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Institutional Differences in Intellectual Property Rights and Their Consequences on Research and Development of Plant Biotechnology Between the U.S.A. and Japan

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Table of Contents

Chapter 1. Introduction 1
Need for Study 4
International Comparison of Patent System 5
Plant Variety Protection 8

Chapter 2. Economic Theory and Some Empirical Studies on Patent 11
Analysis of Optimal Patent 13
Limits of Patent Theory 17
Some Empirical Studies on Patent 19

Chapter 3. Plant Biotechnology and Intellectual Property Rights 23
Basic Science 25
Applied Science 1 28
Applied Science 2 31
Applied Science 3 34
Conclusion 36

Chapter 4. Plant Variety Protection in the U.S.A. and Japan 37
The U.S. Plant Patent Act of 1930 37
The U.S. Plant Variety Protection Act of 1970 38
The U.S. Plant Act after Diamond v. Chakrabarty Case 40
Japan's Seed Law 44
Japan's Patent Law 46
UPOV is going to change 47
Other Institutions That Affect Plant Breeding in Japan 49

Chapter 5. Other Regulations that Affect R&D of Plant Biotechnology 54
Environmental Release Regulation in the U.S.A. 54
Regulation of Environmental Release in Japan 59
Guidelines or Law ? 63
Food Safety Issue in Japan 65
The U.S. Food Safety Regulation 67
Effects of the Difference Between the U.S.A. and Japan 69

Chapter 6. Inputs of R&D of Plant Biotechnology 72
Entry to Plant Biotechnology in the U.S.A. 73
The Year of the First Environmental Release in the U.S.A. 77
Changing Industrial Structure in the U.S.A. 81
Conclusion of the U.S. Case 83
Entry into Biotechnology of All Fields in Japan 85
Entry into Plant Biotechnology in Japan 88
Effect of Institutions in Japan 92
Conclusion of Japan's Case 95

Chapter 7. Outputs of R&D of Plant biotechnology 98
7-1. The U.S. Plant Patents under the General Patent Act 98
7-2. The U.S. PPA and Japan's Seed Law 105
7-3. The U.S. PVPA and Japan's SL 108
The U.S. PVPA 108
The Trend of Certificate Issuance under PVPA 109

Number of Certificates Issued under PVPA·····115
Relation of PVPA to Other Method of Protection·····120
Impact of PVPA to Biotechnology R&D·····122
Japan's Seed Law·····123
The Role of Public Breeding in Japan·····128
The Rice Breeding in Japan·····130
Comparison of Japan's SL with the U.S. PVPA·····135
7-4. Outputs of Genetic Engineering·····136
What Determines the Research Agenda in the U.S.A.?·137
What Determines the Research Agenda in Japan ?·····139
7-5. Vertical Integration, Another Way of Protection·····141
Vertical Integration in the U.S.A.·····141
Vertical Integration in Japan·····142
7-6. Public Role in Plant Biotechnology·····144
Public Role in Plant Biotechnology in the U.S.A.···145
Public Role in Plant Biotechnology in Japan·····146
7-7. International Consequence·····149
The Difference in Patent System·····149
Other Regulations:
Environmental Release and Food Safety····151
7-8. Summary and Conclusion·····153

Chapter 8. Summary and Conclusions·····158

Bibliography·····165

1. Introduction

Situation of Plant Biotechnology

Biotechnology, especially genetic engineering, is a revolutionary tool in life-science research. When it came, people thought it would have the greatest impact both on pharmaceutical and agriculture industries, because both are directly based on knowledge of life-science. As a matter of fact, a lot of knowledge of life at molecular level has been produced using the technology and it is giving big impacts to various industries. With respect to agriculture, to accumulate knowledge on plant physiology at the molecular level is important not just for plant genetic engineering, but to develop a future agricultural system that will be sustainable, environmentally safe and/or productive enough to satisfy expanding global population.

Though the benefit is considered to be enormous in the long run, investment in the basic plant science is not enough and consequently plant biotechnology is still underdeveloped compared with pharmaceutical. In 1981 genetic engineering was expected to generate $3 billion market in the field of agriculture by 1990. This expected market size was four times larger than that of biotechnology pharmaceuticals(1). However, as of August, 1991, there is no commercially available products of genetic engineering in agricultural field except for some veterinary vaccines. On the other hand, several recombinant pharmaceuticals have already been commercialized and attained a big market. For example, Genentech's tissue plasminogen activator(TPA) has $200 million market, and Amgen's erythropoietin(EPO) has also $200

million market in the U.S.A. in 1990(2). There is a significant lag in R&D of agricultural biotechnology.

A typical example is Monsanto's case. Monsanto, which is a U.S. large chemical company and a leading agricultural biotechnology firm as well, has invested $1 billion to develop such products as bovine and swine somatotropins and genetically engineered plants since 1981, but it has no product commercialized yet(3). With respect to plant biotechnology field, in 1984 not only Monsanto but every plant biotech firm expected that the tomato would be the first commercialized product of genetically engineering and Monsanto expected that the earliest date of commercialization would be 1993(4). At that time, however, there was no specific product to develop for commercialization yet. In 1988 the Monsanto's virus-resistant tomato was expected to be commercialized in 1992(5), but this was premature. According to a recent Business Week article, the earliest expected date of commercialization of the Monsanto's virus-resistant tomato is 1997 and its estimated market is just $30 million. Instead, an insect-resistant cotton is expected to be commercialized earlier and to have a larger market. The expected date is 1996 and the estimated market size is $300 million(3). R&D of genetically engineered plants, in general, are taking longer time than expected in earlier stage. And the targeted plant has been affected by not only technical reason but food safety or environmental issues.

Roger Salquist, chairman and CEO of Calgene, a leading plant biotech venture, cited four barriers to the advancement of plant biotechnology: R&D time requirement, lack of money, a national

/international agricultural economic and social structure that hibits new product development, and lack of public acceptance(6).

With respect to the money, according to Salquist, U.S. private industry spends an estimated $350 million annually on plant biotech research, which is not enough to get the job done(6). The average yearly research support for a principal investigator at the National Institute of Health is $340,000 and at the Agricultural Research Service $25,000(7). Both private and public spending for plant biotechnology is not enough to do basic research and product development in the plant biotechnology field in the U.S.A. It is so even in the U.S.A., where in the early age of biotechnology, a university-industry complex was established and both private and public money was poured into university research(8).

Spillover of knowledge of basic research from university to industry is an important source of R&D in pharmaceutical industry(9). However, there was no similar relation between land-grant universities and the seed industry, because the mission of the land-grant university was to provide applied research for the farmer(8). Those universities and seed companies ~~sometimes competed~~ in the same seed market. ~~Therefore,~~ at the beginning of plant biotechnology, a large amount of the funding for molecular research went to universities that were non land-grant universities and medical schools, where there was no experience in agriculture research but knowledge of molecular biology. This is considered to have caused the initial lag in plant biotechnology R&D(8).

However, it cannot explain the still remaining and widening lag

between agricultural and pharmaceutical R&D. Today, basic research is emphasized in all universities, including land-grant universities, but private and public money for basic science is not allocated enough to plant molecular biology compared with medical science. As far as private investment is concerned, the lack of money is due to low profitability of plant biotechnology R&D: 1.Demand for seed is elastic compared with pharmaceutical. 2.R&D of a genetically engineered plant requires more time. 3.Protection of intellectual property rights is not sufficient. These characteristics are derived from the nature of plants. However, technology development and/or different institutions of intellectual property rights will be able to change them. For example, F_1 hybrid seeds will increase protection and a restriction fragment length polymorphism(RFLP) map will reduce investment period. On the other hand, modification of patent system will change protection level and may encourage private/public investment in plant biotechnology. In the pharmaceutical industry, basic product patents are critical and the university research is to provide them(10,11). Similarly if the value of basic product patent is increased in plant biotechnology, private investment may increase and R&D may be promoted in this field.

Need for Study

The descriptions above indicate the difference in basic research effort between the U.S. pharmaceutical and the U.S. agriculture. In an analysis of industrial R&D, not only basic research but also applied research should be examined. We can obtain a direct evidence of the

difference in plant biotechnology R&D, if we compare between two countries, such as the U.S.A. and Japan. Although scientists of both countries can utilize the same knowledge that the scientific progress provides (however, actually there are lags and quality differences) and the ability to utilize the knowledge is not different much on the average, the outcomes of R&D vary being affected by the structural differences between two countries. Therefore, we can predict the path of future technology development and the effect of institutional change based on the empirical evidences of plant biotechnology R&D.

Though such an empirical study is important for designing science and technology policy as well as industrial policy, there are few studies on this issue in the field of plant biotechnology, especially in the context of international comparison. It may be because there is no product yet and as a result, no effect on agriculture production yet. However, R&D is in progress and actually differences in R&D are developing. The difference in R&D in this field between the two countries is significant: for example, almost 400 field trials of genetically engineered plants are going to be carried out in the U.S.A. in 1991, while only one field trial in Japan in the same year.

This paper focuses on the patent system. The difference in the patent system between the U.S.A. and Japan and its consequence on R&D in plant biotechnology will be examined.

International Comparison of Patent Systems

The difference in patent systems between the U.S.A. and Japan has recently become recognized from the trade-related aspects(12). From a

popular American view, the Japanese system is unfair and discriminating foreigners, especially Americans. For example, a recent article in Business Week cited comments "the Japanese system hurts Americans seeking to protect their inventions." and "The systematic scouring of the U.S. technology is continuing"(13). However, in other cases, some people actually feel discrimination against Japanese firms due to the U.S. protectionism of its technology. With respect to this point, Helfgott wrote that it is difficult to specifically identify particular discriminatory sections of the Japanese Patent Law(14). Karjala wrote that Japan has had in place throughout this century patent statutes that make no formal discriminations between domestic and foreign inventions, and that isolated examples of weak protection for foreign patents does not in itself make the case that discrimination was or is being practiced(15).

The recent patent dispute between Amgen and Genetics institute-Chugai Pharmaceutical on erythropoietin (EPO), a recombinant drug for anemia, gave a typical case of an international patent infringement. In this case, Chugai Pharmaceutical, a Japanese pharmaceutical firm, produced EPO in Japan using the process patented by Amgen, a U.S. biotech firm, in the U.S.A. and exported it to the U.S.A., where another U.S. biotech firm, Genetics Institute had a product patent of EPO. Chugai obtained a license from Genetics Institute to produce EPO in Japan and to sell it in the U.S.A. and Japan. On the other hand, Amgen's patent covers DNA coding EPO and the transformed cell producing EPO.

The Federal District Court ruled in March, 1990 that Chugai can-

not prosecuted for infringing Amgen's patent when it manufactures recombinant EPO in Japan (16,17). This decision had made Congress aware of international infringement and its direct result was the Biotechnology Patent Protection Act of 1990 (Boucher bill). Their concern was that Chugai Pharmaceutical can export EPO to the U.S.A which is produced in Japan using the process patented by Amgen in the U.S.A. Congressman Boucher said "It would be illegal for Chugai to make EPO in the U.S. because of Amgen's patent, so it should be illegal to make it abroad and bring it here.""Companies are using a hole in the law to pirate U.S. biotechnology invention"(17). However, in this specific case, the Boucher bill could not help Amgen, because since the act was amended to exclude the cases before the enactment. However, in March, 1991, a higher court decided that Genetics Institute's patent is invalid, and consequently Amgen has won the battle. In Chapter 3, patentability problem of this case is discussed.

An issue here is the international difference in patent systems. If the Amgen's patent had been valid all over the world, such a problem would not have occurred. But actually, patentable subject matter and length and breadth of protection differ in each country(12). Amgen's process patent has not been issued in Japan and even if it is issued, the claim will be narrowly interpreted and similar but a little different process will not infringe it in Japan.

A lot of differences in patent systems do not necessarily mean that there is systematic discrimination. But what is obvious is that the differences may give advantage to some party and disadvantage to others, even if both patent systems are fairly practiced. Institution

of intellectual property rights is based on domestic policy. Abstractly speaking, the purpose of the law is supposed to increase domestic welfare. But in the real world such a policy is to satisfy the demand of domestic industries. In this sense, even a discriminating patent law might be allowed. However, to increase one country's domestic welfare does not necessarily increase other country's welfare or world welfare. This causes international conflict of intellectual property rights, which can be regarded as a part of international conflict of domestic industrial policies.

Both business and R&D are getting more and more borderless today. Accordingly, institutions of intellectual property rights have to somehow seek for maximizing world welfare in the long run. Therefore, it is important to know what kind of consequences the patent system difference has on international R&D of advanced technologies, such as biotechnology.

Plant Variety Protection

In this paper I will examine the difference in patent system between the U.S.A. and Japan and its consequences on R&D in biotechnology field, especially plant biotechnology.

Though there are a lot of differences in patent systems between the U.S.A. and Japan, the most important one is that of product space. Generally speaking, the U.S. patent system allows an inventor to claim broadly based on the "doctrine of equivalents", while Japanese system tends to interpret the claim narrowly. This difference may be based on cultural difference(14) and reflects the difference in the purpose of

a patent system. Very simply stated, "the U.S. patent protects individual inventors" and "the Japan's patent promotes technology-sharing"(13). However, although the difference of product space is clear, it is hard to compare the difference in general.

Plant variety protection is a very special case and good for comparison of product space. In the U.S.A., there are three different laws that protect a plant variety: Plant Patent Act of 1930(PPA), Plant Variety Protection Act of 1970(PVPA) and Patent Act(PA). With respect to product space, PPA and PVPA have a very narrow product space, because they give a variety specific protection, that is, plants with small difference in phenotype are allowed to compete with a patented variety. On the other hand, PA allows a broad product space, because it utilizes the "doctrine of equivalents" as is the general case of patent protection in the U.S.A. On the other hand, in Japan the Seed Law is a rule equivalent to the U.S. PPA and PVPA, and gives a similar variety specific protection. However, Japan's patent office has not issued a plant patent under the patent law yet except for one special case, as is described in Chapter 4. Therefore, there is a clear difference in product space between the U.S.A. and Japan with respect to plant variety protection. This difference in product space is consistent with the general and empirical difference of patent systems between the two countries.

The basic framework of this paper is as follows. The U.S. patent system gives broad protection and Japan's system gives narrow protection with respect to a plant variety. This is a difference of product space, which is in general a basic difference in the patent system be-

tween U.S.A. and Japan. Then, the evidence that institutional difference causes the difference in R&D activities, such as input, output and patent issuance, between the U.S.A. and Japan is examined. In addition, the institutional difference causes international trade conflicts and the paper will contain an examination of the international consequences.

2. Economic Theory and Some Empirical Studies on Patent

Patent systems were not established based on economic theory, for example, patent length was determined based on the amount of time to train two apprentices (14 years) and the length has remained essentially unchanged though the apprentice system has been obsolete(1). There have been a lot of literature on economics of intellectual property rights, and some of them are to try to find the optimal length of patent protection. Nevertheless, the theoretical analysis has had little impact on public policy in this area, and as a result, patent length has remained unchanged, as described above. Besen and Raskind insisted that too few of the profession's resources have been devoted to these issues and that, of those resources that have been employed, too few have been devoted to empirical analysis(2).

In this chapter the economic theory of the patent system and some previous empirical studies are reviewed. In the course of the description, remaining problems are pointed out. Benko wrote, "The economics of intellectual property rights is characterized by a great many unanswered questions"(3).

Justification of Patent System

Modern arguments to support the patent system rely on the two justifications: "monopoly profits incentive" and "to disclose secrets"(3). There was another argument, "reward by monopoly". But this is not popular today, because prospective nature of patents are

more aware. Kitch presented prospect theory in contrast to the award theory, based on the fact that patents are issued long before commercialization and that patents claims are broader than what was actually invented(4).

The first justification is that monopoly profits incentive is necessary to encourage R&D in private industries. The initial product of R&D is knowledge. It is itself a commodity but more importantly it will produce new processes and new products that contribute to economic growth. But a problem is that knowledge is a typical joint-impact good, defined as a good whose marginal cost of another user is zero, although an initial cost to produce the good is required. In this case who pays the initial cost and who pays marginal cost are the problem. With competition, price would equal marginal cost, leaving no revenue to pay for the R&D costs(5).

From an economic point of view, no one will produce knowledge at his own expense, if the knowledge is free to use. Therefore, since knowledge is one of sources of economic growth, institutions to solve the problem are needed. In most countries, there are two solutions. One is public funding for R&D and the other is patent system. Public funding is often used to produce the knowledge which is then made available to all at zero marginal cost. Patent system, on the other hand, is considered to allow temporary monopoly over the use of the knowledge, and as a result secures economic incentive for the private production of knowledge.

The second justification, "to disclose secrets", emphasizes the spillover effects. Historically patent systems require disclosure of

the invention at some point of patenting process and the disclosed written description must be sufficient enough for any person skilled in the ordinary art to make and use the invention. Thus society can share the new knowledge and encourage subsequent production of knowledge by reducing R&D cost. Scotchmer wrote "Most economics literature on patenting and patent races has looked at innovations in isolation, without focusing on the externalities or spillovers that early innovators confer on later innovators. But the cumulative nature of research poses problems for the optimal design of patent law that are not addressed by that perspectives"(6). For example, supposedly if there were no spillover, the monopoly period should be shortened.

Analysis of Optimal Patent

There are a lot of institutional variables with respect to patent system, but length and breadth of patent protection are most often discussed in theoretical analysis. In addition to them, range of subject matter(for example, whether animal is patentable or not), type of protection(for example, whether product patent is possible or not) and priority rule(first-to-invent or first-to-file) are also important variables especially for international comparison(1).

As quoted above, most patent analyses are based on the first justification (monopoly profits incentive) and deal with patent length. The basic idea is as follows. A longer protection is considered to increase incentives for investment in R&D, but at the same time brings more social inefficiencies due to monopoly. An optimal patent life should be determined by the trade-off between the dynamic benefits as-

sociated with innovation and the static costs of patent monopoly power. In theoretical analysis, effectiveness of patent and other factors that complicate analysis is usually ignored.

Nordhaus assumed a production function relating cost reduction caused by process innovation to R&D expenditure. The inventor can choose R&D expenditure to maximize discounted total profit, which is a function of patent life. Then, maximizing a social welfare function, an optimal patent life was obtained(7). This welfare economics approach stemmed from Kenneth Arrow (8). Based on the Arrow-Nordaus model, Kamien and Schwartz introduced rivalry in the R&D process(9). However, as Kitch pointed out(4), in the real world a patent is granted at the early stage of rivalrous innovation and the winner alone continues product development. DeBrock applied this idea and presented a two stage model(10). On the other hand, Tandon introduced an assumption of compulsory licensing using a similar model to Nordhaus's and concluded that theoretically compulsory licensing leads to increased social welfare(11). All of these models assume a single invention, and do not consider subsequent inventions at all.

Another instrumental variable is breadth. Breadth or product space is related with the legal requirement of "novelty" and "nonobviousness", that is to say, to widen product space means to strengthen the requirement of novelty and nonobviousness(16). Few analysts have cast the debate in terms of optimal breadth of patent until recently. This may partly because breadth is more difficult to deal with quantitatively than length. And another reason is that as far as using single innovation model, breadth has the same effect as

length and can be dealt with as a part of patent life. Nordhaus just did so(12). Gilbert and Shapiro dealt with these two variables as a tradeoff, saying that the appropriate margin on which patent policy should operate may not be patent length, but rather breadth, because optimal length may easily be infinite. Their assumption is that greater breadth confers a great flow rate of profits and a smaller flow rate of social surplus. They showed that narrow but infinite-lived patent is optimal(13).

Using similar assumption Klemperer got a different view on breadth of patent(14). His idea is that patent breadth brings different kinds of welfare loss from what patent length does. He pointed out two kinds of welfare losses. One is those on distortion of consumer's choice, that is, consumption switched to less-preferred varieties of the product that are unpatented and so are sold competitively. A wider patent generally reduces the distortion, because it covers more substitutes that consumers will choose. On the other hand, it also permits higher prices, which causes consumers to switch out of the product class. This is the other welfare loss. His conclusion is as follows. If the demand is is elastic, infinite-lived but very narrow patent is optimal. On the other hand, if the demand is inelastic, very short-lived but very broad patent is optimal. These two analyses, Gilbert and Shapiro's and Klemperer's, dealing with breadth also assume a case of a single invention.

The analyses above are very theoretical and use unrealistic assumptions. Dealing with a single innovation is one of them, because spillover effects of patent are an important source of social welfare.

Kenneth Judo presented a general equilibrium model where there is a stream of product innovation determined by profit-maximizing innovators. One of propositions in the model is that patents may be necessary to achieve efficiency even if perfect trade secrecy is available to innovators, since patents also prevent socially wasteful reinvention of a good which may occur if imitation is possible(15). This point is related the second justification of the patent system described above, that is, "to disclose secret". Since breadth of patent affects the disclosure, thinking about breadth in relation with disclosure needs a model of successive inventions.

Since international protection of intellectual property rights has become important recently, people have come to pay attention to the international difference of the patent breadth. For example, one of the most important difference in patent system between the U.S.A. and Japan is the breadth of patent. Scotchmer noted that U.S. patent protection is broader than that in most other countries, particularly Japan, partly due to the "doctrine of equivalents", which can broaden protection beyond the claims in the patent according to similarity of function(6). As a result, the value of a basic patent is significantly reduced in Japan, because subsequent innovators can incorporate the basic innovation in the improvement (however marginal) and then patent the improvement(17). On the other hand, patent lengths do not differ much among countries.

The study of Scotchmer and Green presented a model of subsequent invention under different breadth of patent. Their idea is as follows. If broad protection is granted, then a derivative or a second gener-

ation product will likely infringe the prior patent, so a license on the original patent is required to market it. If patent protection is narrow, then many derivative products and applications can be patented and marketed without infringement. They wrote "The stringency of the novelty requirement in patent law affects the pace of innovation because it affects the amount of technical information that is disclosed among firms. It also affects ex ante profitability of research"(18).

Their premise is the disclosure is beneficial to society. Based on that, they compared strong and weak novelty requirements and concluded that a weak novelty requirement is socially valuable, because it permits interim technologies to be patented. However the value is undermined because firms may be reluctant to disclose interim technologies.

On the other hand, given patent system, research organization can be adjusted to obtain the optimum result. For example, cooperation among firms at the R&D stage can counterbalance weak patent protection by internalization of spillovers from ongoing R&D programs. In addition, cooperative exchanges of patents designed to overcome potentially conflicting intellectual property rights strengthen R&D incentives by increasing expected profits from doing R&D on the average(17). Scotchmer wrote, "It is misleading to ask how broad patent protection should be without simultaneously asking whether research firms can integrate or otherwise cooperate"(6).

Limits of Patent Theory

In the theoretical analysis, the patent system is assumed to in-

crease R&D activity in perfectly competitive input/output market. However, in the real world, the effectiveness of a patent is not always perfect, that is, in some cases patent system does not stimulate invention and in some cases other methods are used to protect inventions.

The effectiveness attributes to goods themselves and/or the market structure. The attribute of goods determines exclusion cost(5). If it is costly to exclude unauthorized users, the patent is not effective. In that case, since firms will be reluctant to disclose their inventions, patent system does not increase subsequent R&D. Even in such a case disclosure contributes to further R&D, and therefore government support to patenting may be necessary.

On the other hand, the market structure is another important factor. Even if assuming perfectly effective patent, patent theories indicate that optimal patent length and breadth depend on the elasticity of the demand, which means the optimal differs in each product. However, due to administration cost, patent laws use constant length and breadth except for some special cases. Therefore, existing patent rule has different effects to each product.

However, real-world markets are almost never purely and perfectly competitive. As a result, some market structures make patent system unnecessary to induce invention and/or innovation. In this case no social benefit can be attributed to a patent grant, but social cost is positive.

Scherer pointed out three case in which business firms may invest in innovation without patent protection: 1.Imitation cannot eliminate

innovative profits so rapidly, that is, there is natural lag due to secret, imperfect knowledge, and know-how. 2.There is competition for product differentiation advantages from being first in the market. 3. There are nonpatent barriers to entry, such as lack of production facilities, managerial experience, and distribution channels(19).

Further it is not clear that patentable knowledge generates any more social benefits that knowledge that is not patentable, which the patent system discourages. If a non-patentable product is socially beneficial, patent system that discourage its development has positive cost. The U.S. Orphan Drug Act of 1983 is an example to solve this problem. In definition, orphan drug is a drug for a disease or condition with a prevalence in the U.S. of less than 200,000 patients or even greater than 200,000 if it is not patentable and so not profitable(20). The latter is a situation where even if a known substance, such as a generic drug, is effective to a new disease, no firms is willing to invest in it. To develop a new drug is costly due to regulation, even if it is a known product. However, if it is a known, widely available substance, the development cost will not be recovered because any firms can sell the same drug without paying the development cost, once the efficacy is proved. The Orphan Drug Law gives an exclusive marketing rights to the first firm that obtain approval for marketing of the drug. It is considered to work like patent.

Some Empirical Studies on Patent

Theoretically patent system promotes investment in knowledge

production, induces innovation and finally realizes economic growth. One type of empirical studies is to examine those relations. And other type is to use patent data as a measure of R&D intensity.

A pioneer work of the latter type of study is Schmookler's. He used number of patents as a measure of inventive activity in some industries and concluded that there is a marked tendency for output and invention(number of patents) in an industry to move together in the long run, in the short run, and in intermediate periods(21). But he found that the variations in invention do not cause those in output. On the contrary output affects invention. This may imply that inventive activity is determined by expected profit. In his study he used unproved assumptions:(a)that the ratio of patents to inventions within the field is constant over time, (b)that the ratio of the number of patented inventions in the field to the number of patents covered by the particular series is constant over time, and (c)that the average invention in one period in the field is of the same importance, in some relevant sense, as the average invention in any other period. To prove these assumptions, we have to examine the contents of patents.

Cockburn and Griliches did regression analysis to explain market value of firms, and showed that R&D expenditures as input measures are stronger measures than the number of patents as output measures(22). It may be because simple patent counts are indicative only of the input side, as reflected in R&D expenditure(23). Trajtenberg insisted that the use of patents in economic research has been seriously hindered by the fact that patents vary enormously in their importance or value, and hence, simple patent counts cannot be informative about

innovation output. However, using patent data has some methodological advantage, because it can be easily obtained all the way to the very beginning of a product class, whereas the gathering of conventional industry data usually starts only when a sector is well established (23).

To obtain a better estimate, Trajtenberg used patent counts weighted by a citations-based index, and showed that they are correlated with independent (over time) measures of the social gains from innovations in Computed Tomography scanners, or CT scanners(23).

Another type of empirical study is to examine effects of the patent system on R&D activities. Mansfield showed, based on survey data, that there is a difference in importance of patent protection for development or introduction of inventions among industries. Pharmaceuticals and chemicals are a group that put the highest importance on patents. Petroleum, machinery, and fabricated metal products are middle group. Electrical equipment, office equipment, motor vehicles, instruments, primary metals, rubber, and textiles are a group that considers patent protection not essential. Although in some industries patents are not so important, the percentage of patentable inventions is not proportionally low. Mansfield thinks that this means firms generally do not prefer to rely on trade secrets(24).

Another empirical study based on a survey to examine the source of the difference in importance of patent protection was done by Levin et al(25). They concluded that other means of appropriation, such as lead time, learning advantages and sales and service efforts is typically more important than the patent system, but that there are sub-

stantial interindustry variation in the level of appropriatability and the mechanisms that provide it. According to their result, pharmaceuticals and chemicals are typical industries where product patents are regarded as effective, which is the same result as Mansfield's.

Using the same survey data, Levin showed that spillovers do not necessarily discourage R&D investment and are conducive to rapid technical progress(26). He speculated that there are two types of nature of technical advance, that is, discrete and cumulative. In industries with discrete technologies, such as pharmaceuticals and chemicals, spillovers may discourage R&D investment, but in industries with cumulative technologies, such as electronics, spillovers encourage R&D investment.

The lesson from those empirical studies is that seemingly uniform adjustment of intellectual property, antitrust, or trade law may affect some industries quite differently than others, and that it should not be taken for granted that more appropriatability is better, and that better protection necessarily leads to more innovation(25).

3. Biotechnology and Intellectual Property Rights

The current concept of biotechnology is broad and sometimes confusing, but the core technology is the genetic engineering, which induced the biotech boom in the U.S.A. The first successful transformation of host cell with foreign genes was done by Cohen and Boyer in 1973. This process and the transformed bacteria itself has been protected by so-called Cohen-Boyer patents, which were not issued until 1980 (process patent, No.4,2372,24) and 1984 (product patent, No.4,468,464). Although the methods were just a laboratory technique and they showed a few examples of recombinant DNA plasmids transformed into bacterial hosts, the patents claimed broadly recombinant vectors and methods of using them. As a result, the patents have become basic patents of biotechnology and have been licensed to most major companies involved in biotechnology(1). The Cohen-Boyer patents are licensed at a very low cost ($ 100,000 per firm and royalty from commercialized products) so that users have little incentive to challenge the patents. If they were challenged, it is not clear that such a broad patents would be held valid by the courts. Although the patents do not cover plants, genetic engineering of plants are directly derived from the same breakthrough in 1973.

As noted above, genetic engineering was born as a research tool, and consequently its product was not commodities, but just new knowledge of life. In other words, biotechnology has contributed to basic research of life-science. This characteristic has not changed

even today. On the other hand, however, the biotechnology is a new transformation technique, that is, a revolutionary method of breeding of not only bacteria but also plants and animals. In addition, transformed cells can produce valuable proteins for therapeutics or other uses, which otherwise are too scarce to be utilized. In this sense, biotechnology is a revolutionary production technology. To sum up, biotechnology is a technology for basic research, for breeding and for production. And the last two views excited investors in late 70's and early 80's.

From an industrial viewpoint, biotechnology consists of genetic engineering(or recombinant DNA technology), cell fusion, large scale cell culture and bioreactor(2). Except for genetic engineering these are not new technologies, but along with development of industrial genetic engineering their values have increased and have become to be considered to be parts of biotechnology. Actually those technologies are not independent, but are jointly used. The first two, genetic engineering and cell fusion, are breeding technologies, while the last two, large scale cell culture and bioreactor, are production technologies.

In this paper I will concentrate on plant biotechnology. Plant biotechnology is often considered to be a new breeding technology, but based on the above definition of biotechnology there are some other aspects with implication for variation in intellectual property rights. It can be divided into four stages as follows: basic science, applied science 1, applied science 2 and applied science 3.

Basic Science

The purpose of basic science is to reveal mechanisms of plant physiology, which knowledge will give support to plant breeding, plant cultivation and utilization of microorganisms. Findings of basic science may be immediately patentable, and the scope of the patent includes plants transformed with the gene of the patented substance, even though such plants have not been produced at the time of the patent application. Therefore, with respect to plant patent, especially patenting of genetically engineered plants, basic research is very critical.

Traditional approach is to find a physiologically important phenomenon, identify molecules that take part in the process and purify a targeted substance. If the purification is successful, to clone its gene and to determine its DNA sequence is a standard procedure of molecular biology today. Sometimes, the substance and its gene are patentable via product patent. However, sometimes the biomolecules are naturally present in an organism and are discovered rather than invented. In such a case, the substance is not patentable because products of nature are not a patentable subject matter. Accordingly, patent protection may be obtainable only via method of use claim(3).

On the other hand, recent development of genetic engineering has made random approaches possible to find a useful gene. Roughly speaking, there are two approaches, positive and negative. Positive approach is to make random DNA fragments express themselves in host cell and to find the target DNA fragment by screening. The negative approach is to randomly inhibit or destroy DNA of a host cell and to

TABLE 3-1. Basic Science Stage of Plant Biotechnology

STAGE	basic science
PRODUCT	knowledge
THEME (technology)	plant physiology (molecular biology) to find new bio-active substances (molecular biology) to clone genes (genetic engineering)
UTILITY	to obtain useful genes that improve quality and yield
PROTECTION	product patent of the substance, its gene and plants transformed by the gene method of use patent

find the target DNA sequence by screening. One of negative approaches is transposon tagging. Transposons are movable elements and randomly inserted into DNA of host cells. Due to the insertion, host cell genes are sometimes destroyed, which causes change in phenotype. If an interesting change in phenotype is found, the responsible gene for the change can be detected using the transposon as a location marker. If the gene is identified, then the responsible protein molecule can be identified. Using this approach, scientists of Louisiana State University are looking for genes that give disease resistance to rice(4).

Those two approaches, traditional and random, will cause patent conflicts. In the traditional approach, a protein molecule is found first, and then the gene coding the protein is cloned. On the other hand, in the random approach a gene is cloned first, and then the product of the gene is determined. Those two approaches have the opposite directions, and consequently both protein and gene that are found independently will sometimes be patented at the same time by

different parties. This is a basic patent issue that biotechnology has brought to light in the existing patent system.

The case of Amgen/Genetics Institute-Chugai illuminates this problem well, see also Chapter 1. In this case, Genetics Institute, a U.S. biotechnology venture, had a product patent for purified natural erythropoietin(EPO) and Amgen, another U.S. biotechnology venture, had a patent covering a DNA coding EPO and the transformed cell producing EPO. EPO is a human hormone naturally produced in kidney and promotes erythrocyte production. Chugai Pharmaceutical, a Japanese pharmaceutical firm, had obtained a license from Genetics Institute to produce EPO in Japan and to sell it both in the U.S.A and Japan. Therefore the patent dispute was actually done between Amgen and Chugai Pharmaceutical in the U.S. court.

The Federal District Court of Massachusette ruled that Genetics Institute is infringing Amgen's patent and that Amgen is infringing Genetics Institute's patent in March, 1990 and required both companies to exchange royalty-free cross licenses for EPO(13, 14). This means that neither patent alone is complete to produce EPO via recombinant DNA technology. However, the Court of Appeals for the Federal Circuit in Washington D.C. decided in March, 1991 that Amgen's patent is valid and Genetics Institute's patent is not, because it had not proven that it had isolated a protein with the biological characteristics described in the patent(15). The decision means that Chugai's recombinant EPO has become infringing it in the U.S.A. As a result, Chugai had to stop EPO development in the U.S.A. However, with respect to the basic patent issue mentioned above, the Appeals Court's decision did

not give a solution to it and the problem still remains unsolved.

Another basic issue related to the basic product patent is its derivatives. The nature of life makes it easy to make a lot of derivatives using biotechnology and as a result the derivative problem is serious in the field of life-science-related industries. Once the DNA sequence is determined, making its derivatives is easy, that is, just to change some DNA sequence and to obtain the product from the modified gene. If the original DNA sequence is published due to requirement of description of patent or other reasons, every one can try to make derivatives. Some of them may have better utility than original, for example, derivative may become resistant to endogenous proteinase, that is, it has a longer half life period when it is injected into body. The problem is how to share the intellectual property rights between the inventor of original and the inventor of improved form. Roughly speaking, in Japan if the utility is increased, the improved form is patentable independently of the original, but in the U.S.A. it is not. These differences affect the value of basic research and the rate of product improvement.

Applied Science 1

In plant biotechnology, finding a useful gene is not the goal, but the starting point of breeding. To obtain a transformed whole plant needs several steps. First, a gene with appropriate form has to be cloned. Second, the gene has to be incorporated into the chromosome of the host cell and should be stable and functional. Third, the transformed cells have to be regenerated to a whole plant.

In 1984 first reports of obtaining a transformed whole plant appeared, using *Agrobacterium tumefaciens*'s Ti plasmid(5). The plant bacteria with recombinant Ti plasmid infects plant cell and the foreign gene contained in the plasmid is integrated into chromosome of the host cell. This transformation was considered to be a general method initially, but is now known to be valid only for some dicotyledonous plants. Soybean, though a dicotyledonous plant, cannot be transformed efficiently by this method. After the transformation, regeneration from tissue or protoplast is the next necessary step, but since the condition and efficiency of regeneration varies in each species and variety, trial and error is required. A patent claiming this basic method was issued in July 1990 in the U.S.A.(U.S. patent 4,940,838). However, since this is not a general method and since a more general method has invented, the patent seems to have no effect on R&D.

TABLE 3-2. Applied Science 1 Stage of Plant Biotechnology

STAGE	applied science 1
PRODUCT	process technology
THEME (technology)	to transform plant cell (genetic engineering) cell fusion (cell culture and cell fusion) callus regeneration protoplast regeneration ·····trial and error in individual case
UTILITY	to increase mutation rate (either targeted or spontaneous) to reduce investment period
PROTECTION	trade secret in specific case process patent in general case general purpose instrument can be patented

Most economically important crops, such as soybean, wheat, corn and rice cannot be transformed efficiently by Ti plasmid method described above. A method that is considered more general has recently become popular. This method, which is called "gene gun" or "particle gun", is to inject a gene directly into the plant cell(6). Small particles made of gold or tungsten are coated by the gene and injected into cells using a "gun". Since this injection does not require protoplasts or cultured cells, the method depends on a less specific condition and has successfully transformed soybean and corn so far(5). The gene gun was invented by scientists of Cornell University in 1987 and its patent is licensed to DuPont. DuPont leases the machine and asks a royalty if the transformed plants are commercialized. This DuPont's condition does not seem to affect its users, because the benefit to use the efficient method is greater than the cost so far.

On the other hand, cell fusion is another breeding technology, which enables distant species to cross, which will never happen in nature. However, it cannot have a specific target, its benefit is just to increase mutation rate. In this sense, somaclonal variation induced by protoplast regeneration is a similar technique, though the range of mutation may be smaller. These mutation techniques are based on trial and error and the optimal condition differs in each species and variety. In early days of biotech boom, those cell culture techniques were intensively examined and several process patents have been issued. But since genetic engineering has developed and since it does not require cell culture techniques any more, such techniques have lost their value. In addition, considering patent protection, genetic

engineering has the advantage over random mutation techniques in terms of description and breadth of claim. Consequently, some biotech ventures specializing in cell culture or random mutation techniques have been acquired or merged recently: for example, DNA Plant Technology, Plant Genetics, and so on.

Applied Science 2

Genetic engineering also produces valuable information for plant breeding, for example, restriction fragment length polymorphism(RFLP). RFLP reflects difference in DNA sequence and if we find a RFLP highly correlated with a phenotype, the RFLP can be used as a genetic marker of the phenotype. Then, collection of RFLP can be a gene map for breeding. Unlike conventional gene maps, the RFLP map is based on real DNA sequence and can be detected using a DNA probe. This means that phenotypes can be known from even a single cell. And therefore, RFLP can reduce the breeding period.

DNA fragments referred to as RFLPs themselves may not be patentable, but can be protected via method of use claims(3). However, though the patents can stop an unauthorized party selling the DNA fragments, they may not stop in-house utilization of the fragments for breeding, because there is the experimental use exception to patent infringement(7). Once a useful DNA sequence is published, it is an easy job to synthesize the same sequence. Moreover, from the final product that is a conventionally bred variety, we cannot know whether RFLPs are used or not for breeding because they are just a gene map. Therefore, even if there is a protection of RFLPs, enforcement is very

difficult. Consequently, most RFLP maps produced privately are protected via a trade secret.

NPI, a plant biotech firm in the U.S.A., has been making RFLP maps for both in-house breeding and sale. When the company sells the RFLP map, it makes a contract with the buyer to keep the content of the map secret. When Japan's Ministry of Agriculture, Forestry and Fishery(MAFF) purchased RFLP maps of tomato and corn from NPI in January, 1988, MAFF agreed that the maps were to be used for only in-house research and the new variety bred using the map will not be public at least for five years(8).

TABLE 3-3. Applied Science 2 Stage of Plant Biotechnology

STAGE	applied science 2
PRODUCT	information
THEME (technology)	RFLP map (genetic engineering) DNA probe (genetic engineering) genome project (genetic engineering)
UTILITY	to reduce investment period both of conventional breeding and genetic engineering to identify variety and to increase effectiveness of patent
PROTECTION	trade secret, method of use patent product patent if new important genes are found

On the other hand, RFLPs will affect effectiveness of protection of plant variety especially of genetically engineered plant under plant patent, because the specific form of the foreign gene contained the genetically engineered plant can be detected by using a DNA probe. This means that information produced by RFLP is not only for breeding but for identification. This technique is already used in the forensic

field to identify criminals and to determine parent-child relation.

Another product of this area is that of genome project, which is to read all the DNA sequence of a life, in other words, to know all the genetic information that nuclei contain(although most sequences have no genetic information at all). The required effort to complete it is extremely greater than that of RFLP maps, but the benefits are also considered to be enormous. The human genome project has already started an international collaboration, where how to share the results and how to give incentive to private firms are critical problems now. On the other hand, no official project with respect to a crop genome has started yet. It may be partly because benefits will be smaller than human genome project, and partly because breeding has been such a domestic matter that it does not fit an international collaborative basic research. In addition to the problem of the human genome project, which crop to choose is also a problem.

The product of this stage is information. The difference between knowledge produced by basic research and the information is that a piece of information has little value while a piece of knowledge has some value in terms of either progress in science or industrial application. Information becomes valuable when it is accumulated beyond a certain scale, which may be called a critical point. In a sense, there are economies of scale in information production, but in this case value of the product jumps at the critical point though the average cost of information production does not differ much. Therefore, independent partial production of information is valueless and a large scale investment or integration of partial information is

required in this area.

Applied Science 3

The final step of plant biotechnology is to produce reproductive materials, such as seeds, seedlings and tubers. Even if a variety is bred using genetic engineering, production of reproductive material is not necessarily different from conventional methods. On the other hand, genetic engineering has increased the value of tissue culture technology as a way of clonal multiplication of plants.

The method of shoot tip culture was established in 1974 by Murashige(5). This method theoretically can produce one million seedlings from a single shoot tip and is valid for all plants. However, since the multiplication and culture process requires a lot of labor, it is not commercially feasible except for flowers, ornamental plants and some vegetables. Shoot tip is not the only tissue for multiplication, today. Embryonic cells can be induced from somatic cells. However this method, which is called adventitious embryo culture, is not so general as shoot tip culture, that is, it is possible only for some species(5).

The importance of clonal multiplication of plants has increased, because the technique will make it possible to multiple genetically unstable varieties, such as F_1 hybrids and genetically engineered plants, for cultivation. Consequently, reduction of multiplication cost by tank culture or other efficient mass production methods has become an important R&D target recently.

For example, rice is a crop whose F_1 hybrid seeds are scarcely

used except for in China. This is partly because the value of the increased yield by hybrid is less than the cost of making hybrid seeds, in other words, keeping male sterile parent lines and pollination with fertility recovery pollen are very labor-intensive and costly. Therefore, only in China, where labor cost is ignored, hybrid rice is feasible today.

TABLE 3-4. Applied Science 3 Stage of Plant Biotechnology

STAGE	applied science 3
PRODUCT	process technology
THEME (technology)	clonal multiplication ·····tissue culture, labor intensive technology, trial and error to find optimum condition ·····tank culture, capital intensive technology, trial and error to find optimum condition
UTILITY	high quality seedling with no virus infection cost reduction of seedling production
PROTECTION	trade secret and/or process patent

But if tank culture makes it possible to multiple seedlings from a small amount of tissue of hybrid rice with low cost, hybrid rice will be feasible in other countries. This idea is attractive especially in Japan, because in Japanese rice production system, seedlings are planted in paddy field, not rice seed. Therefore, tank cultured seedlings will not change the existing rice production system. A venture company specializing in development of large scale multiplication was established in Japan in 1987, in which quasi-governmental foundation, some large companies and some federations of agricultural cooperative have invested(9).

The same idea is valid for unstable varieties in breeding process and transformed plants with foreign genes. Those plants can be clonally multiplied and utilized before they become genetically stable, which means tank culture will reduce breeding period.

Multiplication techniques will be protected by process patent, but in general the protection is weak and substitute processes or improved processes will be invented. On the other hand detail of culture condition for specific varieties will be protected via trade secrets. But anyway, if it is profitable, a lot of companies will be willing to enter and compete in cost reduction. In that situation, lead time and economies of scale will be more effective protection than patents.

Conclusion

As noted previously, there are several technological aspects in plant biotechnology and protection of intellectual property rights are different in each technology. Therefore, it is hard to discuss intellectual property rights of plant biotechnology in general, which means that a single measure of protection does not make sense and we have to know the contents of each invention to discuss the effect of patent protection.

In this paper, in order to examine the difference in product space, I will concentrate on plant patents and their equivalents, that is, simple product patents, though they are only a part of plant biotechnology as described in this chapter.

4. Plant Variety Protection in the U.S.A. and Japan

Generally speaking, there are a lot of differences in institutions of intellectual property rights between Japan and the U.S.(1,2). With respect to plant variety protection, it is more complicated than others because there exist several ways of protection.

In the U.S. there are the Plant Patent Act of 1930(PPA) and the Plant Variety Protection Act of 1970(PVPA) in addition to the Patent Act(PA) which is called general patent or utility patent. On the other hand, in Japan the Seed Law was amended in 1978 to protect plant varieties, while the Patent Law exists.

The U.S. Plant Patent Act of 1930

The Plant Patent Act(PPA) was enacted as an amendment to the Patent Act(PA) in 1930 and consequently has been administered by the Patent and Trademark Office(USPTO). PPA protects plant varieties that are asexually reproduced, including cultivated sports, mutants, hybrids, and newly found seedlings. Tuber propagated plants and plants found in uncultivated state are excluded(3). The inclusion of chance seedlings and exclusion of findings of wild plants are amended in 1954(4). Asexually reproduced plants were considered to have the same progeny as the parent and that new varieties were considered not to be reproduced reliably by seed, which were the reason of the restriction to asexually reproduced plants. One reason of the exclusion of tuber propagated plants is that farmers can store some of the harvest for

next year(5), but it is also suggested that political considerations were involved(6).

Protection under PPA is for only a single variety. The requirements for issuance of plant patents are that the variety is distinct and new. "Distinct" means that the variety must have characteristics that are clearly distinguishable from those of existing varieties. "New" means that the variety has not previously existed. These criteria have been so narrowly interpreted that only exact copies infringe the patent. This makes the product space of the plant patents narrow and the monopoly value of the patents low(4).

On the other hand, full description is not required to obtain a patent under PPA, which requires "as complete as reasonable possible"(4). This is because full description of a new plant variety was considered impossible at the time when the PPA was enacted.

Infringement includes the unauthorized use, sale or asexual reproduction of the patented plant. Not only nurseries but also farmers are prohibited to reproduce the protected varieties. Though the claim covers the whole plant, sale of parts of the plant for asexually reproductive purpose is considered infringement. However, since sexual reproduction is allowed, they can be used as breeding material. In addition, sports originated from patented varieties and the second and third generations of sports can be patented(4).

The U.S. Plant Variety Protection Act of 1970

The Plant Variety Protection Act(PVPA) became law in 1970 and has been administered by United States Department of Agriculture(USDA).

The PVPA protects sexually reproducing plants, excluding fungi, bacteria and first generation hybrids(8).

The criteria of PVPA is distinctiveness, uniformity and stability. The distinctiveness of PVPA is similar to PPA and requires at least a single distinguishable change in a trait. The second and third conditions are to show that the variety reproduce itself true to type, which is required unlike PPA because it is sexually reproduced. Also like PPA, PVPA gives variety specific protection. As a result, PVPA has a narrow product space and open to obvious minor alternations(5). Current law creates an incentive for breeders to make cosmetic changes without improving plant performance.

Although both PPA and PVPA permit breeders to use protected plants as breeding material, PVPA unlike PPA also permits farmers to reproduce protected seed for their own use, provided they do not sell, offer for sale or advertise the seed on a commercial basis. The former permit is called "research exemption" and the latter permit is called "farmer exemption". These two exemptions are characteristics for PVPA(3).

Another difference between PPA and PVPA is that PVPA requires description of breeding procedures and genealogy, that is, it should be clear how the variety has been made stable and uniform. However, the same breeding procedure does not necessarily produce the same variety, especially when the product space is narrow, because of random character of genetic inheritance. It means that the invention itself is not completely described.

The legislation of PVPA was pushed by private seed companies that

were concerned with the formation of the International Union for the Protection of New Varieties of Plants(UPOV) in 1961(6). European eight countries, Belgium, Denmark, France, West Germany, Italy, The Netherlands, Switzerland and Britain, were the first members that signed the 1961 convention. The U.S.A ratified the 1978 second revised convention and joined the UPOV(3). Because of these historical background, registration of varieties under PVPA is based on the international criteria set forth by the UPOV, that is, distinctiveness, uniformity and stability as mentioned above(8).

The U.S. Patent Act after 1980 Diamond v. Chakrabarty case

In addition to PPA and PVPA, the general patent(PA) has become able to protect plant varieties since the patent law case of Diamond v. Chakrabarty in 1980. In that case the Supreme Court ruled that a live, human-made micro-organism is a patentable subject matter under Section 101 as a "manufacture" or "composition of matter"(3). This means that living things themselves are protected by product patents.

Following this logic, in September 1985 the Board of Patent Appeals and Interferences, in its Ex parte Hibberd decision, rules that plants are patentable subject matter under 35 U.S.C. 101(3). This patent was awarded to corn containing high level of tryptophan, which was invented by a scientist Kenneth A. Hibberd of Molecular Genetics, Inc. in Minnesota(No.4,581,847). This is the first plant patent under PA. Since this is a general product patent, this might cover any varieties of corn with the same level of tryptophan regardless of how they were bred. In addition, not only the plant itself but also seed

and tissue culture are patentable(9). All living things that cannot be protected under PPA or PVPA, such as tuber propagated potatoes, bacteria and animals, can be protected only by this PA.

The difference between the variety specific product patent(PPA and PVPA) and the general product patent(PA) is obvious. The product space of PPA and PVPA is very narrow and on the other hand that of PA can be very broad. Section 101 of the Patent Act requires novelty, utility and nonobviousness. Since PPA and PVPA have no criteria about utility, PA is also called a utility patent comparing with PPA and PVPA.

A plant patent under PA is a product patent, and therefore the novelty and nonobviousness are judged by the utility of the invented plant. In this sense, utility is equivalent to distinctness of PPA and PVPA(5). Utility, however, can be claimed broadly, that is, not restricted to a single variety. This makes it possible to claim a broad product patent under PA. In the Hibberd case the utility is the increased level of tryptophan in corn. Even if the company transformed only one variety of corn successfully, the patent issued covers all the corn varieties with the same utility. This is the prospective nature of patent, as described in Chapter 2(10).

As Schmid noted, widening the product space prevents cosmetic alternation from becoming substitutes, but it increases the possibility of eliminating independent invention(5). Because of the difference in criteria the product space of PA tends to be larger than that of PPA and PVPA, however how much larger the product space is depends on how much different the utility should be for a plant to be patentable.

This is subject to varying interpretations and eventual court decisions.

Another requirement for PA is description. The Patent Law requires the applicant to describe the invention so that a person of ordinary skill can duplicate it. This is one of the important functions of patent system, which encourage disclosure to promote further development as noted in Chapter 2. As I mentioned about PPA and PVPA, invention of a living thing, different from machine and chemicals, cannot be described fully due to random nature of genetic inheritance. This is one major reason why patent offices of most countries have hesitated to issue plant patents under general patent law. According to the table presented by Bulter(11), most industrial countries exclude plants from patentable subject matters. Exceptions are the U.S.A, Australia, New Zealand, Iceland and Ireland. Though Japan is included in the exceptions in the table, so far only one plant patent has been issued and it is considered exceptional in Japan. I will discuss this point later. Again, the USPTO allows plants to be protected under PA, which requires utility but not full description.

Protection under PA is stronger than PPA and PVPA, because research exemption (unlike PPA and PVPA) and farmer exemption (unlike PVPA) does not exist. Leaving aside the question of how it is enforced, farmers cannot reproduce the plants patented under PA and breeders cannot use any parts of the patented plants, such as pollen, tissue, and DNA as breeding materials if their intention is to obtain a patent or to commercialize the new variety(3). While there is considerable debate over the issue of research and experimental use, it

is clear that PA are more restrictive regarding research and experimental use than PPA and PVPA(12). In addition, unauthorized sale or manufacture of the protected material for consumption and processing are also infringement(6), which means farmers cannot sell the harvest from the patented plant without permission. This is not considered infringement in case of PPA(4) and PVPA, since it is a normal use of plant. Of course, no farmer would buy a seed without permission to sell the crop. But the fact that PA can control the harvest means PA may be a tool of contract cultivation and vertical integration.

In the U.S.A., breeders can choose one or more ways protection from PPA, PVPA and PA for one invention. As I mentioned above, the U.S. is one of the few countries that allow plant to be protected under general patent law like ordinary industrial products. Another reason why most industrial countries do not issue plant patent is that UPOV prohibits the double protection of a plant. An UPOV member country has to choose one law, general patent law or plant variety protection law(13). The U.S. 1930 PPA has a longer history than UPOV and even though PPA is a part of the general patent law, the nature of the protection is more like 1970 PVPA. Besides a few varieties can be protected under both PPA and PVPA. Therefore, the U.S. was exceptionally allowed to use both PPA and PVPA for plant variety protection, when it joined UPOV in 1978(14). And, since 1985 USPTO has also issued plant patents under PA, which seems to violate the UPOV rule that prohibits the double protection.

Because in the U.S. PVPA and PA have existed since 1980, comparison of plant patents before 1980 and after 1980 may give

knowledge on the effect of PA. However, since 1980 at the same time, biotechnology, especially genetic engineering has become an important research technique and affected plant breeding much. Therefore it is difficult to separate those two effect. The consequence of the unique double protection will be discussed later.

Japan's Seed Law

In Japan the Seed Law(SL) was issued in 1978 as a revised version of the Seed Law of 1947. This is a response to the formation of UPOV and in 1979 Japan became a UPOV member. Before the 1978 SL, there was no patent-like protection of plant varieties. The 1947 SL was to regulate circulation of seeds, that is, it encourages registration of new varieties and requires proper labeling in circulation. This law allowed the breeder to use the registered name of the new variety exclusively, but gave no protection to the new variety itself(14).

The 1947 SL is similar to the U.S. Federal Seed Act of 1939 as far as described in Bulter(8). The revised SL of 1978 has introduced patent-like protection of new varieties, which is administered by Ministry of Agriculture, Forestry and Fishery(MAFF). This is the only one law under which new plant varieties can be protected in Japan.

The SL corresponds with UPOV rule and therefore is similar to the U.S. PPA and PVPA. However there are some differences. One difference with respect to protectable species is that the U.S. uses a negative list and Japan uses positive list. A negative list does not exclude any species except those are named and a positive list excludes all species that are not named in the list. Using negative

lists, the U.S. PPA covers all asexually propagated plants except tuber propagated plants and bacteria and PVPA covers all sexually reproduced plants except bacteria, fungi and first-generation hybrids. On the other hand, the SL, using a positive list, names the plant genus and species that are patentable (eligible to be registered), the number of which is 430 as of 1989. This is the biggest number among UPOV members that use positive list(13). In addition to the U.S.A., only Hungary, New Zealand and Australia use negative list. Hungary and Australia have no exception, unlike the U.S.A.

UPOV recommends that the protection should be extended to all plant species, but change from positive list to negative is not so easy because new varieties are subject to official field trial to establish that the conditions for protection are satisfied in most countries(3). In Japan not all new varieties are subject to official field trial, but as of December 1990 about one fourth of registered(patented under SL) varieties were required to have official field trial(848 per 2567). Most of others passed the examination only by the investigation of breeding field, which is to see whether the breeding was properly done or not(13). According to a MAFF's examiner, it depends on how reliable they think the breeder and the data submitted by the breeder is(personal communication). In addition to the positive list, Japan's SL exclude forestry trees, because there is other law that covers them(16).

Japan and probably other UPOV members using positive list show not only plant species list but also what kind of traits they count in each species. According to UPOV criteria, distinctiveness requires

that a new variety should be distinguished from all the known varieties by one or more important traits. Whether a trait is important or not may be difficult to determine in general, but MAFF is making a list of traits that they consider important. Those who apply for protection under SL have to describe these traits required.

Another difference is that first-generation hybrids of sexually reproduce plants are protected under SL. In the U.S. they are not patentable under PPA or PVPA.

Japan's Patent Law

It is well known that there are a lot of institutional and philosophical difference between Japan's Patent Law and the U.S. Patent Act(1,2). However, the criteria of patentability is not different, that is, novelty, utility and non-obviousness, though the interpretation may not be the same. With respect breadth of patent, see Chapter 2.

In Japan patent is administered by the Japan Patent Office(JPO), which is equivalent to the USPTO. JPO does not say that living thing is non-patentable subject matters(17) and actually bacteria patents have a longer history than the U.S. and even an animal patent was issued in 1989(14). However only one plant patent under the Patent Law has been issued in Japan.

The plant patent was issued in 1985 to Nihon Shinyaku Co., Ltd. who applied for it in 1977. The patent (No.1,281,544 and No.1,282,545) claims a new plant that contains increased level of a substance for vermicide. The company described the new plant at the chromosome

level, which JPO considered enough description for a plant patent(18). Since then no plant patent has been issued in Japan. An official of the Ministry of Agriculture, Forestry and Fishery(MAFF) explained that the plant patent is exceptional because it had been applied before the Seed Law was enacted in 1978. MAFF's position is to protect UPOV rule that prohibits double protection of one variety. One the other hand, JPO is said that it is willing to issue plant patents if the requirements are satisfied(19).

During the 80's decade when biotechnology developed tremendously, there had been only SL in Japan, while PPA, PVPA and PA had coexisted in the U.S.A. The comparison of these two countries in terms of plant biotechnology R & D will give us knowledge on performance of plant variety protections, although there are some other differences that affect R & D between two countries. Brief comparison of plant variety protections is shown in Table 4-1.

UPOV Rule Is Going To Change

As described above, UPOV rule affects the institutions of plant variety protection of each member country, especially Japan and others that keep UPOV rule rigidly. However, recent rapid development of plant biotechnology are requiring some change of the rule. And as a result, the UPOV rule will be more similar to general patent, although the protection is variety specific.

According to the discussion so far and the draft, the new rule that is going to be established among UPOV members allows double protection, prohibits unauthorized propagation, production, storage

and process, and prohibits unauthorized use of parts of the protected plant, such as tissue, pollen and DNA(13, 20, 21).

TABLE 4-1. Comparison of Plant Variety Protections

	The U.S.A.			JAPAN	
	PPA	PVPA	PA	SL	PL
Subject Matter	Asexually propagated plants	Sexually propagated plants	Human-made living things	Listed plants	Human-made living things
Exception	Tuber Bacteria Wild plants	Bacteria Fungi F_1 hybrid	No	Forestry trees	No
Criteria	Distinct New	Distinct Uniform Stable	Novel Useful Non-obvious	Distinct Uniform Stable	Novel Useful Non-obvious
Description	Incomplete	Procedure Genealogy	Should be complete	Procedure Genealogy	Should be complete
Official Field Trial	No	No	No	Case by case	No
Exemption	Research	Farmer Research	Non-commercial research	Farmer Research	Non-commercial research
Protection	One variety Whole plant	One variety Whole plant	Group of varieties with common traits Whole plant & plant parts	One variety Whole plant	Group of varieties common traits Whole plant & plant parts
Protection Period	17 years	18 years	17 years	15 years 18 years (perennial)	15 years
Major Plants Protected	Flowers Fruits	Soybeans Peas, Beans Wheat	Corn	Rice Flowers Vegetables	Only one issued so far

Other Institutions That Affect Plant Breeding in Japan

One of the most important goals of Japanese agricultural policy has been food security. Rice has been a staple food in Japan, but domestic rice production had never filled domestic demand until mid-1950's. Since rice is a tropical plant originally, Japanese cold weather often destroyed the harvest and made famine. The selection of cold-resistant or disease-resistant rice had a long history in Japan, and extended the northern limit of rice cultivation. After the introduction of modern breeding techniques, improvement of rice varieties became a national project. In addition, government had to direct efficient allocation between rice for diet and for seed, otherwise improved seed could not circulate nationwide.

In 1919 the Japanese government began a systematic breeding project of rice, wheat and barley in national agricultural research stations. By 1930 it had built a national system including breeding, production of seed and distribution of seed. The national agricultural research stations' role was breeding and prefectural agricultural research stations were to do field trials, to decide recommended varieties for local climate, to produce foundation seeds and to distribute them to local seed production farmers. By the beginning of World War II 60% of farmers had adopted improved rice varieties and 20% of rice seed was purchased annually(22).

Due to the War and post-war chaos, the national breeding system declined. In order to re-establish the national system, in 1952 the Major Crop Seed Law(MCSL) was enacted. The hierarchial system was re-established. The major crops that the law covered were rice, wheat,

barley and soybean. Since the law allowed only prefectural agricultural research stations to produce foundation seeds, private firms were actually omitted from the breeding of those crops even though the law did not bar them to breed those crops. In addition, prefectural seed production was under the control of prefectural seed committee. This committee collects data of seed demand through regional farmer's cooperatives and orders seed production for next year to farmers specializing seed production. Retail and price of the seeds were also controlled by the committee. Therefore there was no room for private firms to do commercial activity(22).

Even after the Seed Law was enacted in 1978, the Major Crop Seed Law kept incentive significantly low for private firms to do breeding of those crops. This situation was criticized a lot, especially in terms of deregulation and privatization, which was an international trend in 80's. Besides, expanding biotechnology intensified the criticism. Finally, the Law was revised in 1986. Then private firms can not only breed those crops but also produce foundation seed and certified seed to sell to farmers. However private firms have to be under control of the seed plan established by the prefectural seed committee, which means public field trial for recommendation is required.

A recommended list of varieties is not unique in the world, though there is no equivalent public system in the U.S.A. In Europe, there is a more severe regulation of commercialization of new seed. As described above, European countries adopt UPOV criteria for plant protection. However, in addition, breeder has to show significant

utility(value for cultivation and use) in comparison to already li: varieties in order for the new variety to be listed in the "national list". The national list also requires official field trial in addition to that required for plant protection. Variety listed in the national list also can be listed in EC common catalogue. Without listing in the national list or the common catalogue, the new variety cannot be sold(13). Moreover, there is a "recommended list". To be recommended officially, the new variety has to take additional field trials done in public research stations(22).

On the other hand, in the U.S. there is no such regulation on release of new varieties, but land-grant college system plays a similar role to recommendation: 1.The U.S. agriculture colleges do publish seed trial results. 2.Those breeders would not release a new varieties unless it is significant better than existing varieties. Private breeders, on the other hand, sell varieties only marginally different from a competitors varieties.

In Japan, although there is a recommendation list of major crops, release of new varieties is not regulated, either. In other words, any varieties can be sold in Japan, which is the same situation as the U.S.A., but different from the EC. However, most farmers choose recommended varieties, because it is disadvantageous to choose unrecommended varieties. As described above, the recommended varieties are decided by the prefectural seed committee, some of members of which are representatives of local agricultural cooperatives. Consequently, the agricultural cooperatives usually choose a variety from the recommendation list. And their members usually follow the decision, because

otherwise they cannot sell the harvest through the cooperative. Since each Japanese farmer usually produces a small amount of crops, cooperative marketing is a common practice in Japan. As a result, although it is possible to sell an unrecommended variety, few farmers would buy it and consequently there is no incentive for private firms to release unrecommended varieties.

The EC type regulations probably decrease the number of releases of new varieties in EC compared with the U.S.A. and Japan, while information cost imposed on farmers is less. But as far as comparing the number of issuances of plant patents, there is no significant difference among France, Germany, the U.S.A and Japan. The numbers are between 200 and 400 every year(13). This may imply that the regulation on release in EC does not affect the rate of producing new varieties, or that it has the same effect as the U.S.A and Japan, which have different systems to control the release of new varieties as described above.

Another institutional change in Japan is that MAFF opened its genetic resource to private firms in 1986. Before this decision, private breeding firms could not utilize the genetic resource collected by national agricultural research station(23).

Privatizations in Japan described above is not so drastic as was done in Britain, where the government sold the National Plant Breeding Institute with breeding staff and genetic resource to Unilever, a multinational huge food company, in 1987. The British Agricultural and Food Research Council explains that competition between public institute and private firms is unfair because public institute is sup-

ported by tax. As a result, the role of the national institute was confined to basic research(24). In Japan, though it is not so significant, national agricultural research has focused on basic fields, too. The conflict between public and private research also exists in the U.S.A. I will discuss this point in later chapter.

5. Other Regulations That Affect R & D of Plant Biotechnology

There are two major regulations that have been affecting R & D in the field of plant biotechnology, especially plant genetic engineering. One is that of environmental release and the other is related to food safety. With respect to these regulations, there has been significant difference between the U.S.A and Japan, though the gap has been getting smaller.

Environmental Release Regulation in the U.S.A.

Before utilization in commercial cultivation, a new variety will be grown in private field trials regardless how it has been bred. If the plant is produced by genetic engineering, to cultivate outside the closed green house requires a permission from USDA in the U.S.A.

Historically the regulation of genetic engineering (or recombinant DNA technology) started in an unusual way in the U.S.A. where the new research technology had been found. Scientists who were concerned with the possible hazards of the new technology proposed a voluntary moratorium on recombinant DNA research and held an international conference in California in February, 1975, which is well known as the Asilomar conference. It is said today that the hazards were overestimated at that time, but the discussion in the conference contributed the first guideline of recombinant DNA research(1). Based on the drafted statement made in the conference, a committee of scientists appointed by the National Institute of Health(NIH), known as the

Recombinant DNA Advisory Committee(RAC), completed formal guidelines, which was issued in June, 1976 as "the Guidelines for Research Involving Recombinant DNA Molecules" (2).

The NIH guidelines cover also environmental release of genetically engineered organisms and require approval by both the RAC and the director of NIH. However, they are merely guidelines not a law and consequently there is no penalty for violating other than to stop NIH research funding. With respect to the commercial development of agricultural biotechnology, therefore, there were some problems: First, compliance with the guidelines by private firms is voluntary. Second, the guidelines focus more on research than on commercial development. Third, there are other laws administered by other federal agencies that regulate utilization and/or commercialization of new products(2).

The issuance of guidelines---the goal scientists had sought---rather than end debate served only to further publicize the "danger" of rDNA, wrote Kenney in *Biotechnology: The University-Industrial Complex*(3). By 1978 the debate over regulation had become increasingly bitter as environmental groups and public interest activists fought to tighten control over rDNA research and scientists and increasingly industry resisted these demand. At that time the concern of environmental groups were not environmental release which was far from research agenda at that time, but the environmental effects of research facilities.

However, in exchange for provisions regarding public participation in Institutional Biosafety Committees established at each in-

stitution, the guidelines were revised to be more relaxed in 1978. Since then the guidelines were relaxed several times and finally the 1983 revision made nearly all conceivable genetic engineering experiments exempt from the guidelines. On the other hand, public concern and interest had been subsiding(3).

Those processes of relaxing guidelines and subsiding of public concern coincided with increasing industrial and public perception that the biotechnology could be beneficial. In 1978, Genentech, a bioventure established in 1976, successfully produced human insulin using genetically engineered *E. coli* and in 1982 Eli Lilly, a large pharmaceutical company, commercialized the insulin produced by Genentech process, which was the first pharmaceutical produced via genetic engineering process in the world.

On the other hand, with respect to environmental release of genetically engineered organisms, the RAC had approved three such experiments applied by universities by 1983; two of them were the releases of genetically engineered plants, which were not carried out eventually due to technical deficiency(2). The other is the release of genetically engineered bacteria. This approval was sued by the Foundation on Economic Trends in September, 1983, the president of which foundation is the famous anti-biotechnology activist, Jeremy Rifkin(4). The U.S. District Court's decision in June, 1984 and the U.S. Court of Appeals for the District of Columbia's decision in February, 1985 ruled that NIH was not the agency that approves environmental release of genetically engineered organisms(2).

Reflecting these decision, in addition to the increasing demand

for guidelines of industrial use of biotechnology, the federal government established the "Coordinated Framework for the Regulation of Biotechnology" and published in the *Federal Register* in June, 1986(5). This was to determine regulatory jurisdiction of each agency. The basic idea was product-base regulation using existing laws(6,7). The Environmental Protection Agency(EPA) covers the environmental release of any genetically engineered microorganisms, including pesticides, insecticides, fertilizer, environmental treatment and so on. Existing laws, the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA) and the Toxic Substances Control Act(TSCA) can be applied for regulation. On the other hand, the environmental release of genetically engineered plants and animals is regulated by the U.S. Department of agriculture(USDA). USDA's Animal and Plant Health Inspection Service(APHIS) regulates environmental release of genetically engineered plants based on the Plant Pest Act(2,5).

However, partly because the Plant Pest Act does not give sufficient legal background for regulation and partly because laws are not so flexible as to deal with developing technologies, the USDA has become to need guidelines(5). For that purpose, the USDA established the Office of Agricultural Biotechnology(OAB) and subsequently, the Agricultural Biotechnology Research Advisory Committee(ABRAC) in 1986(5). The USDA was intended to provide an outdoor equivalent to the NIH guidelines. However, no formal guidelines have been issued so far, except for some proposals(8). Even without guidelines, the USDA has issued approvals on case-by-case basis since 1986.

In 1986 environmental releases of genetically engineered plants

were carried out for the first time in the world. They were approved by the USDA. Three field trials are as follows:

Agracetus:Tobacco transformed with succinate dehydrogenase gene, which is resistant to disease. Ciba-Geigy:Tobacco transformed with Atrazine resistance gene, which is resistant to herbicide, Atrazine. Rohm & Haas:Tobacco transformed with *Batillus thuringiensis*(BT) toxin gene, which is resistant to insect.

Common comments from those three firms were that tobacco was just a model of field trials of genetically engineered plants and that they wanted to know how the USDA's approval process would work(9). In addition, there was no strong opposition like those that happened in the case of bacteria. Since those first experiments, the number of approvals by the USDA has been increasing rapidly every year. As of January, 1990, forty-seven recombinant varieties have been approved for environmental release. Forty-two of them were of private firms and five were of non-profit institutes, shown in Table 5-1(5).

Table 5-1. Field Trials of Genetically Engineered Plants Approved by the USDA as of January, 1990(5)

Type of Institute	Crop	Number of Varieties
Private Firm	Tomato	9
	Tobacco	7
	Cotton	3
	Alfalfa	2
	Potato	1
	Soy Bean	1
	Continues from 1989	19
Non-Profit Institute	Tobacco	2
	Cucumber	1
	Poplar	1
	Continues from 1989	1
Total Number		47

As a result, in 1990 field trials were carried out in about two hundred fifty places in the U.S.A. In 1991, the number of varieties is about fifty and number of plans of field trials is more than four hundred, according to the USDA(10).

Regulations of Environmental Release in Japan

"There is a possibility that if regulatory delays prevent the timely development of these products(genetically engineered wheat and corn seeds) in the United States, we will lose our lead." said Richard J. Mahoney of Monsanto(2). This was a typical view of the U.S. industry that demanded clear and favorable governmental regulation of biotechnology. As a result of such regulations, more than four hundred field trials are going to be carried out in 1991 in the U.S.A. On the other hand, in Japan the first environmental release experiment of genetically engineered plant has begun in February, 1991, which is five years later than the U.S. The National Agricultural and Environmental Technology Institute, one of national agricultural research stations, carries out the experiment in which scientists intend to examine ecological effects of recombinant tomatoes with tobacco mosaic virus(TMV) coat protein gene. This experiment is considered to have little commercial value, but their intention is to demonstrate how an environmental release trial should be carried out(11). However, as of July, 1991 no other trials, whether public or private, have been approved yet.

The first guidelines of recombinant DNA research were issued in August, 1979, in Japan. There were two research level guidelines. One

was completed by the National Committee on Academia, and was to regulate research done in universities. The other was completed by the National Science and Technology Committee, and was to regulate research done in industry(private firms and non-university research institutes). The former guideline was issued in March, 1979 and administered by Ministry of Education and the latter was issued in August, 1979 and administered by Science and Technology Agency. These two guidelines were very similar.

At that time when the guidelines were issued, there was three-year regulatory delay from the U.S.A. This delay imposed disadvantage in patenting of products and process using genetic engineering, because the Japan Patent Office(PTO) officially announced that inventions using those technologies before guidelines were issued cannot be patented. The reason is that the Patent Law says that inventions violating public order are not patentable. This rule was not applied to foreign inventions(12).

In October, 1983, two universities and one national research institute independently applied for the approval of recombinant DNA research of plants for the first time in Japan. These researches were to transform plants only in closed laboratories(13). In September, 1984, the next year, International Symposium of Plant Genetic Engineering was held in Tokyo and Jeff Schell of the Max Planc Institute in Germany concluded that they had established a transformation system of dicotyledonous plants. But regeneration from the cell was still difficult and it was successful in only limited species, such as tomato, tobacco and petunia(14). Therefore it was very natural that tomato and

tobacco were the first target of environmental release of genetically engineered plants. Since those discussion was done openly in science meeting, Japanese scientists could receive technical information and could perform similar research. In 1986 three firms in the U.S.A carried out the first environmental release of genetically engineered tobacco as I described. On the other hand, in Japan during 1986 and 1987 some laboratories successfully produced genetically engineered plants in a closed environment. However, no one tried to do environmental release due to lack of regulation.

In Japan there were two guidelines focusing on research. Environmental release experiment could be approved by one of those guidelines on a case-by-case basis. However, there were two problems: One is that the guidelines presented nothing about what kind of data would be required. The other was that there was uncertainty about how to connect the research oriented experiment to commercialization oriented ones, because no industrial biotechnology guidelines were available at that time.

In December, 1986, the Ministry of Agriculture, Forestry and Fishery(MAFF) established a draft of industrial guidelines in agricultural field, which covered environmental release of genetically engineered plants and bacteria, unlike the USDA guidelines(15). However the draft was not converted to the formal guidelines until April, 1989(16). The reason for this delay was considered to be that the Science and Technology Agency(STA) did not show the procedure to obtain approval of environmental release research until December, 1988. Experiment under STA guidelines is supposed to be prerequisite for

every industrial experiment(17). Since there was no central framework like that of the U.S.A., it usually takes a long time to make regulatory jurisdiction clear and to harmonize among agencies, in this case MAFF negotiated not only with STA, but also the Environmental Protection Agency and the Ministry of Health and Welfare(18). Since bacteria are more complicated than plants, the final forms of STA and MAFF guidelines did not cover bacteria yet.

As a result of negotiation between MAFF and STA, they established two kinds of environmental release experiments, unclosed stage and open stage. According to their explanation, unclosed stage experiment which is relatively small scale and for research purpose is regulated by STA and open stage experiment which is relatively large scale and for commercialization is regulated by MAFF(17,19).

Following the procedure determined by guidelines, MAFF's National Agricultural and Environmental Technology Institute obtained approval and began the unclosed stage experiment in September, 1989(20). Then in February, 1991, as described above, they started the first environmental release experiment of genetically engineered plant, that is, recombinant tomatoes with tobacco mosaic virus(TMV) coat protein gene(11).

The USDA guidelines are still just a proposal, not a formally issued one, as described above. The difference is that the USDA issues approval even based on drafted guidelines, while Japan's MAFF cannot do it. Besides U.S. firms are willing to have experience of regulatory process even though it is not clear yet, on the other hand Japanese firms usually wait for the presentation of clear regulatory process.

In Japan it is often the case of a new regulation that officials of a regulatory agency ask leading firms in the industry concerned to apply for approval, which will be a demonstration of the regulatory process to the industry. As described above, in the case of environmental release of genetically engineered plants in Japan, MAFF's national research institute played the role of demonstration.

Guidelines or Law ?

The regulation under guidelines are generally considered to be flexible and good for such rapidly developing fields as biotechnology. However, the problem is that there is no legal enforcement(5).

Denmark was the first country that issued a law regulating biotechnology. In 1986 the Environment and Gene technology Act passed the Congress. As a result of the passage of the law, the widespread popular opposition to biotechnology has disappeared and Danish industrial biotechnology could continue to grow. Between 1986 and 1990, about twenty permissions for genetically engineered production process were issued(21). In 1989, even an environmental release of genetically engineered plants was permitted for the first time(22).

In Germany, the Genetic Engineering Law was enacted in July, 1990. This, following Denmark, is the second law regulating genetic engineering in general in the world. The law, like Danish law, regulates not only environmental release but also utilization of genetically engineered bacteria in a fermentation process. This law forces firms to insure against possible damages caused by their activity using genetically engineered live material. In Germany, unlike in

Japan and the U.S.A., even a fermentation plant to produce insulin using recombinant bacteria was opposed by environmental activists, such as the Green Party(23). It is said, however, that thanks to the law, industrial plants which are generally considered safe are legally permitted(24). However, it is not clear yet how the law will affect the environmental release experiments.

On the other hand, in Japan the Environmental Protection Agency(EPA) announced that they intended to make a new law that regulates all kind of utilization of genetically engineered lives in open environment(25). However, the working group for making the draft could not complete the job by 1991 Congress(26). There were a lot of opposition against enacting such laws from academia and industry. And among other governmental agencies, there were some concern about how to coordinate such a new law with existing regulatory guidelines(24).

In the U.S.A., the basic principle of regulations of biotechnology is to apply existing laws to the new technology. This principle appeared in 1986 Coordinated Framework for Regulation of Biotechnology produced by governmental Biological Science Coordination Committee(BSCC) as described previously. In August, 1990, President Bush approved the Four Principles of Regulatory Review Oversight of Biotechnology prepared by BSCC. This was a confirmation of 1986 principle. Following them, in 1991 the President's Council on Competitiveness(COC) has released a Report on National Biotechnology Policy, in which it says that the administration should oppose any legislative efforts to create new or modified existing regulatory structure for biotechnology(27). This means that regulations should be

based on the safety of the product, not on the process to produce it. Using biotechnology in process may make the judgment of safety more difficult than chemical process, but product-base regulation should be valid for both products.

This approach is the same as that of the U.S. FDA's regulation. The former president of FDA, Frank E. Young called it scientific in an interview(28). And this is a basic conceptual difference in regulation between Japan and the U.S.A. Japan's guidelines regulates both process and products just because biotechnology is involved in the process. Even if both natural and recombinant process can produce exactly the same product, product produced by recombinant bacteria has to be regulated in Japan. This difference makes the food safety issue more complicated in Japan.

Food Safety Issue in Japan

The environmental release of a genetically engineered plant is just an entrance of commercialization of the plant. Since most crops are finally consumed as food, the genetically engineered crops should be safe to eat. Exceptions are flowers, ornamental trees and some industrial crops such as cotton, flax, rubber and so on. Whether genetically engineered crops are safe or not, how to prove their safety is a difficult problem to solve before the commercialization.

In Japan, the Ministry of Health and Welfare(MHW) is the regulatory agency for food safety and it regulates food based on the Food Hygiene Law. The coverage of this law is mainly contamination in food manufacturing process and utilization of chemical food additives.

Accordingly, MHW actually has no regulation on safety of the food itself. MHW's idea is that because food has been consumed safely, food is safe and that people would not eat something non-food. On the other hand, to obtain permission to commercialize a new chemically produced food additive requires a lot of safety tests, while naturally derived food additives, such as color extracted from flowers, are not regulated at all. If existing rules were to be applied to biotechnology food, MHW had to answer to two critical questions: One was whether genetically engineered food, such as herbicide resistant tomato, is food or food with food additive. The other was whether food additives produced via recombinant process are natural or chemical. To avoid answering these questions, MHW decided to make new guidelines only for biotechnology food and to regulate it under the existing law and the guidelines. This is a process-based regulation of product safety.

MHW organized a scientists group to work on the guidelines in July, 1986(29). The group released a draft in 1988 and finally the Food Safety Committee of MHW completed a proposal of the guidelines in May, 1991, which will be enacted. The intention of the guidelines is to regulate safety of food produced using biotechnology, not only genetic engineering but cell culture, cell fusion and bioreactor. However, the 1991 proposal covered only genetic engineering and besides the coverage was limited to purified products already used in food or food processing, such as amino acids and enzymes(30). If the final product is exactly the same, no matter what process is used, all that is required is to evaluate the contaminated by-products, which may differ in each process. This is the easiest case, but they

postponed the decision on more difficult cases: genetically engineered organisms themselves, for example, fermented food and genetically engineered crops and new food that we have never eaten. Without clear regulation on the safety of genetically engineered crops, it is hard to invest in such a field.

The U.S. Food Safety Regulation

The U.S. Food and Drug Administration (FDA) regulates food safety under the Food, Drug and Cosmetic Act. As described previously, the FDA's regulation is only based on the product and this is the difference from that of Japan.

With respect to safety of food additive, FDA uses the concept of generally recognized as safe substance(GRASS). In 1958 FDA introduced the GRASS, which are substances that had been permitted before 1958 and substances that people had used traditionally until 1958. New substances for food other than in those categories are required to submit data to prove safety. In Japan there is no equivalent concept in food safety regulation.

Since FDA's regulation does not care about the process, it can be applied to biotechnology food immediately. As a matter of fact, in the U.S.A. some enzymes produced by genetically engineered bacteria are commercialized as GRAS substances. In 1988, FDA admitted Enzyme Bio-Systems' genetically engineered amylase, an enzyme for starch processing, as a GRAS substance(31). In 1990, Pfizer's recombinant chymosin obtained the GRASS status and the company began marketing it(32,33). Chymosin, or rennin, is an enzyme to be used in cheese

production and is naturally obtained from calf's stomach. The recombinant chymosin is much cheaper than natural one. They are case of purified substance and what was required is safety test for contaminated substances. But how about crops?

The U.S. biotechnology industry expects that genetically engineered plants and animals will be admitted as GRASS, which will make it possible to avoid substantial safety tests. When I interviewed Richard D. Godown, the President of Industrial Biotechnology Association(Washington D.C.) in September, 1988, he insisted that they should be GRAS because the protein that the foreign gene is producing in the plant cells, such as coat protein of tobacco mosaic virus, exists naturally and consequently we are eating it. However, this problem is not so simple. Industrial Biotechnology Association and International Life Science Institute(Washington D.C.) had jointly produced a proposal of guidelines on biotechnology food safety and released it in June, 1990(34). This proposal is intended to influence the FDA's guidelines. It covers not only purified substances but also combinations and whole recombinant organisms, and classified risk based on the technique utilized. According to the proposal, much attention is paid to antibiotics resistant genes(35). The genes are commonly used as selection markers to pick up transformed cells, but they may transform other bacteria to be antibiotics resistant, which can be hazardous.

Based on such concern, Calgene, a plant biotech firm, asked FDA for safety assessment on use of kanamycine resistance gene in plants(36). The gene is a popular selection marker for plant genetic

engineering. The FDA asked the biotechnology industry to submit comments on it and the final decision was not yet done as of July, 1991(37). Although there are a lot of discussions in the U.S.A., how genetically engineered food crops will be regulated is not clear, either in Japan.

Effect of the Difference Between the U.S.A. and Japan

The food safety guidelines released in 1991 in Japan are very similar to the U.S. regulation of GRAS substances. But as described previously, there is no equivalent concept to the U.S. GRASS in Japan, that is, what kind of food should be regulated is not defined.

A typical example is the case of polydextrose. It is chemically synthesized, water-soluble dietary fiber developed by Pfizer, which started its R&D in the late 60's and obtained permission from the FDA to commercialize it as a food additive in 1981. Though raw materials of the polydextrose are glucose, sorbitol and citric acid, all of which are GRASS, the synthesized form is new for food and accordingly Pfizer had to obtain permission as a new food additive. When Pfizer's affiliate in Japan introduced it in 1983, Japan's Ministry of Health and Welfare could say nothing but "no problem". Their explanation was that since it is composed by food items, it is food even though it is chemically synthesized and new to eat(personal communication from Pfizer Japan). A MHW's official said that it was not a permission because there was no rule, but that it was ignorance(personal communication). But it was not scientific, because hazardous substances can be produced from only food items.

The commercialization of recombinant chymosin has already begun in the U.S. and Europe, but in Japan it has not yet been commercialized because the proposal of the guidelines is not authorized yet as of July, 1991. "No rule" means that it is possible to import and sell the chymosin and cheese produced using it in Japan without any permission, as is the case of polydextrose. But the MHW asks traders to wait for the completion of the guidelines and the recombinant chymosin is not sold yet in Japan. However, since we cannot distinguish cheese produced using recombinant chymosin from that produced using natural chymosin, there is a strong suspicion that people have already eaten the recombinant cheese. Since recombinant chymosin is GRASS, there is no need to disclose its use.

The process-based regulation will make no sense, if it cannot regulate imports. But the MHW's food regulation without GRASS concept may not easily changed, due to enormous transaction costs. Therefore, MHW will have to continue patch work of process-based regulations. This is making uncertainty in regulations in Japan and may encourage to invest in foreign countries.

A brief history of institutions of biotechnology is on the next page.

Table 5-2. History of Institutions Related With Biotechnology

	The U.S.A	Japan
1970	·PVPA enacted	
1973	·First genetic engineering research by Cohen and Boyer	
1974		
1975	·Asilomar conference	
1976	·First NIH guidelines	
1977		
1978		·The Seed Law revised
1979		·First guidelines equivalent to the NIH guidelines
1980	·Diamond v. Chakrabarty	
1981-84		
1985	·Ex parte Hibbert	
1986	·Coordinated regulatory framework ·First environmental release of genetically engineered plants	·MAFF's draft of guidelines ·Major Crop Seed Law revised
1987		
1988		·MHW's draft of guidelines
1989		·STA's and MAFF's guidelines for environmental release of rDNA plants ·First experiment in unclosed environ ment under STA's guidelines
1990	·Proposal for rDNA food guidelines ·Recombinant chymosin commercialized ·Four principles of regulation	
1991		·First environmental release under MAFF ·Guidelines for rDNA food proposed (only purified substance)

6. Input of R & D of Plant Biotechnology

As described in previous chapters, there are a lot of differences between Japan and the U.S.A. in institutions that affect plant breeding, especially plant genetic engineering. In this chapter I will examine the consequences of those differences in terms of R&D inputs.

Although plant genetic engineering has more than a ten-year history, no genetically engineered plant is commercialized yet. Consequently, the output measures are neither sales of seeds nor crop production. Instead of them, assuming knowledge production function, new varieties and patents for them as output measures will be used. As described in Chapter 2, simple patent counts are not a good measure of R&D output, because neither each variety nor each patent contain the same amount of knowledge. Therefore other information need to be used in addition to them. I will examine R&D output in Chapter 7.

On the other hand, inputs to produce knowledge are previous knowledge, expenditures on R&D and research labor. Institutions change expected profit from investment in R&D, which reflects expenditures on R&D and number of researchers employed. However, since available data of those measures is very limited, other measures reflecting expected profit, such as number of firms with plant biotechnology program, have to be used. Previous knowledge is also an important input. This is related to diffusion and institutions affects the rate of diffusion, as described in Chapter 2. However, it is hard to measure diffusion using available data. Due to limitation of data, the entry of firms to the

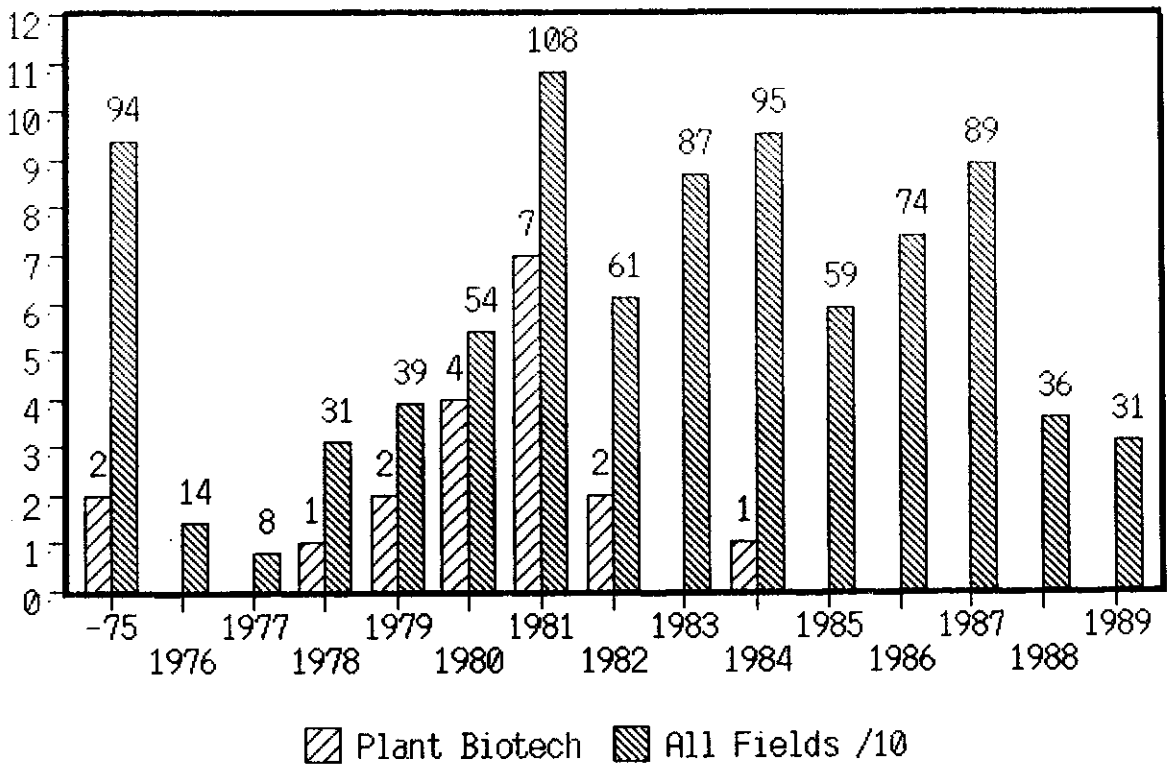
R&D of this field will be examined as an input measure in this chapter.

The number of firms entering the field of R&D of plant biotechnology is a measure of industrial expectation of profitability of this field. I gathered the data mainly from NIKKEI BIOTECHNOLOGY's *'83 World 300 Bio-Companies*(1), *'89 World 800 Bio-Companies*(2) and *'90 World Bio-Companies; Technologies and Strategies*(3), which were compiled from original world-wide mail survey, original interview and publications. In addition to those, I used recent newsletters for data up-date.

Entry to Plant Biotechnology in the U.S.A.

There were twenty-six firms in the field of plant biotechnology, 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. See Table 6-2. The year when a firm entered R&D of plant biotechnology is identified with respect to nineteen of those twenty-six firms. How many firms started R&D of plant biotechnology in each year, that is, the yearly number of entries to plant biotechnology is shown in Fig. 6-1 as "Plant Biotech". Probably very minor biotech ventures were missed, but it may not matter in this purpose. For comparison, yearly number of foundings of firms that are doing business in any fields of biotechnology is also shown in Fig. 6-1 as "All Fields". This data is from *Biotech 90:Into the Next Decade* written by Ernst & Young High technology Group(4).

Fig. 6-1. Number of Entries into Plant Biotechnology and Number of Foundings of Biotech Venture of All Fields in the U.S.A.



"Plant Biotech" is a 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, "All Fields" is a number of founding, that is, since Monsanto was established before 1975, it is counted in -75. Therefore, "All Fields" after 1976 includes only new biotech ventures in all fields biotechnology, not only plant but also pharmaceutical, diagnostics, food etc. In order to show two kinds of data in one figure, the total number of "All Fields" is divided by ten, and the total number is shown at the top of each year's bar.

Seeing "Plant Biotech" in Fig.6-1 and Table 6-2, two bioventures, Cetus and Agrigenetics, were established before 1975, which means that they did not intend to apply genetic engineering to plant breeding initially. In 1984 W.R. Grace acquired the 51% of equity of Cetus-Madison, a subsidiary of Cetus and specializing in plant biotechnology. This is the one entry of 1984 in the figure. Otherwise, the entry concentrates around 1980 and the peak year is 1981. On the other hand, seeing "All Fields" in Fig.6-1, there are three waves of biotech boom and the entry in the plant biotechnology coincides with only the first biotech boom.

The first boom arose directly from the breakthrough of genetic engineering, that is, to produce foreign protein in *E. coli* had become possible and the boom was accelerated by the first success of Genentech/Eli Lilly's human insulin, which was finally commercialized in 1982. People expected that culture cells could produce every valuable human protein as drugs, which otherwise was too scarce to be

utilized. This opportunistic dream was destroyed later, when people got to know that very few human proteins can be applied directly as drugs.

On the other hand, with respect to plant biotechnology, no one transformed a plant cell successfully yet in the first boom. According to *Official Gazette of the United Sates Patent and Trademark Office* since January, 1986, which is the oldest one available in the Michigan State University library, the earliest patents claiming the methods are as follows.

US Patent 4,684,611: Process for the *in vitro* transformation of plant protoplasts with plasmid DNA. Inventor is University of Leiden, the Netherlands. Date of priority claim is February 11, 1982. Issued in the U.S.A. on August 4, 1987.
US Patent 4,693,976: Process for the incorporation of foreign DNA into the genome of dicotyledonous plants using stable cointegrate plasmids *Agrobacterium tumefaciens* Ti plasmid. Inventors are individuals in the Netherlands. Date of priority claim is February 24, 1983. Issued in the U.S.A. on September 27, 1987.

These two patents claim transformation of cells or protoplasts(cells whose cell wall is removed), but not regeneration from the transformed cells to plant. According to a report appeared in a newsletter, *NIKKEI BIOTECHNOLOGY*, researcher group of Agrigenetics and University of Wisconsin succeeded in transformation of cultured sunflower cells with a gene from a bean in 1983, which was the first time of confirmation of expression of a foreign gene in plant cells(5). That group did not report a successful regeneration, either. The difficulty of regeneration depends on plant species. Since tobacco, tomato and petunia are the easiest ones, they were the first target of plant biotechnology. In 1984, reports of successful transformation of a whole plant with a foreign gene appeared in scientific

journals for the first time(16). Considering these facts, it can be said that it was not until 1983 that researchers had the basic techniques of plant biotechnology. Therefore, investing in plant biotechnology was completely speculative.

The Chakrabarty case in 1980 established that human-made plants could be patented. This Supreme Court rule could affect investment in plant biotechnology, but considering the coincidence with the general biotech boom, the Chakrabarty case is considered to have little effect. The Board of Patent appeals and Inferences' in 1985 ruled that plants are patentable subject matter for the first time. But the decision had no effect at least on the entry into the field of plant biotechnology.

To summarize, the entries into plant biotechnology were affected by the general biotechnology boom of around 1980. On the other hand, the actual development of plant genetic engineering (after 1983) and the new patent rules (in 1980 and 1985) had little effect on the entries, though they may have affected research agenda of existing firms.

The Year of the First Environmental Release in the U.S.A.

In a situation of continuous investment, number of entries is not a good measure of yearly change in expectation of profit. However, such data as public offerings, private investments, R&D contracts and so on are very limited and cannot be utilized here.

The environmental release of genetically engineered plants is the first and inevitable step to commercialize them. As described in Chap-

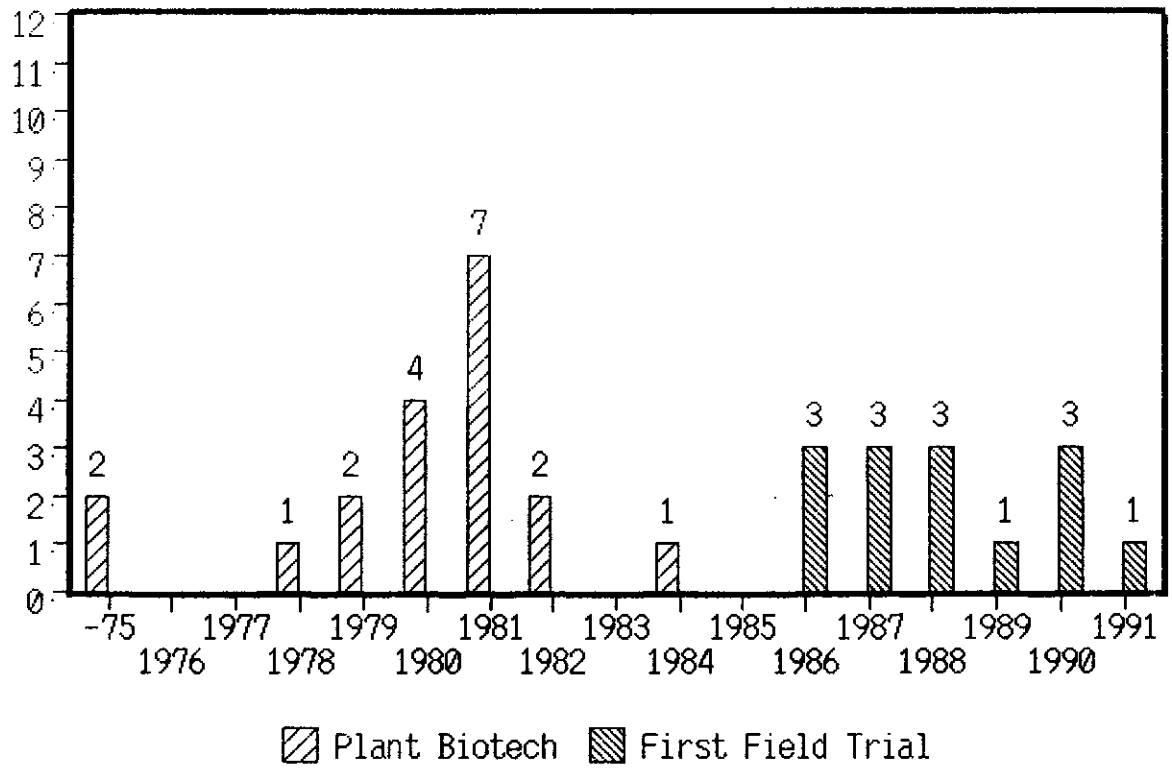
ter 5, the total number of the environmental releases has been increasing rapidly since 1986. The number is 3 in 1986, 250 in 1990 and 400 in 1991. These numbers include both private and public experiments, but since the majority are private, it implies the intensity of private R&D effort has been increasing at the industry level.

The year when a firm made its first environmental release was collected and is shown in Fig.6-2. As far as I know, thirteen firms have started such experiments so far. Although number of experiments is increasing rapidly, the increase of the number of firms is relatively slow. This means that firms that have already entered plant biotechnology are expanding R&D. For example, Monsanto plans to do field trials of one variety in forty different places in 1991(6). The thirteen firms are shown in Table 6-1.

Table 6-1. Entry of Firms in Environmental Release of rDNA Plants by Year

Firm	Firm Type	Year to Enter	First Crop
Agracetus	start-up	1986	tobacco
Ciba-Geigy	established	1986	tobacco
Rohm and Haas	established	1986	tobacco
Calgene	start-up	1987	tomato
Du Pont	established	1987	tobacco
Monsanto	established	1987	tomato
Agrigenetics	start-up	1988	tobacco, tomato
Ecogen	start-up	1988	potato
Sandoz	established	1988	tobacco
Pioneer Hi-Bred	seed	1989	alfalfa
Asgrow Seed	seed	1990	cantaloupe, squash
Biotechnica Intl.	start-up	1990	corn
Northrup King	seed	1990	cotton
DNA Plant Tech.	start-up	1991	chrysanthemum

Fig. 6-2. Number of Entries into Plant Biotechnology and Number of Starts of Field Trial of Genetically Engineered Plant in the U.S.A.



Firm type and the first crop have changed during those five years. Since the transformation of tobacco and tomato is easy, they were chosen as model plants for environmental release experiments, as described in Chapter 5. However, in accordance with technology development, the crops for the first environmental release experiment have been diversified and become more realistic. It is not only because of technological development, but due to a change of type of new entrants. Pioneer Hi-Bred International in 1989, Asgrow Seed in 1990 and Northrup King in 1990 are big companies specializing in seed. Pioneer Hi-Bred International is the biggest independent seed company, while Asgrow and Northrup King are subsidiaries of large pharmaceutical companies, Upjohn and Sandoz respectively(7). Though they had seemed to be conservative to the new biotechnology, they finally started genetic engineering. Pioneer's alfalfa of 1989 was supplied by Agrigenetics. It was not a product of its own, but in 1990 they tried recombinant sunflower produced by in-house research. The entries of those authentic seed companies mean that genetic engineering has become one of necessary breeding techniques(8). In addition, plant patenting since 1985 may have changed their attitude towards the technology. I will analyze patents later.

On the other hand, two bio-ventures started environmental release of plants after 1990, but they had previous experience in environmental release of genetically engineered bacteria: DNA Plant Technology did a field trial of recombinant ice-minus bacteria in 1987 and Biotechnica International did a field trial of recombinant nitrogen-fixing bacteria in 1988. They have changed their focus from bacteria

to plants. Since they are not really new entrants, recent new entrants are only authentic seed companies.

Changing Industrial Structure in the U.S.A.

During the 1970's a large number of seed companies were acquired by large chemical, pharmaceutical or oil companies. The perception that PVPA of 1970 would increase the profitability of seed companies was an important factor in the acquisition. But a tightening of world grain markets and higher commodity prices in early 70's also stimulated investment(9).

Lists of parent companies are available from (7) and (9), according to which it is known that not all parent companies entered plant biotechnology R&D, even though the parent companies are actively engaging in biotechnology in the pharmaceutical field. Only Ciba-Geigy and Sandoz started plant genetic engineering research actively. On the other hand, Monsanto and Du Pont entered seed business after the emerging biotechnology boom.

Biotechnology was associated with a second wave of acquisitions of seed companies during 1980's. This time, not only large companies but also biotech start-up firms purchased seed companies, mainly to secure income and future sales outlets.

In early 80's there were roughly two types of biotech firm with respect to technology, that is, genetic engineering oriented firms and tissue culture oriented firms. But since mid-80's tissue culture oriented firms became hard to survive and were finally purchased by other firms. This may be because genetic engineering has recently be-

come more and more critical for plant breeding due to technology development and plant patenting. Following are the cases:

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 Calgene, a bio-venture specializing in genetic engineering of plants purchased Plant Genetics, a bio-venture specializing in tissue culture.
In 1989 Lubrizol purchased Sungene Technology, a bio-venture specializing in breeding via tissue culture.
In 1989 Biotechnica International purchased plant biotechnology section of Molecular Genetics, in which corn breeding via tissue culture were carried out.

There are fourteen biotech venture firms among the nineteen firms that entered plant biotechnology(Table 6-2). And only eight of those fourteen biotech ventures still survive as of July, 1991. Among survivors, only three above mentioned are financially stable and keep relatively high R&D activity.

Roger Salquist, chairman and CEO of Calgene, a leading plant biotechnology company, said in 1991 "It will be impossible to finance new agbiotech start-ups in the U.S. Adding that many existing companies will disappear or be absorbed by large U.S. or foreign firms in the next 24 months"(10).

Other players in this field are large established companies and seed companies. Entry of large companies into this field has stopped since the first biotech boom except for purchasing biotech ventures. On the other hand, large seed companies recently have started R&D of genetic engineering. In addition to the three seed companies listed in Table 6-1, Dekalb will soon start field trials of genetically engineered corn. However, other seed companies seem to be still inac-

tive.

In Table 6-2, the U.S. plant biotechnology companies are listed.

Conclusion of the U.S. Case

The number of plant species that can be transformed with foreign gene has increased since mid-80's. Human made plants have become patentable since 1985. Environmental release of genetically engineered plants has been permitted relatively easily since 1986. These three facts have increased the importance genetic engineering in plant breeding, which has caused a shift in breeding technique and promoted acquisition and merger in the U.S. plant biotechnology industry.

However, considering that there are few new entrants, those technological development and institutional change did not stimulate private investment in establishing new ventures, which is different from what has been happening in other fields of biotechnology, especially in biotech pharmaceutical. This is because people know that it will take a long time to obtain return from investment in plant genetic engineering, even if it is successful.

In addition, there are still regulatory uncertainty, such as food safety, and technological uncertainty. Public acceptance of genetically engineered food is also very uncertain.

Table 6-2. U.S. Agricultural Biotechnology Firms

FIRMS	Found	Start PlantBio	Acquired or Absorbed
<START-UPS>			
Advanced Genetic Sciences	1980	1980	1988
····merge with DNA Plant Sciences			
Agracetus	1984	1984	1990
····was purchased by W.R.Grace			
Agrigenetics Company	1975	1975	1984
····was purchased by Lubrizol			
Biotechnica International (BTI)	1981	1981	
Calgene	1980	1980	
Cetus	1971	1971	1990
····sold Agracetus to Grace			
Crop Genetics International	1981	1981	
DNA Plant Technology	1981	1981	
····merge with Advanced Genetics Science			
Ecogen	1981	1981	
International Plant Research Institute	1978	1978	1985
····Due to bankruptcy re-established as ESCAGenetics	1987		
Molecular Genetics	1979	1979	1989
····sell plant-bio section to BTI			
NPI	1973	1980	
Phytogen	1980	1980	1984
····was purchased by Boswell, a seed company			
Plant Genetics	1981	1981	1989
····was purchased by Calgene			
Sungene Technologies	1981	1981	1989
····was purchased by Lubrizol			
United Agriseeds	1981	1981	1987
····was purchased by Dow Chemical			
<LARGE ESTABLISHED FIRMS>			
Ciba-Geigy			
Dow Chemical			
----purchased United Agriseeds	1987		
Du Pont			
W.R. Grace			
····established Agracetus with Cetus	1984		
····purchased Agracetus	1990		
Lubrizol			
····purchased Agrigenetics	1984		
····purchased Sungene technologies	1989		
Monsanto		1979	
Rohm and Haas			
Sandoz			

Table 6-2. U.S. Agricultural Biotechnology Firms(continued)

FIRMS	Found	Start PlantBio	Acquired or Absorbed
<SEED COMPANIES>			
Asgrow			1972
····was purchased by Upjohn			
Dekalb Pfizer Genetics	1982	1982	
····joint Pfizer and Dekalb AgResearch			
Northrup King			1975
····was purchased by Sandoz			
Pioneer Hi-Bred International		1982	

Source: (1),(2),(3)

Entry into Biotechnology of All Fields in Japan

With respect to plant biotechnology in Japan, similar analysis to that of the U.S.A. is done. The yearly number of firms that entered plant biotechnology "Plant Biotech" and all biotechnology fields "All Biotech Fields" are counted respectively using the same references noted previously and a survey done by NIKKEI BIOTECHNOLOGY(11).

Since unlike in the U.S.A. there were only few biotech ventures in Japan, entries are counted in both "Plant Biotech" and "All Biotech Fields". Therefore, the yearly number represents how many established firms started R&D of a biotechnology field in the year. This is not the year when the firms were established. As a result, most established firms have appeared after the first biotech boom of around 1980, which is different from the presentation of the U.S. data where each firm is counted in the year when it was established. The results are shown in Fig.6-3.

The time series pattern of "All Biotech Fields" looks very much like that of the U.S.A. in Fig.6-1. However the type of entrants are

different. The biggest difference is that there were very few biotech ventures in Japan as noted above. Some independent companies specializing in biotechnology have been established, but they are owned by one company or a group of companies privately. Such companies will never be public. Since 1986, a different type of biotech venture has emerged. The number of such companies is thirty-two as of July, 1991. Though this is a quite big number, they are excluded from the graph given in Fig.6-3, because they are financed by quasi-governmental foundations. In the process of privatization of large public corporations during 80's, such as the Japan Telegraph and Telephone and the Japan Tobacco and Salt, government has made a lot of money by selling government owned stock. Using some of the money plus donations from industries, the Ministry of Agriculture, Forestry and Fishery(MAFF), the Ministry of International Trade and Industry(MITI) and the Ministry of Health and Welfare(MHW) have established three quasi-governmental foundations respectively. The funds of those foundations are used to encourage R&D of high technologies including biotechnology in the industries that are under the control of those agencies. One of those foundations, two or more firms and sometimes industrial associations or agricultural cooperatives jointly invest to establish a new venture firm. Such a firm has a very specific focus and researchers are from the parent firms temporarily. In the field of plant biotechnology, MAFF's foundation, Bio-oriented Technology Research Advancement Institution(BRAIN), has established a lot of new ventures, which I will discuss later.

Most of the entrants in Fig.6-3 are established firms. They can

be divided into three types: One is companies that need biotechnology for R&D in their own fields, typically pharmaceutical. Second is companies that seek for diversification to related fields, for example, from food or chemical to pharmaceutical or/and agriculture. The last is companies, such as steel, shipbuilding and oil industries, that want to diversify their business into completely different fields. Looking at the Fig.6-3, there are two waves of entry: The 1982 peak corresponds to companies of the first two types and the second wave peaked in 1985 corresponds to the last type(11).

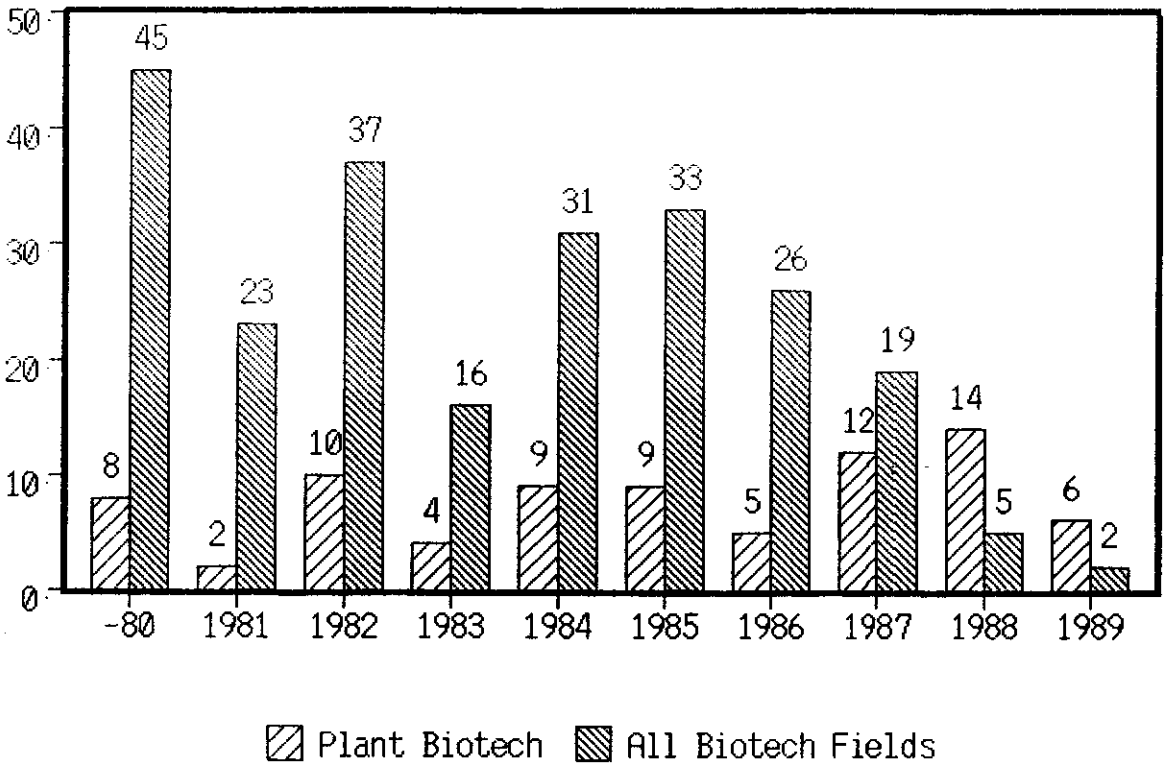
Therefore, though the wave pattern looks like that of the U.S.A., the meaning is different. In the U.S., new generations of biotechnology, such as transgenic animals, gene therapy, anti-sense RNA (RNA that has a complementary sequence to normal messenger RNA. Anti-sense RNA inhibits normal function of the messenger RNA in cells and as a result stops expression of the target gene) and so on, promoted investment in new bio-ventures. In Japan the second wave of entry reflects merely recession due to rapid increase of yen value against dollar. As a result of the Plaza agreement, the value of yen had almost doubled, that is, from about 250 yen per a dollar in 1985 to about 125 yen in 1988. In the recession, steel, shipbuilding and mining industries had the most severe damage and had a large surplus of labor. In order to absorb surplus and to avoid layoffs, those companies invested in every possible new fields: some of them were to make immediate income and others were to diversify the business and to be profitable in the medium and long run. Biotechnology was one of the latter fields(12,13).

Entry into Plant Biotechnology in Japan

For most established firms except for seed and seedling companies, plant biotechnology was a new field and they started R&D in order to diversify business. Since such diversification usually starts from in-house research using existing researchers, sometimes "doing plant breeding" means that one researcher who was a specialist of chemical engineering has begun to grow flowers. Therefore, it does not make sense to compare absolute number of entries between the U.S.A. and Japan. R&D expenditure per person and per firm should be compared, but it is hard to know how much they spend for plant biotechnology because they usually reveal only total biotechnology R&D expenditures which include pharmaceutical, chemical, agriculture etc.

In addition, at least during 1980's, plant biotechnology seemed to have different meaning between the U.S.A. and Japan. In the U.S.A. it meant plant breeding using genetic engineering and/or tissue culture. In Japan, in addition to those definition, it meant multiplication of seedlings using mericlone culture or tissue culture. Of course this technology was not new in early 80's, but for the companies that wanted to diversify, investing in such a classic biotechnology was attractive because entry barrier is small and because the return would be quick. In the U.S.A. 1930 PPA prohibits unauthorized asexual propagation of patented plants, although the effectiveness is doubted. On the other hand, there had not been an equivalent law in Japan until the Seed Law in 1978, and consequently most flowers released before the law are free to copy. This may be another reason why in Japan multiplication of seedlings is so popular business even among large com

Fig. 6-3. Number of Entries into Plant Biotechnology and Number of Entries into Biotechnology of All Fields in Japan



panies. Of course those companies doing multiplication business are also trying breeding, that is, to induce mutation and to select variants from regenerated plants. Therefore, it is difficult to distinguish multiplication companies from breeding companies completely.

Consequently, the entrants are more heterogeneous than the case of the U.S.A. and one entry does not imply the same amount of R&D effort. However, the tendency tells something.

The time series pattern of entry in plant biotechnology shown in Fig.6-3 is obviously different from that of the U.S.A shown in Fig.6-1. As discussed previously, the U.S. pattern means that entries in plant biotechnology coincided with the first biotechnology boom. On the other hand, there are small three peaks of entry in Japan.

The entrants before 1980 were mostly seed and/or seedling com panies. They used tissue culture to multiple expensive orchids or for breeding. The entrants around 1982 were large companies mainly from food and chemical industries. Their entries coincide with biotechnology boom. Since they saw slow growth of their main business, they needed new fields of investment around it. At the same time, biotechnology boom came from the U.S.A. As a result, such companies invested not only in plant biotechnology, but also pharmaceuticals. However, though biotechnology boom was induced by the development of genetic engineering, plant biotechnology in Japan does not necessarily mean genetic engineering but as noted previously included classic biotechnology, such as tissue culture. As is shown in Table 6-5, most firms do not use genetic engineering in plant breeding even today.

In 1983 the Ministry of Agriculture, Forestry and Fishery(MAFF)

established a group "New Breeding Technology Research Group" in order to collect information from new entrants and to influence them. Fourteen major Food and Chemical companies joined the group, shown in Table 6-2(14). Most of them are still major players of plant biotechnology in Japan.

On the other hand, those companies' lobby activities succeeded in amending the Major Crop Seed Law in 1986. As a result they became able to do business in rice, wheat and soybean seed, although anticipation had made them start breeding of those crops before 1986. Since those companies that were interested in the major crops had already entered plant biotechnology before 1986, the amendment had little effect on new entry.

However, the graph in Fig.6-3 shows that the entries in plant biotechnology had continued after the first surge and increased again

Table 6-3. MAFF's New Breeding Technology Research Group

Firm	Field	Total Sales of the firm in 1981(billion yen)
Asahi Chemical Industry	chemical	592,400
Ajinomoto	food	393,100
Kagome	food	NA
Kikkoman	food	128,900
Kyowa Hakko Kogyo	food	206,500
Kirin Brewery	brewery	984,800
Sapporo Brewery	brewery	348,000
Suntory	brewery	NA
Sekisui Chemical	chemical	297,600
Teijin	textile	460,000
Mitsui Petrochemical Industries	chemical	280,300
Mitsui Toatsu Chemicals	chemical	433,300
Mitsubishi Chemical	chemical	756,000
Meiji Seika	food	189,500

exchange rate: $1=¥250(1981), ¥140(1991)

in 1987 and 1988. Seeing the names of those entrants and their initial targets, it was found that these entries were not because of the 1986 amendment but because of the "high yen recession" as described previously and because of domestic flower boom since 1986. The flower boom is considered to be due to governmental conversion program from rice to some other crops and due to increasing demand for flowers. Since homogeneity is demanded by not only producers but large scale consumers, such as company gift and decorations, the demand for homogenous tissue cultured seedlings is increasing. These market situations have promoted entries in plant biotechnology, but not genetic engineering. The entrants were heavy industries in recession and local small or middle sized manufacturers. The domestic cut flower productions are shown following Table 6-3.

Table 6-4. Japan's Domestic Cut Flower Production

YEAR	1985	1986	1987	1988	1989
PRODUCTION(100billion yen)	1577	1596	1743	1917	2106

(Source: MAFF)

Effect of Institutions in Japan

It is hard to distinguish the effect of the Seed Law(SL) of 1978 from the biotechnology boom on the entries in plant biotechnology in Japan. The peak of entries was 1982, which coincided with bio-boom well. But on the other hand, in 1981 industrial association for new variety protection was established and most of the members also entered plant biotechnology. Therefore, the 1978 SL can be considered to have some effect.

As I discussed previously in this chapter, the Major Crop Seed

Law(MCSL) of 1986 did not affect the entry in plant biotechnology. But 1986 MCSL has made it possible to establish new bio-ventures specializing in rice using the government funds of BRAIN, mentioned previously. From 1986 to 1991, thirty-two companies have been founded by the three quasi-governmental foundations. BRAIN, which is under control of MAFF, has invested in twenty-two of them. Among them, three companies are doing research in rice, as shown in Table 6-5.

Table 6-5. Rice Biotech Ventures Financed By BRAIN

FIRM(Found)	INVESTORS OTHER THAN BRAIN	THEME
Nursery Technology (1987)	Kirin Brewery(brewery) Taisei Corp.(construction) Nippon Steel(steel) Kyowa Hakko Kogyo(food) Federations of Agricultural Cooperative of Hiroshima, Saga, Shimane and Miyagi prefectures	to develop technologies of mass production of F_1 hybrid rice seedlings using tissue culture and of distribution to farmers
Hokkaido Green-Bio Institute(1987)	The Hokuren Federation of Agricultural Cooperative Hokkaido Electric Power and etc.	to develop new cold-resistant rice, wheat and soy bean good for cold whether of Hokkaido prefecture
Rice Breeding Research Laboratories (1988)	The Japan Tobacco(tobacco) Kirin Brewery(brewery) Tohoku Electric Power and etc.	to develop new varieties of rice good for processing using genetic engineering

Source:(3)
BRAIN = Bio-oriented Technology Research Advancement Institution

As described in chapter 4, it is still uncertain whether plants are patentable subject matter or not in Japan, even though the patent office(JPO) does not deny the possibility(15).

The problem is the description of invention. As discussed in

Chapter 4, description of a plant variety based on conventional breeding method cannot be complete. It can be described how the new variety has been bred, but the breeding procedure may not always bring the same result due to random nature of life. Moreover, conventional breeding cannot explain why the utility of the new variety can be obtained. The general patent requires description of how to secure the utility and ignores other minor differences in phenotype, as a result, the claim can be broad. Genetic engineering has made it possible or at least easy to describe how to obtain the utility, because a foreign gene, such as tobacco mosaic virus coat protein gene, is usually responsible for the new utility, such as tobacco mosaic virus resistance. This is generally believed in Japan. However, on the other hand, as is the case of other industrial fields, the product space of the patent will be narrowly determined by the JPO, and consequently the effectiveness of patent will be small in Japan.

What kind of effect the Japan's plant patent will have on the R&D input? Firms are expecting the issuance of plant patents, but thinking that the product space will be narrow, as described above. Therefore, the patent may not be so critical to secure profit in Japan, and besides patenting plants will not damage those who do not have patents so much. As described above, plant genetic engineering may be a way to obtain relatively broad patent on plant. But in Japan, since plant patents are not so important, plant genetic engineering is not always necessary. In addition, since genetic engineering in general requires more R & D expenditures, a longer investment period and additional legal work for commercialization, there is little advantage in genetic

engineering relative to other substitute technologies in Japan.

These expectations and available substitutes discourage the private sector to do genetic engineering R&D, but make entry in plant biotechnology easy. As a matter of fact, a lot of companies are doing tissue culture business in Japan, see Table 6-5.

Moreover, the regulatory delay discussed in chapter 5 seems to have no effect on entry in plant biotechnology, because as noted above, most entrants consider that genetic engineering is not the key technology of plant biotechnology.

Conclusion of Japan's Case

Most firms that entered plant biotechnology are considering diversification of their business. Since some of them expect immediate return from the plant biotechnology, they are less interested in breeding, especially genetic engineering.

The Seed Law of 1978, coupled with biotech boom, had some effect, but the Major Crop Seed Law(MCSL) had no effect on entry of firms into plant biotechnology in Japan. But the amendment of MCSL allowed firms to invest in rice breeding, and as a result, private rice breeding program has been stimulated in Japan. MAFF supports this tendency by establishing cooperative research ventures.

On the other hand, plant patent and environmental release regulation discourage private investment in genetic engineering research. But this fact does not reduce entry to plant biotechnology, on the contrary, it lowers entry barrier in this field.

Table 6-5. Entries of Firms in Plant Biotechnology in Japan by Year

FIRM	ENTRY YEAR	TYPE	ORIGINAL BUSINESS	START of GE
Akatsuka Orchid	1966	B, M	seedling	
Miyoshi	1969	M	seedling	
Miura Mericlone	1971	M	seedling	
Kawano Mericlone	1977	B, M	seedling	
Mitsui Petrochemical Industries	1978	B	chemical	1988
Mikado Seed Growers	1979	B, M	seed/seedling	
Kyowa Seed	1979	B	seed	
Dai-ich Seed	1979	B, M	seed/seedling	
Kagome	1981	B, M	food	1987
Nakajima-Tenkoen	1981	M	seedling	
Tokita Seed	1982	B, M	seed	
Plantech Research Institute	1982	B	trade/chemical	1984
Oji Paper	1982	B	paper	1989
Mitsui Toatsu Chemicals	1982	B, M	chemical	1989
Tohoku Seed	1982	B, M	seed	
Verde	1982	M	venture	
Kirin Brewery	1982	B, M	brewery	1987
Kyowa Hakko Kogyo	1982	B, M	food	
Kikkoman	1982	B	food	
Kao	1982	B, M	toiletry	
Takii	1983	B	seed	
Takeda Chemical Industries	1983	B, M	pharmaceutical	1988
Asahi Industries	1983	B, M	food	
Saitama Genshu Ikuseikai	1983	B, M	seed	
Calbee Potato	1984	B, M	food	
Nichirei	1984	B	food	
Ezaki Glico	1984	M	food	
Yokohama Nursery	1984	B, M	seed	
Gakken	1984	B, M	publishing	
Kaneko Seeds	1984	B, M	seed	
Dai-Nippon Sugar	1984	M	food	
Bio Industry Okinawa	1984	M	venture	
Nippon Beet Sugar	1984	M	food	
Fuji Seito	1985	M	food	
Minoru Industrial	1985	M	agri. machine	
Japan Tobacco	1985	B, M	tobacco	1988
Iwakura Shubyo	1985	B	seed	
Asahi Chemical Industry	1985	B, M	chemical	
Sumitomo Chemical	1985	B, M	chemical	
Plantech	1985	M	seedling	
Nippon Mining	1985	M	mining	
Daiei Food Industry	1985	M	food	
Tohoku Oil	1986	B, M	oil	
Sakata Seed	1986	B, M	seed	

(continue)

Table 6-5. Entries of Firms in Plant Biotechnology in Japan by Year (continued)

FIRM	ENTRY YEAR	TYPE	ORIGINAL BUSINESS	START of GE
Ishikawajima-Harima Heavy Indus.	1986	M	shipbuilding	
Nippon Oil	1986	B, M	oil	
Tsuneishi Shipbuilding	1986	M	shipbuilding	
Shimizu Shokhin	1987	B	food	
Sumitomo Forestry	1987	M	forestry	
Suntory	1987	B	brewery	1990
Toho Gas	1987	M	energy	
Okinoerabu Bio Laboratory	1987	B, M	BRAIN	
Ueshima Coffee	1987	M	food	
Eastern Foods	1987	M	food	
Nursery Technology	1987	M	BRAIN	
Usuki Seiyaku	1987	M	pharmaceutical	
Ajinomoto	1987	B, M	food	
Nippon Steel	1987	B, M	steel	
Hokkaido Green-Bio Institute	1987	B	BRAIN	1987
Nippon Flour Mills	1987	B	food	
Pola Chemical Industries	1987	M	cosmetics	
Asahikawa-Seika-Oroshi-Ichiba	1987	B, M	retail	
Daiwabo	1988	M	textile	
Seiyo	1988	B, M	developer	
Harima Chemicals	1988	M	chemical	
Sanyo Noen	1988	M	seed	
Jujo Paper	1988	B, M	paper	
Pokka	1988	B, M	food	
Jidosha Buhin Kogyo	1988	M	autoparts	
Tobishima	1988	M	construction	
Sapporo Breweries	1988	M	brewery	
Green Research Center	1988	B, M	BRAIN	
Rice Breeding Research Laboratories	1988	B	BRAIN	1988
Osaka Gas	1988	B	energy	
NKK	1988	M	steel/ship	
Saite Neige Wine	1988	M	brewery	
Taisei	1988	B	construction	
Lion	1988	B	toiletry	
Nichiro	1989	B	food	
Sumitomo Metal Industries	1989	B	steel	
Mitsui Plant Biotechnology Research Institute	1989	B	Mitsui group joint venture	1989
Snow Brand Milk Products	1989	B	seed	
Taiyo Kagaku	1989	B, M	food	
Japan Turf Grass	1989	B	BRAIN	
Onoda Cement	1989	M	cement	
Okinawa Orchid Research Institute	1991	B, M	BRAIN	
Feed Crop Breeding Institute	1991	B	BRAIN	

Source: (1),(2),(3). TYPE B=Breeding, TYPE M=Multiplication, GE=Genetic Engineering, BRAIN=Bio-oriented Technology Research Advancement Institution

7. Output of R&D of Plant Biotechnology

In this chapter, I will examine outputs of R&D using patent data and other available information. I deal with not only research outputs, but also marketing efforts and the public role. Comparing differences between the U.S.A. and Japan, finally I discuss the international consequences.

7-1. The U.S. Plant Patents under the General Patent Act

In the U.S.A. human-made plants are patentable subject matter under the Patent Act, or utility patent as noted in Chapter 4. The first utility patent of plant was granted to a biotech firm, Molecular Genetics Research and Development on April 15, 1986. This was the direct result of PTO's Board of Patent Appeals and Interferences(BPAI)'s decision of 1985. When the decision was announced, the attorney of Molecular Genetics commented "Without patent protection, to develop a new variety is so risky and so unprofitable that we cannot have incentive to intensify the R&D"(1, re-translated from Japanese). This was a typical view of private firms doing R&D of plant biotechnology in the U.S.A.

The first patent was classified in patent class 47, but the others were classified in patent class 800, which was established to cover inventions of multicellular organisms after the issuance of the first plant patent. The number of patents classified as 800 is forty-nine as of January 1, 1991, excluding animal patents. In Table 7-1 all plant patents are listed.

TABLE 7-1. U.S. Patent Classified in 800

Number	Issue	File	Firm	Claim
4581847	860415	840904	Molecular Genetics Research & Development	Tryptophan overproducer mutants of cerial crops Patent Class 47
4616099	861007	820719	Individual Britain	Family group of successive radiation induced chrysanthemum mutant named snapper Rapid growth rate, etc.
4616100	861007	840126	U of Saskatchewan Canada	Production of improved plants having an induced tolerance to the presence of a normally deleterious concentration of a plurality of inorganic salts Non-halophytic angiosperm crop in vitro tissue culture
4626610	861202	850111	Dekalb-Pfizer Genetics	Iron deficiency chlorosis resistant soybean variety Process to produce the seeds of a soybean variety resistant to iron deficiency chlorosis Cross of pure plant lines
4629819	861216	850426	Dekalb-Pfizer Genetics	Novel hybrid corn plant DK524
4642411	870210	850221	Molecular Genetics Research & Development	Tryptophan overproducer mutants of cerial crops
4654465	870331	850718	Agracetus	Genic male-sterile maize
4654466	870331	850429	Dekalb-Pfizer Genetics	Inbred corn line Designation 78010
4658082	870414	840725	Atlantic Richfield Company	Method for producing intact plants containing foreign DNA Infection of Rizobiaceae bacteria to dicotyledenous plant
4658083	870414 priority	850322 840323	Somycel France	Strains of Pleurotus Storeless pleurotus strains

Source:Official Gazette of the U.S. Patent and Trademark Office

TABLE 7-1. U.S. Patent Classified in 800 (continued)

Number	Issue	File	Firm	Claim
4658084	870414	851114	U of Guelph Canada	Hybridization using cytoplasmic male-sterility and herbicide tolerance from nuclear genes
4658085	870414	851114	U of Guelph Canada	Hybridization using cytoplasmic male-sterility, cytoplasmic herbicide tolerance and herbicide tolerance from nuclear genes
4677246	870630	850426	Dekalb-Pfizer Genetics	Protogyny in Zea Mays
4677247	870630 priority	850826 840827	Taishi Food Company Japan	Process for producing new variety of oderless soybeans Lopoxygenase lacking soybean
4686318	870811	860527	Individual New Zealand	Kiwifruit Plant Distinct variety of kiwifruit Long and substantially cylindrical shape
4686319	870811	850725	Rutgers Univ.	Synthesis of genetic females and their use in hybrid seed production True breeding female line of squas
4696674	870929	860210	Frito-Lay	Novel potato cultivar Dark green, slow-growing, but ultimately vigorous vine growth and white flowers and resistance to a golden nemetoda race
4705910	871110	850918	Standard Oil Company	Tetraploid corn and method of production Inbred line of tetraploid corn
4713491	871215	850923	Individual	Nina's Buttercup-Tihitian squash New variety of winter squash
4723052	880202	860613	Individual	Potato variety named LC-1 New and distinct variety of potato as having no known parentage

Source:Official Gazette of the U.S. Patent and Trademark Office

Number	Issue	File	Firm	Claim
4724276	880209	860807	Individual	Process for altering poinsettia growth characteristics
4727219	880223	861128	Agracetus	Genic male-sterile maize using a linked marker gene
4731499	880315	870129	Pioneer Hi-Bred	Hybrid corn plant and seed Designated 3790
4737596	880412	870129	Pioneer Hi-Bred	Hybrid corn plant and seed Designated 3471
4762964	880809	860929	Salt Weeds	Yensen 3a, Distichlis palmeri Vigorous growth, high pollen production and ideal height for pollination
4764643	880816	870106	Ring Around Products	F1 hybrid Oryza sativa Improved process for efficient production of seeds capable of growing male fertile F1
4767887	880830	860929	Salt Weeds	Yensen 1a, Distichlis palmeri Vigorous growth, high grain yield, ideal for harvesting
4767889	880830	860929	Salt Weeds	Yensen 2a, Distichlis palmeri Pleasing coloring of the grain that may grade from light brown posteriorly to dark brown anteriorly, reduced shatter characteristics. High grain fertilization rate, grain form suitable for harvesting
4767888	880830	870224	U of Guelph	Production of cole crops which exhibit triazine tolerance. Tolerance gene on 18 chromosome
4769512	880906	860924	NPI Seed	Bean plant having low pod detachment force
4774381	880927	850620	Du Pont	Herbicide resistant tobacco produced via somaclonal mutation

Source:Official Gazette of the U.S. Patent and Trademark Office

TABLE 7-1. U.S. Patent Classified in 800 (continued)

Number	Issue	File	Firm	Claim
4795855	890103	860224	Individuals Davis, CA	Transformation and foreign gene expression with woody species Transformation of poplar
4806652	890221	880127	Pioneer Hi-Bred	Inbred Corn Line PHR25
4806669	890221	880127	Pioneer Hi-Bred	Inbred Corn Line PHk05
4812599	890314	880127	Pioneer Hi-Bred	Inbred Corn Line PHV78
4812600	890314	880127	Pioneer Hi-Bred	Inbred Corn Line PHk29
4822949	890418 priority	870420 860420	Yeda Research development co. Israel	Production of hybrid cucumber seed
4827061	890502	880805	Yoder Brothers, Inc.	Chrysanthemum plant named Caricia
4827079	890502	850103	DNA Plant Technology	Generation of somaclonal non-Mendelian variants Cytoplasmic variants of Lycopersicon esculentum
4835339	890530	860214	Campbell Soup	Tomato anther culture Haploid itsself
4843186	890627	860728	LSL, Inc	Long shelf life hetrozygous tomato plant Cross bred, very firm
4886937	891212	880622	North Carolina State Univ.	Method for transforming pine Using Agrobacterium
4940834	900710	831205	Lofts, Inc	Plants having endophytio-fungus-enhanced performance and method of producing same Perennial ryegrass, peresistent, dense, attractive lower growing turf

Source:Official Gazette of the U.S. Patent and Trademark Office

TABLE 7-1. U.S. Patent Classified in 800 (continued)

Number	Issue	File	Firm	Claim
4940835	900710	860707	Monsanto	Gyphosate-resistant plants Using genetic engineering
4940836	900710 priority	851001 850220	Kikkoman and MAFF Japan	Somatic hybrids of rutaceae plants
4940837	900710 priority	871007 861009 861113	Takara Shuzo Japan	Strains and their cultivation Mushroom, Lyphyllum ulmarium
4940838	900710 priority	840223 830224	Individual Netherland	Process for the incorporation of foreign DNA into the genome of dicotyledonous plants Using Agrobacterium's Ti plasmid
4940839	900710	860718	DNA Plant Technology	Method of tomato protoplast fusion and regeneration of hybrid plant therefrom
4940840	900710	870526	DNA Plant Technology	Chitinase-producing bacteria and plants Using rDNA to inhibit chitinous fungal pathogens
4943674	900724	870526	Calgene	Fruit specific transcriptional factors Tomato's transcriptional initiation region

Source:Official Gazette of the U.S. Patent and Trademark Office

The patents are heterogeneous as is shown. Some of them claim only a single variety just like under PPA or PVPA. Among them there are patents for potato varieties, because potatoes are patentable only under the utility patent, as noted in Chapter 4. Others claim methods for producing a plant with new utility and the plant itself. This group includes hybrids and mutants, which are not patentable under PVPA due to instability. Genetic engineering belongs to the latter category.

The utility patent is expected to encourage genetic engineering of plants, but only six patents covering genetic engineering have been issued by January 1, 1991. The first two (No.4,795,855 and No.4,886,937) are methods for transformation of poplar and pine and the transformed plants, and the fourth (No.4,940,838) is methods for transformation of dicotyledonous plants and the transformed plants. Since those patents does not specify a gene to be used for transformation, they seems basic patents like Cohen-Boyer patent in a sense. But they are not the patents that plant breeding biotech firms are seeking for. Genetic engineering is considered to make it possible to add new utility to plants by using foreign genes.

There are three such patents finally issued in 1990(No.4,940,835, No.4,940,840, and No.4,943,674). As of January 1, 1991, they are all. Since the method for transformation is already known, to obtain such kind of patent requires to find a new, useful gene. Patent for the new gene can also protect the plant itself transformed by the gene, but plant patent may be stronger because it considers that a plant with the same utility using different genes is equivalent and because plant

patent may cover all parts of the plant even though they do not contain the gene, such as oil and starch. Anyway, to find a new gene is the key to protect genetically engineered plant under the utility patent. Consequently, it will encourage private investment in basic research of plant molecular biology. However as far as seeing patents as R&D output, the effect of utility patent is not so significant yet.

7-2. The U.S. PPA and Japan's Seed Law

The U.S. PPA protects asexually propagating plants, such as flowers and fruit trees, as described in Chapter 4. The protection is very similar to that of Japan's Seed Law, though it also protects sexually propagated plants. Most plants protected under PPA are flowers and fruit trees. In both countries, flowers are usually bred by private firms and fruit trees are usually bred by public agricultural stations, which may be explained by the difference of investment period, according to Stallman(2).

In Table 7-2, the number of patents issued under PPA and the number of registrations issued under SL are shown. The partial listing of species is from the OTA report(3). The data of PPA is obtained from (3) and the PTO's Official Gazette from January 1986 to December 1990. The data of SL are obtained by picking up asexually propagated plants from MAFF's annual report of variety registration(4). Comparing the recent three periods, 1979-83(5years), 1983-87(4years) and 1987-90(4years), the average number of patents/registrations issued per year is increasing in both countries, but of course the species that are responsible for the increase are a little different. That is why

TABLE 7-2. Number of Patents/Registrations under U.S.PPA and Japan's SL

	U.S.A.							Japan		
	31-62	63-68	69-73	74-78	79-83	84-87	87-90	79-83	84-87	87-90
African Violet	9	0	12	45	54	49	111	8	0	5
Almond	6	15	9	11	15	7	1	0	0	0
Apple	55	22	17	36	33	17	38	12	13	27
Azalea	49	40	34	27	7	4	7	15	8	12
Begonia	4	0	7	28	7	11	32	2	9	4
Camellia	38	5	4	1	0	1	0	5	20	6
Carnation	50	6	11	33	10	83	81	7	67	149
Chrysanthemum	133	38	68	155	99	128	220	16	20	96
Fuchsia	27	3	0	0	0	1	0	0	0	0
Gladiolus	30	53	8	6	0	0	0	4	0	2
Grape	10	8	5	9	16	14	25	21	20	28
Kalanchoe	0	0	5	33	14	30	28	0	0	9
Nectarine	9	14	25	29	17	23	28	2	10	10
Peach	151	29	29	30	34	30	39	32	14	23
Plum	25	18	6	16	14	31	32	1	4	6
Poinsettia	13	14	17	22	0	15	31	0	0	0
Rose	1061	232	141	239	232	201	276	54	112	99
Strawberry	30	8	13	18	21	14	13	13	15	15
Sum	1700	505	411	738	573	659	962	192	312	491
Annual Average	53.12	84.16	82.2	147.6	114.6	164.7	240.5	38.4	78	122.7
Total Issuance	2207	647	556	946	808	907	1508	421	733	1009
Annual Average	68.96	107.8	111.2	189.2	161.6	226.7	377	84.2	183.2	252.2
Sum/Total	0.770	0.780	0.739	0.780	0.709	0.726	0.637	0.456	0.425	0.486

Source: (3), (4) and USPTO Official Gazette

the OTA's listing covers only about 45% of total patents for asexually propagated plants in Japan.

Generally speaking, the total breeding effort has been increasing in the recent decade in both countries. But it is unclear what kind of effects it had from other protection rules or the development of biotechnology.

In the U.S.A. as far as known from the PTO Official Gazettes, there are some varieties patented under both utility patent class 800 and PPA. All of them were granted to Salt Weeds on August 9 and August 30, 1988(see Table 7-1. No.4,762,964, No.4,767,887, and No.4,767,889). The same varieties were also patented under PPA, on December 6 and December 13, 1988. Since the protection under the utility patent includes all possible protections under PPA(3), there is no reason to obtain patent under PPA in addition to utility patent. However, we cannot know whether patents will be granted or not when application is submitted, the double protection cannot be avoided. PPA's role is a kind of insurance in this case.

Recent technology development has made it possible to regenerate a whole plant from its tissue in quite a wide range of species. This means all plants can be asexually propagated, if necessary. F_1 hybrids and genetically engineered plants that are usually genetically unstable can be multiplied from the tissue. Therefore, without utility patent or PPA patent, copies will appear depending on the comparison between copy cost and benefit. PPA may be useful to protect those plants from copying, if they fail to be patented under utility patent.

According to Stallman, private investment in plant breeding that

is protected by PPA is determined by both investment period and exclusion cost, which are attributes of plant species(2). Recent technology development is going to change the attributes.

On the other hand, Japan's SL has two exemptions like PVPA and cannot stop asexual propagation done by farmers.

7-3. The U.S. PVPA and Japan's SL

First, the U.S. PVPA is discussed here, and then Japan's Seed Law is discussed.

The U.S. PVPA

The U.S. PVPA covers major crops for food and feed, and most vegetables that are propagated sexually. Some crops covered by PVPA are being bred by both private firms and public institutes, which is different from plants covered by PPA.

Historically breeding major crops was a job of the government. Since late nineteenth century, state agricultural experiment stations and land-grant universities has started plant breeding using federal budget(5). The legislation of PVPA in 1970 gave incentive to private firms to start breeding, although the protection is not so effective. As a result, a lot of private varieties have appeared, as discussed in Chapter 4.

Since the requirement of distinctiveness of PVPA is not severe, there are incentives for private firms to do cosmetic breeding, which means that important economic traits do not differ much(6). However, farmers prefer private varieties to public, partly because private

varieties sound progressive, although the performance is the same(7). Therefore, the private/public distinction is important in analysis of PVPA.

The Trend of Certificate Issuance under PVPA

In table 7-3, the yearly numbers of PVPA certificate issuances are shown, distinguishing public varieties from private ones. The data were collected from Plant Variety Protection office Official Journal of USDA. The species shown in the table sometimes represent a group of species. For example, alfalfa includes some other forage crop, such as clovers, grass includes various species of grass and the vegetables includes all kind of vegetables.

Using those time series data, a regression analysis was done to know a yearly trend of each species. One regression assumes simple linear relation between the number of certificates and the year. The other assumes simple linear relation between moving average of numbers of certificates and the year. The moving average is made from data of recent three years including the corresponding year. Although there is some trend, yearly numbers of certificates are fluctuated for reason other than time. Moving average is considered to eliminate the fluctuations. To do this analysis, the data of initial one or two years are sometimes eliminated, when those numbers seem artificially large reflecting accumulation of applications. The eliminated numbers are surrounded with [] in Table 7-3.

The results are shown in the Table 7-3. With respect to public varieties, there is no significant time series trend, except for

TABLE 7-3. Number of Certificates Issued under PVPA

	Alfalfa		Barley		Bean		Corn		Flower		Grass		Cotton	
	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.
1973														
1974					[32]				[16]				[24]	1
1975					11				[17]		1		10	3
1976	1	2	[8]	2	10				6		4		6	1
1977	0	0	2	0	14		1		2		2	[9]	5	1
1978	2	3	0	0	8		0		3		4	[0]	8	1
1979	2	4	2	0	1		0		0		7	1	6	5
1980	1	7	0	0	8		4		5		3	2	11	1
1981	6	5	0	0	6		1		8		6	3	9	1
1982	10	4	0	0	11		1		4		12	0	9	1
1983	2	1	0	0	9		3		3		11	2	11	0
1984	8	2	3	0	3		11		5		8	3	6	1
1985	2	1	14	1	3		7		1		5	3	6	2
1986	19	3	4	0	18		29		5		13	1	13	0
1987	18	1	0	0	10		16		3		17	2	7	4
1988	18	3	2	0	4		27		8		21	1	7	1
1989	4	2	0	0	5		19		1		8	2	0	0
1990	10	2	4	0	3		31		0		7	2	14	1
SUM	103	40	31	3	124	0	150	0	54	0	129	22	128	23
coeff.	0.98	-0.08	0.20	-	-0.29	-	2.40	-	-0.09	-	0.77	0.01	0.02	-0.04
sig.	***						***				***			
Rsq.	0.42	0.04	0.05		0.09		0.75		0.02		0.44	0.00	0.00	0.02
MAcoeff.	1.21	-0.15	0.25	-	-0.34	-	2.55	-	0.05	-	0.97	-0.02	0.00	-0.03
sig.	***						***				***			
Rsq.	0.77	0.17	0.13		0.18		0.89		0.03		0.87	0.04	0.00	0.03

Source: USDA

sig. = significance level, ***=0.5%, **=0.1% and *=5%.

MA = moving average, Rsq. = R squared

Numbers in [] are eliminated in regression analysis.

TABLE 7-3. Number of Certificates Issued under PVPA (continued)

	Oat		Pea		Peanut		Rape Seed		Rice		Ryegrass		Safflower	
	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.
1973														
1974			[21]											
1975			6						[4]				1	
1976		3	13		5				2		4		0	
1977	2	3	21		0	1			0		4	1	0	
1978	1	0	8		0	0			2		2	0	2	
1979	1	1	8		0	0			1		0	0	0	
1980	0	1	15		0	1			0		8	0	2	
1981	0	0	5		1	0			1		1	0	0	
1982	2	1	16		0	0			2		5	0	0	
1983	1	0	10		0	0			0		2	1	0	
1984	0	0	18	1	1	0			0		22	0	0	
1985	0	0	20	0	0	0			1		7	0	0	
1986	1	0	18	0	1	1		2	1		4	0	0	1
1987	1	3	8	0	1	1	7	0	1		7	0	2	1
1988	0	0	6	0	0	0	1	0	4		4	0	2	0
1989	2	0	2	0	0	0	0	0	0		3	0	0	0
1990	0	2	1	0	0	0	0	0	0		19	0	13	0
SUM	11	14	175	1	9	4	8	2	15	0	84	2	22	2
coeff.	-	-	-0.38	-	-	-	-	-	-0.01	-	0.59	-	-	-
sig.														
Rsq.			0.08						0.00		0.17			
MAcoeff.	-	-	-0.32	-	-	-	-	-	0.04	-	0.50	-	-	-
sig.											*			
Rsq.			0.11						0.11		0.35			

Source: USDA

sig. = significance level, ***=0.5%, **=0.1% and *=5%.

MA = moving average, Rsq. = R squared

Numbers in [] are eliminated in regression analysis.

TABLE 7-3. Number of Certificates Issued under PVPA (continued)

	Soybean		Sunflower		Tobacco		Tomato		Vegetables		Wheat	
	pri.	pub.	pri.	pub.	pri.	pub.	pr	pu	pr	pu	pr	pu
1973	10	3							8			1
1974	20	1							7		6	5
1975	9	5							10		13	3
1976	14				[3]				8	1	9	2
1977	21	1			[5]				15	2	9	8
1978	18	2			1				10	1	9	3
1979	19	2			1				16	0	8	2
1980	28	13	1		1				18	0	3	3
1981	30	2	4		1				5	1	8	2
1982	30	8	0		2		7		12	0	25	7
1983	32	2	0		1		2	2	19	4	1	0
1984	23	4	1		1		4	0	5	0	2	0
1985	36	12	0		0		7	1	16	1	11	3
1986	42	2	0		2		3	1	22	3	12	4
1987	36	5	0		2		3	0	19	5	2	0
1988	34	14	1		1		3	0	26	0	30	12
1989	12	3	1		0		4	1	9	0	19	10
1990	10	0	0		1		3	0	3	0	6	3
SUM	424	79	8	0	14	0	36	5	228	18	173	68
coeff.	0.82	0.22	-	-	-0.02	-	-0.06	-	0.35	0.02	0.36	0.16
sig.	*											
Rsq.	0.18	0.07			0.01		0.01		0.08	0.00	0.05	0.06
MAcoeff.	1.23	0.35	-	-	0.00	-	-0.24	-	0.56	0.08	0.46	0.15
sig.	***	***					*		***		*	
Rsq.	0.52	0.59			0.01		0.61		0.52	0.12	0.29	0.14

Source: USDA

sig. = significance level, ***=0.5%, **=0.1% and *=5%.

MA = moving average, Rsq. = R squared

Numbers in [] are eliminated in regression analysis.

moving average analysis of public soybean varieties. Public soybean shows an increasing trend. With respect to private varieties, five groups show a statistically significant relation(at 0.5% level of significance). They are soybean, alfalfa, grass, corn and vegetables. All of them show an increasing trend. Wheat and ryegrass also show a positive trend, but significance level is 5%. A decreasing trend was observed in tomato at 5% significance level. Peas and beans, although total number of patent is relatively large, show a negative trend, but it is not statistically significant.

With respect to soybean, the results are in partial agreement with those of Bulter and Marion(8). They showed that the strongest positive impact of PVPA appears to have been on soybeans, based on the survey data of R&D expenditures of 14 firms and on the number of certificates under PVPA by year of application from 1971 to 1982. But they do not distinguish public from private. Growth rate of private varieties (1.23 per year) is much larger than that of public varieties (0.35 per year). This corresponds with the observation of Shephard(7). The difference in growth rate may mean that the production of private varieties of soybean is a process of cumulative invention and that the the production of public varieties of soybean is a process of relatively discrete invention, as noted in Chapter 2. It means that public varieties may be different enough from each other.

On the other hand, contrary to the results of Bulter and Marion(8), corn shows a significant increase and the growth rate (2.55 per year) is the highest among species. Since F_1 hybrid corn seeds are prevailing in the U.S.A., it was considered that there is no reason to

obtain PVP certificates for their inbred parent lines, which can be protected as trade secrets. However, since mid 80's the number of corn certificates has been increasing rapidly. PVPA requires deposit of seed, but it cannot be utilized without permission of patent holder(3), and therefore obtaining a certificate under PVPA does not mean that other firms can use inbred parental lines for breeding, although there is a research exemption. I will discuss this point later with utility patent.

The correlation of growth rates of number of PVP certificates of private varieties and the size of the U.S. seed market or the total value added by the seed industry were examined. The growth rates are shown in Table 7-3. I used only statistically significant ones, that is, alfalfa, grass, corn, soybean, ryegrass, vegetable and wheat. The estimated size of the U.S. seed market and value added by the seed industry were obtained from Bulter and Marion(8). Since they used 1979 data, the estimation may be a little old, but the general tendency may not have changed so much. The results are shown in Table 7-4.

Table 7-4. Correlation Between Growth Rates and Seed Market of 1979

Species	1.Seed Market ($1000)	2.Added Value ($1000)	3.Growth Rate
alfalfa	235969	125586	1.21
corn	946757	899419	2.55
grass	302454	249936	0.969
ryegrass	2842	1421	0.502
soybean	489650	235032	1.23
vegetable	124823	71574	0.563
wheat	232638	117819	0.460
Correlation	0.943 (1 & 3)	0.947 (2 & 3)	

Thus, the growth rate of private varieties are strongly correlated with both the size of seed market and the size of value added by seed industry.

Number of Certificates Issued under PVPA

The number of varieties given by PVP certificates is also considered to reflect the R&D effort, although every variety may require a different amount of R&D effort, such as time and money. Besides, since PVPA does not cover F_1 hybrid, the number of PVPA certificates does not reflect the whole R&D effort if F_1 hybrid is available. According to Bulter and Marion, about 70% of R&D expenditure is spent for corn breeding and most of them are hybrid(8). However, the number of corn certificates is not proportional to the expenditure. Except for corn, such distortion is considered small.

The correlation of the number of certificate issuances and the size of the U.S. seed market or the total value added by the seed industry measured by total dollar sales in 1979 given by Bulter and Marion(8) were examined. The results are shown in Table 7-5.

As noted above, corn is quite different and therefore the correlations are calculated both with corn and without corn. With corn, the number of certificates has positive correlation with both the size of the U.S. seed market and the value added by the seed industry , but the correlation is weak. Excluding corn from the data, the positive correlations becomes strong, especially the number of public varieties is very strongly correlated with the market size of seed(correlation coefficient=0.90). And the correlation of number of private varieties

is 0.71, smaller than that of public varieties. On the other hand, correlations with the value added by the seed industry are generally smaller than with the market size. But again, public varieties are more correlated than private varieties, when excluding corn.

Table 7-5. Correlation Between Number of PVPC and Seed Market

Species	1.Seed Market ($1000)	2.Value Added ($1000)	3.Private Varieties	4.Public Varieties
alfalfa	235969	125586	103	40
barley	34938	18867	39	3
bean	21780	19820	156	0
corn	946757	899419	150	0
cotton	60225	49987	152	23
grass	302454	249936	129	31
oat	34349	24397	11	14
pea	22960	18368	196	1
peanut	55661	33953	9	4
rice	70350	42210	19	0
ryegrass	2842	1421	90	2
soybean	489650	235032	424	79
tobacco	2621	2595	22	0
vegetable	124823	71574	228	18
wheat	232638	117819	173	68
correlation with seed market (with corn)			0.433	0.307
correlation with seed market (without corn)			0.706	0.900
correlation with added value (with corn)			0.261	0.077
correlation with added value (without corn)			0.597	0.794

Seed market data is from (8) and of 1979.

The relations between number of varieties without corn and the market size are plotted in graphs of Fig.7-1(private varieties) and Fig.7-2(public varieties). According to the graphs, it is clear why the correlation of private varieties is lower than that of public varieties. The number of public varieties clearly depends on the

Fig. 7-1. Relation of Number of Private Varieties Given by PVP Certificate and Size of the U.S. Seed Market

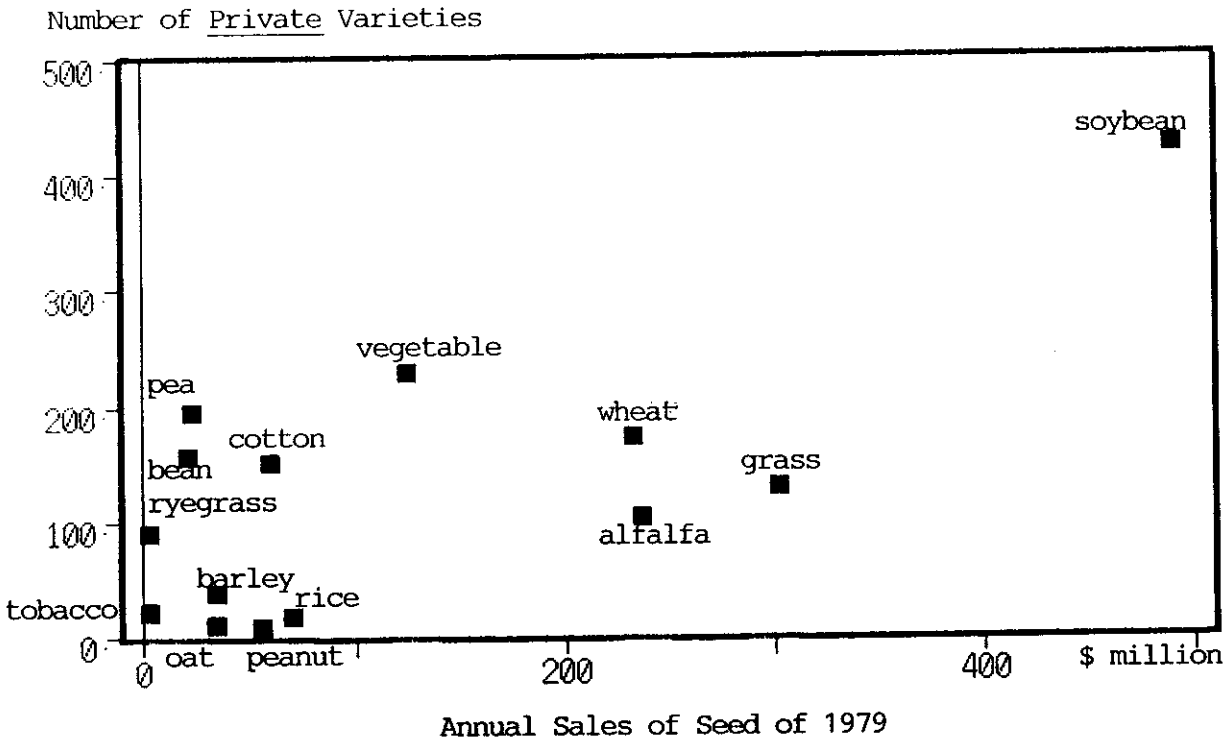
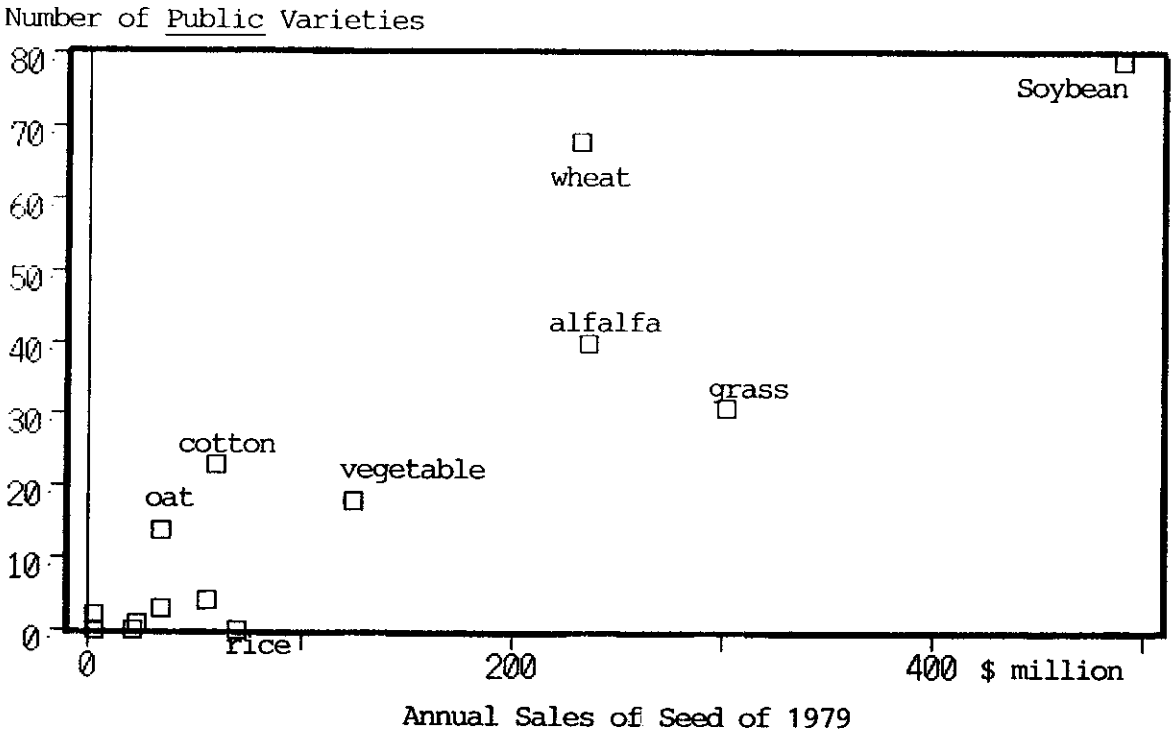


Fig. 7-2. Relation of Number of Public Varieties Given by PVP Certificate and Size of the U.S. Seed Market



market size. On the other hand, the private varieties can be divided roughly into two groups, which lowers the correlation. One group includes pea, bean, vegetables, cotton, barely, tobacco, and ryegrass. These species, except cotton, were mostly bred by private firms. And they show no or weak increasing trend of number of certificates over time. The other group includes wheat, alfalfa, grass and soybean. All of them show a strong increasing trend(Table 7-4). Another characteristic of this group is that private and public breeding programs of these crops coexist and compete each other in the seed market. Soybean is a typical case(7).

The statistical analysis implies that the public institutes have had constant R&D effort and fixed the allocation of R&D effort among crops based on the seed market size. This implication is consistent with the observation that the public field crop research effort had increased by only 0.3% from 1975 to 1980 according to a survey of Agricultural Experiment Station directors(7). On the other hand, private firms concentrate their effort on some crops, such as soybean and alfalfa, and as a result, new private varieties have been increasing and capturing market share. In Michigan the total acreage of soybean has increased by 19.0 percent since 1983, but the share of public varieties has been shrinking(7).

However, although the public varieties have been losing market share, the public breeders constantly release new varieties. Why do they continue breeding? As noted in Chapter 4, the U.S. public breeders would not release a new varieties unless performance is improved significantly and as discussed above, the time trend of the

number of releases of public variety shows a discrete process of inventions. These data means that the public breeding has some different roles from private breeding. The time series data tells that the increasing private varieties are coupled with the constant release of public varieties. Exception is only corn. It can be interpreted that the public breeding does not discourage private investment but encourage private breeding by supplying breeding material to private sector, which utilizes the public varieties to do so-called cosmetic breeding.

Relation of PVPA to Other Method of Protection

As noted in Chapter 4, the protection under the general Patent Act(utility patent) is broader than that of PVPA and includes all the possible protection given by the PVPA. The major advantage of the utility patent is that two exemptions of PVPA, farmer's exemption and research exemption, are not allowed under the utility patent(3). Therefore, there is no reason to obtain both protections. However, as mentioned in the case of PPA, firms will apply for both because of uncertainty, and consequently double protection will occur.

Inbred corn varieties that produce F_1 hybrid corn seed have been protected by private firms using trade secret law for years, but recently firms try to protect them under PVPA and utility patent, as noted previously. PVPA requires deposit, but access to the deposited material requires permission from the patent holder. In contrast, deposit for utility patents requires unrestricted access to the deposited seed(3). However, they cannot be used as breeding material.

Therefore, parental lines can be protected by either law. As far as known from the available data of issuance of utility patents classified as 800(Table 7-1) and issuance PVP certificates as of December, 1990, three companies obtained protection of corn under both utility patent and PVPA, as shown below.

Dekalb-Pfizer Genetics
PA: No.4,654,466 "Inbred corn line 78010" issued on March 31, 1987
PVPA: No.8,500,126 "78010" issued on April 30,1986

Standard Oil Company

PA:	No.4,750,910 "Tetraploid Corn and Methods of Production" issued on November 10, 1987	
PVPA:	No.8,400,110 "SX-5-11"	issued on February 28, 1986
	No.8,400,114 "SX-5-6"	issued on October 31, 1986
	No.8,400,116 "SX-4-4"	issued on October 31, 1986
	No.8,400,117 "SX-4-2"	issued on February 28, 1986
	No.8,400,118 "SX-6-3"	issued on February 28, 1986
	No.8,500,045 "SX-5-9-1-2"	issued on October 31, 1986
	No.8,500,046 "SX-5-13-3"	issued on March 31, 1986
	No.8,500,047 "SX-4-33-4-2"	issued on March 31, 1986
	No.8,500,048 "SX-4-6-2"	issued on March 31, 1986
	No.8,500,049 "SX-4-32-1"	issued on March 31, 1986
	No.8,500,046 "SX-6-15-21"	issued on October 31, 1986
	No.8,500,047 "SX-5-14-1-2"	issued on October 31, 1986

Pioneer Hi-Bred International
PA: No.4,806,652 "Inbred Corn Line PHR25" issued on Feb. 21, 1989
PVPA: No.8,800,002 "PHR25" issued on May 31, 1988
PA: No.4,806,669 "Inbred Corn Line PHK05" issued on Feb. 21, 1989
PVPA: No.8,800,001 "PHK05" issued on May 31, 1988
PA: No.4,812,599 "Inbred Corn Line PHV78" issued on March 14, 1989
PVPA: No.8,800,003 "PHV78" issued on May 31, 1988
PA: No.4,812,600 "Inbred Corn Line PHK29" issued on March 14, 1989
PVPA: No.8,700,214 "PHK29" issued on May 31, 1988

In the case of Dekalb and Pioneer, patented variety under utility patent is the same as the variety patented under PVPA. It means that both patents are variety specific and may have the same breadth. On the other hand, the patent that the Standard Oil Company obtained is different. The patent under utility patent claims that an inbred line

of tetraploid corn wherein said inbred line has the characteristics of SX-5-11, SX-5-6, SX-4-4, SX-4-2, SX-6-3, SX-5-9-1-2, SX-5-13-3, SX-4-33-4-2, SX-4-6-2, SX-4-32-1, SX-6-15-21, or SX-5-14-1-2. The patent is divided into twelve variety-specific PVP certificates as is shown above. This is a typical case when a patent under utility patent can claim broader than that under PVPA. But the utility patent is just a sum of PVP certificates and does not cover varieties that do not exist yet, which is different from a utility patent of genetically engineering plant.

It is not clear how much description and utility is required for the U.S. utility patent. In Japan and perhaps other industrial countries, the description requirement is the barrier of issuance of plant patent, where conventional inbred varieties are not patentable under general patent law, as described above and in Chapter 6.

Impact of PVPA to Biotechnology R&D

PVPA is not effective because of the narrow product space and the two exemptions, and therefore there is little benefit to obtain PVP certificate. This is common weakness, not particularly to genetically engineered plants. But due to high R&D expenditure, genetically engineered plants require broader and more effective protection. If double protection is allowed like in the U.S., PVPA itself has no effect on breeding via genetic engineering.

Seeing the weakness, UPOV has decided to strengthen the plant variety protection law. In the U.S. there is already double protection and so no need to strengthen PVPA, but in other countries plant

variety protection law may be strengthened.

Japan's Seed Law

As is noted in Chapter 4, Japan's Seed Law gives a similar protection to that of PPA and PVPA. Considering the coverage, the Seed Law is equivalent to the combination of PPA and PVPA. To compare the U.S. PVPA with the Seed Law, data were collected from (4) and classified them into private and public. In Japan, public varieties are bred by the national agricultural research stations and prefectural agricultural research stations. Japan, though a small country with the same area as California, is divided into forty-seven prefectures. Recently prefectural research stations have become more active in breeding than before, which will be discussed later.

The Trend and Number of Registrations under SL

As is done with the data of U.S. PVPA, the time trend of yearly number of registrations of new variety (patents) is analyzed using ordinary least squared estimation. Public varieties of vegetable, public and private varieties of rice show a statistically significant positive relation with year. On the other hand, public varieties of tomato are decreasing(Table 7-6). Since there are only three varieties that have a significant time trend, the correlation between growth rate and size of seed market is not examined.

Then using Japan's seed market data of 1989, which was obtained from *BIOTECHNOLOGY ANNUAL REPORT 90/91*(16), the correlation between number of registrations and the size of seed market is examined. Dif-

TABLE 7-6. Number of Registrations Issued under SL

	Alfalfa		Barley		Bean		Corn		Grass		Oat		Pea	
	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.
1978														
1979					1									
1980					0								1	
1981	1	1	2	1	1						1		1	8	1
1982	0	0	0	1	0	1					2		0	2	0
1983	0	1	0	0	0	0		1			0		0	3	0
1984	0	1	1	0	1	0		1	1		0		0	7	0
1985	0	1	1	1	0	0		1	0		2		0	4	0
1986	0	0	1	0	2	2		1	1		1		0	17	1
1987	0	0	2	1	2	0		1	1		0		0	1	3
1988	0	0	2	2	0	0		1	0		4		0	3	0
1989	0	0	1	2	0	0		1	1		2		0	3	0
1990	0	1	0	2	5	5		1	1		0		1	6	2
SUM	1	5	10	10	12	8	0	8	5		12	0	2	55	7
coeff.	-	-	-	-	-	-	-	-	-		-	-	-	0.13	-
sig.															
Rsq.														0.01	
MAcoeff.	-	-	-	-	-	-	-	-	-		-	-	-	0.07	-
sig.															
Rsq.														0.01	

TABLE 7-6. Number of Registrations Issued under SL(continued)

	Rice		Ryegrass		Soybean		Tabacco		Tomato		Vegitab		Wheat	
	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.	pri.	pub.
1978														
1979									1		11	1		
1980									0		13	0		
1981		7				4			0		14	1		
1982		18	1			3			2	1	12	1		1
1983	4	0	0			0			2	3	9	5		1
1984	0	14	0	1		2			6	3	24	7		1
1985	3	7	0	0		2			2	2	15	4		1
1986	2	12	0	1		4			8	4	13	3		0
1987	2	15	1	0		1	5		3	1	16	14		4
1988	4	20	0	1		2	0		2	0	10	3		2
1989	0	7	0	0		3	0		1	1	7	3		0
1990	7	27	0	2		2	2		3	2	26	13		2
SUM	22	127	2	5	0	23	7	0	30	17	170	55	0	12
coeff.	0.28	1.27	-	-	-	-0.05	-	-	0.22	-0.15	0.37	0.39	-	0.10
sig.												**		
Rsq.	0.09	0.24				0.02			0.11	0.10	0.06	0.80		0.05
MAcoeff.	0.25	1.32	-	-	-	0.05	-	-	0.27	-0.33	0.11	1.13	-	0.15
sig.	***	***								*		***		
Rsq.	0.64	0.77				0.08			0.23	0.69	0.01	0.84		0.41

Source: MAFF

sig. = significance level, ***=0.5%, **=0.1% and *=5%.

MA = moving average, Rsq. = R squared

Fig. 7-3. Relation of Number of Private Varieties Given by SL Registration and Size of Japan's Seed Market

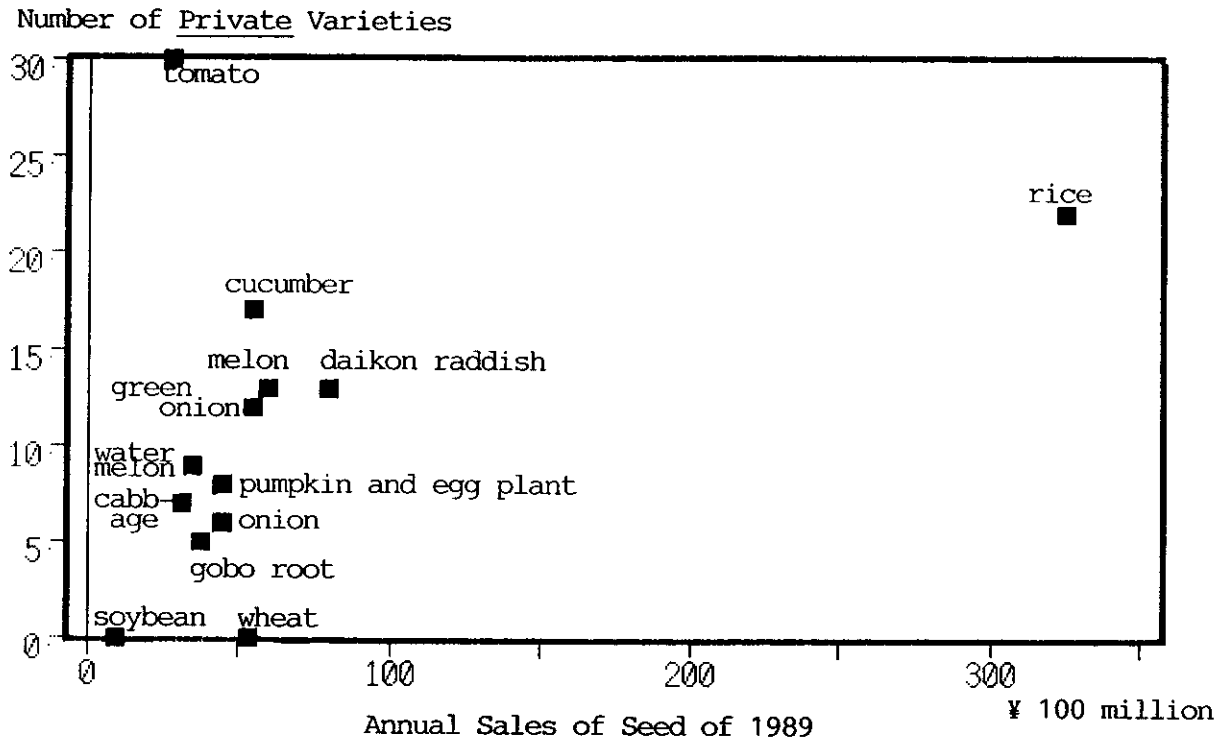
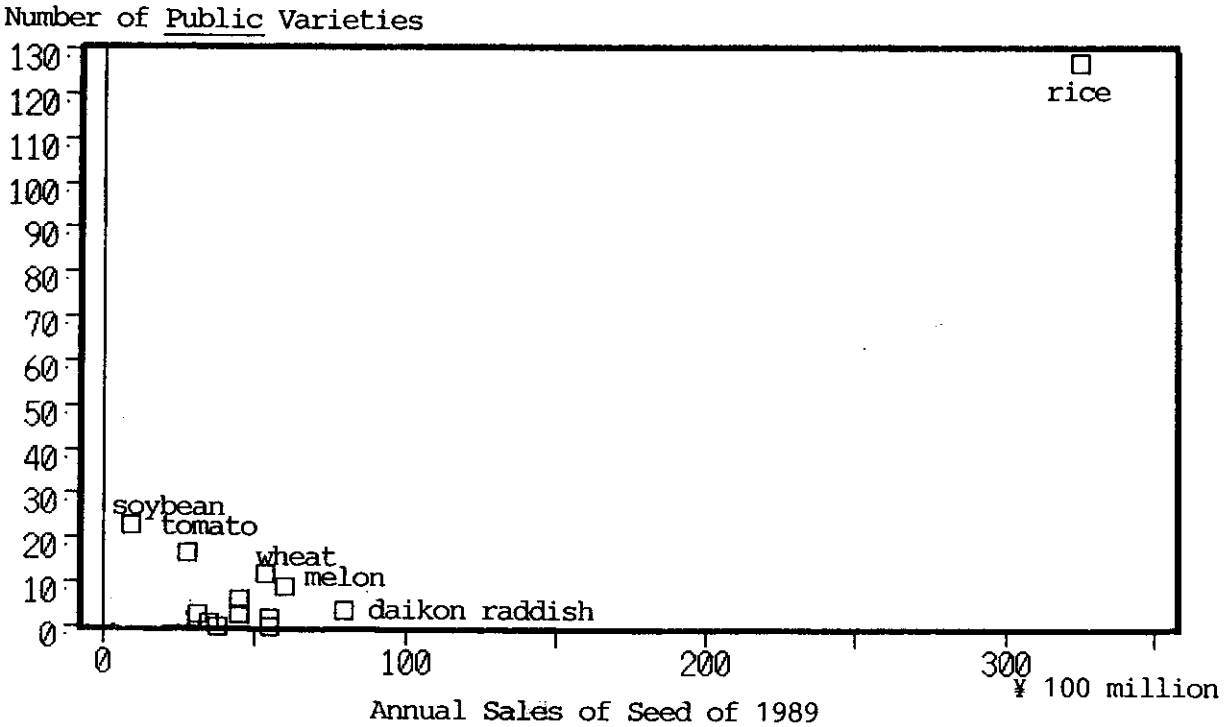


Fig. 7-4. Relation of Number of Public Varieties Given by SL Registration and Size of Japan' Seed Market



ferent from the U.S. data, vegetables are divided into species and there are no forage crops. The plots of number of registrations against the size of seed market are shown in Fig.7-3(private variety) and in Fig.7-4(public variety). Among them, number of tomato varieties are large in spite of small seed market. This may because the category of tomato varieties contains variation for both fresh food and for processing. Also breeding of processing tomatoes is done by manufacturers whose effort may be indifferent to the seed price of tomatoes for fresh food. Therefore I exclude tomatoes from calculation of correlations.

In addition, as is seen in those graphs, rice seed has an extremely big market and skews the distribution. Therefore I tried to calculate correlation coefficients with and without rice. Moreover, I tried to exclude all major crops, that is, rice, wheat, and soybean. Since they have been covered by the Major Crop Seed Law, their breeding has been done mainly by public agricultural stations. The results are shown in Table 7-7.

The correlation coefficients of private varieties are positive enough and do not differ much by excluding rice or major crops. On the other hand, public varieties show a very strong correlation with the seed market when including rice. However, as is seen in the Fig.7-4, rice has a very exceptional position. Without rice, the public varieties show negative relation with the seed market size(correlation coefficient is -0.44). The correlation gets positive again if all major crops are excluded from the data.

These results means that the Major Crop Seed Law has significant

influences on public breeding. It is related to how the job was shared by private and public in Japan.

Table 7-7. Correlation Between Number of Registrations and Size of Seed Market of 1989

Species	1.Seed Market (¥billion)	2.Private Variety	3.Public Variety
cabbage	3.1	7	3
cucumber	5.5	17	2
daikon radish	8.0	13	4
gobou root	3.8	5	0
green onion	5.5	12	0
melon	6.0	13	9
onion	4.5	8	6
pumpkin, egg plant	4.5	6	3
rice	32.5	22	127
soybean	0.95	0	23
watermelon	3.5	9	1
wheat	5.3	0	12
correlation with seed market size		0.706	0.944
correlation with seed market size (without rice)		0.636	-0.437
correlation with seed market size (without major crop)		0.682	0.343

The Role of Public Breeding in Japan

As described in Chapter 4, the Major Crop Seed Law(MCSL) had prohibited private breeding of rice, wheat, barley and soybean until the amendment of 1986. Even before the amendment, the MCSL allowed private breeding of those major crops, but since private firms could not sell the seed, no private firm except for beer breweries that had breeding program of beer barley did breeding of major crops. By the way, we are used to call them major crops, but actually only rice is major and the others are minor crops in Japan today, as is known from the Table 7-7. Therefore, even after the amendment, no private

varieties of soybean and wheat have been released yet.

When the national system of major crop breeding was established, breeding was a task of central and regional national agricultural research stations. Prefectural agricultural research stations' role was to find the best varieties for the local climate, to propagate them and to promote them. However, the breeding job has shifted from national to prefectural stations gradually and today almost all prefectural stations have breeding program of rice and vegetables to satisfy local demand.

On the other hand, vegetable breeding has been done by private firms. Japan has a long history of horticulture, but Japan had not had plant variety protection rule until 1978. As a result, most vegetable seeds are F_1 hybrids in Japan. Japan's Ministry of Agriculture, Forestry and Fisheries(MAFF) released a report "*Future Vision of Seed Industry*" in 1988, in which they wrote "Because Japanese high-quality hybrid seeds have competitiveness compared with those of other industrial countries, the export of seeds has been increasing"(9). It is said that recently Japanese hybrid seeds have captured 80 percent of broccoli seed market in the U.S. (10). MAFF's report concludes that seeds are the most promising agricultural products that Japan can export. As noted previously, Japan's SL protects F_1 hybrid seeds unlike PVPA. Therefore the numbers of registrations shown in tables include some hybrid seeds.

The central agricultural research station also has breeding program of vegetable, but their major effort has been devoted to producing not final products but parental lines. The role of prefec-

tural research stations in breeding is to release new varieties good for the prefecture. Collaborations between prefectural stations and prefectural federations of agricultural cooperative are often seen in each prefecture. The federation chooses a new variety bred locally, promotes cultivating it and markets it. In marketing effort, they make a brand of the new variety and try to differentiate it from products produced in other prefectures in the consumer market. This kind of competition among prefectures has increased in this decade, and prefecture-bred varieties have increased. The most typical case is rice, the most important crop in Japan.

The Rice Breeding in Japan

Like most Asian countries, rice has been the most important food in Japan, although rice is now responsible for only 26.3 percent of total calories consumed in 1988(National Diet Survey by MAFF). In 1930, it was about 60 percent. The change is partially because the total calories have increased, but mainly because net consumption of rice per capita has declined: In 1930 rice consumption per capita was about 140kg per year and in 1988 it was 71.0kg(MAFF). The declining trend has been continuing since 1960, when Japanese economy had recovered completely from the damage of the war.

Rice production and distribution has been controlled by government based on the Food Control Law, which was enacted during world war II and survived even after the war to secure a fair distribution of rice under shortage. Based on this law government purchased all rice except for farmers' own consumption at the price determined by the na-

tional committee every year. The producers' price was determined based on production cost and was intended to secure reproduction of rice. The rice was distributed through designated retailers. Consumer price is also determined by the committee, and sometimes it was lower than the producer price. This law gave incentive to farmers to produce more rice and secured their income. This incentive, in addition to the rice consumption trend, resulted a large surplus of rice in late 60's(11).

Thus, surplus reduction program and deregulation of retailing was begun in 1970. The deregulation is not complete and government still purchases about 30 percent of total rice production and distributes it as "standard rice"(12), whose price is still determined by the national committee and is actually the lowest. Remaining 70 percent is shared by premium rices whose prices, though affected by the price of government rice, are generally higher than that. Because of shrinking total pie and threat of import, the maintenance of consumers' preference for the premium rice is considered the only way to survive. This perspective has made competition among prefectures more intense.

Variety is one of the important factors of the premium rice. Another factor is where it is produced. Both affect taste of rice. Even though they are the same variety, they are differentiated products if they are produced in different places, whose unit is usually a prefecture.

Under the surplus, both national and prefectural research stations were not so interested in rice improvement, and therefore old varieties have still dominated. Table 7-8 shows the share of popular varieties against the total acreage. The share of the top two has been

Table 7-8. Percentage of planted acreage of rice varieties in Japan

	1987	1988	1989	1990	1991
Koshihikari	19.8 (1)	22.3 (1)	25.4 (1)	28.1 (1)	29.0 (1)
Sasanishiki	9.5 (2)	10.0 (2)	10.9 (2)	11.2 (2)	10.6 (2)
Nihonbare	8.3 (3)	8.0 (3)	7.7 (3)	6.6 (3)	5.7 (3)
Akihikari	6.4 (4)	4.7 (4)	-	-	-
Yukihikari*	1.8 (8)	3.4 (5)	3.8 (4)	3.4 (5)	3.0 (5)
Akitakomachi*	-	2.2 (9)	3.0 (5)	4.4 (4)	5.3 (4)
Kirara397*	-	-	-	2.5 (8)	3.0 (5)

Source: MAFF. "*" means new variety. Order of share is shown in parenthesis.

increasing. This is because "Koshihikari produced in Niigata prefecture" and "Sasanishiki produced in Miyagi prefecture" are the most popular premium brands. But those varieties are old: Koshihikari was released in 1957 and Sasanishiki was released in 1963(10). The market seemed to be getting more oligopolistic with respect to variety. However, the success of Akitakomachi released in 1984 and Kirara397 released in 1988 is encouraging to release new varieties. In a few years, they become top five varieties. Both varieties were bred in prefectural stations, Akita prefecture and Hokkaido prefecture respectively. The prefectural government and the prefectural federation of agricultural cooperative are collaborating on promoting production of the new variety and marketing it as a new brand of rice. Since consumers' recognition is important, they designed new attractive packages and did sales promotion at retail stores(10,13). In Japan, rice is no more an undifferentiated identical commodity. A new variety has more economic impact than before if it is coupled with marketing.

The number of registrations of rice varieties under the Seed Law

is shown in Table 7-9, in which the number is divided into five categories: central national research station, regional national research stations, prefectural research stations, individuals and private firms.

Four of five varieties of the central national research station are parental lines, which every one can utilize for breeding. There are five regional national research stations that represent different climates in Japan. Three of sixteen varieties of them are parental lines. Other varieties usually are tested and modified by each prefectural stations. Without any promoting and marketing force at regional level, their new varieties are not to be utilized by farmers immediately. The prefecture is an important political and economical unit in Japan. The public breeding done by prefectural station is to serve farmers of the prefecture so that their products can compete with others and obtain more share in the shrinking rice market, although the original intention was to satisfy the local demand for rice at the prefectural level. As noted above, since the competition has been getting more intense, new varieties are increasing. By March 31, 1991, the end of fiscal year of 1990, twenty-one out of forty-seven prefectures have obtained registrations of rice variety under the SL.

To reduce breeding time, some prefectures use anthen culture (The anthen is an organ to produce pollen. The anthen culture is an easier version of pollen culture). The anthen culture is a kind of biotechnology and five varieties produce by the technology have been registered under the SL as of March 31, 1991. The anthen culture reduces the stabilization period and can produce a new variety of rice

in five years, while conventional breeding takes seven years (14).

As noted previously, the 1986 amendment of MCSL encouraged private firms to enter rice breeding. As a result, in 1990 the first registrations of rice under the SL were granted to three companies and one federation, that is, Mitsubishi Kasei Corporation, Mitsui Toatsu Chemicals, Sumitomo Chemical and the National Federation of Agricultural Cooperative. Every prefectural federation of agricultural cooperative joins the National Federation, which has been developing F_1 hybrid rice seed under the governmental acreage reduction program.

Two of the six private varieties were bred using biotechnology, that is, Mitsui Toatsu's "Hatsuakari" and Mitsubishi Kasei's "Hatsuyume" which was bred by Plantech Research Institute, a joint venture of Mitsubishi Kasei and Mitsubishi Corporation. They are variants induced by protoplast culture. In addition, Sumitomo Chemical obtained another patent for a rice variety produced by anthen culture

Table 7-9. Number of Registrations of Rice under the SL

Year	Central	Regional	Prefectural	Individuals	Firms
81	0	1	6	0	0
82	0	1	17	0	0
83	0	0	0	4	0
84	0	1	13	0	0
85	0	1	6	3	0
86	1	0	11	2	0
87	1	3	11	2	0
88	2	3	15 (1)	4	0
89	0	4	3	0	0
90	1	2	23 (4)	1	6 (2)
Total	5	16	105 (5)	16	6 (2)

Source:MAFF, The number of varieties produced using biotechnology is in parenthesis.

in 1991, though it is not listed in the Tables. Those three are big chemical companies that have some experience in agrochemicals.

Comparison of Japan's SL with the U.S. PVPA

As described previously, the protection under PVPA and under SL are very similar, though there are some differences(see Chapter 4). The number of certificates/registrations is much related to the market size of the seed in both countries. However, in the U.S.A. corn is an exception because F_1 hybrid seeds are prevailing. In Japan, since SL covers F_1 hybrid seeds there is no similar exception. However, MCSL had effectively excluded private breeding of major crops and as a result the number of private varieties of rice is very small compared with its market size. In addition, since there had been no competition between public breeders and private breeders due to the MCSL, public breeding programs, unlike private breeding, do not necessarily depend on the market size, but is affected by political consideration. As a result, public breeding programs even show a negative correlation between the market size and the number of registrations, because government stresses breeding of soybean and wheat which are substitutes of rice under rice conversion program. On the other hand, in the U.S.A. both private and public patents are well correlated with the seed market size.

With respect to the weak effectiveness, PVPA and SL are similar and consequently encourage private firms to use other ways for protection.

Japanese consumers' taste makes it possible to differentiate

agricultural products by using a brand. Not only private firms, because of severe competition among prefectures, prefectural breeding program also need a vertical coordination. This gives another protection. As described above, a rice variety "Akitakomachi" is a case of successful marketing done in collaboration of Akita prefectural government with the Akita Federation of Agricultural Cooperative(10).

In the U.S.A. major crops are commodities without varietal identity, and therefore such vertical coordinations as done in Japan will not work. Instead, F_1 hybrid seeds are prevailing in corn and sorghum. However, hybrid seeds are not available for all crops or do not always show significant increase in yield. On the other hand, crops for processing, such as tomato and rape seed, can be protected by trade secrets within vertical coordination between variety and manufacturers(17).

7-4. Outputs of Genetic Engineering

The difference in protection system between the U.S.A. and Japan is, as described in Chapter 4, that man-made plants are patentable under the general patent law in the U.S.A. Though the "man-made" does not necessarily mean genetic engineering, genetically engineered plants must be patentable logically. In fact as of January, 1991, three patents for genetically engineered plants using a specific gene has been issued in the U.S.A.(Table 7-1). On the other hand, in Japan no plant patent has been issued, though there is one exception as noted in Chapter 4.

What Determines the Research Agenda in the U.S.A.?

Plant genetic engineering research activity can be measured by the number of field trials in the U.S.A. Exact data are not available, but partial data is available from the directory listed previously in this chapter. Classified by the number of field trial, the top group includes tomato and tobacco. The second group includes cotton, alfalfa, potato and rape seed. The third is soybean, corn and so on. Though the seed market of soybean and corn is large, these crops have few trials. It is due to technical difficulty. Recent development of the gene gun has made it possible to obtain transformed plant of soybean and corn. The gene gun was invented in 1987 by J.C. Sanford(18). The gene gun has solved the problem of difficulty in regenerating a whole plant from protoplasts, because it can inject a gene through a cell wall, as described in Chapter 3.

Another factor is protection of intellectual property rights. Because plant breeding using genetic engineering requires a lot of R&D expenditure and time in general, a big market is necessary to recover investment. Therefore the target crops of genetic engineering should have a large seed market and the protection should be effective and broad.

One advantage of genetic engineering is that description of invention is easy and claims can be made broadly, as described previously. The broad coverage assures a big market, because the total market of seeds within the patent scope can be large, even if one variety does not have a big market. However, if the protection is not effective, the advantage disappears. However, genetic engineering it-

self enables an effective and broad protection due to its nature. This is the second advantage of genetic engineering, that is, copies and offspring of the patented plant can be distinguished easily and less costly by using DNA probe. Since transformed plants contain a specific form of gene, standard laboratory technique can find it from any tissue of a suspected plant. This technique is already used in forensic medicine to identify a criminal and to determine parent-child relationship. This advantage is valid only in utility patent, because it has no exemptions as does PVPA.

There is one more factor affecting the choice of target. It is the FDA's regulation of food safety. There is no clear answer yet. Because of this problem, cotton is predicted to be the first genetically engineered crop to be commercialized in the U.S.A.(19). In 1989, when I interviewed a director of Industrial Biotechnology Association in Washington D.C. he said that the first crop would be tomato and he expected commercialization in early 1992 (20). Regulation has delayed this expectation.

The importance of patenting genetically engineered plants means that finding new, patentable genes is more important. Therefore, the utility patent should have increased private investment in basic plant science, such as molecular plant physiology. This will give benefits to both universities and industry(21). This university/industry relationship is typical in pharmaceutical industry, where basic product patents are critical. It is observed that there is a strong geographically mediated commercial spillover from university research to pharmaceutical industry(22), where the broad protection given by

the U.S. patent has successfully encouraged both basic life science research and pharmaceutical R&D. The same effects are expected:"The exciting advances in biotechnology, along with opportunities for intellectual property protection, have created incentives on the part of companies to invest more heavily in biological research aimed at developing novel agricultural product and services", Lechtenberg and Schmid wrote(21). But if the other regulations delay commercialization of genetically engineered crops, such effect cannot be developed.

What Determines the Research Agenda in Japan?

As noted previously, Japan has not issued plant patents and guidelines for environmental release of genetically engineered plant were delayed. As a result plant genetic engineering research has been staying at a low level and thus basic research has been poor.

In Japan, there had not been a product patent rule until 1976(14). The lack of product patent is considered to have made Japanese pharmaceutical industry less competitive internationally, because product patent is essential in pharmaceutical industry as described in Chapter 2. On the other hand, Japanese industries in general invested in development of new and efficient processes, which is considered to have strengthened Japanese production technology. Product patent rule is a kind of permission to enter international market, but the effect is not equal to each industry. In Korea, product patent rule has been enacted since 1987, which has seriously damaged its primitive biotechnology industry(23).

Without plant patents, Japanese plant biotechnology is investing

in process technology. A typical case is Nursery Technology, a government supporting bio-venture described previously. The main target of its research is to develop a tank tissue culture system for mass-production of rice seedlings. The system will reduce breeding time because selection and stabilizing process of breeding is not necessary. Besides, it will reduce the cost of producing F_1 hybrid rice seed. Another example is Mitsui Petrochemical Industries. It has started operating tank tissue culture of Easter lily since late 1990. The tank's capacity is 400 billion bulbs per year, which is about 20-25 percent of total supply in Japan. The size of tissue cultured bulb is one tenth of normal bulb, but due to virus free nature the growth is faster than normal. The company's strategy is not to sell bulbs, but to sell cut lilies produced by contract farmers(24).

With respect to product patent, plant biotechnology industry is similar to pharmaceutical industry, but with respect to sensitivity to cost, they are different. No matter how excellent the idea and how effective the patent, if the production cost is too high, it will be difficult to commercialize the product. Since marginal benefit of a new plant is usually small, unlike pharmaceuticals, if the production cost is high, it is not feasible. Therefore, investing in the production process coupled with basic research is necessary. The U.S. industries has often ignored it and as a result market share is captured by Japanese firms(25). The strong product patent makes it possible to sell the patent like a commodity, but it sometimes discourages the U.S. firms to manufacture the patented product.

As noted previously, genetic engineering requires economies of

scale due to its high R&D cost. In Japan, rice and potato are the only candidates. Rice has about 32,500 billion yen seed market, or 240 billion dollars. Potato has about 21,000 billion yen tuber market or 155 billion dollars. However, the Major Crop Seed Law had prohibited private breeding of rice, and Plant Pest Control Law still allows monopoly of primary tuber production by national agriculture research stations(16). This is another factor to have lowered investment in plant genetic engineering R&D in Japan. On the other hand, firms seek for vertical integration (seed through consumer market) instead of economies of scale, and try to get return to R&D from retail market.

7-5. Vertical Integration, Another Way of Protection

In agriculture, integration is found in nearly all commodity subsectors(26). Will biotechnology affect it? First, the case of the U.S.A. is discussed and then, the case of Japan is discussed.

Vertical Integration in the U.S.A.

The broad U.S. utility patent for genetically engineered plant makes the patented plant a non-specific good, relative to a patented plant under PVPA or PPA. A non-specific good in this case means that the plant patent can produce a wide range of varieties. In addition, genetic engineering makes the patent more effective with less cost than conventional breeding method, that is, genetic engineering lowers transaction cost. In these situations, according to Williamson(27), there is no economic rationale to integrate vertically. Actually, genetic engineering firms do not seem to integrate breeding into com-

modity marketing in case of most species. However, tomato, rape seed and chemical resistant plants are exceptions.

Tomato processors, such as Campbell Soup and Heinz, had combined breeding programs with contract cultivation before genetic engineering came. Though Campbell Soup is developing a new genetically engineered variety of tomato in collaboration with Calgene, we do not know whether it will be exclusively used by Campbell Soup or if the company will sell the seed to other manufactures. It just depends on which is more profitable. With respect to rape seed, the situation is the same. Calgene has already acquired an oil manufacturer and is trying to modify fatty acids content using genetic engineering(28). In this case, the genetic engineering is more specific technology and needs vertical integration. If the technology successfully transforms rape seed, it will add value to consumer products. Thus, this is the case that joint profit maximizing will return in greater total profit to the two stages if firms on either side of the stage interface have market power(26).

Chemical resistant plants are another example of vertical integration. There are some crops genetically engineered to be resistant to specific herbicides, such as Monsanto's glyphosate "Round-Up" and Ciba-Geigy's "Atrazine". If those companies succeed in commercialization of chemical resistant crops, they will be able to make profits from both seeds and herbicides.

Vertical Integration in Japan

While plant genetic engineering is under developed in Japan,

other plant biotechnologies, such as tissue culture and its related technologies, are growing in popularity. Those technologies can reduce breeding period, increase mutation rate, or mass-produce homogenous seedlings, but they are variety specific technologies. Besides, plant variety protection under the Seed Law is not effective, that is, requires much transaction cost to protect a variety. In these situations, a vertical integration will occur, according to Williamson(27). In fact, as described previously, prefectures are trying to establish a vertical integration from rice breeding to marketing.

Not only for prefectures but also private firms, the fact that variety is a factor in consumers' choice of rice will be beneficial, because it increases the possibility of vertical coordination based on varieties. However, the Food Control Law is still valid and has not been deregulated yet so that private firms can freely retail rice.

Kirin Brewery, the largest beer brewery in Japan keeping fifty percent share, is also one of leading biotechnology companies. Unlike those three chemical companies that obtained the first registrations for private rice varieties, Kirin has strength in retailing food products.

In 1990, Kirin started to commercialize rice of its own brand. Kirin contracted with farmers to cultivate it, and purchased all the harvest while the company designed and produced a final consumer good. With respect to rice, this kind of coordinating activity is illegal in Japan. However because the rice that Kirin sells is *indica* type, not *japonica* type, it is out of Food Control Law. Japanese people usually do not eat long or medium grained *indica* rice, but recent ethnic diet

boom has induced some demand for it(15). Although this *indica* variety has nothing to do with biotechnology, it suggested that the vertical coordination of rice marketing will happen in commercialization of biotech rice, if the law permits. Kirin also uses similar coordination in commercialization of new potato varieties, which are variants induced by protoplast culture, a kind of biotechnology. Finding variants, Kirin propagated them using tissue culture and made seedlings, not tubers. Farmers contracting with Kirin planted the seedlings and Kirin sold Kirin brand potatoes in groceries in 1990 for the first time(16). Kirin does not intend to obtain any legal protection of the new potato varieties at all, which is why the company could sell the new varieties immediately after breeding. Not only farmers who produce them but also anyone who buys the potatoes can copy them, thanks to the nature of potatoes. However, it does not matter, because only Kirin can use the Kirin brand name, a strong consumer brand in Japan. Trademark ownership is the actual protection in this case.

7-6. Public Role in Plant Biotechnology

Plant biotechnology, especially genetic engineering, has confined public sector to "basic research". This tendency is common in both countries, though its meaning may be a little different. On the other hand, public sector that is supposed to do applied research, the state agricultural experimental stations in the U.S.A. and prefectural agricultural experimental stations in Japan, are continue breeding. In the U.S.A., genetic engineering is the most popular plant biotechnol-

ogy, but public breeders seem to unwilling to use it due to lack of incentive. On the other hand, in Japan, entry barrier to plant biotechnology is small for even public breeders, because tissue culture is a poplar plant biotechnology.

Public Role in Plant Biotechnology In the U.S.A.

The U.S. agricultural production system has had its own publicly funded research system for over one hundred years. The missions of this research system has been to provide applied research for the various clientele groups that compose the U.S. food and fiber system(29). However, because of 1970 PVPA and 70s' commodity boom, private breeding effort had been strengthened, and consequently, as described previously, competition between public sector and private sector in new variety release is occurring. In soybean breeding, publicly bred varieties are the same or even better than privately bred ones, but some farmers prefer private varieties and as a result the share of public varieties have been decreasing(7). On the other hand, biotechnology boom since late 70's has put pressure on the public research agenda toward more basic and fundamental investigations(21).

As far as biotechnology is concerned, public research seems to have shifted to basic fields. In fact, public institutions have not done so many environmental release experiments of genetically engineered plants as private firms have done. As of January, 1990, the number of private field experiments is forty-two, while the number of public is five(30). And the species of public field trials are two tobacco, one cucumber and one poplar, which implies their aim is not

practical: tobacco is a typical model plant of genetic engineering and genetically engineered cucumber and poplar may have a too small market to be commercialized. However, considering the fact that public breeding continues to release new varieties, it means that public breeders are unwilling to use genetic engineering in breeding. If genetic engineering is a way to obtain effective plant patent, public breeders may not have incentive to use it. Even if it is a sophisticated way of breeding, they seem to think it is too costly relative to the benefit.

On the other hand, environmental release experiments done by public institutions will have more impact on basic research. In 1990, scientists of Louisiana State University started field trial of genetically engineered rice. The rice is carrying corn transposons, or "jumping genes", which will be inserted randomly in rice gene and sometimes cause mutation in phenotype. Thus, using the transposon as a marker, they can find out the responsible gene for the mutation(31). The method is promising, but in order to make useful gene libraries for breeding, large scale experiments will be required due to its random nature. And accumulated knowledge will serve for both private and public breeding. It may be a public role, but surely needs private funds. Then, protection of intellectual property rights is a problem, especially when private financing contributes partially to something whose value will be reduced significantly if it is separated.

Public Role in Plant Biotechnology In Japan

Since the Major Crop Seed Law had distinguished the public role from the private role in plant breeding, there is little conflict be-

tween them so far. However, since 1986 some private companies have started rice breeding using biotechnology, and on the other hand, there has been a rice breeding boom among prefectures and the prefectural breeders are willing to use tissue culture and its derivative technologies. Consequently, conflict between them is likely to happen in the near future, not only in seeds market but also in consumer markets. Biotechnology may accelerate it.

About sixty percent of R&D expenditure in the agricultural field is by public institutions and universities. Comparing other industrial fields, the share of public expenditure is high(12). In Japan, there is no university equivalent to the U.S. land-grant universities. Almost all MAFF's R&D spending goes to national of prefectural agricultural research stations. University's agricultural research is financed by Ministry of Education. There is at least one national university in every prefecture and most of them have a department of agriculture, but their research is not applied or even if it is applied it is not for the local farmers. On the other hand, MAFF's research funds had been used for applied research for a long time. This distinction may be based on historical belief that academia should not do something practical. Of course a lot of exceptions exist. However, this attitude has made universities isolated from industry and caused difficulty to obtain research funds from industries.

With respect to plant breeding, national agricultural research stations recently have released parental lines, as noted previously. Since both prefectural and private breeders can utilize them, the role of national research stations is considered to facilitate breeding.

Even in the case of biotechnology, the role is not different. The national research station did the first environmental release of a genetically engineered plant and showed to those who were interested how a field trial should be done(32). Besides, national research stations started making gene maps of rice using RFLP(restriction fragment length polymorphism) in collaboration with prefectural research stations and private firms in 1991(16). RFLP is the genetic markers that can be detected by differences in DNA sequence. In sum this technique can tell whether a genetic trait is inherited to the next generation or not at DNA level before the trait appears. This technique is actually used to diagnose a genetic disease at embryo stage. Similarly the gene maps are expected to reduce breeding period.

But a problem is who can utilize the map. Some R&D expenditure is financed by private firms and the other is by tax through MAFF. If it is free to use, private firms' incentive to join the project will be reduced significantly. Moreover, researchers of other countries will be free riders of the gene maps. Of course Japan will have to allow it, because with respect to other cases of the free-rider problem Japan has been criticized.

In the U.S.A. some biotech ventures are making RFLP maps. One of them is NPI. It has already made RFLP maps of tomato and corn, and sells them to breeding firms. Not only selling maps, but the company itself is breeding crops using the maps. The map is protected as a trade secret. Japan's MAFF bought a set of RFLP maps of tomato at 290 million yen or 2.4 million dollars from NPI under the governmental urgent program to import something from the U.S.A. in order to reduce

large trade surplus against the U.S.A. in 1987. At that time, NPI asked MAFF to keep not only the contents of the maps but also the varieties bred by using it secret at least five years(34).

7-7. International Consequence

Institutional differences between countries have recently caused trade related conflicts. Patent system, environmental protection and food safety often make problems in every industry. Plant genetic engineering will not be exceptional.

The Difference in Patent System

As described previously, the U.S. patent system encourages firms to invest in basic research and to seek for economy of scope. On the other hand, Japanese patent system induces firms to use different protections, such as F_1 hybrid and vertical integration. As a result, basic research in plant molecular biology in Japan stays underdeveloped.

A plant patent has not been issued in Japan so far and even if it is issued, the coverage will be narrow as is the case of other patents issued in Japan. Consequently, the U.S. firms cannot realize the economy of scope in Japan. Since the Japanese seed market is small, it may not matter with the U.S. big firms. On the other hand, Japanese firms can obtain a broad plant patent in the U.S.A. As a matter of fact, Taishi Food's odorless soybean(U.S. Patent 4,677,247), Takara Shuzo's new mushroom(U.S. Patent 4,940,836) and Hybrid citrus codeveloped by MAFF and Kikkoman(U.S. Patent 4,940,837) have been

patented under the U.S. utility patent. They are also protected under the SL in Japan, but as noted previously, the protection under the SL is very weak compared with the U.S. utility patent.

The difference gives Japanese firms the possibility to do seed business in the U.S., either exporting from Japan or producing in the U.S.A. This idea is found in a MAFF's report "*Future Vision of Seed Industry*" in 1988(9). Plantech Research Institute, a leading plant biotechnology firm in Japan, has produced rape seed in the U.S.A. since 1988 while breeding it using genetic engineering(17). Kirin Brewery, one of the largest food companies in Japan, has established a joint venture in the U.S.A. with Calgene in 1990 and is commercializing potato microtubers, tissue cultured virus-free tubers, while doing genetic engineering research(17).

A typical scenario of product development between the U.S.A and Japan is as follows: A U.S. company invents a new product and patents it both in the U.S.A. and in Japan. Then the company exports the product to Japan. In Japan, the patent protection is weak and a lot of companies commercialize similar products. Due to competitive market, the production process and the quality of the product are improved significantly in Japan. According to Japanese sense, those improved products are no longer the same as the original. Thus, Japanese companies export the improved products to the U.S.A., sometimes paying royalty to the inventor, sometimes after the expiration of the patent and sometimes insisting that they are different products. The U.S. consumers prefer improved products and the original inventor is often satisfied with royalty. Then Japanese companies start manufacturing

them in the U.S. And finally the U.S. company cannot compete and stops manufacturing. Though each case has some differences, this general scenario is valid for many industries, such as steel, consumer electronics and automobiles.

Will the same thing happen in plant biotechnology? As noted previously, plant biotechnology is similar to pharmaceuticals in terms of the importance of product patents. The effective U.S. product patents, coupled with strong basic research, keep the U.S. pharmaceutical industry competitive in the world. However, production cost of seed or seedling will be one factor that determines the feasibility of a genetically engineered crop, that is, seed has more elastic demand than pharmaceutical. Therefore, as I pointed previously, investing in process technology is also necessary. If the U.S. manufacturers depend only on their strong product patent position and are unwilling to improve process technology, again the U.S. will lose a manufacturing. Kenney and Florida describe it as Japan's remarkable capacity to make important follow-through innovations in products and manufacturing process in contrast with the U.S. breakthrough innovation(25).

Other Regulations: Environmental Release and Food Safety

The delay of establishing clear guidelines for environmental release of genetically engineered plants has caused underdevelopment of R&D in this field in Japan. Even though the first field trial was done in February 1991, it will take a few year to start commercial-oriented large scale trials in Japan. Firms will not be able to wait so long. One very likely solution is to do field trial in the U.S.A.

It will not cost much. As noted previously, Kirin Brewery has already established a joint venture in the U.S.A. which is considering field trial of genetically engineered potatoes. And several Japanese seed companies have trial fields in the U.S.A., though they do not intend to use for environmental release trials so far. Different from pharmaceuticals, performance of crop varieties are climate and soil specific, which means that final trial has to be done where it is going to be sold. It is true, but if Japanese firms are going to do seed business in the U.S.A., the difference in regulation does not matter. On the other hand, the U.S. seed companies will be affected by the difference. In addition, Japanese firms may start crop production and integrate with export under some brands for Japanese consumers. In this case, field trials in Japan can be skipped.

The environmental release of genetically engineered plant is generally considered to be safe in the U.S.A. and there is little opposition so far. However, if foreign companies do it, opposition might happen saying they purchase not only land but also environment which they do not want to sell. In addition, Greenpeace, international aggressive environmentalists group, recently announced that they are considering a worldwide program aimed at the biotechnology's agricultural applications. In Europe they already started protest against environmental release of genetically engineered plants(33). This movement may occur even in the U.S.A.

With respect to food safety of genetically engineered crops, there is no rule in both countries. However, as mentioned in Chapter 5, there is the concept of GRAS substance in the U.S.A., while Japan

has no equivalent rule. Regardless production process, once a food is granted GRASS status, it is not subject to regulation. As a result of this difference, the problem of the cheese processed by enzyme produced by genetically engineered bacteria is occurring, as described in Chapter 5.

If Japan's Ministry of Health and Welfare thinks that consumers' concern is strong in Japan and if it bans genetically engineered food, which is very unlikely, it will be another trade barrier between the U.S.A. and Japan. Making a new rule that the U.S. government might consider a barrier is what Japanese government is unwilling to do. Therefore, Japan's regulations will follow that of the U.S.A. But the problem is, as mentioned, there is a basic difference in concept of regulations. This makes Japan's regulation more uncertain, and as a result causes less incentive to invest in R&D. On the other hand, if the Japanese government use a double standard, and applies weak regulation against imported foods, Japanese firms will try to produce genetically engineered crops in the U.S.A. and export them to Japan.

7-8. Summary and Conclusion

With respect to varieties of asexually propagated plants protected under Plant Patent Act of 1930(PPA), number of patents has been increasing. In Japan, asexually propagated plant varieties equivalent to those protected under PPA are also increasing, which is protected under the Seed Law(SL). The effect of biotechnology on the breeding of those asexually propagated varieties is not clear, but because recent development of biotechnology has made it possible to

propagate any plants asexually, PPA will be more important.

In the U.S.A. sexually propagated varieties protected under PVPA are bred by both public institutes and private firms in the U.S.A. They are competing in the seed market. The number of PVP certificates of each crop is well correlated with its seed market size in either public or private varieties. In Japan, major crops, such as rice, wheat, and soybean had been monopolized by public agricultural stations based on the Major Crop Seed Law until 1986. As a result, there is no registered private variety of the major crops yet, except rice. Private firms have recently started breeding program of rice, and some of them have obtained registrations under the Seed Law. In Japan, number of private varieties except rice is well correlated with the size of the seed market, but the number of public varieties except rice is negatively correlated with the size of the seed market, because it is affected by political consideration. Rice is excluded, because it has extremely big market compared with other crops.

Time trend of the number of PVP certificates was examined: number of private alfalfa, corn, grass, soybean ryegrass, vegetables and wheat are significantly increasing, and only public soybean shows a positive growth rate among public bred crops. However, growth rate of private soybean is much larger than that of public soybean. This can be explained that public varieties are generally well distinguished from existing varieties, in other words, the invention of public varieties is in a discrete process, while private varieties do not differ so much each other. In this situation, one of roles of public breeding is to provide breeding materials to private firms.

Time trend of the number of SL registrations was also examined: public vegetables and rice and private rice show significantly positive growth rate. Since the amendment of the Major Crop Seed Law of 1986, private breeding of rice has grown rapidly, and finally they may compete in the seed market, which is happening in the U.S.A.

The difference between the U.S.A. and Japan is that in the U.S.A. plant can be protected under the general patent (PA). The U.S. PA is expected to encourage R&D of genetic engineering, because PA allows an inventor to claim broadly based on the "doctrine of equivalents". As of January 1, 1991, there are only three patents that claim product patent of genetically engineered plants, all of which were issued in 1990. Considering the increasing number of field trials of genetically engineered plants as described in Chapter 6, product patents of genetically engineered plants will increase. In the field of plant genetic engineering, U.S. private firms are devoted to breeding, that is, applied research. On the other hand, U.S. public institutes are devoted to basic research. There is no such a clear distinction as in the case of plant breeding under PVPA. In Japan, both private and public breeders are using tissue culture instead of genetic engineering, which makes entry barrier to plant biotechnology small not only for private firms but also for public agricultural stations.

In the U.S.A., there are PPA, PVPA and PA. Since PA covers all possible protection given by PPA and PVPA, there is no reason to obtain protection of a variety under PPA or PVPA if it is patented under PA. However, there are some cases of double protection, that is, a variety protected under both PPA and PA or both PVPA and PA. When ap-

plication is submitted, no one knows whether a patent is granted or not. Therefore, the double protection is unavoidable, if an inventor applies for both protections. Since the double protection itself does not increase protection level any more than that of PA, the problem is not the double protection but the fact that a plant is patentable under PA.

Genetic engineering makes it possible to describe an invention as having a large scope, and also makes the patent effective by lowering exclusion cost. Therefore, in the U.S.A., private R&D of plant biotechnology is concentrating on genetic engineering, although there are some regulations for environmental protection and food safety.

On the other hand, because there is no plant patent and because protection of SL is not effective, not only private firms but some prefectural agricultural stations are trying protect a variety by other than patent in Japan. Since consumers recognize varietal identity, vertical integration through breeding to marketing of a crop and product differentiation via brand based on a variety is a typical strategy. In this situation, popular biotechnology is not genetic engineering, but tissue culture and its related technologies. They are variety specific and requires less investment than genetic engineering. Also due to weak product patent, private firms and the public sector as well are investing in process technology, especially in a technology of efficient multiplication of seedlings.

As far as plant biotechnology is concerns, there is no case of international infringement. It is because plant breeding has been very domestic. However, genetic engineering tend to require economies of

scope, that is, firms will want to expand one invention to a lot of varieties. Therefore, difference in patent systems will be a problem. As is usual, U.S. firms will complain that their patents cannot claim in Japan as broadly as in the U.S. Not only patent systems but also other regulations, such as the regulation on environmental release of genetically engineered lives and the regulation on safety of genetically engineered food, are affecting R&D. The regulatory delay in Japan is also the reason why genetic engineering is not so popular technology in plant biotechnology R&D. The regulatory difference will encourage Japanese firms to do breeding and integrated crop production in the U.S.A.

8. Summary and Conclusion

Plant biotechnology was expected to have a big impact on agriculture when the genetic engineering boom came to the world in late 70's. However, genetic engineering, an important part of plant biotechnology, has not had any impact on agricultural production yet. Compared with pharmaceuticals produced via genetic engineering, there is an obvious lag in commercialization of genetically engineered plants. Agricultural industry and pharmaceutical industry, though both are based on knowledge of life-science, have different R&D structures and different market structures. With respect to intellectual property rights protection, pharmaceutical industry is characterized by the importance of product patent. On the other hand, in plant breeding, plant variety protection is usually ineffective.

However, since 1985 plants have been patentable in the U.S.A. under the general patent, or utility patent, which means that a product patent of a plant can claim broadly based on the "doctrine of equivalents", like a product patent of a pharmaceutical. In addition, development of genetic engineering makes it possible to claim broadly and to protect patents effectively at a lower cost. As a result, patent effectiveness has been improved. Thus, in the U.S.A. there are three different laws that protect a plant variety: Plant Patent Act of 1930(PPA), Plant Variety Protection Act of 1970(PVPA) and plant patent under the general Patent Act(PA). On the other hand, in Japan, there is only the Seed Law(SL) revised in 1978, which is equivalent to the U.S. PPA and PVPA. There is no plant patent under the general Patent

Law issued yet in Japan.

The difference in plant variety protections between the U.S.A. and Japan is theoretically the difference in breadth of patent, or product space. In other words, a plant patent under the U.S. general Patent Act requires more novelty and more non-obviousness than a plant variety protection under the Japan's Seed Law. This difference in product space is a general difference in the patent system between the two countries, but it is very clear when we compare the U.S. PA with Japan's SL because the protection of SL is variety specific. In other words, the product space given by one registration under the SL is the smallest unit.

Patent length and breadth are instrumental variables that a policy maker can modify. As far as considering a single invention, theoretically length and breadth can be traded off. However, in the real world, an invention usually depends on the previous inventions. Therefore, the breadth, unlike the length, affects the rate of spillover, which determines successive nature of inventions.

This paper examines what kind of effect the difference in product space between the U.S.A. and Japan has on the R&D of plant biotechnology, that is, to compare mainly the output of R&D under the U.S. PA with that under the Japan's SL. However, plant biotechnology is a very complex technology, including from molecular biology to multiplication of seedlings. The product patents of plants under PPA, PVPA, PA or SL are just a part of it. Finding bio-active substances, cloning their genes, transforming whole plants and multiplication of seedlings are necessary steps of breeding and effectiveness and impor-

tance of patents differ in each step. However, as mentioned previously, the difference in product space is very clear when comparing PA with SL, and therefore, this paper focused on it.

Empirical Evidence

The number of plant species that can be transformed with a foreign gene has increased since mid-80's (technology development). Human-made plants have become patentable since 1985 in the U.S.A.(effective patent). Environmental release of genetically engineered plants has been permitted relatively easily since 1986 in the U.S.A.(clear and favorable regulation). These three facts have increased the importance of genetic engineering in plant breeding, which has caused a shift in breeding technique and promoted acquisition and merger in the U.S. plant biotechnology industry: Since mid-80's tissue culture oriented firms had become hard to survive and finally disappeared by being acquired or merged by genetic engineering oriented firms. On the other hand, in the U.S.A. there have been few new entrants into plant biotechnology since the first biotech boom of early 80's. The technological development and institutional changes did not stimulate private investment in establishing new ventures, which is different from what has been happening in other fields of biotechnology, especially in biotech pharmaceutical. Plant genetic engineering requires a long investment period, which makes entry barrier of this field in the U.S.A.

Available scientific and technological information does not differ much between the U.S.A and Japan(technology development). But, in

Japan, there has been only Seed Law. It is still uncertain whether plants are patentable subject matter or not under the Patent Law and even if a plant patent is issued, as is the case of other industrial fields, the product space of the patent will be narrowly determined by the Patent Office(JPO). It means the effectiveness of patent will be small in Japan(ineffective patent). Therefore, plant patents may not be so critical to secure profit in Japan. As described above, genetic engineering can be a way to obtain relatively broad patents on plant. But in Japan, since plant patents are not so important, plant genetic engineering is not always necessary. In addition, because genetic engineering in general requires more R & D expenditures, a longer investment period and additional legal work for commercialization (unclear regulation), there is little advantage in genetic engineering relative to other substitute technologies in Japan. On the other hand, it makes entry in plant biotechnology easy.

As a matter of fact, a lot of private firms and prefectural agricultural stations are using tissue culture in plant breeding and multiplication in Japan. Tissue culture and its related technologies are more variety specific and requires less investment than genetic engineering. In this situation, private firms and even prefectural governments are trying to protect a variety not by patents but by marketing effort. Since consumers recognize varietal identity of crops, vertical integration through breeding to marketing of a crop and product differentiation via brand based on the variety is a typical strategy in Japan. In addition, due to the weak product patent, private firms and public sector as well, are investing in process

technology, especially in technology of efficient multiplicat.. seedlings.

Another problem related to the patent system is the public role in plant breeding. In the U.S.A. sexually propagated varieties protected under PVPA are bred by both public institutes and private firms. They are competing in the seed market. The U.S. ~~effective~~ patent is giving incentive ~~to~~ investing in plant genetic engineering to private firms, ~~but no incentive to public breeders~~. As a result, plant breeding using genetic engineering ~~is done by mainly~~ has grown rapidly in private firms. ~~On the other hand~~, public institutes ~~have~~ are concentrating more on basic research and ~~show no increasing effort in breeding~~.

In Japan, major crops, such as rice, wheat, soybean and barley had been monopolized by public agricultural stations based on the Major Crop Seed Law(MCSL) until 1986. As a result, there is no private variety of the major crops yet, except rice which has a extremely big market compared with other crops. Since the amendment of the MCSL, private breeding of rice has grown rapidly, and some firms obtained registrations of rice variety in 1990 for the first time. Private and public sectors will soon compete not only in the seed market but also consumer market, because both are trying to establish integration. On the other hand, Ministry of Agriculture, Forestry and Fishery (MAFF) established some research consortia specializing in rice genetic engineering, in which not only public institutes but also private firms can join. Since patent is weak in Japan, such cooperative research will work and is considered to provide a lead time in R&D to contributors.

Conclusions

The difference in the breadth of a plant patent between the U.S.A. and Japan obviously affects R&D of plant biotechnology. The U.S. firms tend to depend on effective product patents and Japanese firms tend to invest in improvement of process technology and to use marketing effort. This consequence is quite a common phenomenon in industries of both countries. But future consequence will depend on the industrial structure and the product attribute.

If seed industry is like pharmaceutical industry, the U.S. firms can depend on their strong product patents. If seed industry is like consumer electronics industry, Japanese firms will gain market share by improving product and process. But neither may be the case.

However, the problem is that agriculture need more intensive basic research in life-science, but neither private firms nor governments of both countries can afford it. Knowledge derived from such basic science will surely be beneficial to plant genetic engineering in the long run. Policy should be designed to increase investment in basic plant science, not only from private sector but also from public. In this sense, R&D of plant biotechnology should be like R&D of pharmaceuticals. However, different from pharmaceuticals, production cost is a critical factor in seed and seedling production. In this regard, Japan's weak patent has advantage, because it will induce competitive investment in process technology. On the other hand, marketing effort done by Japanese firms, though it works under a situation of weak patent, will not encourage investment in basic plant science.

The U.S. plant biotechnology and Japan's plant biotechnology will be complementary, in other words, both are required just like patents of EPO case (see Chapter 1 and 3). The U.S. strong product patent may be good for basic research, but if it discourages product and process improvement, plant biotechnology will not contribute to agriculture much. Therefore, the U.S. patent system should have a way to share the return among the original inventor and improvers. At the same time, Japan's protection level should be increased to be the same as the U.S.A., otherwise the weak patent induces too much wasteful effort in marketing. In addition, length of plant patent under general patent law can be extended just like pharmaceuticals, because it takes a long time to develop genetically engineered crop after a basic idea or finding is patented.

Basic research also should be supported by public funds. In pharmaceutical field, to save life is a strong value that justifies the public funds for basic research. In agriculture also, a new value should be created to justify the increase of public investment in basic research, for example, sustainable and environmentally safe agricultural system.

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