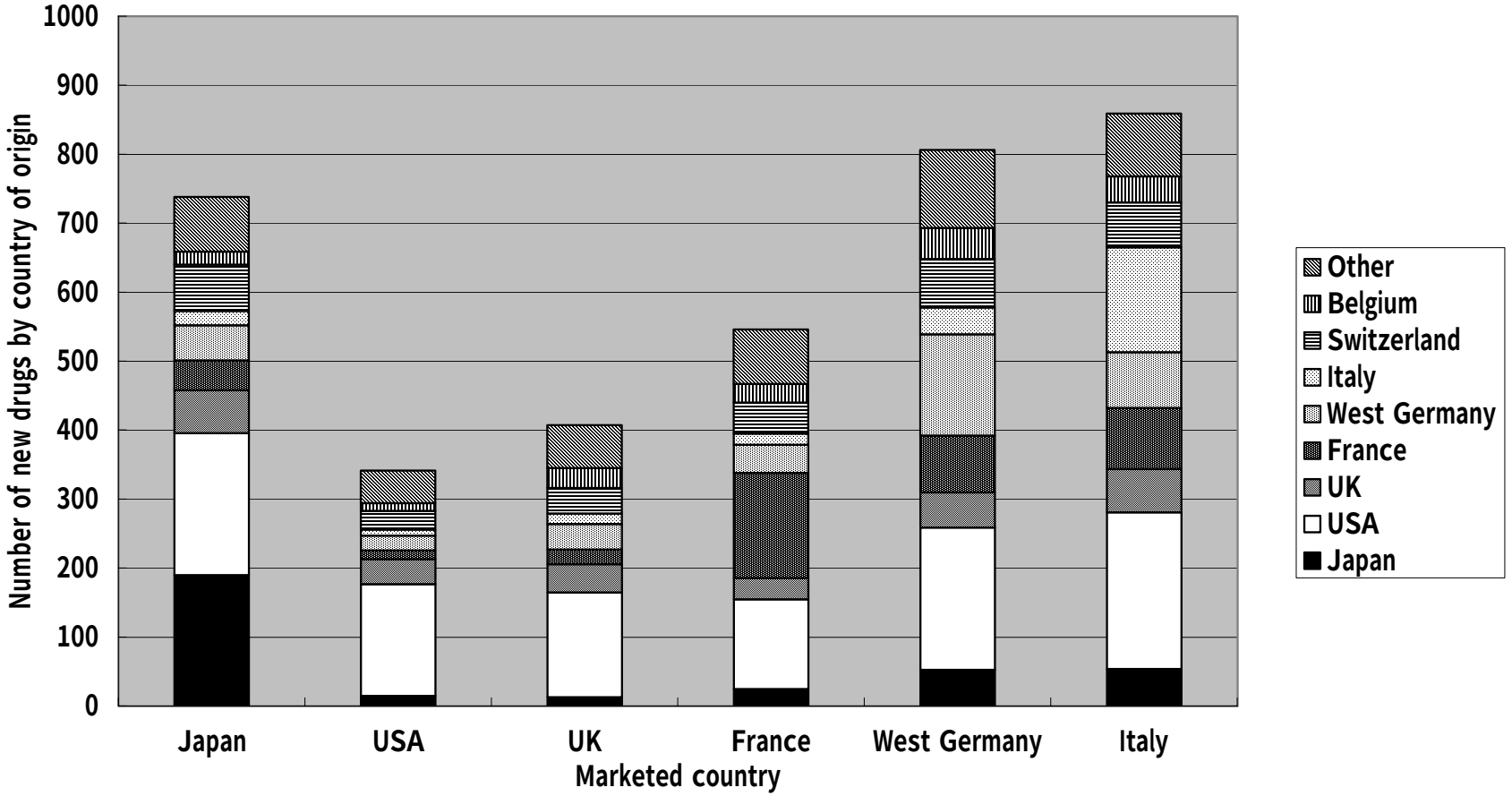
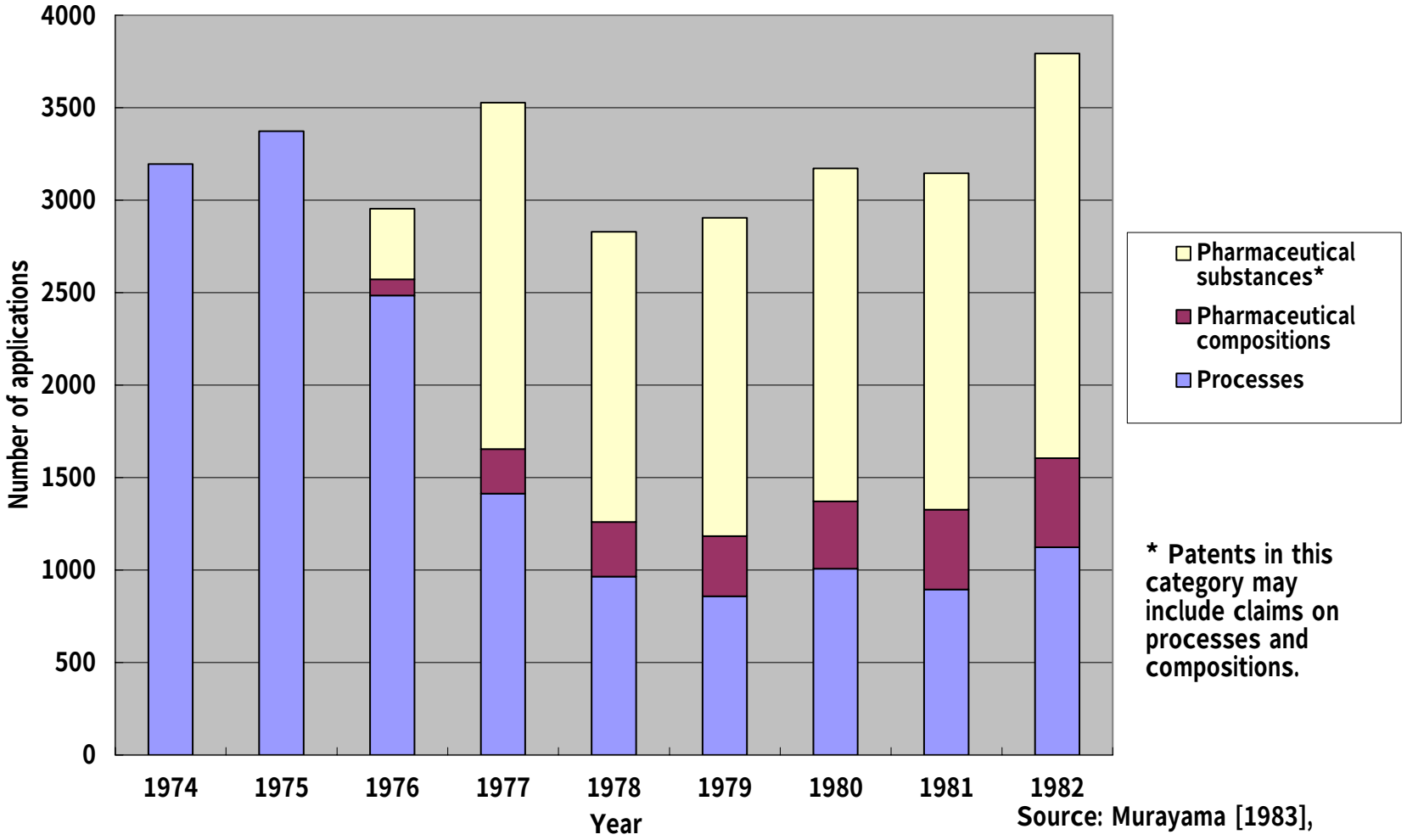
Fig. 1. Sources of Drugs Marketed in Selected Countries (1970-85)



Source: Japan Pharmaceutical Manufacturers' Association [1987]

Fig. 2. Pharmaceutical Patent Applications Before and After Product Patent Introduction



Source: Murayama [1983],