Staff Paper

INTELLECTUAL PROPERTY IN BIOTECHNOLOGY IN THE UNITED STATE AND JAPAN

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ABSTRACT

Plant biotechnology R&D is significantly different in the U.S. and Japan. One makes greater use of genetic engineering, and the other of tissue culture. This has affected the structure of the industry and firm entry pattern. Much of the difference can be attributed to differences in intellectual property rules.

INTRODUCTION

The pattern of biotechnology R&D is significantly different in the U.S. and Japan. The U.S. had a rapid growth of firms entering into plant biotechnology[1] from 1978 to 1981 and none after 1985. Japan on the other hand has had a relatively stable and continuing large number of new entries from 1980 to 1989. The breeding technologies used in the two countries also differ. Some of the difference in this pattern can reasonably be attributed to differences in science policy and intellectual property rights in the two countries.

The impact of institutional change is not easy to prove. This paper will briefly review what is known and then examines how a U.S. and Japanese comparison can extend our knowledge. With respect to protection of intellectual property rights, it is known that the importance of patent protection differs among industries. Empirical studies show that in the pharmaceutical and chemical industry a product patent is effective and necessary for private investment in R&D (Mansfield 1986, Levin et al 1987). On the other hand, in plant breeding, plant variety protection of phenotype is not so effective due to narrow product space and high exclusion cost (Schmid 1985). However, since 1985, plants have been patentable in the U.S. under the general patent act, or utility patent, which means that a product patent of a plant can make a broad claim based on the

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1 Plant biotechnology includes tissue culture, cell fusion, genetic engineering and so on. Genetic engineering, or recombinant DNA technology is a part of plant biotechnology. The distinction between biotechnology and genetic engineering is important in this paper.

"doctrine of equivalents". However, it is little known what kind of consequences the plant patent has had. In this paper, effects of the plant patent rule on plant biotechnology R&D will be examined empirically.

Effects of the U.S. introduction of plant patents in 1985 may be estimated by a comparison of R&D investment before and after 1985. However, it is difficult to eliminate the effect of general development of biotechnology during 80's. For example, before 1985 only tobacco, tomato and petunia were successfully transformed with a foreign gene, but after 1985 most major crops, such as corn, rice and soybeans have become targets of recombinant DNA technology. The effect of plant patent rules on this technological development is not clear. Therefore, instead of doing a time series analysis, an international comparison between the U.S. and Japan is carried out, because Japan has not had plant patent rights during the 80's. The assumptions here are that both countries can have the same scientific knowledge and that the general ability to utilize it does not differ. There are institutional differences in the two countries other than the patent system with regard to plant biotechnology, such as regulations on recombinant DNA research, on environmental release of genetically engineered plants and on food safety. But these can be considered to be the results of the differences in R&D paths of the two countries and they do not seem logically related to the observed differences caused by the difference in patent systems.

It is too early to study the effect of alternative intellectual property rights on agricultural production since there are few plant biotechnology products to date. However, R&D is in progress and differences in R&D are developing. Therefore such an empirical study is important for designing science and technology policy as well as industrial policy. In addition to that, international comparison of patent system is also important from the trade-related aspect.

Plant Patent Rules

With respect to plant variety protection, there are three different laws in the U.S.: Plant Patent Act of 1930 (PPA), Plant Variety Protection Act of 1970 (PVPA) and plant patent under the general

Patent Act (PA). Impacts of PPA and PVPA have been well studied recently (Bulter and Marion 1985, Stallman 1987, Knudson and Pray 1991)

Table 1. Comparison of Plant Variety Protections

	U.S. PPA	U.S. PVPA	U.S. PA	Japan SL	Japan PL
Subject Matter	Asexually propagated plants	Sexually propagated plants	Human-made living things	Plants that are listed	Human-made living things
Exception	Tuber, Bacteria, Wild plants	Bacteria, Fungi, F1 hybrid	No	Forestry trees	No
Criteria	Distinct, New	Distinct, Uniform, Stable	Novel, Useful, Non-obvious	Distinct, Uniform, Stable	Novel, Useful, Non-obvious
Descrip tion	Incomplete	Procedure, Genealogy	Should be complete	Procedure, Genealogy	Should be complete
Official Field Trial	No	No	No	Required case by case	No
Exemption	Research use	Farmer, Research use	Non-commercial research use	Farmer, Research use	Non-commercial research use
Protection	One variety, Whole plant	One variety, Whole plant	Group of varieties with common traits Whole plant and parts	One variety, Whole plant	Group of varieties with common traits Whole plant and parts
Protection Period	17 years	18 years	17 years	15 years or 17 years (perennial)	15 years

SOURCE: Author's compilation from numerous sources.

Comparison of the three laws and effect of the difference in terms of intellectual property rights are also available (Schmid 1985, Stallman and Schmid 1987, Buttel and Belsky 1988, U.S. Congress, Office of Technology Assessment 1989). In Japan, new plant varieties are protected only under the Seed Law (SL) revised in 1978. SL is equivalent to the U.S. PPA and PVPA., because all of them are supposed to be consistent with the rule of International Union for the Protection of New

Varieties of Plants (UPOV). There is no plant patent under the general Patent Law issued yet in Japan[2] The differences of those rules are summarized in Table 1. This paper is to compare the U.S. PA with Japan's SL. Although there are a lot of differences between them, the most important one is in breadth of patent, or product space (difference between existing and new variety). The difference means that to qualify for a plant patent under the U.S. PA requires more novelty and more non-obviousness than a plant variety protected under Japan's SL., whose protection is variety specific. Effectiveness of the product space in eliminating competing substitutes also has to be considered. It is given by interaction of institutions and attributes of the product. As is shown in the table, Japan's SL (U.S. PVPA also) allows scientists to use a patented plant and any of its parts for commercial research (research exemption), such as breeding, and also allows farmers to keep seeds for cropping (farmer exemption)[3]. Both are prohibited in the U.S. PA. As a result, a patent under the U.S. PA can in principle gain a larger return.

Effectiveness of a patent is determined by the exclusion cost, which is an attribute of the patented good (Schmid 1987). One problem of patenting living organisms is that they can reproduce themselves. As a result making a copy is easy and to distinguish unauthorized copies from the authorized one is hard and costly. Therefore, legal protection of a plant variety is generally

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2 This does not necessarily mean that the Japan's Patent Law excludes plants from patentable subject matters. As a matter of fact plant patents were issued in 1985 in Japan to a pharmaceutical firm, Nihon Shinyaku (No. 1,281,544 and No. 1,282,545). But this has been considered to be an exceptional case, because those patents had been applied in 1977, which was before the revised Seed Law was enacted. UPOV) prohibits double protection, where a variety is protected under more than two rules. In addition, the difficulty of description of an invention of a plant has made the Japan Patent Office (JPO) be unwilling to issue a plant patent (NBT, Feb. 26, 1990). As a result, no plant patent other than the exceptional ones has been issued in Japan. However, because biotechnology may be enough to describe an invention as much as JPO requires, and because in the UPOV meeting in March 1991, they decided to revise the rule to allow double protection (Egashira 1991), plant patents under the general Patent Law will be issued in Japan. However, even if plant is patentable in Japan product space will still be narrow.

3 In a meeting held in March 1991, UPOV members countries agreed to discard those two exemptions. If implemented domestic rules corresponding to UPOV rule, such as the U.S. PPA, PVPA and Japan's SL will have to be changed. This change implies that the legal product space of those plant variety protections will be widened. However, in comparison with the U.S. general patent, the product space, will not be as wide. For example, PA requires utility, but PPA, PVPA and SL do not. Therefore, the difference in product space will remain, although it will be smaller.

ineffective. However, genetic engineering can lower the exclusion cost and make the patent effective. For example, unstability of genetically engineered plants will be well protected like F_1 hybrid seeds and a restriction fragment length polymorphism (it is often called RFLP, which is a kind of I.D. based on the DNA sequences) map will lower the cost to detect copies and also will reduce the investment period.

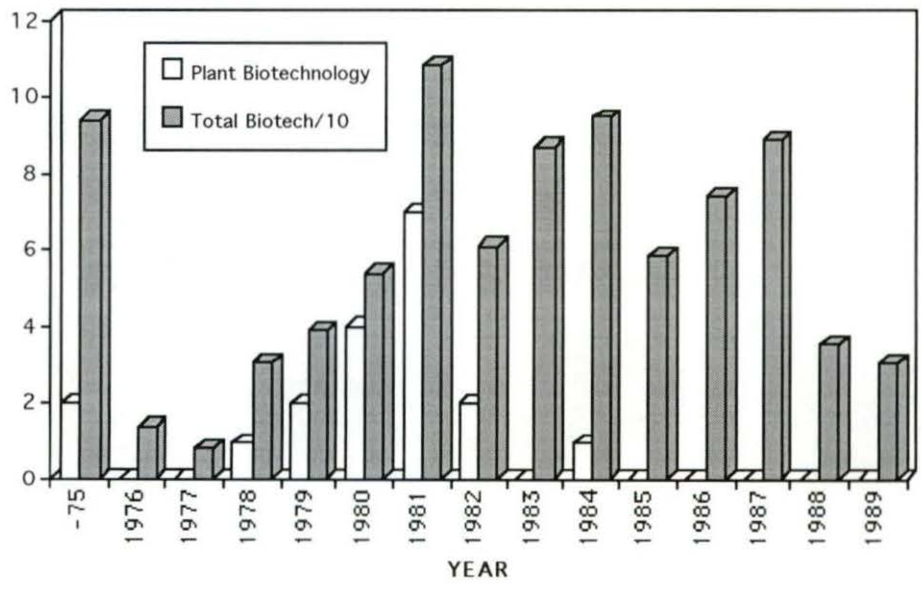
Using genetic engineering as a research tool, an unknown substance that is useful for plant breeding can be taken from living organisms. The substance and its gene can be patented under a general patent (PA). Even if it is not patentable, the use of the product may be patentable. Therefore, the inventor can claim a patent that covers plants transformed with the patented gene. Unlike variety specific protection, such as Japan's SL, PA gives a broad product space based on the doctrine of equivalence, which means that the plant patent covers all possible plant varieties transformed with the patented gene even if they are not produced yet. Typical example is Monsanto's patent for herbicide-resistant (glyphosate-resistant) plants This patent is considered to cover all plants transformed with glyphosate-resistant gene, even though they may have succeeded to produce it only with tobacco and tomato when the application was submitted.

In the case of genetically engineered plants, the foreign gene is directly responsible for utility that is created. This technological feature makes it possible to claim a broad product space, and besides, it makes it easy to distinguish the patented plants from others. In other words, the boundary of the product space is clear. Furthermore, genetic engineering may make it easy to exclude unauthorized copies because the transformed plants may be genetically unstable as are F_1 hybrids and/or it may make it possible to detect unauthorized use of patented plants as a breeding material, because the specific form of the foreign gene and the site on the genome where the gene is inserted can be markers. In short, genetic engineering has some advantages to protect invented plants, because of possible broad product space and lower exclusion cost.

EMPIRICAL EVIDENCE

Twenty-six firms are identified as doing or having done plant biotechnology in the U.S., including established large firms, seed companies and new biotech ventures. Since some of the biotech ventures have been acquired, twenty-six is not the actual number of existing plant biotechnology firms. Fig.1 shows how many U.S. firms started R&D of plant biotechnology in each year in comparison with number of firms that were established in each year in all biotechnology fields. Fig.2 is the Japanese case. Since there are only a few biotechnology ventures in Japan, most entrants were established firms. Therefore, unlike Fig.1, both "Plant Biotechnology" and "All Biotech Fields" represent the number of entries in each year.

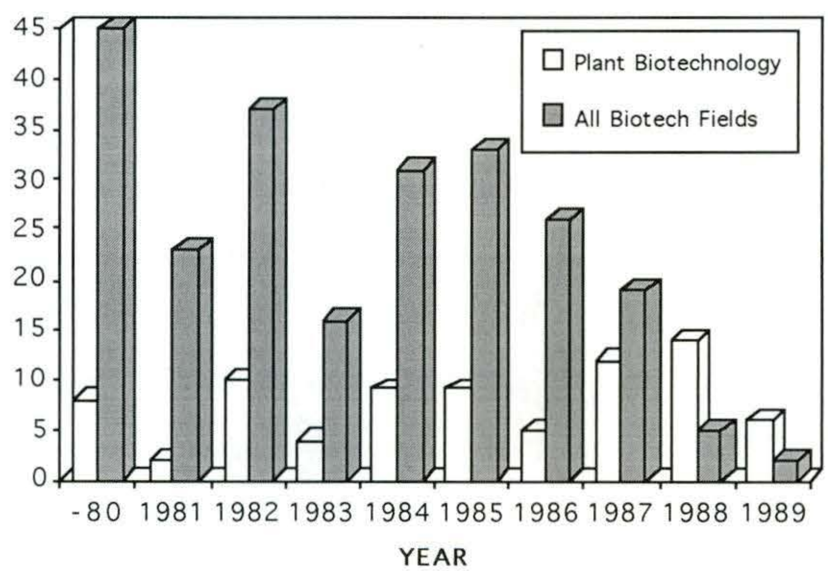
Fig.1 Number of Entries into Plant Biotechnology in Comparison with Total Foundings of Biotech Venture in the U.S.A.



NOTE: "Plant Biotechnology" is the number of entries, that is, if an established large firm, such as Monsanto, started R&D in plant biotechnology in 1979, it is counted in 1979. On the other hand, "Total Biotech/10" is a number of firms that were founded in each year, that is, since Monsanto was established before 1975, it is counted in -75. Therefore, the latter category contains only new biotech ventures in all fields of biotechnology, not only plant. In order to show the two data in one figure, the total number of foundings of biotechnology firms is divided by ten.
SOURCE: Author's compilation from numerous sources.

The time series patterns of entry in plant biotechnology of both countries are different. In the U.S., the number of entries is limited and concentrates around 1980-81. This means that most entrants were motivated by the potential of genetic engineering. Neither the patentability of plants given by *Ex parte Hibberd* (1985) nor technological development of actual plant genetic engineering were yet available. On the other hand, in Japan entries are more constant and the number of entries is larger than in the U.S.A. This may imply that there are more structural barriers to enter in the U.S. However, we have to see what happened inside the industry.

Fig.2 Number of Entries into Plant Biotechnology in Comparison with Number of Entries into Biotechnology of All Fields in Japan



NOTE: "Plant Biotechnology" is the number of entries in plant biotechnology in each year. "All Biotech Fields" is the number of entries in biotechnology regardless of fields. In Japan most of entrants are established firms. For example, Sapporo Breweries has started biotechnology in fermentation related field before 1980, so it is counted as "All Biotech Fields" in -80, and it has begun plant biotechnology since 1988, it is counted as "Plant Biotechnology" in 1988. This is a case that a firm is counted in different years, which makes the phenomenon in 1988 and 1989 when entries in "Plant Biotechnology" is more than entries in "All Biotech Fields". If a firm starts with plant biotechnology, it is counted in the same year.
SOURCE: Author's compilation from numerous source

In the U.S., of the twenty-six plant biotechnology firms started , only eighteen firms were remaining as of August, 1991. Others were absorbed by large firms or merged. Among the eighteen firms, fifteen have been involved in environmental release experiments of genetically engineered plants. In 1986 three firms carried out environmental release experiments independently for the first time. For the first two years, experiments were limited to tobacco and tomato for technical reasons, but today almost all the major crops can be transformed and some of them are under field trial. The number of environmental release experiments has been increasing rapidly every year, 3 in 1986, 200 in 1989 and 400 in 1991 (NBT, June 3, 1991). In accordance with this trend, three seed companies, Pioneer Hi-Bred, Asgrow Seed and Northrup King finally started environmental release experiment of genetically engineered plants[4]. This was the first time seed companies carried out such experiments, which implies that genetic engineering has become a more standard technique in breeding. On the other hand, tissue-culture-oriented plant biotechnology firms have disappeared recently[5] in contrast to the trend in Japan.

The time series pattern of entry into plant biotechnology in Japan is quite different from that of the U.S. Most of the entrants, whether in plants or other fields, were established firms. Though thirty-two bio-ventures have been established in Japan since 1986 as of July 1991 (eight of them are using plant biotechnology), they are excluded from the number because they are intra or inter-industry joint-ventures partly financed by quasi-governmental foundations. Seeing what

4 Actually Pioneer Hi-Bred did an experiment of genetically engineered alfalfa in 1989, but the alfalfa was supplied by Agrigenetics. In 1990 , the company tried genetically engineered sunflower which was made in in-house research. On the other hand, in 1990 Asgrow Seed tried genetically engineered cantaloupe and squash, and Northrup King tried genetically engineered cotton. Their initial target crops are more realistic than that of early days.

5 Examples are as follows. In 1987, Dow Chemical purchased United Agriseeds, a bio-venture specializing in corn breeding via tissue culture. In 1988, DNA Plant Science, a bio-venture specializing in breeding via tissue culture merged with Advanced Genetic Science, a bio-venture specializing in genetic engineering of agricultural bacteria. In 1989, Plant Genetics, a bio-venture specializing in tissue culture was purchased by Calgene, a bio-venture specializing in plant genetic engineering, Sungene Technology, a bio-venture specializing in breeding via tissue culture was purchased by Lubrizol, Molecular Genetics sold its plant biotechnology section where corn breeding via tissue culture was carried out to Biotechnica International, a bio-venture that has experience in genetic engineering.

kind of firms entered and what kind of technology they used, it appears that the entrants before 1980 were mostly seed and/or seedling companies that used tissue culture to multiply flowers. and that the entrants around 1982 were relatively large companies mainly from food and chemical industries. Their entries coincide with the biotechnology boom and also may have been affected by the 1978 revised Seed Law. When Japanese firms were seeking new fields of investment because of slow growth of their main business, the biotechnology boom in the U.S. caught their attention. As a result, they invested not only in plant biotechnology, but also in pharmaceuticals. However, though they used genetic engineering in R&D of pharmaceuticals, they rarely used it in plants. Rather they used tissue culture instead. Entries increased in 1987 and 1988. This is due to the so-called "high yen recession". As a result of Plaza agreement in 1985, the value of yen against dollar had almost doubled in two years and Japan had a recession. Steel, shipbuilding and mining industries had the most severe damage and a large surplus of labor. Those companies invested in every possible field to absorb the labor in the short run and to restructure and diversify their business in the long run. Plant biotechnology was one of them. In this case also, the plant biotechnology means multiplication and breeding using tissue culture, because it requires less capital and more labor, and they can expect an immediate return. In brief, there are a lot of entrants in plant biotechnology in Japan, but most of them use tissue culture to multiply and/or breed plants. Among seventy-nine entrants, only twelve are using genetic engineering as of August, 1991.

Differences in biotechnology intellectual property rights helps explain the different pattern of development in the U.S. and Japan. In the U.S.A., plants are patentable under PA, which means that broad product space is possible. Genetic engineering is a way to obtain a broad product space based on the "doctrine of equivalence" and makes the patent more effective. This makes genetic engineering in the U.S. more attractive, even though R&D cost is high. The availability of plant patents in the U.S. increases the importance of genetic engineering compared with other breeding techniques. The cost of new firms to enter plant genetic engineering is now high and as a result there have been no new entrants recently. On the other hand, in Japan there is no broad patent equivalent to that in the U.S. Because genetic engineering is a way to make a broad claim, it is not as useful in Japan and other breeding methods are more attractive. These other methods are cheaper than genetic engineering, and as a result, it is easy to enter R&D of plant biotechnology in Japan.

The weak plant variety protection in Japan has made firms try to protect varieties without using patents. Typical cases can be observed in rice where varieties are protected by consumer brands Rice has been the most important food and its distribution and price has been controlled by the government. However, due to a large surplus of production, deregulation began in 1970. Today, under the surplus and threat of import, producers are competing to survive by maintaining consumers' preference for domestic, premium rice. Since a premium rice is distinguished by the variety and the place where it is produced, prefectures are competing to produce a new variety.

"Kirara 397" is the name of the new rice variety introduced by Hokkaido prefecture in 1988. The prefectural government and the prefectural federation of agricultural cooperative are collaborating on production of the new variety and marketing it as a new brand They decided the name, designed packages to attract consumers, and did sales promotions at retail stores, based on a proposal of an advertising company. So far it is said that their effort to make consumers recognize the new product is successful (Tsuzi 1991). As a result, according to Japan's Ministry of Agriculture, Forestry and Fishery, the planted acreage of "Kirara 397" was 2.5% of total rice acreage in 1990, which is the eighth largest and 3.0% in 1991, which is the fifth largest. The successful breeding of a new rice variety has an important role in this story and the new variety is protected under the Seed Law. However, because of the farmer exemption, it is impossible to prevent unauthorized farmer from planting the new variety. But, since the package design and the brand name are also protected as a trademark, and consequently the unauthorized farmers cannot sell the product as the premium rice. This shows that product differentiation can protect invention without a patent. To accomplish the product differentiation, vertical coordination from production to retail is important. In this case, the coordinator is the prefectural federation of agricultural cooperative.

"Kirara 397" was bred using conventional techniques, but the strategy will be the same in case of biotechnology. In 1990, twenty-three new varieties bred by prefectural agricultural stations were registered under the SL, and four of them were bred using anthen culture, a kind of biotechnology. The anthen culture is an easier version of pollen culture, and reduces the breeding period. In 1990, six private rice varieties were also registered, and two of them were bred using protoplast culture, which promotes induction of variants. These kinds of biotechnology other than genetic engineering are becoming popular recently in both public and private rice breeding to introduce a new variety quickly. Those varieties will also be protected by vertically coordinated product differentiation.

CONCLUSION

It is too early to observe how differences in intellectual property rules in the U.S. and Japan will affect the efficiency of agriculture in the two countries. But it is clear that the different rules are affecting the R&D agenda and breeding methods. The weaker patent laws available in Japan are leading them down a different path.

The results are consistent with theoretical predictions of the effect of different product space (Scotchmer and Green 1990), and potentially similar to that found in other industries where the U.S has led the way in scientific breakthrough while the Japanese lead the way in the market place. In industries with discrete technologies, such as pharmaceutical, the U.S. strong product patent strengthens the industry, while in industries with cumulative technologies, such as consumer electronics, the Japanese weak patent may encourage successive R&D. But agriculture may be a mixed case, which means neither set of rules may be able to promote R&D efficiently.

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