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Implications of Product Patents : Lessons from Japan

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Implications of Product Patents – Lessons from Japan

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Abstract

Product (material) patents were introduced to Japan in 1976. We examine data prior to 1976 and years immediately following to determine the law's effect on domestic pharmaceutical market, innovation by pharmaceutical firms, and relationship of the Japanese market to the rest of the world. There is evidence that the domestic market became more concentrated and *quality* of pharmaceutical innovation changed after the introduction. This is because introduction of product patents is different from simple strengthening of existing technology protection such as increasing breadth.

*We are grateful to Kazuyoshi Hirai and Yoko Konno at Japan Pharmaceutical Manufacturers Association for providing the data, Yosuke Okada and Charles Clift for valuable advice, and Chihiro Kawashima for research assistance.

Implications of Product Patents – Lessons from Japan

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Executive Summary

We identify possible consequences of the introduction of the product patents in Japan in 1976. We look at changes that occurred in the domestic pharmaceutical market, innovation and changes in the context of the international pharmaceutical market.

At the time it was envisaged that stronger patent protection, such as product (material) patents, would make some substitutes unavailable to the market and result in higher price of products that are protected by patents. In case of Japan, prescription drug prices are set by the Ministry of Health, Labor and Welfare for the purpose of insurance reimbursement and not determined by the market. The availability of products was not adversely affected by the stronger patents. This was the case for over the counter (OTC) products as well, of which prices have been falling. We actually observe a steady increase in number of drug products after the introduction. We suspect there was a mild reorganization of pharmaceutical market. Changes in concentrations ratios suggest that the very largest firms became more dominant while some large firms either left the market or lost shares. Since the total number of pharmaceutical firms did not decline, the most dominant products seem to have increased market share. Stronger protection increased foreign investment in production and research facilities in Japan.

Both the absolute number of R&D expenditure and as proportion of sales increased around 1976 and continued to increase. Firms also increased the proportion of research employees. Foreign firms also became innovative by building research facilities in Japan after the law change. Although we do not observe significant increase in number of patents, there was significant reduction in use of process patents, meaning firms did in deed take advantage of product patents. At the same time there was a significant increase in original drugs developed in Japan and a change in trading pattern of pharmaceutical technologies. These facts lead us to conclude that *quality* of Japanese pharmaceutical innovation shifted (such as from modification to application (Hara, 2002), or from process modification to product modification) after the introduction. The quality became more in line with the imported technologies suggesting Japan "caught up".

In considering product patents, public health policy and industrial policy should be separated. In case of Japan, product patents were introduced from industrial policy point of view. Governments control price of drugs and delivery of health services to counter patent protection. The long run benefits from introduction of patents take longer to materialize. But such benefits may increase the national resources available for public health eventually.

1. Introduction

The most significant change for the Japanese pharmaceutical industry in terms of intellectual property regime was the introduction of product patents in 1976. This was followed in 1988 with extension of protection length and relaxation of the description requirements for patent specifications in 1994.

The object of this paper is to identify the consequences of the introduction of product patents to the pharmaceutical industry. We will first examine its effect on the domestic market, prices, product availability and concentration of firms. One expects the most direct effect of intellectual property will be to innovation. Level of innovation may not be the only measure of change in innovation behavior from change (Sakakibara and Branstetter, 2001). We focus on the heterogeneous nature of pharmaceutical innovation (Hara, 2003). We will look at how R&D behavior, patenting and product introduction was affected in addition to the traditional measurements such as R&D expenditure and number of patents. Finally we will examine how the change in domestic law affected Japanese firms in the international pharmaceutical market context.

We note that establishment of the National Health Insurance System (NHI) in 1961 which included reimbursement of drugs increased profitability of the pharmaceutical industry significantly. The liberalization of capital investment in 1975 meant that foreign firms were now able to produce and market directly in Japan and no longer needed to rely on Japanese firms to produce under license. There were also two important changes in the Japanese patent system in 1970. The automatic early publication of patent applications and examination request system were introduced. After 1970, patent applications, independent of if it becomes a registered patent or not, are published automatically 18 months ("early publication") after application is lodged.

1.2 Background

Since the Japanese patent system was established in 1985, modeled after the French system, chemical materials including pharmaceuticals were not patentable. This remained the case through several major changes (in years 1999, 1899, 1909 and 1921). Introduction of product patents was considered in 1970 but the state of innovation in Japan was judged not to have reached the level to benefit from such change. Only the early publication of applications and the examination request system were introduced.

Initially, process patents were considered effective in promoting introduction of products with more efficient production, lowering costs and promoting competition. If a patentable inventive step were easier to achieve with process innovation than with product innovation, restricting patents to process also means greater number of firms producing, promoting production efficiency. However soon it became evident that opportunities for process innovation of a given drug were being exhausted. This resulted in increase in patent infringement suits as new "innovations" became less innovative and similar to existing ones. But the firms continued to pour resources into finding new

process methods rather than finding new drugs. The whole innovation system at all levels of research and development were devoted to finding new processes. It seemed that protection of the new drug itself was necessary to change the direction on innovation, not only at the application and development levels but to promote greater basic research.

In 1970, Japan Patent Association asked its 335 member firms their view on chemical product patents and pharmaceutical patents (Table 1). The proportion of those in favor of making new chemical materials was 59.6% and the proportion for pharmaceutical patents was only 38.2%. The high proportion of "No Opinion" could just be because the effect of pharmaceutical patents will be industry specific and reflects indifference of other industries. The survey numbers did not suggest an overwhelming support but the reservations did not translated to political opposition. There was also agreement among government officials that material patent is more desirable than just pharmaceutical patents since it would also provide incentives to innovate in chemical industries as well. The amendment to the patent law to introduce material patents was passed unanimously on May 29, 1975 and became effective from January 1, 1976.

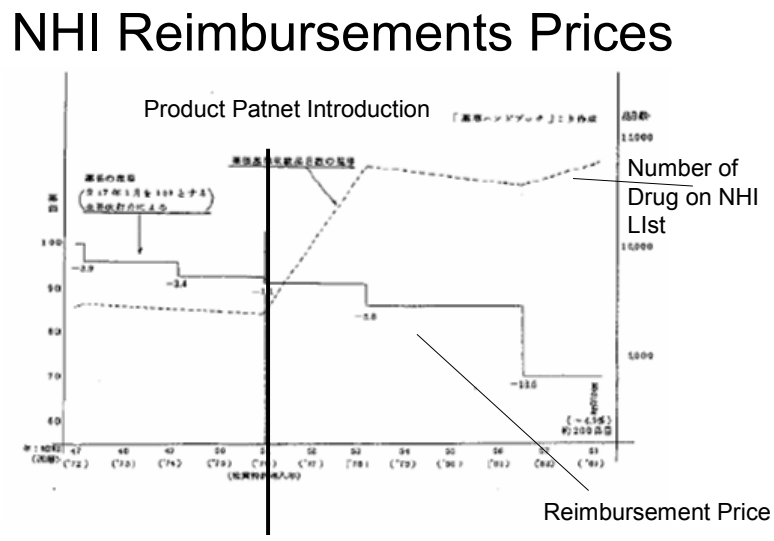
		Total			Without "No Opinion"	
		In Favor	Against	No Opinion	In Favor	Against
Chemical Material Patents	Total	59.60%	5.60%	31.80%	87.40%	12.60%
	Unconditional	6.00%			8.80%	
	Conditional	53.60%			78.60%	
Pharmaceutical Patents	Total	38.20%	15.90%	45.90%	7.60%	29.40%
	Unconditional	5.20%			9.50%	
	Conditional	33.00%			61.10%	

Table 1: Survey of Japan Patent Association Members (Murayama 1982)

2. Effect on Domestic Pharmaceutical Market

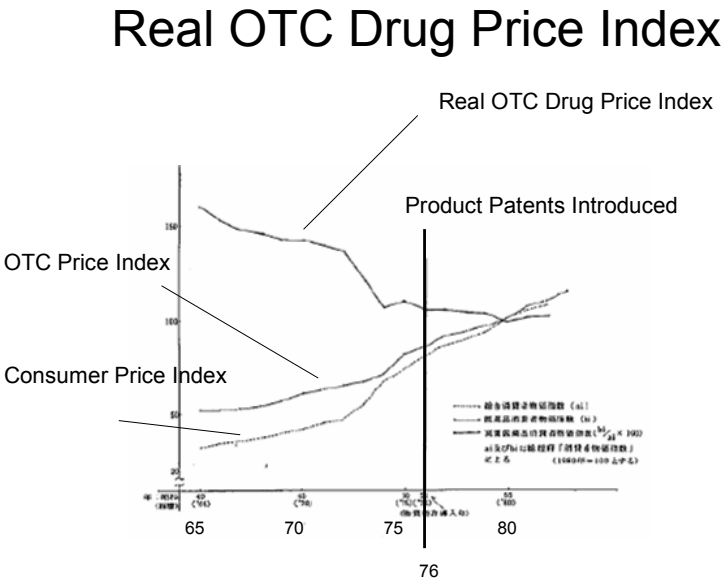
2.1 Prices

The National Health Insurance (NHI) reimbursement prices are set by the Ministry of Health, Labor and Welfare (MHLW). These are the retail prices of drugs in Japan. A price for a drug is determined by a formula that takes into account the size of the market as well as the age of the drug. The price does not reflect what a price usually does: cost of production. Since the NHI, and not the consumer, pays for the drug, the price probably does not influence the consumption decision. Thus price not conveying the marginal cost of production is not as detrimental to allocative efficiency as when consumption decision is based on price. In case of prescription drugs, the consumption decision is actually made by the doctor, which makes price even less relevant for the consumption decision. Figure 1 "NHI Reimbursement Prices" shows that the reimbursement prices has been on steady decline, including those years immediately following 1976.



Source: http://www.kantei.go.jp/jp/singi/titeki2/tyousakai/iryou/dai7/7siryou1.pdf

Figure 1: NHI Reimbursement Prices



Source: http://www.kantei.go.jp/jp/singi/titeki2/tyousakai/iryou/dai7/7siryou1.pdf"

Figure 2: Real OTC Drug Price Index

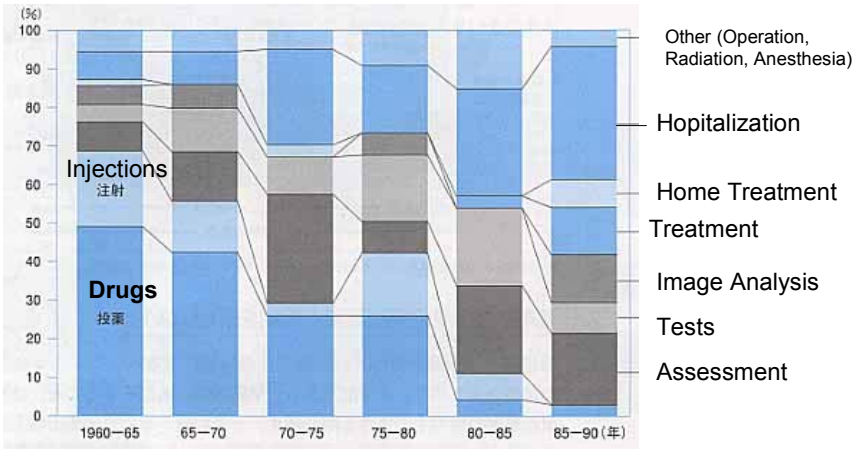
We also note that the price of over the counter drugs have been declining in Japan since 1970s. (Figure 2 "Real OTC Price Index"). It actually declined significantly few years

before introduction of the product patent. As we will observe later, number of products increased in years following 1076. This probably contributed to the decline of OTC drug prices

Pharmaceuticals contribute to human well-being by preventing and curing diseases, and improving over all health. Did people become healthier because of cheaper drugs? One common measurements of public health is infant mortality, which in Japan has been declining steadily. Life expectancy of people of all ages has been increasing. One could argue that life expectancy of older people, in times of peace, are closely related to medical service, particularly pharmaceutical products.

Actually health expenditure has increased in the mean time. Per capita medical expenditure, percentage of medical expense of Gross National Product (GNP) and National Income (NI) all have increased. There is no notable change between 1975 and 1980, except the rate of annual increase. (We believe this is due to the large recession from the large increase in petroleum in 1973 and 1976, the so called "Oil Shock". Medical expenditure as part of GNP and NI did not change in those years.) These facts show that pharmaceutical products are only a part of the total medical service.

Breakdown of Additional Expenses Per Incident



Source: JPMA Facts & Finding 1997 http://www.jpma.or.jp/jpmalib/f_f/f&f-08.html

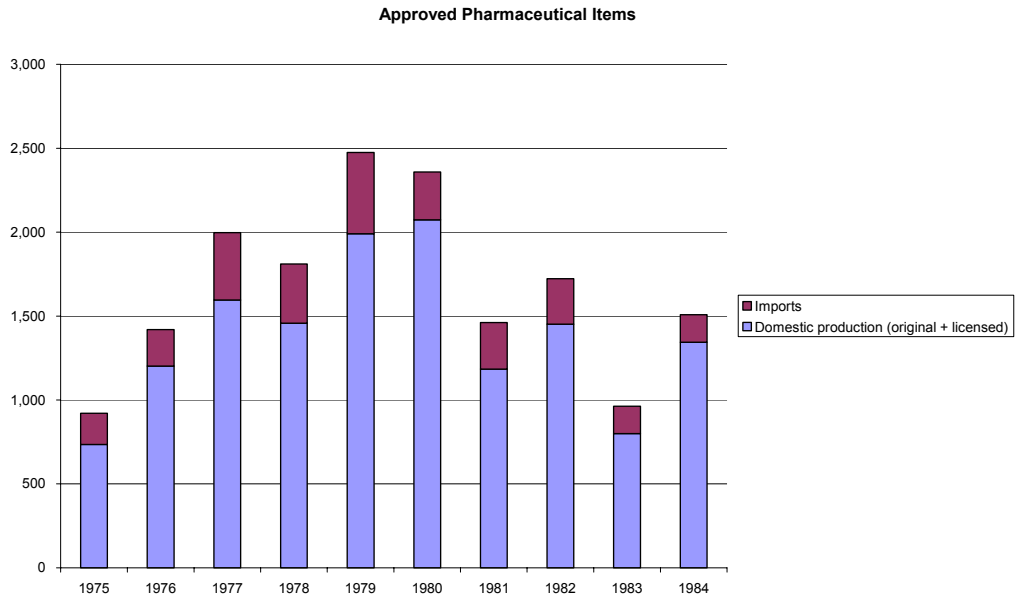
Figure 3: Breakdown of Additional Expenses per Incident

The proportion of pharmaceuticals for marginal increase of cost per treatment was little under 50% for 1960-65, and has been declining. The proportion for 1970-75 and 1975-80 did not change significantly at around 25%. It declined significantly for 1980-85 to below 5%. In the meantime proportion of hospitalization increased. In 1970-65, it was about 10%, It grew to about 25 % for 197075 and, was about 30% in 1980-85. (Figure

3: Breakdown of Additional Expenses per Incident.) This shows that controlled drug prices did not contribute to the increase in medical costs.

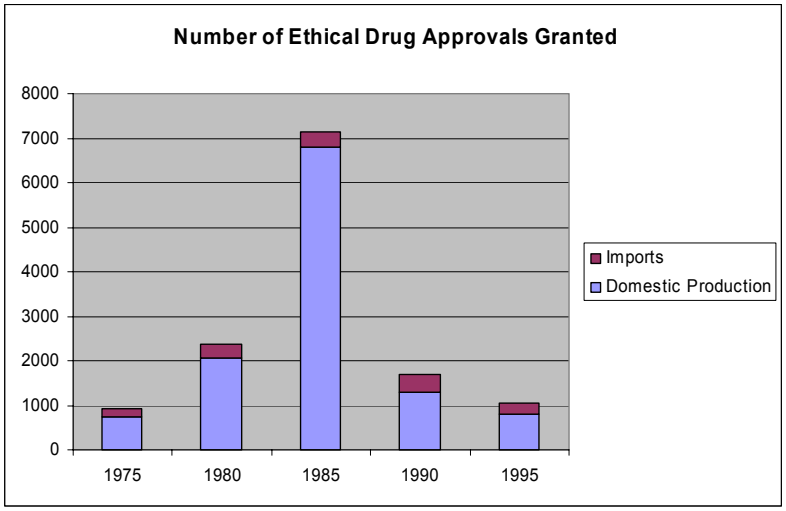
2.2 Availability of Drugs

One concern from introduction of stronger patent protection is that strong protection for one product will result in keeping other similar products out of market because they now infringe. This might result in fewer drugs available. Fortunately this did not occur in Japan as the following figures demonstrate. Figure 4 "Approved Pharmaceutical Items" show that although there was a slight drop in number of approved drugs in 1978, the number was on an increasing trend for years immediately following introduction. The increase occurred for both domestically produced (includes domestically developed and produced under license) and imported. We can see that number of approved drugs (ethical and OTC) increased after introduction (Figures 5 and 6).



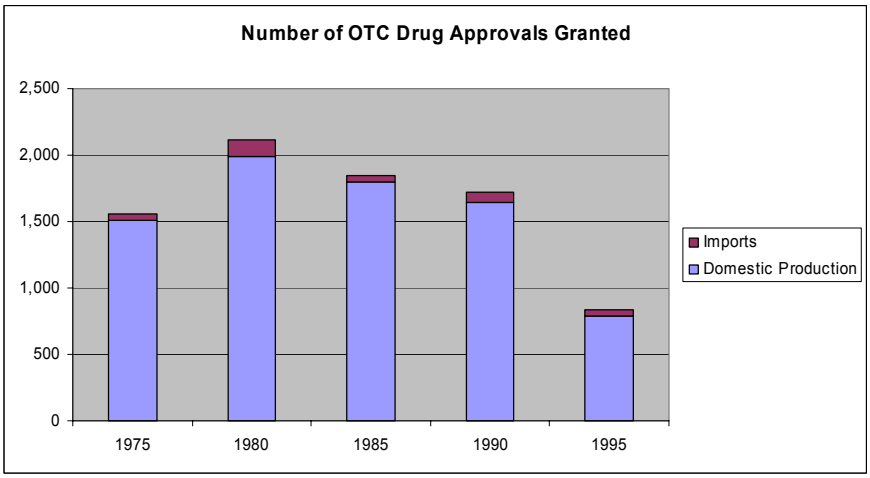
Source: JPMA Data Book 1978

Figure 4: Approved Pharmaceutical Items



Source : The Yakuji Nippo,Recent New Drugs 2004

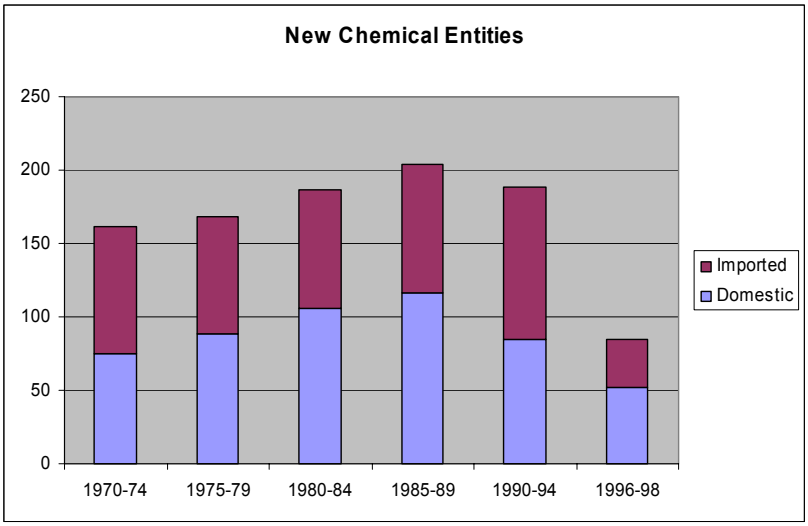
Figure 5: Number of Ethical Drug Approvals Granted



Source : The Yakuji Nippo,Recent New Drugs 2004

Figure 6: Number of OTC Drug Approvals Granted

The increase of products was supported by steady approval of New Chemical Entities (NEC). The number of NECs is far less than number of products and a much larger proportion is imported. Imports increased but they were not driving domestic NECs. Strengthening of patent law was thus not driving domestic manufacturers out but helped by making the environment more conducive to drug research.



Source: JPMA 2001 "Pharmaceutical Industry of Japan -International Competitiveness Perspective"

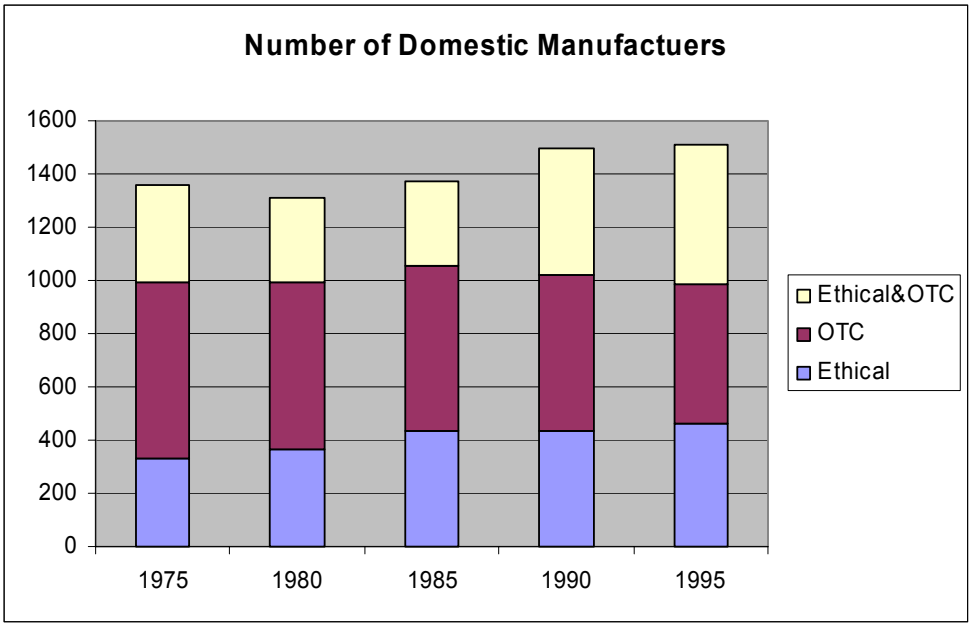
Figure 7: New Chemical Entities

2.3 Pharmaceutical Firms

Stronger patent protection means some products are found to be infringing, forced to stop production. A stronger IP regime means firms that cannot obtain patents will be forced to go out of business. In fact, the number of firms did declined between 1975and 1980.

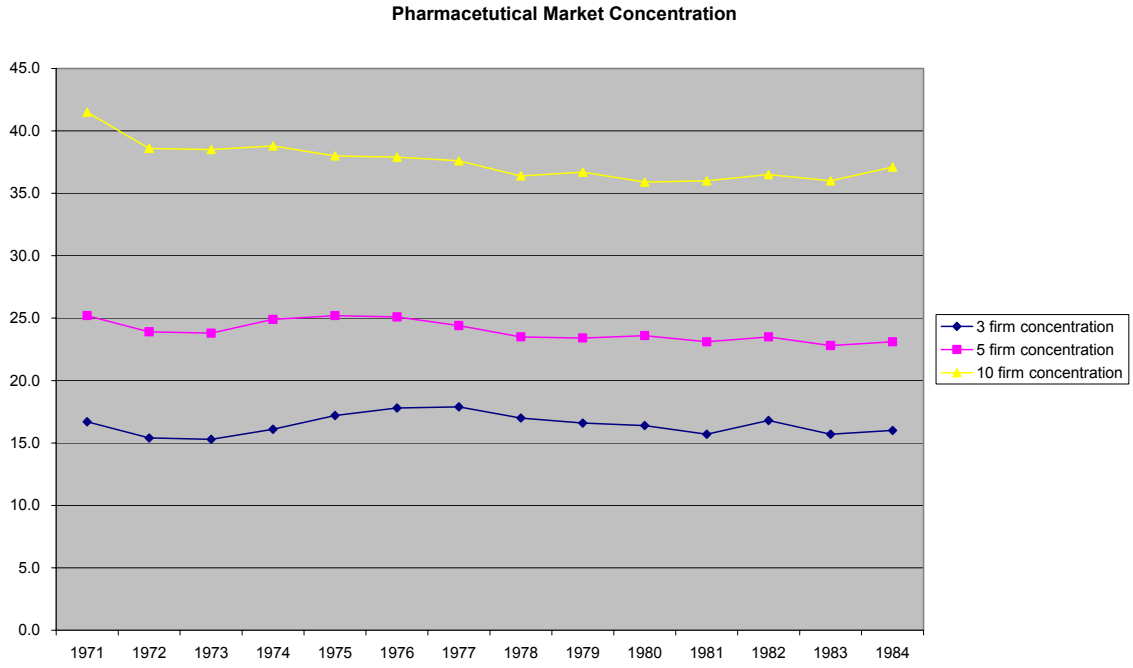
There were 330 ethical drug manufacturers, 666 OTC manufacturers, 363 ethical & OTC manufacturers (total 1359) in 1975 (Figure 8 "Number of Domestic Manufacturers"). The total number dropped slightly in 1980 but the trend is on the increase. The increase can be attributed to increase in number of manufacturers of ethical only and ethical & OTC drugs. Number of OTC manufacturers has been declining. Although there is some research required for OTC drug production, ethical drugs require substantially more. Even in 1980 when the total number dropped, the number of ethical only manufacturers increased.
Firms that produce only ethical drugs increased but both OTC only and ethical & OTC producing firms declined. A mild reorganization of the industry did in deed take place.

The reorganization seems to have started prior to the actual introduction of product patents. There were notable increases in 3 and 5 firm concentration ratios while the 10 firm concentration ratio has declined. The very largest firms increased market share while even the large firms (number 6-10) lost market share (Figure 9: Pharmaceutical Market Concentration).



Source: JPMA Data Book 2004

Figure 8: Number of Domestic Manufacturers

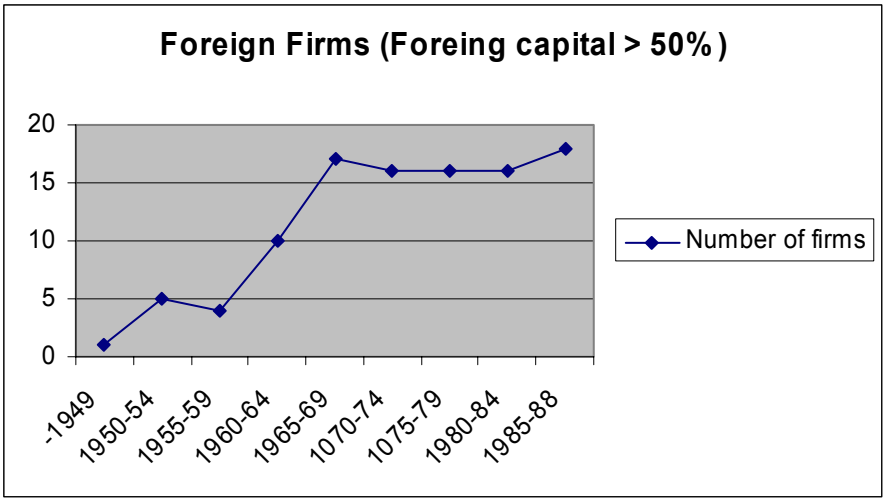


Source: JMPA Data Book 1987

Figure 9: Pharmaceutical Market Concentration

2.4 Foreign Firms

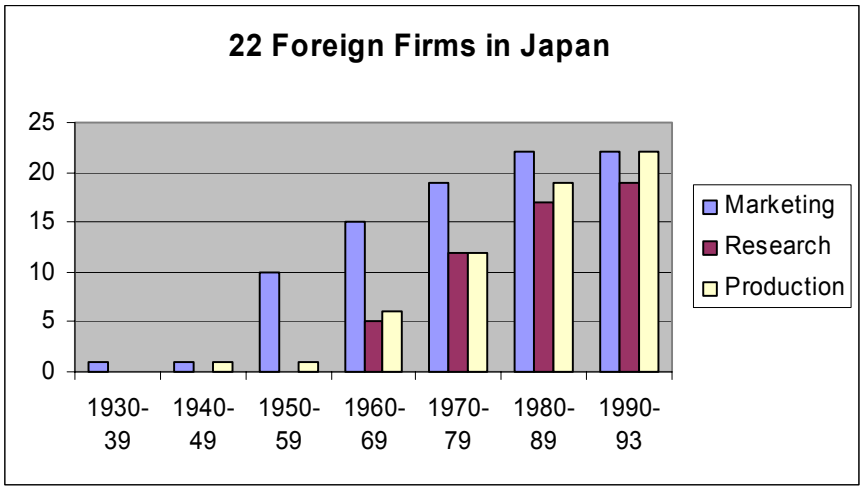
Entry of foreign firms into the Japanese market also occurred after the new patent law. The number of foreign firms (foreign capital accounts for more than 50% of capitalization) is shown in Figure 10 "Foreign Firms". There was a surge over 1965-75 which coincides with the liberalization of foreign investments during 1967-75. Probably this is the reason for the increase rather than the change in patent law. However we can see there was a qualitative change in investment as result of patent law. Figure 11 "22 Foreign Firms in Japan" elaborates the functions of 22[1] major "foreign firm" in Japan. A subsidiary in Japan can have one or more of three roles: marketing, research, and production. Interestingly, the numbers of research and production facilities are almost the same (we do not have the information to judge how many of these are for the same firm. Obviously some overlap.) We see the increase coincides more with introduction of product patents than capital liberalization. We observe the effect of capital liberalization in the number of foreign firms (more than 50% foreign capital)



Source: JPMA 2001 "Pharmaceutical Industry of Japan -International Competitiveness Perspective"

Figure 10: Foreign Firms

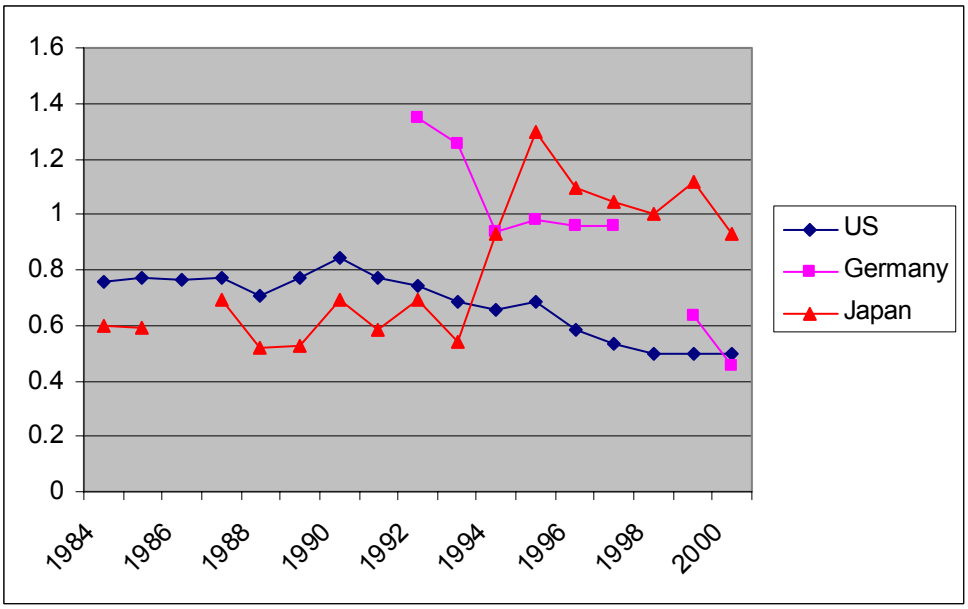
[1] Upjohn, Serle, Sandoz,Schering-Plough,Smith-Kline-Beecham,Zeneca,Glaxco,Schering,Ciba－Geigy,Boehringer Ingelheim,Roche,Novo,Bayer,Banyu,Pfeizer,Fujisawa-Astra,Bristol-Myers Squibb,Hoechst,,Mrion-Merryl-Dow,Rhone-Poulenc Rorer.



Source: JPMA 2001 "Pharmaceutical Industry of Japan -International Competitiveness Perspective"

Figure 11: 22 Foreign Firms in Japan

Foreign firms had marketing facilities even before capital liberalization. However they began to invest in production and research facilities from the 1970s. Introduction of products patents helped improve Japan as a place to do research.



Source: JPMA Data Book 2002

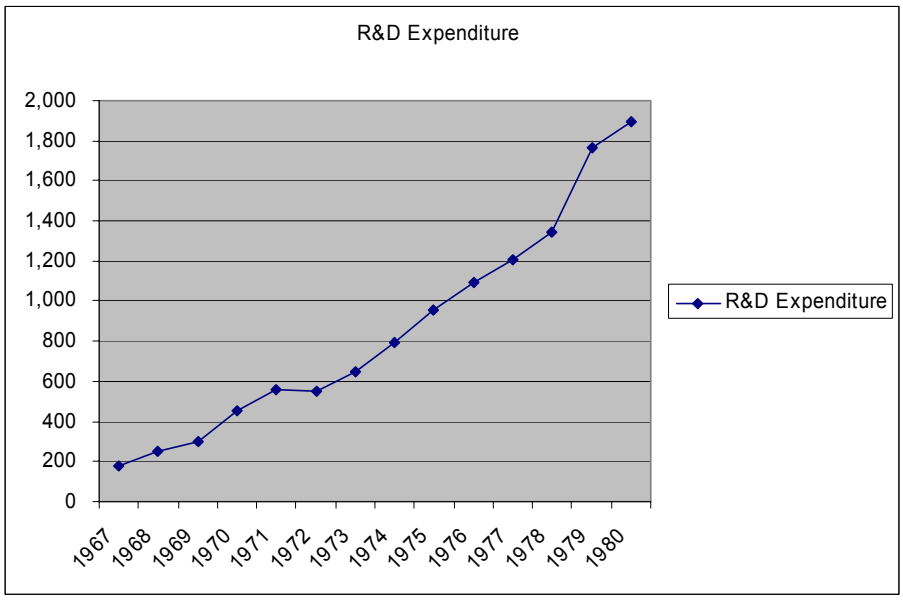
Figure 12: Foreign to Domestic Applicant Ratio of Pharmaceutical Patents

3. Innovation

In this section we analyze the effect of product patents on innovation. In addition to looking at levels of R&D expenditure and patent application, we will try to account to change in quality of innovation.

3.1 R&D Activity

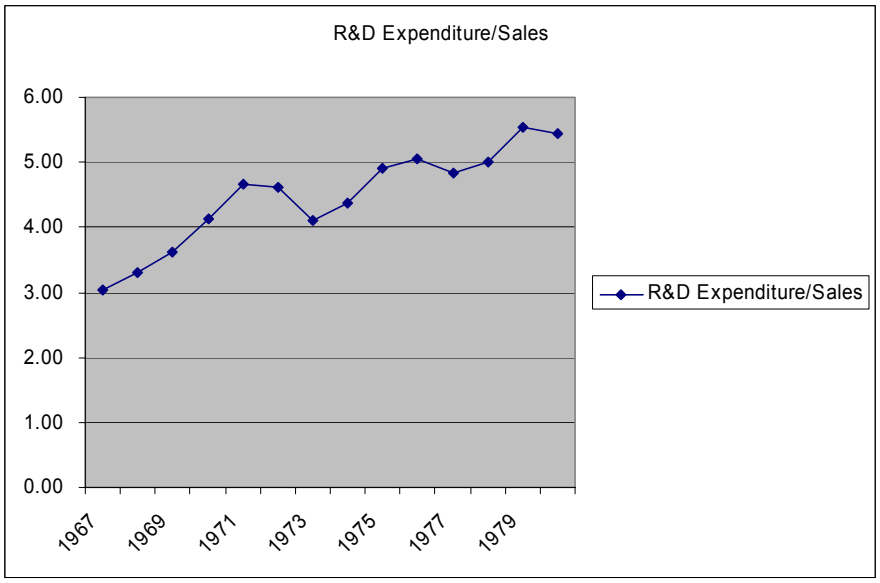
Pharmaceutical industry's total R&D expenditure was under 200 million yen in 1967 which was about 3 % of the total sales. By the year 1980 R&D expenditure was 190 billion yen, about 5.5 % of total sales. By 2000, total R&D expenditure had grown to 746.2 billion yen and, more importantly, it was 8.6% of sales.[2] (Figures 13 and 14).



Source: JPMA Data Book 1987

Figure 123: R&D Expenditure

[2] R&D expenditure has not been deflated. However taking the ratio to sales eliminates the problem.



Source: JPMA Data Book1987

Figure 14: R&D Expenditure to Sales Ratio

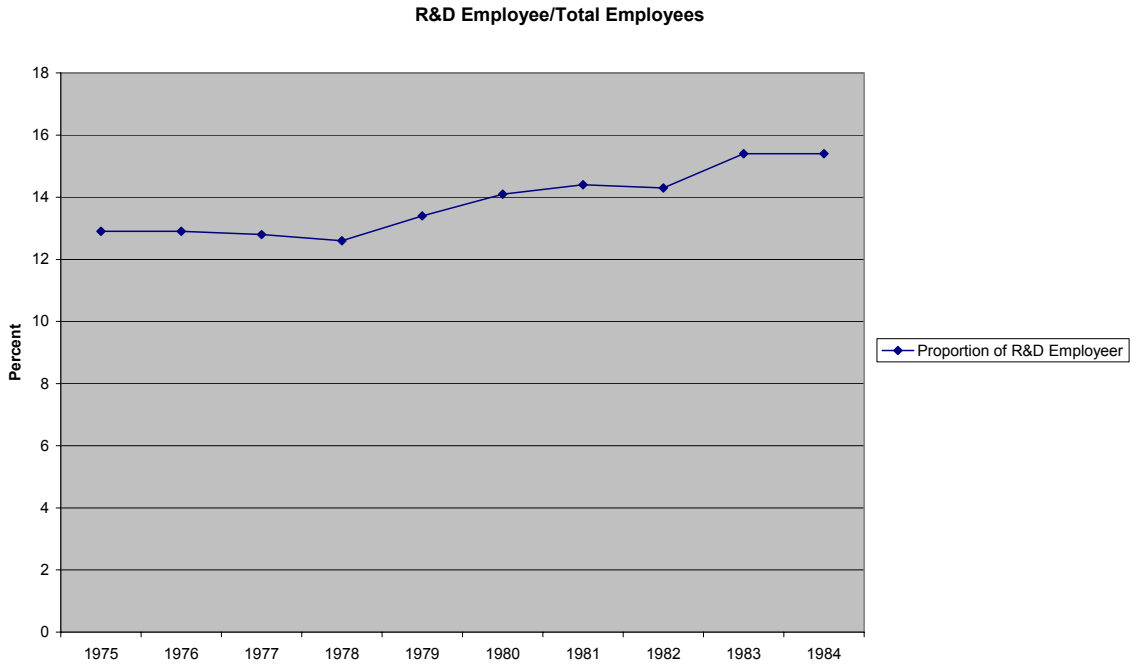
	1983	1984	1985
USA	9.2	9.5	10.1
W. Germany	13.3	15.5	
U.K.	13.1	13.7	
Switzerland			
France	12.3	12.3	12.7
Italy	9.6	9.9	
Denmark	10.3	12	
Japan	6.59	6.49	7.04

Table 2: International Comparison of R&D Expenditure to Sales Ratio

Although R&D expenditure as proportion of sales increased significantly in late 1970s, the proportion was till quite small by international standards (Table 2). More recent numbers for the top twenty firms is given in Table 3.

Worldwide (excluding Japan)					Japan				
Company	1998	1999	2000		Company	1997	1998	1999	2000
Abbott	9.8	9.1	9.8		Takeda	11.9	11.1	8.4	9.3
A H P	12.3	13	12.7		Sankyo	11.2	12.5	10.9	14.4
Astra-Zeneca	NA	16	15.8		Yamanouchi	12	17.5	12.6	11.9
Aventis	NA	15	14.8		Daiichi	13.1	13.9	11.4	12.6
Bayer	7.1	8.2	7.7		Eisai	16	18.9	15.4	13.7
Boehringer Ingelheim	18.1	16	15.6		Shionogi	12	12.2	6.8	7.1
Bristol-Myers Squibb	8.6	9.1	10.6		Taisho	8.2	8.8	8.4	12.2
Eli-Lilly	18.8	18	18.6		Fujisawa	15.1	16.8	15.8	17.5
GlaxoSmithKline	14.6	15	13.9		Chugai	20.1	20.3	20.5	20.3
Johnson & Johnson	9.6	9.5	10		Banyu	10.2	10.6	11.1	11.1
Merck	6.8	6.3	5.8		Tanabe	11.3	11.1	10.5	10.2
Novartis	11.8	13	13		Welfide	8.4	9.6	9.7	10.5
Novo Nordisk	NA	NA	16.3		Kyowa Hakko Kogyo	6.7	7	6.7	7.5
Pfizer	16.8	17	15		Ono	13.2	14.6	15.8	17.6
Pharmacia	NA	17	15.2		Dainippon	9.1	9.3	7.8	7.9
Roche	13.8	14	13.8		Meiji Seika	5.7	5.8	4.4	4.9
Sanofi-Synthelabo	NA	17	15.8		Santen	10.9	10.6	11	11.9
Schering	NA	NA	18.1		Kaken	8.1	6.7	7.5	7.1
Schering-Plough	12.5	13	13.6		Tsumura	8.8	8.4	6.3	6.2
UCB	11.3	12	8.3		Mochida	14.9	13.5	12.9	12.6
Average	12.3	13.2	13.2		Average	11.4	12	10.7	11.3

Table 3: R & D Expenditures Proportion of Sales by 20 Leading Pharmaceutical Manufacturers (World Wide and Japan)



Source: JPMA Data Book 1987

Figure 135: R&D Employee/Total Employees

As shown in Figure 15, in 1975, the earliest for which numbers are available, 12.9% of employees at a pharmaceutical company was devoted R&D, on the average for the industry. The number did not change very much until 1979 when there was a noticeable increase. The proportion of R&D employees continued to increase thereafter. There are no international compatible numbers for 1975 but in 1996 the industry average for U.S. was 29% for production and engineering and 25% for R&D. We suspect that in the 1970s Japanese pharmaceutical companies specialized in manufacturing and had R&D capability (14.1 % of employees in 1975) but that was below the level of international pioneering firms.

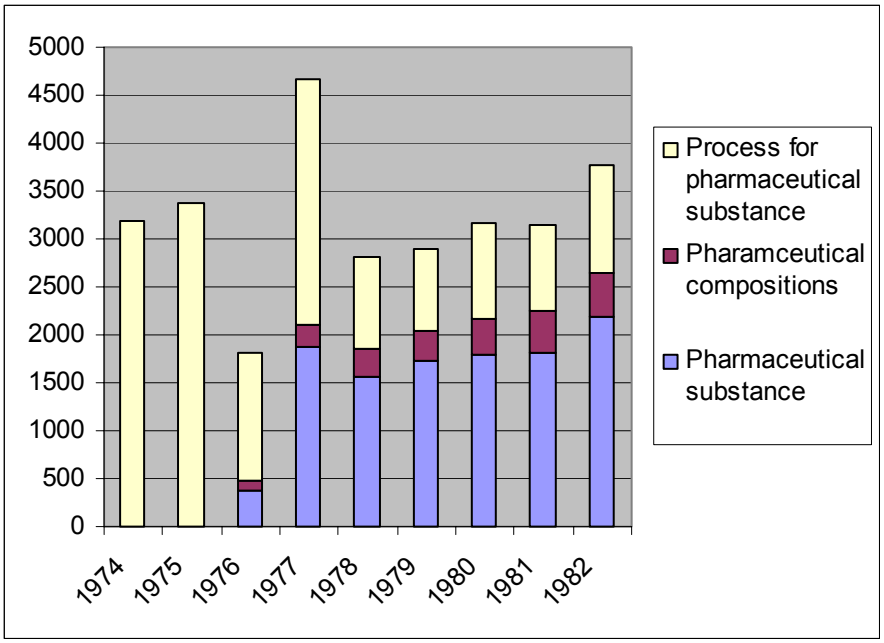
As shown in Table 4, in the decade 1960-70 Japanese firms introduced only 2 new products, the number was 4 during 1970-1980. The number of new products jumped to 18 in 1980-1990 and was 14 in 1990-2000. This suggests that Japanese firms began to transform from copy drug manufacturers to pioneering drug developers after 1975.

Table 4: New Product Introduction by Decade

Decade of Introduction	Entity Name	Product Name
1960–70	Sucralfate	
	Mitomycin C	
1970–1980	Estazolam	
	Diltiazem hydrochloride	
	Cefazolin sodium	
	Josamycin	
1980–90	Pravastatin sodium	Mevalotin
	Cefpodoxime proxetil	
	Surfactant	
	Cefixime	
	Formoterol fumarate	
	Leuprorelin acetate	Lupron
	Enoxacin	
	Famotidine	Gaster
	Ofloxacin	
	Alprostadil alfadex	Prostandin
	Nicorandil	
	Cefotetan	
	Norfloxacin	
	Ceftizoxime sodium	
	Nicardipine hydrochloride	
	Cefoperazone sodium	
	Latamoxef sodium	
	Piperacillin sodium	
1990–2000	Pioglitazon hydrochloride	Actos
	Candesartan cilexetil	Blopress
	Donepezil hydrochloride	Aricept
	Sodium Rabeprazole	Pariet
	Meropenem trihydrate	
	Imidapril hydrochloride	
	Tamuslosin hydrochloride	Harnal
	Tacrolimus hydrate	Prograf
	Sparfloxacin	
	Levofloxacin	Cravit
	Ceftibuten	
	Lenograstim	
	Lansoprazole	Takepron
	Clarithromycin	Clarith

3.2 Patenting Behavior

First we note that immediately following the introduction of product patents, new applications were made and number of process patent applications declined (see Figure 16). Product patent applications are broken down into pharmaceutical compositions and pharmaceutical substances.

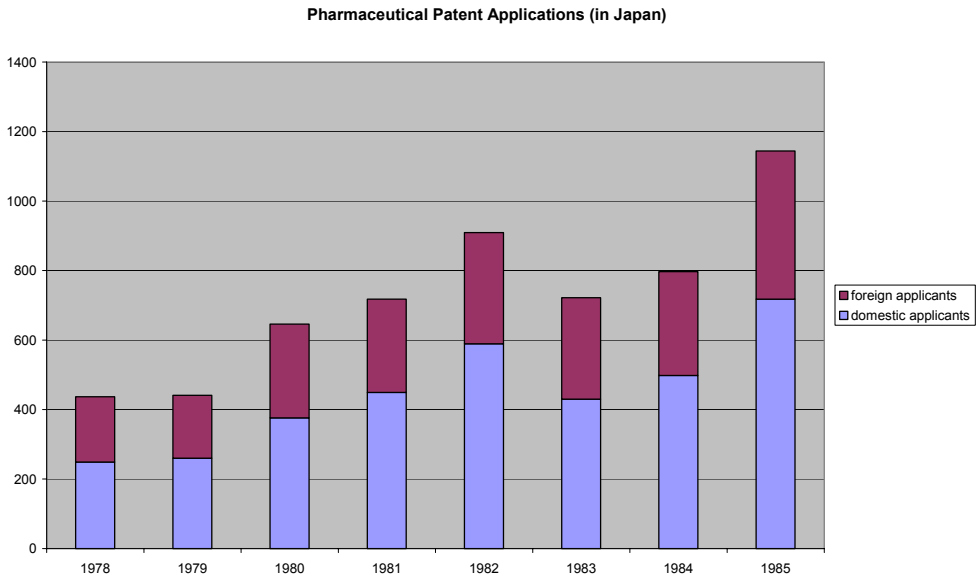


Source: Murayama 1982

Figure 16: Product and Process Patent Applications (Early Publication) in Pharmaceutical Field

Number of patent applications declined for the year the new law came into effect. But this deficit was made up in the following year. Application for product patents steadily increased in numbers and also as proportion of patents in pharmaceutical field.

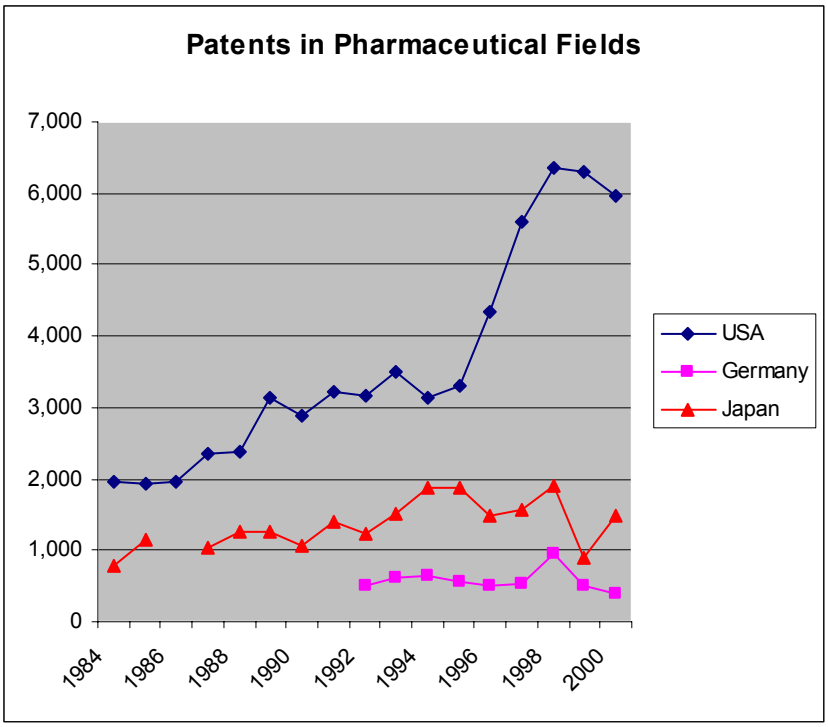
One suspects that this is an indication of change in type of innovation that firms engaged in. Firms concentrated on developing new methods of making existing drugs before 1976. When it became possible to patent product or material patents, firms began to concentrate on developing new compounds and substances.



Source: JPMA Data Book 1987

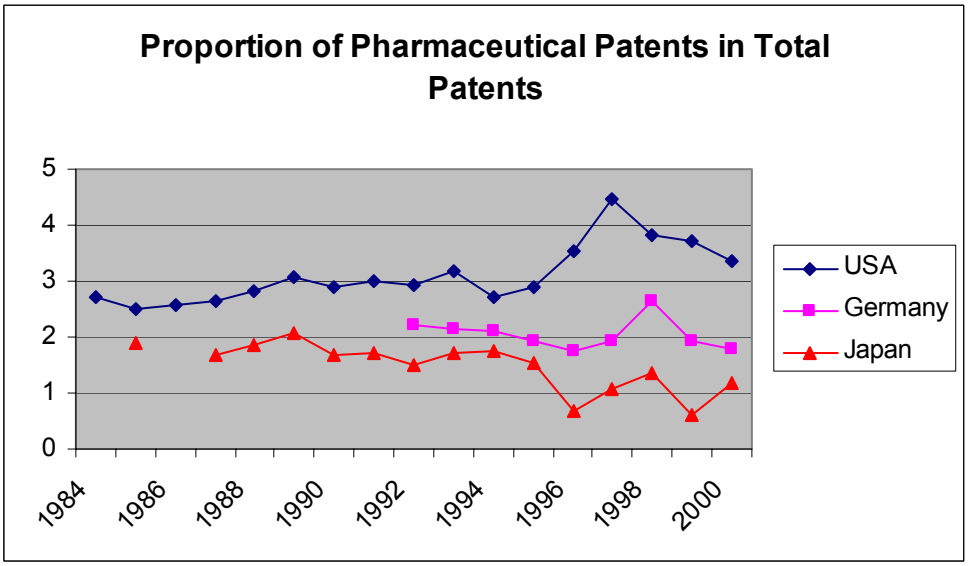
Figure 147: Pharmaceutical Patent Application (in Japan)

Number of pharmaceutical patents in Japan has continued to increase, although the increase is small compared to Germany and U.S.A. (Figure 18). The proportion of pharmaceutical patents among all patents is small compared to other countries and the trend is to decline (Figure 19). This could reflect decline in productivity of the pharmaceutical industry, other industries are more productive, or size the pharmaceutical industry has declined relative to the whole economy. Because number of pharmaceutical patents has not declined (Figure 17), the last two explanations are more likely. It could be that electronic industries are particularly productive.



Source: JPMA Databook 2003, Databook 1987

Figure 18: Number of Patents Issued in Pharmaceutical Field in U.S.A., Germany and Japan



Source: JPMA Databook 2003, Databook 1987

Figure 19: Proportion of Pharmaceutical Patents in Total Patents in U.S.A., Germany and Japan

3.3 Quality of Innovation

Both levels of R&D and patenting have risen but not so significantly. This was the case when patent scope was enlarged in 1988 (Sakakibara and Branstetter (2001). Okada and Kawara (2002) have provided evidence based on US patent citations that Japanese firms indeed became innovative as result of introduction of the product patent. One measure of innovativeness of a new patent is how often that patent is cited in applications of later patents, i.e., number of forward citations. Between 1975 and 1980, number of Japanese patents (patents registered by Japanese firms in the U.S.) cited by more than 10 patents doubled while the number remained steady over those year for U.S. originating patents (U.S. patents registered by U.S. firms). This implies there was definitely a significant improvement in quality of research output by Japanese firms and this was not based on some underlying scientific breakthrough available internationally.

We have observed that proportion of R&D workers has also increased. Most importantly, that firms indeed switched from process to product patenting. This seems to imply a change in quality or direction of pharmaceutical innovation. We could interpret the change as from modification to application innovation as classified by Hara (2003). Probably the modification should include process modification. Both switch from process modification to product modification and from modification to application would be consistent with Table 2 "New Product Introduction by Decade". Either interpretation is consistent with increase in the inventive step from introduction of product patents.

3.4 Individual Firms

Figures 13 and 14 demonstrated that that R&D expenditure itself and its ratio to total sales both increased significantly after 1975.[3] What is suggested by the macro data is supported by evidence of several firms (all one of the top 10 firms in terms of capitalization in fiscal year 2003). Although there is no increase in case of Firm A, other firms show increase in both R&D expenditure as percentage of sales and R&D employees as percentage of total employees. (These percentages increases could be due to decrease in the denominators, but both total sales and total number of employees increased for all firms during the period.)

There is a significant increase of foreign patenting by Firms A, B and E. There is increase in R&D effort by Firms B and E and but not by Firm A. there was no noticeable increase in R&D effort but a significant increase in number of patent application abroad. Firms C and D has increase in R&D effort but there seems to be no significant change in patenting behavior.

In interpreting these numbers, it is important to remember the two changes: publication of patent applications and examination request system, introduced in 1970. Publication makes patent applications more risky (Aoki and Spiegel 1998). This might have worked

[3] Many of our data begin from 1975. We looked for date prior to 1975, but interestingly many of the data for the industry starts from 1975.

against the incentive to patent more after the products became patentable. Need to request examination also increased the cost of patent application.

(Figures 20- 29 were constructed by data provided by individual firms to the Japan Pharmaceutical Manufacturers Association.)

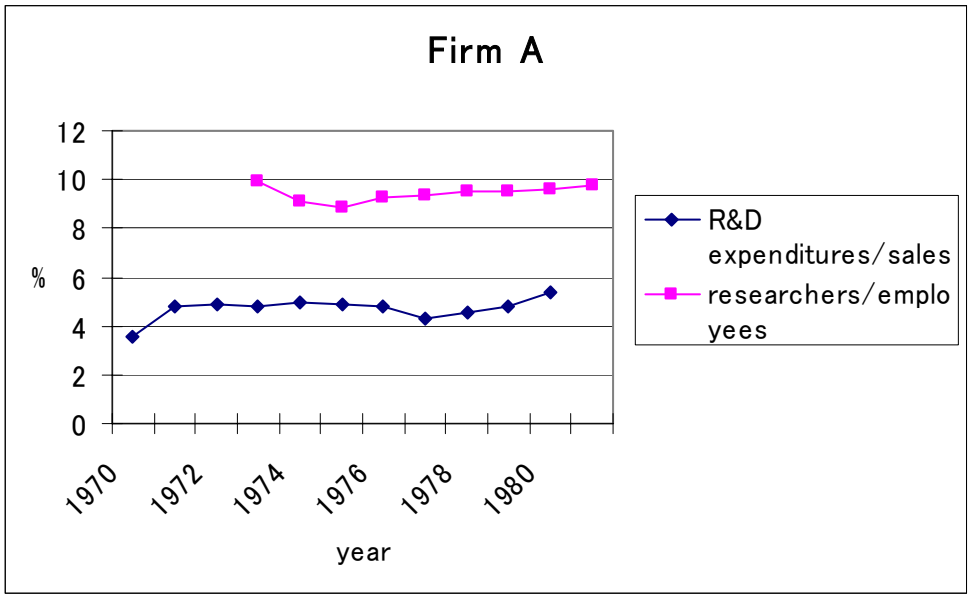


Figure 20: Firm A R&D Expenditure & Employee

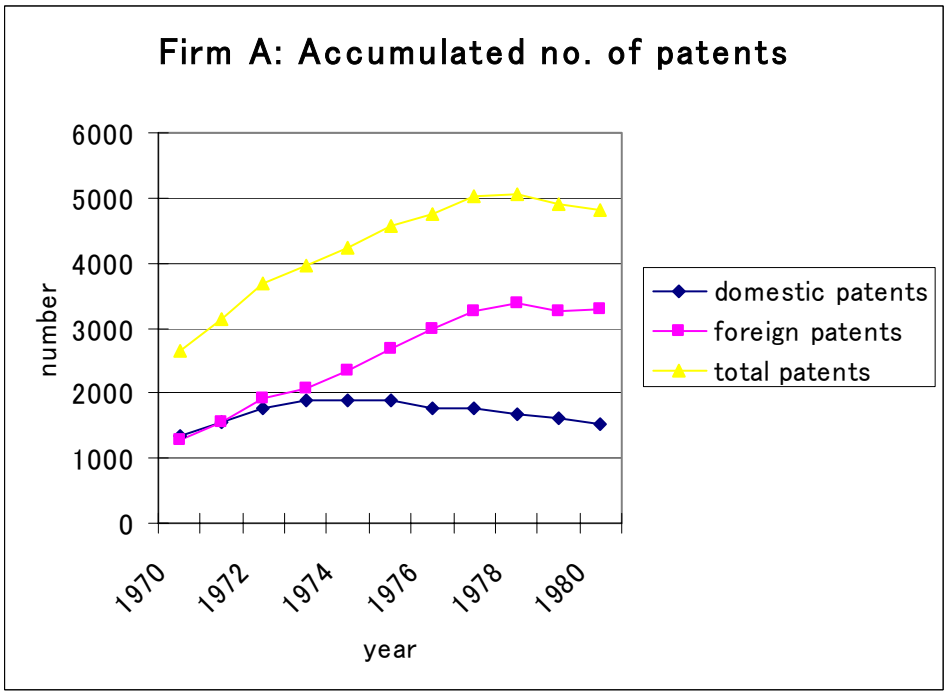


Figure 21: Firm A: Accumulated Number of Patents

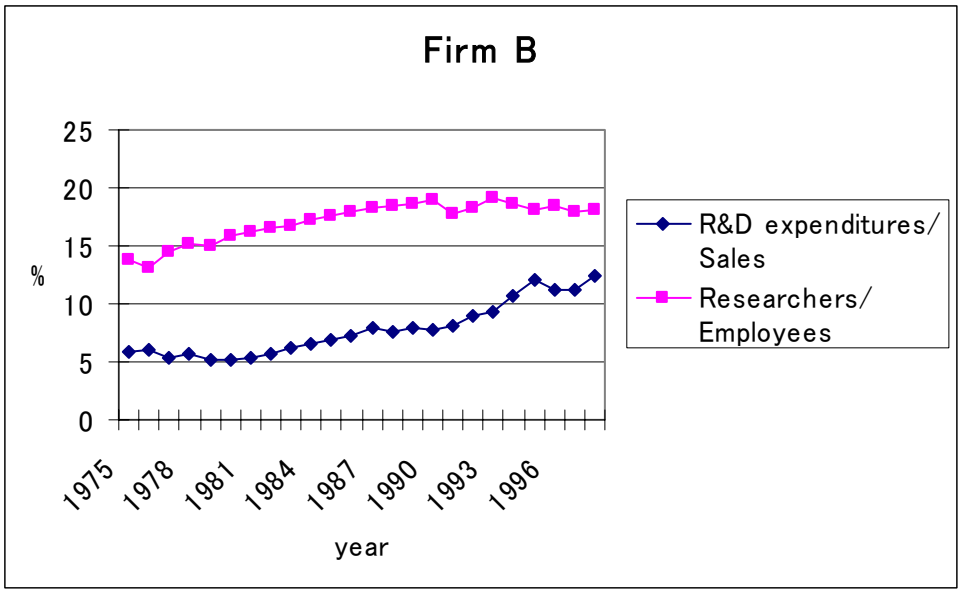


Figure 22: Firm B R&D Expenditure and Employees

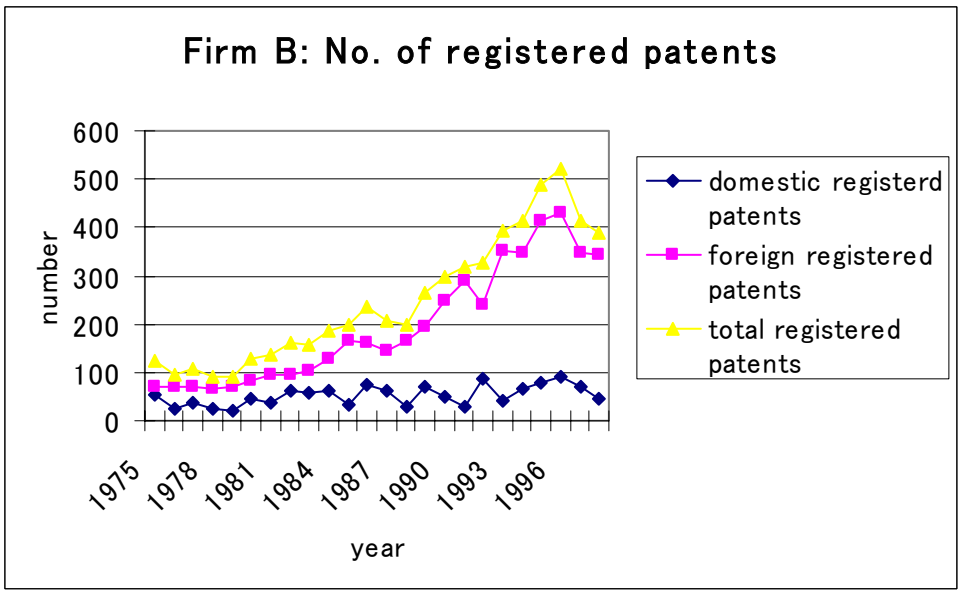


Figure 23: Firm B Registered Number of Patents

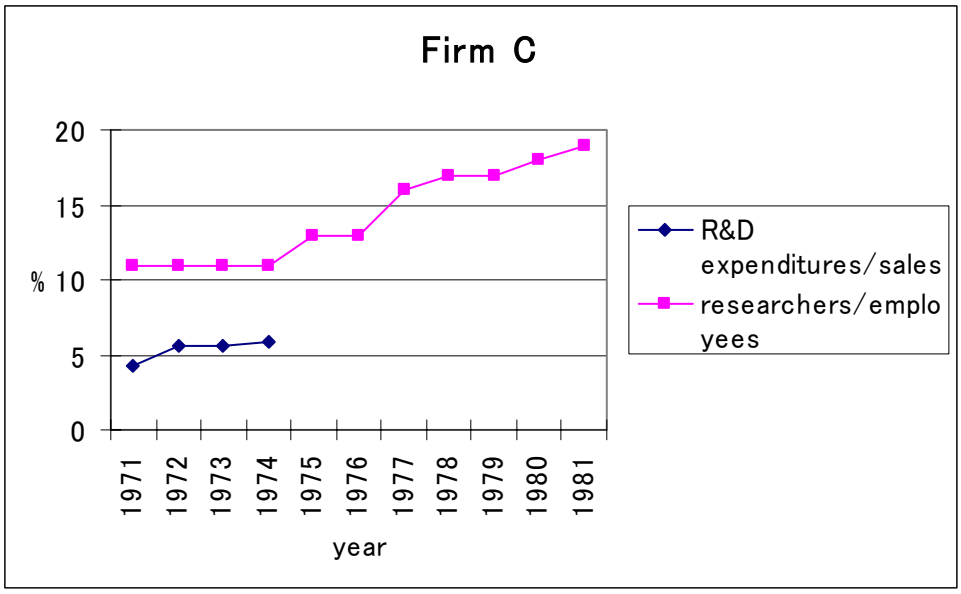


Figure 154: Firm C R&D Expenditure and Employees

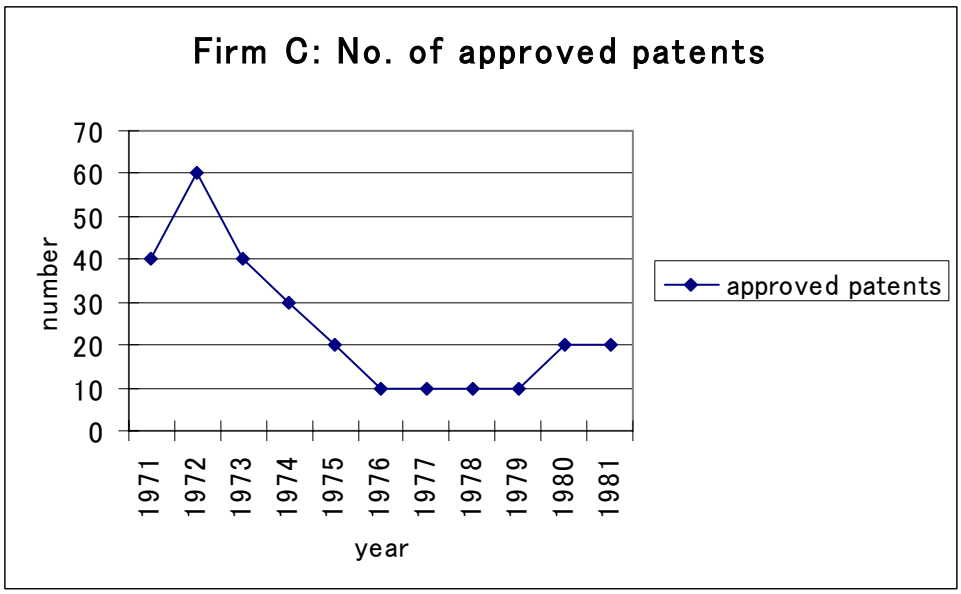


Figure 165: Firm C Number of Approved Patents

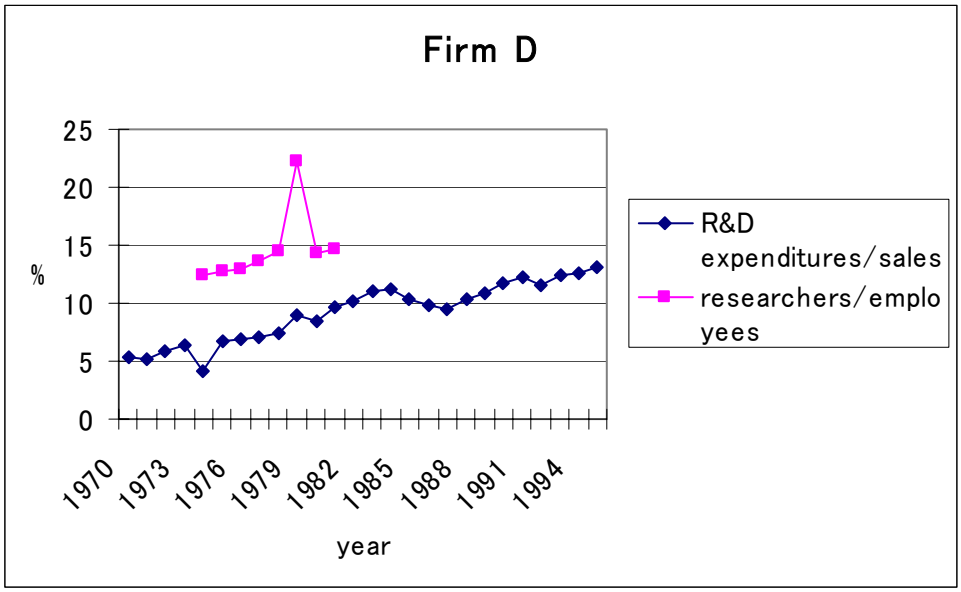


Figure 26: Firm D R&D Expenditure and Employees

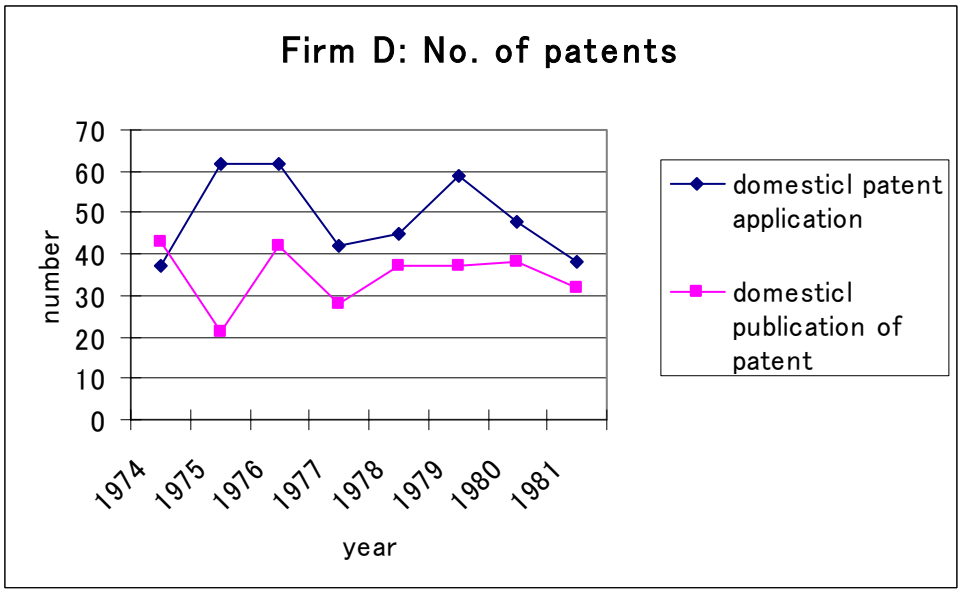


Figure 177: Firm D Number of Patents

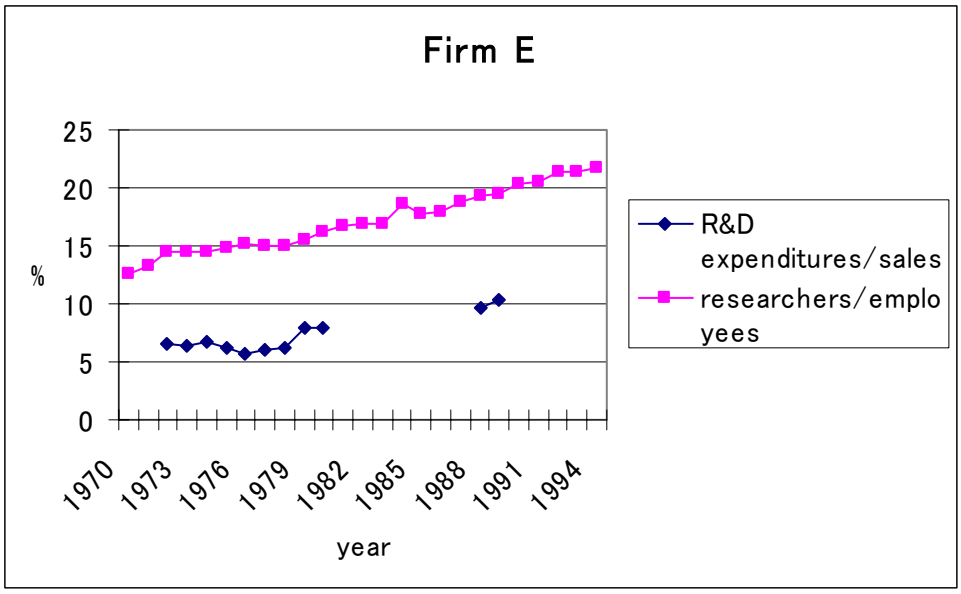


Figure 28: Firm E R&D Expenditure and Employees

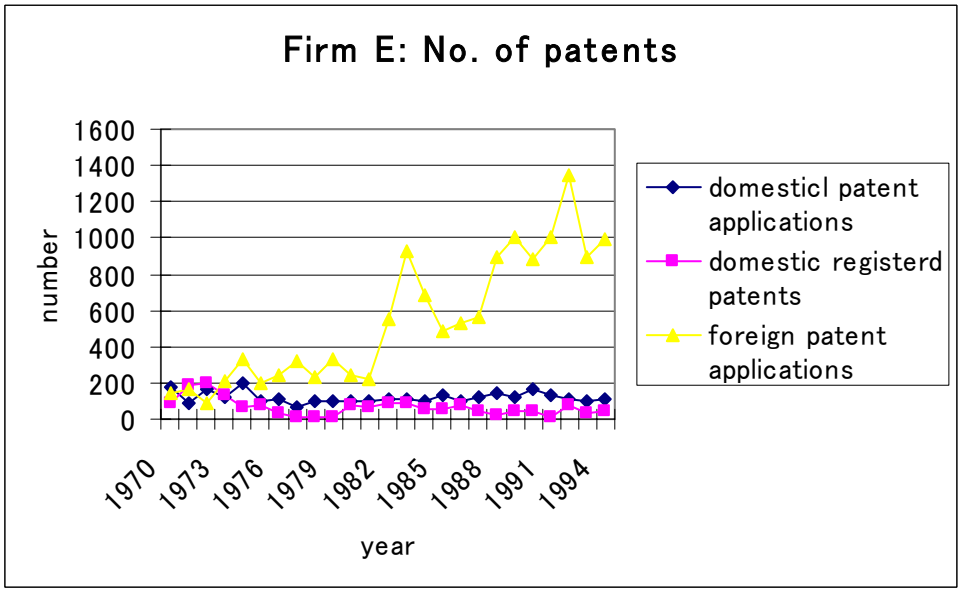


Figure 29: Firm E Number of Patents

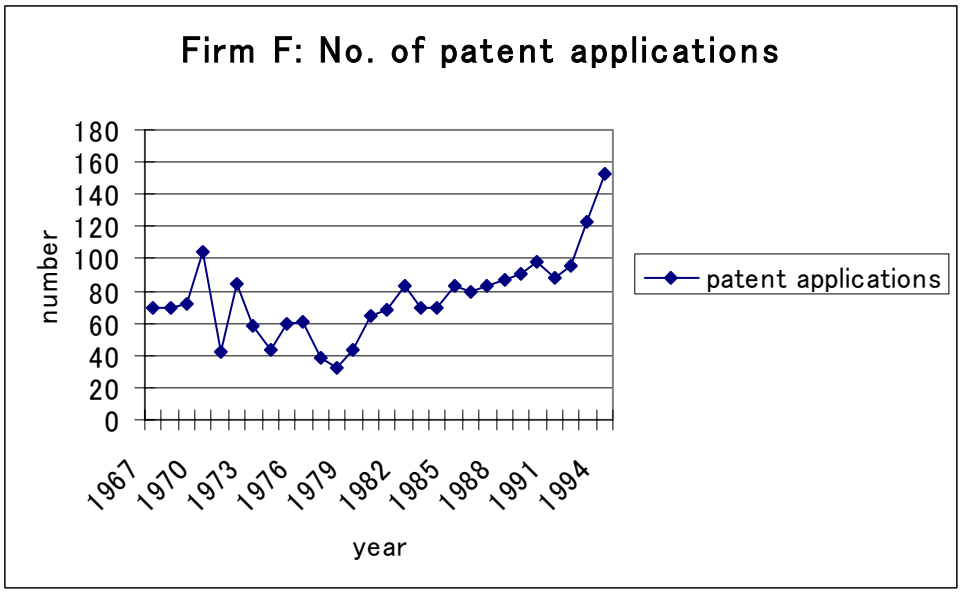


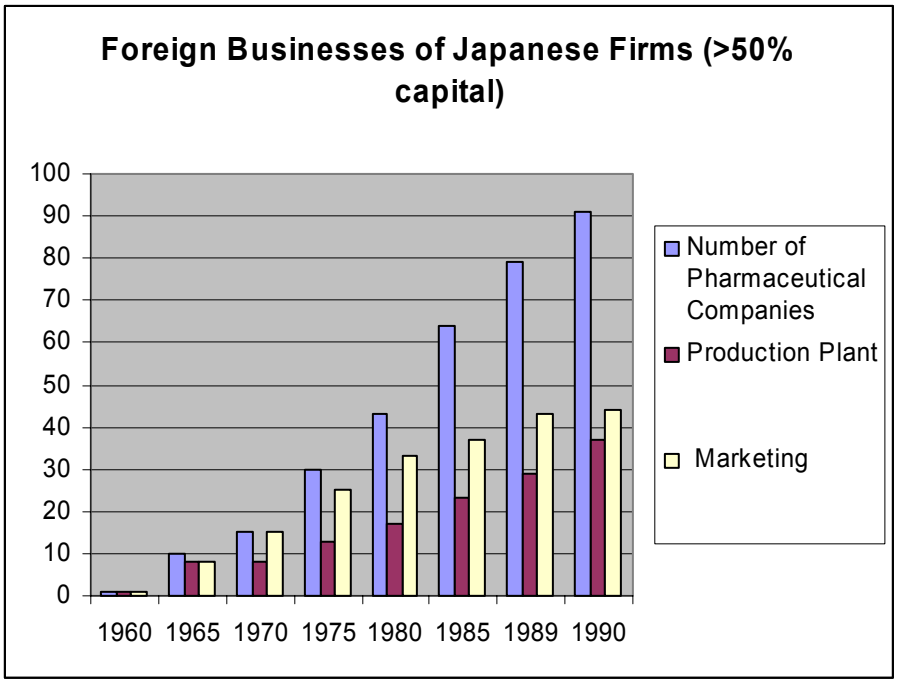
Figure 30: Firm F Number of Patents

4. Relationship to International Market

4.1 Foreign Markets

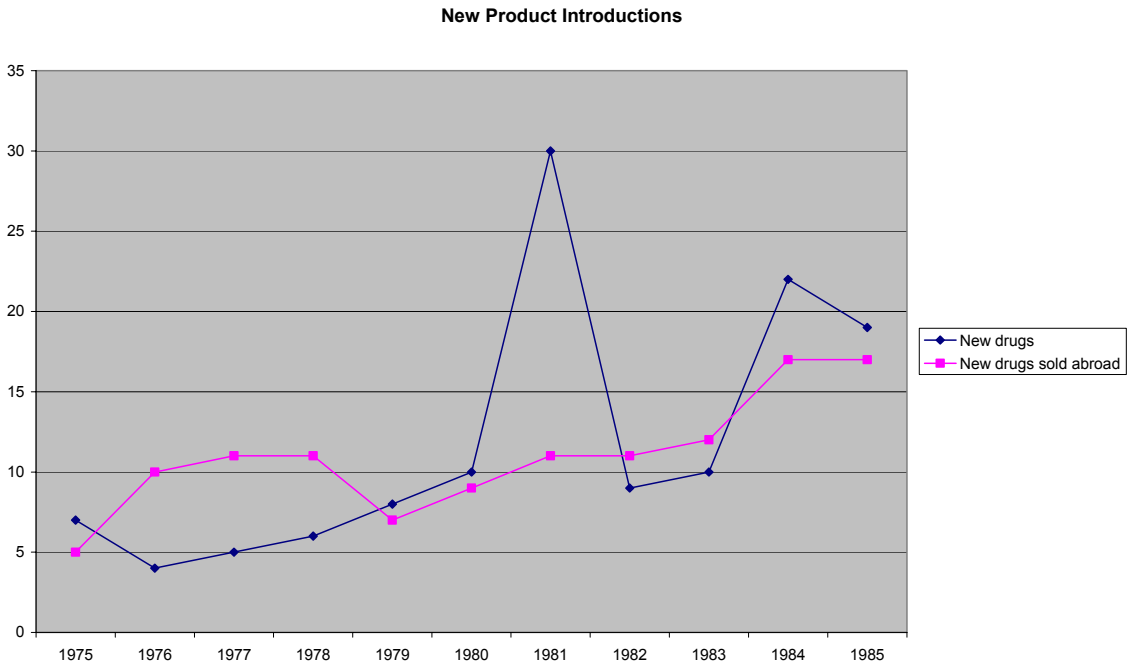
There is evidence that Japanese firms are producing products that are competitive on the international market. In 1972 there were no Japanese firms in the top 20 firms according to sales. In 2002, there was one (Takeda) in the top 20 at number 15. Japanese firms also occupied 21-23rd places. This fact has often been cited as evidence of Japanese pharmaceutical firms becoming more competitive. In this section, we look at the matter for years immediately following introduction and in more detail.

Growth in sales could be attributed simply to expansion of the size of the Japanese domestic market relative to the international market. But the growth in sales seems to be from greater penetration of the international market (Figure 31 "Foreign Businesses of Japanese Firms". The numbers include pharmaceutical raw materials, medical devices and tools, food supplements businesses and research facilities.). In 1975 there were only 30 foreign subsidiaries of more than 50% ownership. In 1995, there were 146 such subsidiaries.



Source: Yano Research Institute (JPMA Website)

Figure 31: Foreign Businesses of Japanese Firms

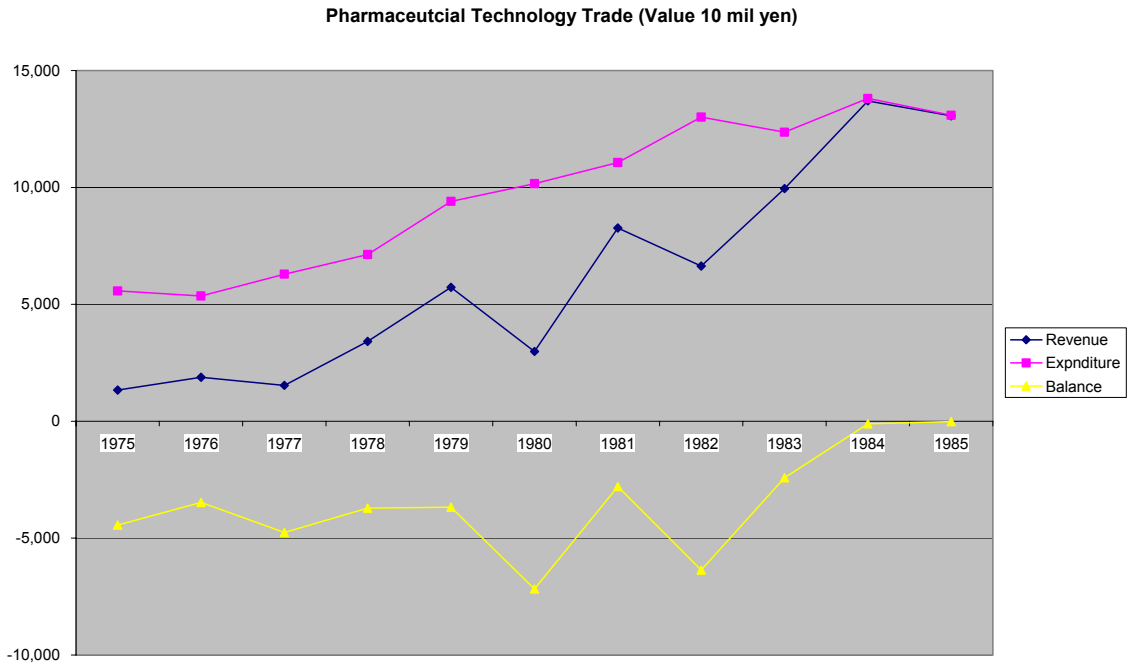


Source: JPMA Data Book 1987

Figure 32: New Product Introductions

4.2 Technology Trade

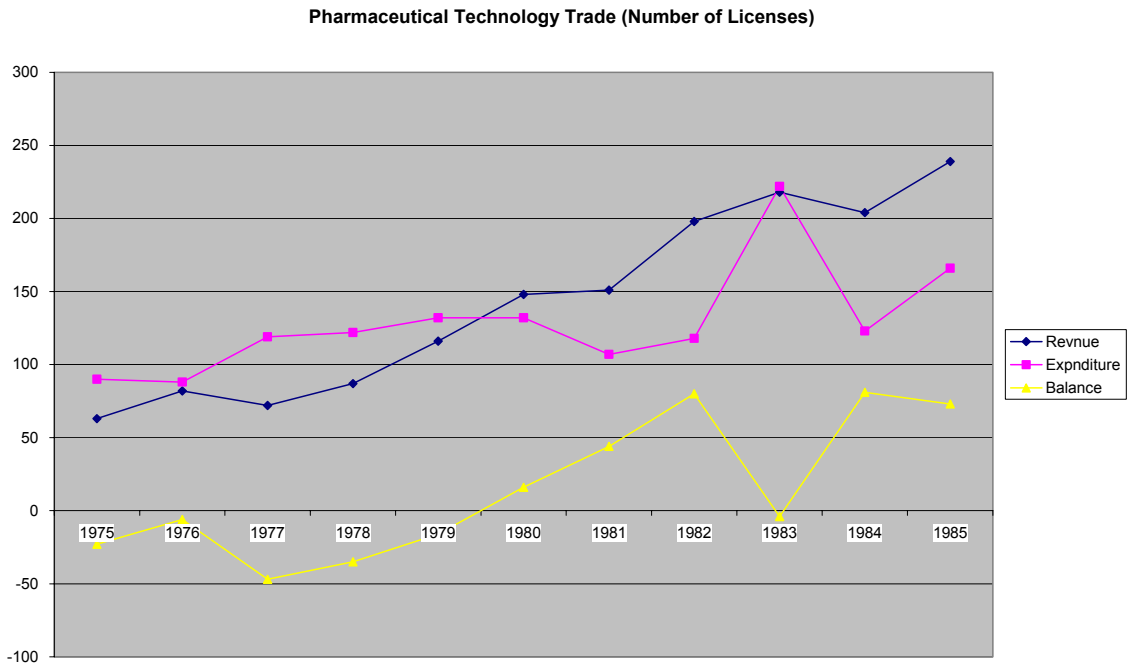
Revenue in Figures 33-37 refers to revenue from technology exports and expenditure is payment for imports. Both values of imports and exports were on an increasing trend, but always in deficit until 1984. The following figures show import and export of pharmaceutical technologies. We refer to them as "licenses" although they are not restricted to production under licenses. Selling production know-how would be included in technology trade.



Source: JPMA Data Book 1987

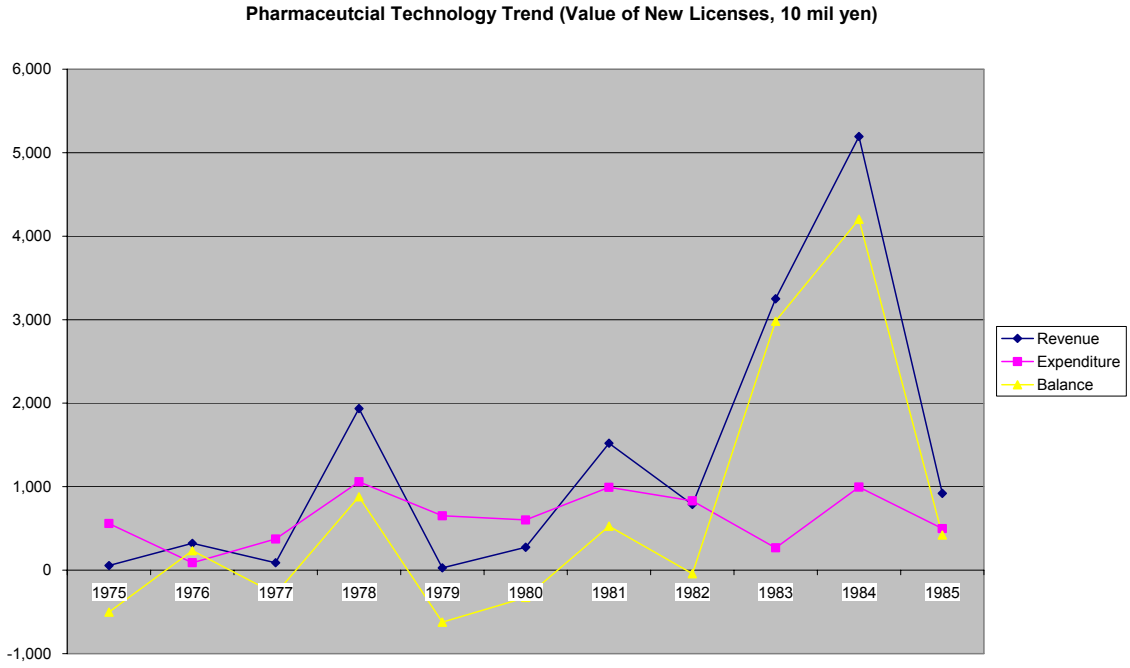
Figure 33: Pharmaceutical Technology Trade (Value 10 Mil yen)

Technology trade in terms of value was in deficit for years after product patent introduction. Number of licenses (as noted before, not only production under license but includes other technology transfers), were more balanced. This means the imported technologies are on the average more valuable than exported technologies. The change in balance of trade in value changed because the new technologies exported were significantly more valuable than those imported. The balance of trade of new technologies narrowed and became balanced after the introduction of product patents. Both number and values of new exports is greater than new imports. The average value of newly exported licenses is significantly larger than those imported. This suggests that the Japanese technology level (value) lagged those of the world market prior to introduction of product patents but the level improved significantly after the introduction.



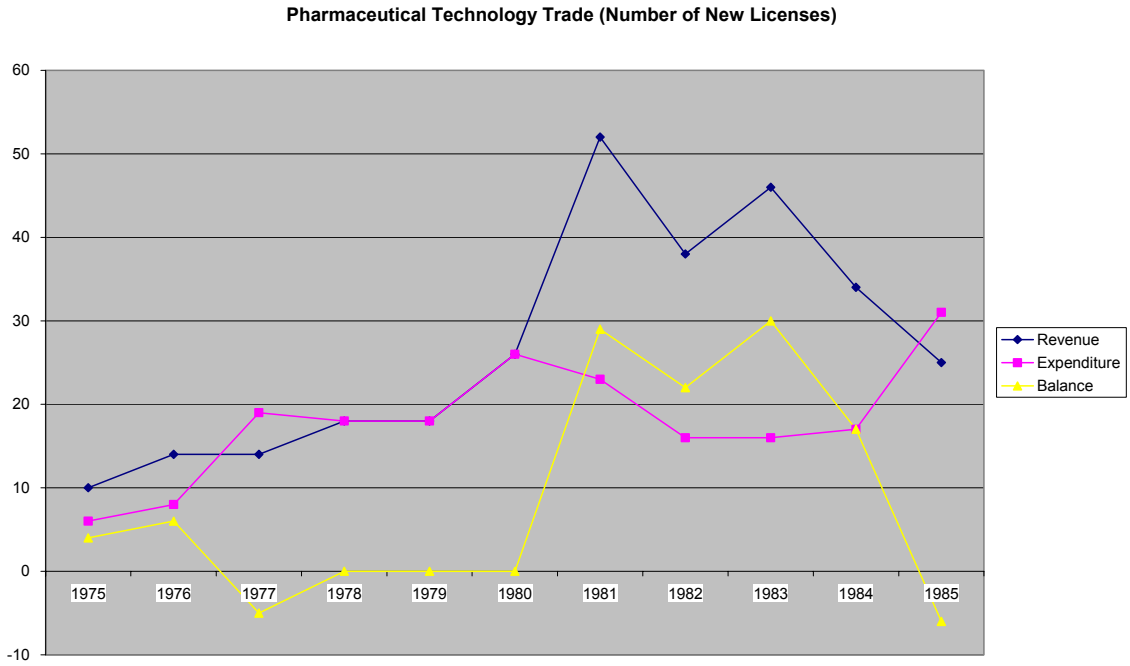
Source: JPMA Data Book 1987

Figure 34: Pharmaceutical Technology Trade (Number of Licenses)



Source: JPMA Data Book 1987

Figure 35: Pharmaceutical Technology Trade (Value of New Licenses, 10 mil yen)



Source: JPMA Data Book 1987

Figure 186: Pharmaceutical Technology Trade (Number of New Licenses)

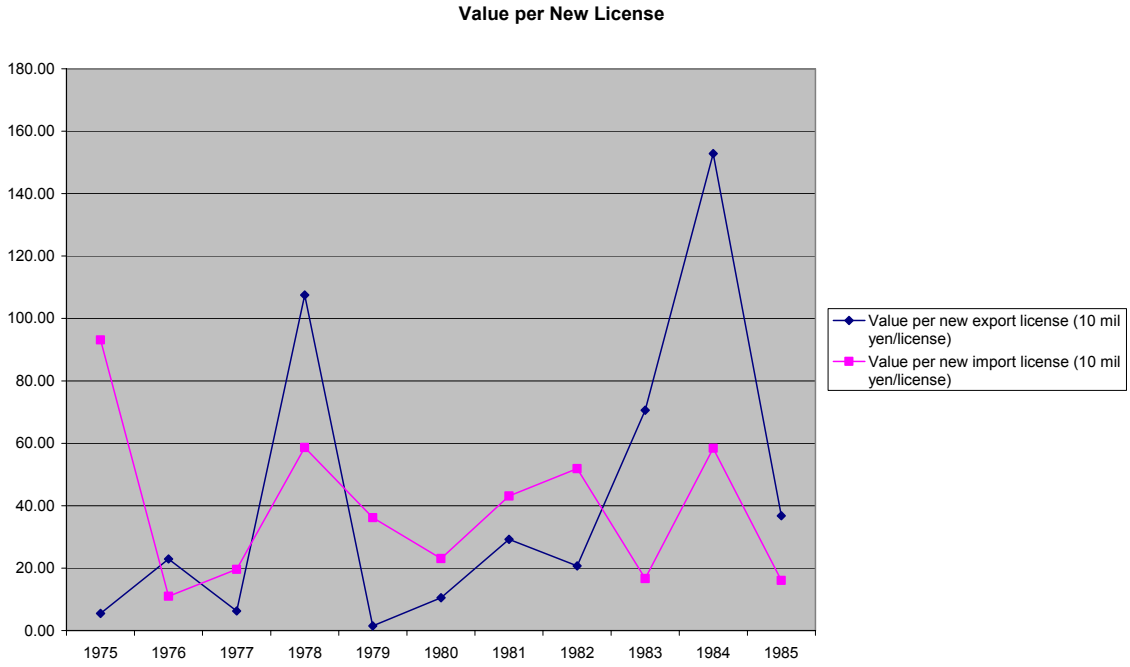
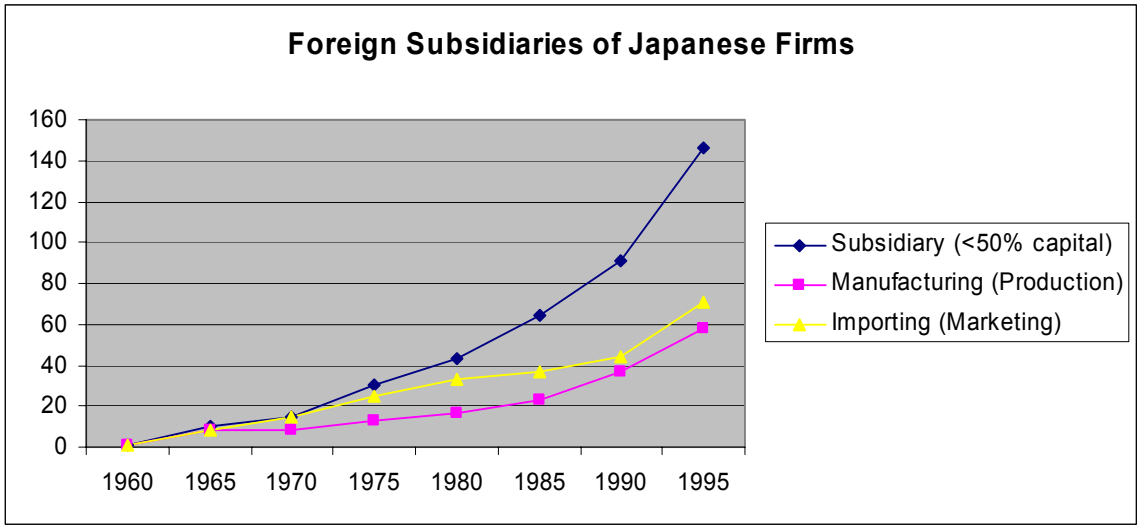


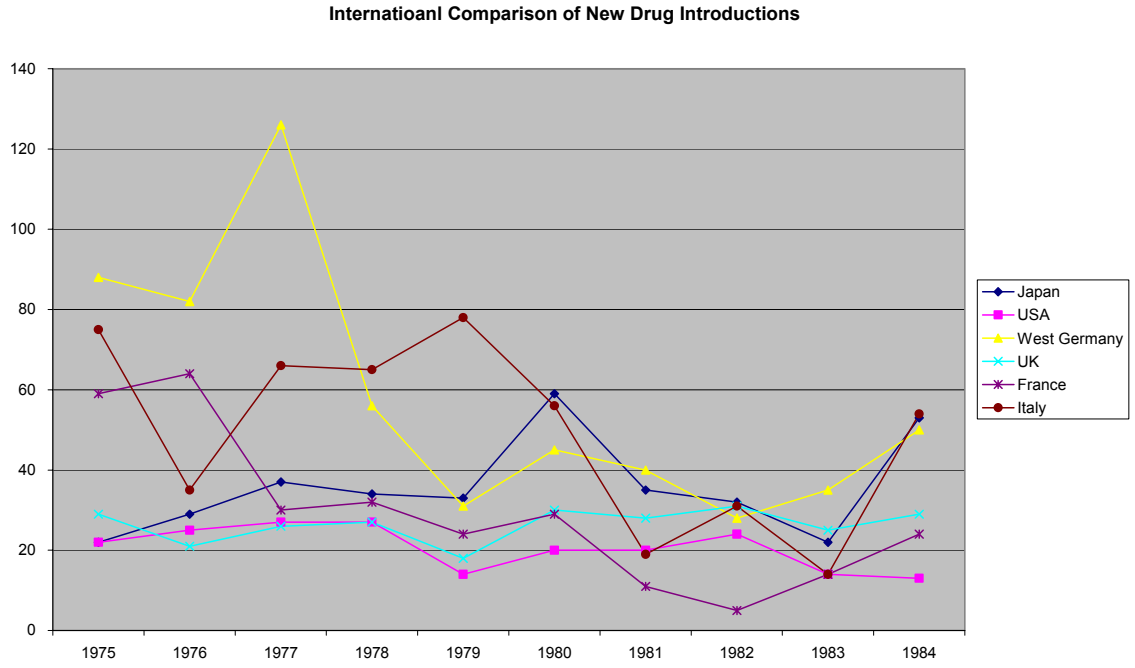
Figure 197: Value per New License

While increasing technology exports, Japanese firms have also made direct foreign investments abroad. (Figure 38). We see that there was a significant increase of marketing and production facilities in late 1970s and in 1980s. This could mean that Japan started to develop products that were more competitive on the international market, making such investments worthwhile.



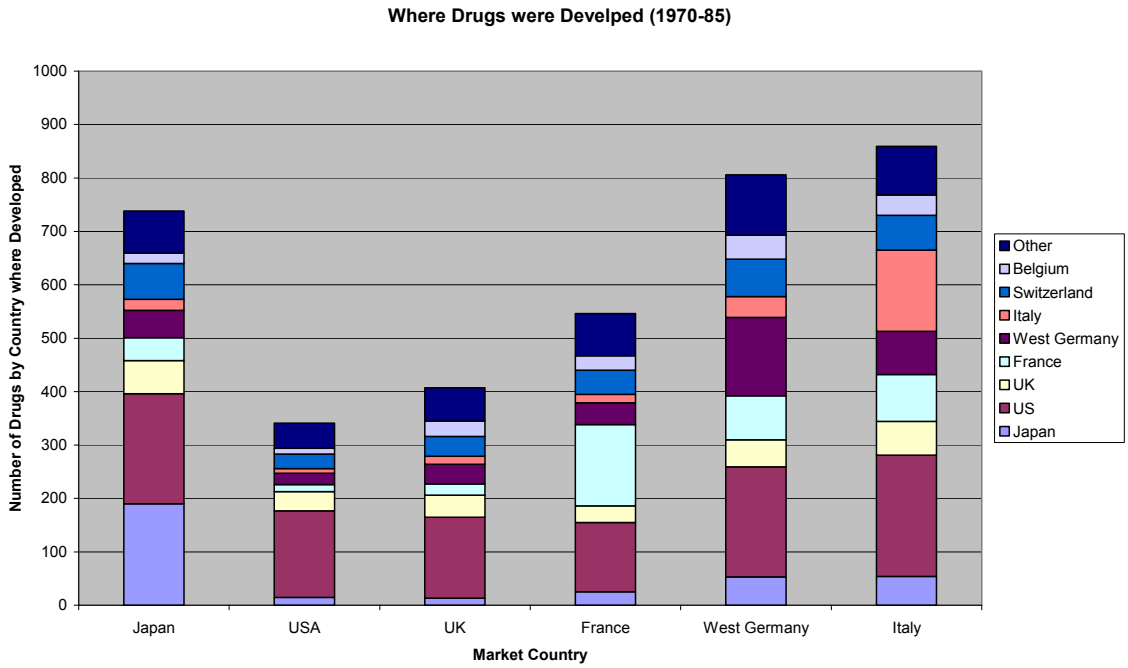
Source: JPMA Data Book 1987

Figure 208: Foreign Subsidiaries of Japanese Firms



Source: JPMA Data Book 1987

Figure 39: International Comparison of New Drug Introductions



Source: JPMA Data Book 1987

Figure 40: Where Drugs were Developed

Figure 39 "International Comparison of New Drug Introductions" shows that Japan's introduction of new drugs increased slightly after introduction of new drugs. From a country with relatively few new introductions, it became more comparable with other nations after the introduction. Interestingly, the number of new drug introductions in different countries converged in the 1980s. Notice the number in West Germany was much larger than other countries in 1975, the number dropped and has converged to be level similar with other countries.

Figure 40 "Where Drugs were Developed" shows that 25% of drugs available in Japan were developed in Japan. This is a very high domestic origin with exception of USA and France. While the number of drugs of U.S. origin that are available in U.S. itself is similar or less than what is available in other countries, number of drugs developed in Japan and available elsewhere is very small. Japan (as well as France) has a disproportionate preference to drugs developed domestically.

5. Analysis and Conclusion

Intellectual property achieves dynamic efficient allocation of scare resources by introducing a short run inefficiency into the economy. The short run dead weight loss can be tolerated only if there are benefits in the long run. Introduction of product patents strengthens protection and changes the balance of short run loss and long run benefit. However there is a slight difference between introducing new protection and simply strengthening existing technology protection such as widening breadth. When patent protection is simply strengthened, newer technologies must overcome a greater inventive step to be patentable. In case of introduction of product patents, new processes are still protected, with the same level of inventive step. Thus there is short run loss from forgone introduction of new products but the legal opportunities for cost reduction have not been compromised. This difference is important in understanding the data.

In case of Japan, retail prices are set by the MHLW and are independent of market structure. Thus consumers do not immediately lose from stronger protection. Firm profit is determined by the wholesale market and the introduction of product patents could have restricted competition in the wholesale market in the short run. But there is no evidence of decline in availability of products. We observed the availability of OTC was not affected (and prices have been on a decline) after the introduction of patent laws. This could be because marginal productivity of product innovation was sufficiently high so that long run benefit of protection was realized very quickly. There was however a mild reorganization of the industry. Concentration at the very top increased, but concentration of top 10 firms declined. The increase in concentration may be the result of higher entry barrier due to greater inventive step of patentability. Also, because technological opportunities for cost reduction had been declining for existing drugs, it could have been only the largest firms that could continue to make use of the process patent.

One notable pro-competitive phenomenon is that entry of foreign firms into Japan increased after the introduction. This was aided by capital liberalization which started before the patent law change. We infer that increase of research facilities was motivated by the new law. Foreign firms contributed to competition in the short run but also helped increase the number of new products available in Japan in the long run.

In considering the long run benefit, we again need to take into account the fact that introduction of product patents is different from simple strengthening. The long run benefit may not just be an increase in R&D activity. In fact we observed a qualitative change in R&D. After the introduction of the law, number of process patents decreased significantly but the total number of pharmaceutical patents increased slightly due to the new product patents. Firms increased both the absolute number of R&D expenditure and as proportion of sales increased around 1976 and continued to increase. Firms also increased the proportion of research employees.

These changes lead us to conclude that *quality* or *type* of pharmaceutical innovation changed as result of introduction of the law. This resulted in change in quality of innovation: from process to product and modification to application. As the law was

intended, firms reallocated resources from finding new ways of producing an existing drug to finding new products. This qualitative change is also reflected in the shift if the trading pattern of pharmaceutical technologies. The quality became more in line with the imported technologies suggesting Japan caught up.

The change in innovation output was achieved by a change in the innovation regime from basic to applied research. The long run benefit of such changes would take decades to materialize. Japan continues to increase foreign direct investments for marketing and production of products developed in Japan. Both number of Japanese subsidiaries abroad and foreign subsidiaries in Japan increased. However both shares are small suggesting the Japanese market continues to be somewhat separated from the rest of the world.

Implications to Developing Countries

The Japanese experience shows that the analyses of pharmaceuticals as part of health policy and pharmaceuticals as part of technology or industrial policy need to be separated. In case of Japan, merits of product patents were not debated as part of health policy. This may be due to the fact that prices are regulated and other medical services readily available. Alternative to a drug at a particular price is not only the same drug at another price, but a similar drug or a different medical treatment. It is true that drugs that can be administered with minimum professional advice are probably very cost effective and should be considered essential. But perhaps this is not the case for all drugs.

Japan focused on the benefits of product patents form industry policy point. It was felt that the benefit from protecting only process innovations had been exhausted and there was a need for change of direction. It is important to note that debate was actually on changing the nature of protection and not simply strengthening. And the data show that implication was just that. There was some short run inefficiency from introducing new protection, as expected.

In the current debate in developed countries, it is important to separate the industrial policy from the public health debate. In countries such as India where a certain level of technology has been achieved, this aspect is very important as was in Japan in the 1970s. And it is important to note that the long run benefit may not only be from more innovation but a change in quality of innovation. It may be that most technological opportunities that are meaningful under current scope of protection have already been exhausted. More productive and internationally competitive industry will benefit a country in the long run and eventually increase resources available for public health.

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