

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology

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I Introduction

The number of intellectual property claims relating to plant material is increasing due primarily to advances in biotechnology. There are two important systems in place to protect intellectual property rights in relation to plant material:

- a) the protection of new varieties of plants (hereinafter referred to as the “UPOV system”, in line with the Union Internationale Pour La Protection Des Obtentions Végétales – the International Convention for the Protection of New Varieties of Plants) and
- b) the patent system for plant genes (“patent system”).

After extensive legal discussion of the relationship between these two systems, it can be concluded that both systems can coexist since each system has different objectives and rationales.

Legal matters, such as the scope of the protection of plant breeders’ rights and patent rights have dominated these discussions to date. However, technological matters, such as the methods and conditions, under which new plant material is examined in each of the systems, have not been adequately discussed. Such matters have been considered as being quite distinct in each of the two systems: the examination of the UPOV system has focused solely on the phenotypic characteristics of plants, whereas the patent system for plant genes has examined both their genetic structure and phenotypic characteristics.

However, the author believes that, due primarily to advances in genetic technology, the UPOV system is now changing in its practice. This paper attempts to show that the UPOV

system is now taking into consideration the genetic structure of plant varieties, in addition to their phenotypic characteristics.

This paper takes as a case the administrative procedures and activities in the UPOV system in Japan, a system entirely consistent with the international convention. It attempts to show that DNA analysis, which is a method to identify genetic structure, is increasingly used in the examination, inspection of plants, and in other administrative procedures of the government, under the UPOV system. If it can be demonstrated that DNA analysis is widely used in the various procedures of the UPOV system, then it can be validly concluded that the government is introducing the concept of genetic structures into the UPOV system, although the mandate of the system is to grant rights based solely on phenotypic characteristics. Consequently, in practice, both the UPOV system and the patent system for genes consider both the phenotypic characteristics and genetic structures of plants as key factors in examinations carried out under each of the systems. In other words, the demarcation between these two systems can be said to be becoming technologically “blurred”.

This paper firstly clarifies the point of argument raised in the paper. Secondly, it examines various studies and discussions which have addressed the issue of the demarcation between the two systems. Thirdly, it attempts to identify the DNA analysis used in the administrative procedures and activities of the government of Japan. Finally, it expresses the view that the technological demarcation between these two systems is becoming increasingly “blurred” and makes reference to the possible future integration of these systems.

The author expects that with further advances in genetic technology, many other countries are likely to have already encountered, or will soon encounter, similar issues.

II Point of argument

The UPOV system and the patent system for plants genes have coexisted together. However, in recent times, there have been instances in which, single plants have occasionally been protected through both breeders’ rights and patent rights. This in turn has given rise to discussion of the demarcation between these two systems. Such discussion is influenced by the conflicts between the big companies, which are developing new plant varieties by

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology (並河) using genetic technology, and traditional plant breeders, who develop new plant varieties through conventional cross-breeding and variety-selection.

The relevant domestic law of the patent system in Japan is known as the “Patent Law”. The objective of the law is the protection of invention. The conditions under which protection of patent rights is provided include proof of “novelty, utility (industrial applicability), and non-obviousness”. At present, patent rights for genes are granted when both the genetic structure (nucleotide sequence) and its utility (genetic function) are identified. For plant gene, “utility” refers to the corresponding phenotypic characteristics - such as the colour of the flower, the resistance of the plant to cold temperatures and yield characteristics of the plant - or to the function of the protein which corresponds to such phenotypic characteristics. That is, the conditions under which patent rights for plant genes are granted include both the determination of the genetic structure of the plant, and the definition of its phenotypic characteristics.

The relevant domestic law of the UPOV system in Japan is known as the “Seeds and Seedlings Law”. According to the law, any person who has bred a new plant variety which fully meets the requirements relating to novelty, distinctness, uniformity and stability, is granted breeders’ rights (Article 3 (1)). The examination for granting breeders’ rights requires, in principle, growth testing of the variety in the field. Officials of the Ministry of Agriculture, Forestry, and Fisheries (hereinafter referred to as MAFF) conduct on-site inspections, or the National Centre for Seeds and Seedlings (hereinafter referred to as NCSS), a laboratory affiliated with MAFF, conducts growth testing to examine the variety for which an application for breeders’ rights has been filed (Article 15 (2)). Both on-site inspections and growth testing compare the new variety with a similar variety in the field and establish the differences and similarities between each based on their respective phenotypic characteristics. These differences and similarities in phenotypic characteristics are the results of their respective nucleotide sequences. However, the method of examination established under the Seeds and Seedlings Law does not specifically refer to the genetic structure of the plant.

The conditions under which intellectual property rights are granted are, on the one hand, the genetic structure and the phenotypic characteristics determined by the plant genes (patent system) and, on the other hand, solely the phenotypic characteristics of a new plant variety (UPOV system). It is a basic principle of the Seeds and Seedlings Law, and its most

important distinction from the Patent Law, that the plant variety is examined solely by observing its phenotypic characteristics.

This paper attempts to demonstrate that in practice, the government is introducing DNA analysis into its administrative procedures relating to UPOV system. This leads to the conclusion that the government actually takes into consideration both the genetic structure, as well as phenotypic characteristics of plants.

III Recent discussions

1 International discussions

The relationship between the UPOV system and the patent system has been extensively discussed in symposia organized jointly by UPOV and the World Intellectual Property Organization (WIPO) in 2002 and 2003. In the USA, the relationships among the three existing systems – the Utility Patent, the Plant Variety Protection Act and the Plant Patent Act – has been strongly disputed, reflecting the conflicts which exist between the big seeds companies, traditional plant breeders and farmers. The disputation in the USA has strongly influenced international discussions. The point at issue in these discussions and disputes is whether the UPOV system can coexist with the patent system. In other words, whether the UPOV system is in fact necessary has been discussed.

Various studies and reports addressing the coexistence of these two systems can be broadly divided into three categories: those that are “affirmative” and support the existence of both systems; those that are “negative” and do not support the existence of two systems; and those that adopt a “neutral” position.

Firstly, the author reviews “affirmative” studies and reports. Roberts (2002) compared the research exemption of the UPOV system with that of the patent system, and proposed that a system separate from the patent system is required for plant varieties. From a practical perspective, and from the standpoint of a breeder, Desprez (2002) maintained that breeders should resolutely choose UPOV protection for the varieties they create. Straus (2002) compared the European (EU) regime with the US system from the viewpoint of access to patented germplasm, and suggested that the introduction of appropriate research exemption rules in the corresponding patent laws should be seriously considered. In the symposium

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology (並河) of 2003, studies regarding the biotechnological research and development (R&D) of plants in China, Kenya and Argentina, and a study on comparisons of the R&D in developing and developed countries were reported. Each of these reports supported the coexistence of the UPOV and patent systems. Recently, Medaglia (2009) refers to mutual supportiveness among the UPOV, WIPO (patent regime) and related regimes, implying the need to make compatible multiple regimes.

Among the “negative” studies, Janis (2001, 2002) compared the effects of patents and plant breeders’ rights on the stimulation of R&D in the USA, and stressed that the specialized intellectual property systems for plants, which continue to exist alongside the general patent system, result in a confusing array of overlapping intellectual property regimes. Janis and Kesan (2002) also stressed that, in order to encourage plant innovation, reformers should direct their energies towards the improvement of the utility patent regime rather than to the refinement of the US Plant Variety Protection Act. McManis (2002), expanding on their studies, suggested that the *sui generis* forms of protection for plant innovation that are offered in the USA, are neither necessary nor particularly effective.

Among the “neutral” studies and reports, Joerdens (2002) clarified precisely the similarities and differences between these two systems.

In summary, therefore, there are many studies and reports which have examined the relationship between the UPOV system and the patent systems. However, each of these studies and reports has concentrated on the demarcation between these two systems, focusing largely on legal matters such as the scope of protection.

Unlike these studies and reports, there have been a few studies and reports which have examined the two systems from the perspective of technology. The Working Group on Biochemical and Molecular Techniques (BMT) of UPOV has studied ways to introduce DNA technology into the examination of new plant varieties, and into the identification of already-protected varieties. The International Seed Federation (ISF) considers that “distinctness, uniformity, and stability” (DUS) testing should continue to be based on phenotypic characteristics, and opposed the use of DNA markers alone for DUS testing, believing that DNA marker profiles are not yet predictive of most phenotypic characteristics. However, the ISF does consider that DNA markers may be used for the identification of an already-protected variety. (ISF, 2000, 2003 and 2006)

This paper discusses the technological issues involved, using as a case study the

administrative procedures applied in Japan.

2 Discussions in Japan

In Japan, discussions of the relationship between the Seeds and Seedlings Law and the Patent Law began in the late 1990s. The Seeds and Seedlings Law, based on UPOV 1991, was established in 1998, and was subsequently amended in 2003, 2005, 2007 and 2008, in response to dramatic advances in biotechnology.

The official view of the Japanese Government is that the demarcation between the two systems is quite distinct and, the Seeds and Seedlings Law should coexist with the Patent law. M. Takagi, Director General for Agricultural Production and Horticulture Bureau of MAFF stated in 1998 in presentations to both the House of Councilors (1998) and the House of Representatives (1998) of the Japanese Diet, that the demarcation between the two systems was distinct. As reasons, he cited the facts that, firstly the focus of each system is quite different; the focus of the Seeds and Seedlings Law is new plant varieties whereas the focus of the Patent Law is invention. Secondly he noted that there have been few inventions the objects of which were new plant varieties. The government (the Seeds and Seedlings Division of MAFF (2003) and Nozawa of MAFF (2004)) has reiterated Takagi's view. Each has pointed out that the Patent Law protects both the upper level of classification (the family, genus, and species), and the lower level (genes) rather than the plant variety itself. Each confirms that it is not easy for new plant varieties to fulfil the conditions necessary to obtain patent rights, especially the novelty and non-obviousness conditions.

Some legal studies have discussed the demarcation between the two systems when single plants are protected under both the breeders' rights and patent rights. Shibuya (1999) and Ihara (2004) proposed that the rights that take precedence should be determined by the date of the filing of the application. Saito (1997) discussed the relationship between the breeder's rights to a variety and the patent rights to the family and genus to which the variety belongs. Based on his own business experience, Hiraki (2000) reported that the relationship between the breeder's rights and the patent rights is usually determined by a cross-license contract.

Thus, studies and reports in Japan have also focused on the overlapping scope of the protection offered by the two systems from a legal viewpoint, and have concluded that the two systems can coexist.

IV Methodology and materials for analysis

1 Methodology

This paper adopts the methodology of seeking to identify procedures relating to the use of DNA analysis, as described by documents, which provides the legislative framework for administration of the UPOV system in Japan.

Breeders' rights is granted when phenotypic characteristics of a plants variety fulfil the conditions listed in the UPOV system. Therefore, all procedures under the Law ought to be based solely on the phenotypic characteristics of the plants: examination of new varieties ought to be based solely on phenotypic characteristics of the plants; conflicts about the breeders' rights ought to be settled based solely on the phenotypic characteristics; Customs inspection whether an importing or exporting plant infringes the breeders' rights ought to be based solely on the phenotypic characteristics; and judgment whether processed products infringe the breeders' right ought to be based solely on the phenotypic characteristics.

If it can be demonstrated that DNA analysis is widely used in the various procedures of the UPOV system, then it can be validly concluded that the government is introducing the concept of genetic structures into the UPOV system, although the mandate of the system is to grant rights based solely on phenotypic characteristics.

This paper analyzes documents issued by the government and other affiliated organizations, which are related to the administration and practical operation of the UPOV system in Japan. Such documents provide concrete procedures, forms and technological details etc. under which the UPOV system operates in Japan; on the other hand, the law merely expresses the basic principles and does not allude to the detailed operational aspects of the system. When a system becomes significantly removed from reality, because of, for example, rapid advances in technology, the government in Japan usually modifies the relevant administrative procedures, as described in such documents, in order to make the system more closely conform with the actual situation. Such modified administrative procedures show the underlying trends of the system, which reflect recent advances in technology, within the limits set by the basic principles of the law. Subsequently, the Diet will amend the law in order to make the principle more closely align to the actual situation.

2 Materials

The documents analyzed in this paper can be classified to three categories.

- a) Documents such as ordinance, notifications, guidelines and manuals for officials or applicants, which are issued by MAAF and the Customs Bureau. In such documents, the government shows its official stance on the administration and operation of the system, including detailed rules and procedures, official interpretation of law and the introduction of specific cases. Judicial precedents are also considered in this category. These are official and legal documents and therefore prove useful for the author to gain an understanding of the actual administration and operation of the system.
- b) Documents including reports, minutes and materials of meetings of ad-hoc research committees in MAAF. These committees consist of specialists who meet to discuss new policy initiatives which require specialist knowledge. Although such committees are no more than advisory bodies to the government, their reports are de facto official statements of the government. This is because drafts of the various committee reports are made by the secretariats of the respective committees, who are officials of the government. Accordingly, policies established by such committees are rarely modified by Ministries, or even by the Diet itself. Committee reports are useful because they include not only conclusions, but also provide the rationale and background data upon which their conclusions are based.
- c) Materials issued by or for the NCSS, which plays an important role in the administrative procedures and activities under the UPOV system. Such materials include the certificate of incorporation, which was given at incorporation of the NCSS, medium-term plans and reports, annual plans and reports, manuals and guidelines. The NCSS, which had been a government institute, was formally separated from the government in 2001. However, it remains under government control and receives most of its funding from the MAFF. Therefore, documents issued by the NCSS can be considered to be de facto documents of the government.

The sources of these documents are listed in reference or note.

V DNA technology used in the plant variety protection system

1 DNA analysis in Customs inspections

DNA analysis is often used in the inspection processes associated with importation and exportation, and it has become the de-facto standard method of inspection. The outline of the processes is summarized in Figure 1.

Firstly, DNA analysis is used to cope with the requirement for a prompt inspection process. According to the Custom's Notification⁽¹⁾, Customs should determine whether the goods infringe the breeder's rights within one month of the commencement of the inspection process (Process <1> in Figure 1), because holding uncleared goods in port for any longer period would impose an unacceptable burden on, and a risk to, the importer. Since it is impossible to carry out growth testing within one month, Customs must rely on DNA analysis. The Notification⁽²⁾ clearly states that when it cannot assess the goods by their documentation or appearance, Customs should conduct DNA analysis in the Central Customs Laboratory (CCL) without delay (Process <2>).

Secondly, DNA analysis is used to cope with the short term requirement of lodging a claim with Customs. In accordance with the notification⁽³⁾, a rights holder or an importer, should they so wish, may lodge a claim the rights or the legitimacy with Customs, with the appropriate evidence, within three days (in the case of perishable goods), or within 10 days (in the case of non-perishable goods) from the commencement of the inspection process (Process <3> and <4>). Such a short term is specified because holding uncleared perishable commodities in port for more than a few days would cause their decomposition and would impose an unfair burden on the importer. The only evidence that either the rights holder or the importer could submit within such a short time frame would be previously ascertained DNA analysis data.

Thirdly, DNA analysis is used in the procedure to lodge an application for a suspension of importation. When a holder of breeder's rights lodges an application for a suspension of importation, the holder must attach DNA analysis data to the lodgement form (Process <5>), according to the requirements of the notification⁽⁴⁾ and as required by the Customs form (C-5840). Furthermore, the lodger must also submit a written confirmation by MAFF that this DNA analysis was properly conducted⁽⁵⁾. That is, Customs requires the lodger to

submit reliable data, since lodging an application for a suspension of importation imposes a burden on, and risk to, the importer. In practice, the importer is also required to submit DNA analysis data to Customs to counter the claim of the lodger (Process <6>). It is fair to consider that DNA analysis is a standard method in the this procedure because the lodger will not have the opportunity to conduct field testing prior to the importation, and will therefore have less information about the goods than does the importer.

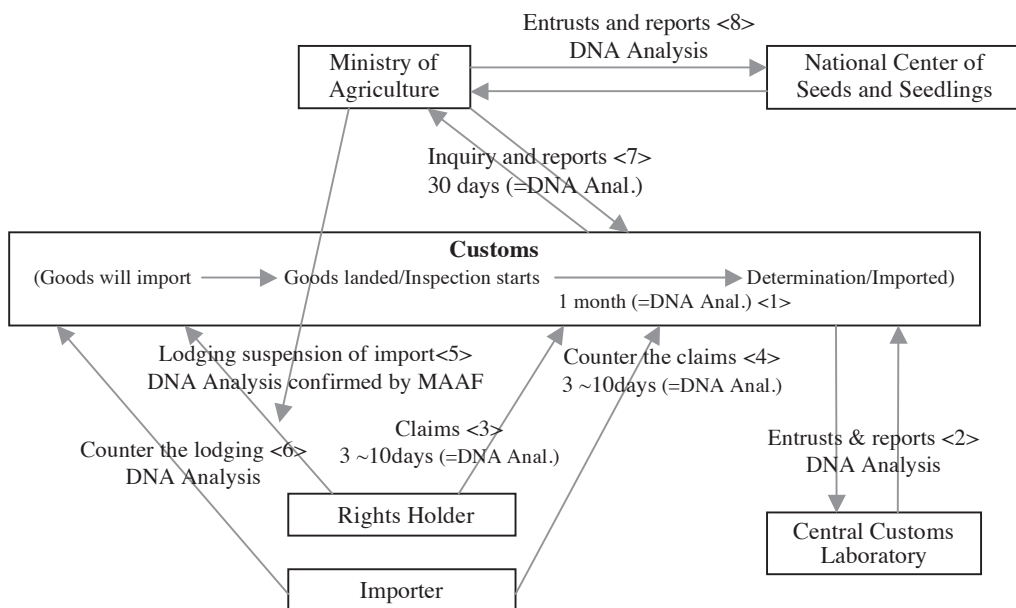
Finally, DNA analysis is used in the inquiry procedure. The notification⁽⁶⁾ states that Customs may make inquiries of MAFF about the information regarding the breeders' rights (Process <7>). MAFF is required to respond to Customs within 30 days of the initial inquiry⁽⁷⁾. This short period of 30 days means that in practice, MAFF is precluded from performing a growth test in the field. If necessary, MAFF may entrust its affiliated laboratory (the NCSS) with the analysis of the goods⁽⁸⁾ (Process <8>). In accordance with its certificate of incorporation⁽⁹⁾, and its business guidelines⁽¹⁰⁾, the NCSS must report the results of its DNA analysis promptly to MAFF. Thus, DNA analysis is considered to be a standard method in the inquiry procedure.

There exists a case in which Customs suspended the importation of a plant which infringed the breeders' rights, in accordance with this system. In December 2003, the local laboratory in Kumamoto lodged a successful application for the suspension of the importation of Igusa plants (tatami straw matting material, variety denomination "Hinomidori"), the breeder's rights for which were held by the laboratory. Subsequently, Nagasaki Customs uncovered 8,800 kilograms of Igusa plants imported into the port from China and conducted DNA analysis which determined that the material was identical to the variety Hinomidori. The importer was subsequently prosecuted and found guilty.

In another case, a breeders' rights holder, and an importer, were reconciled after successfully lodging an application for the suspension of importation. In 2005, the local laboratory in Yamagata submitted DNA analysis data as part of an application for the suspension of the importation of cherries (variety denomination "Benishuho"), the breeders' rights for which were held by the laboratory, because the cherry plant material had been removed to Australia without the prior approval of the rights holder.

These cases demonstrate that the government of Japan regularly uses DNA analysis in the administrative procedures and activities of Customs inspections.

Figure 1. Customs inspection process that uses DNA analysis



2 DNA analysis in the inspection of processed products

Breeders' rights were extended to include processed products, which are directly made from the plants protected by those rights, following the amendment of the Seeds and Seedlings Law (Article 2 (5)-3), in line with UPOV Article 14 in 2005. The law was amended because there had been many cases in which agricultural products protected by breeders' rights were intentionally processed to evade the law. It is impossible to carry out growth testing of processed products to judge whether the breeders' rights are infringed, and therefore, DNA analysis must be used. Consequently, the extension of breeders' rights to processed products means that DNA analysis has become a standard method under the UPOV system. At this point, the principle of defining a plant variety by its phenotypic characteristics was, in fact, abandoned.

The law does not protect breeders' rights over all processed products. The processed products covered by breeders' rights are several items designated by Cabinet order⁽¹¹⁾. The notification issued by MAFF⁽¹²⁾ clearly states that a condition required for products to be covered by the Cabinet order is that a DNA analysis methodology for the processed

products has been established. Thus, breeders' rights can extend to only those plants and processed products for which a DNA analysis method has been scientifically established.

MAFF⁽¹³⁾ plans to add more processed products onto the list included in the Cabinet order, in response to advances in DNA analysis technology. MAFF⁽¹⁴⁾ directed NCSS to concentrate the R&D of DNA analysis methods for processed products made from vegetables and fruits, in the five years from 2006. In response to this directive from MAFF, the NCSS, which had already undertaken R&D on DNA analysis for processed fruits in 2005⁽¹⁵⁾, formulated a new policy to gear up its R&D activities on DNA analysis, as part of its Medium-term plan⁽¹⁶⁾.

3 DNA analysis in the examination of new varieties

To date the government has been prudent in introducing DNA analysis into the procedures involved in examining new plant varieties. However, it is preparing to introduce DNA analysis into these examinations in the future.

The Seeds and Seedlings Law requires that, in line with the requirements of the UPOV, for the examination of a new plant variety (Article 15 (2)), either MAFF officials conduct on-site inspections, or that the NCSS conducts growth testing. That is, the law does not specifically refer to DNA analysis. Similarly, the Ministerial Ordinance⁽¹⁷⁾ on the method of examining new plant varieties also does not specifically refer to DNA analysis, merely describing the prescribed method of growth testing. Furthermore, neither the manual⁽¹⁸⁾ which sets out the procedures for the examination of new plant varieties, nor the manual⁽¹⁹⁾ which provides guidance to applicants for breeder's rights for a new variety, refer to DNA analysis. Hence the government has strictly maintained a policy that defines a new variety by its phenotypic characteristics measured and observed by growth testing, rather than by DNA analysis.

However, two recent developments have required MAFF and NCSS to introduce DNA analysis as part of the examination of new plant varieties.

One is the spread of new breeding technologies based on genetic technology. These technologies include genetic recombination technology, and marker-assisted selection (MAS). The DNA analysis method is very useful for examination of new varieties bred by such genetic technologies.

Secondly, MAFF needs to reduce the time required for the examination of new plant

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology (並河) varieties in order to meet strong international R&D competition for new varieties. Growth testing requires at least one year and, in some cases, several years. The average period required to complete the examination for new plant varieties in 2000 was 3.9 years. By 2005, MAFF has reduced this period to 3.2 years and plans to further reduce it to 2.5 years by 2010. The best way to reduce the time drastically is undoubtedly to introduce DNA technology into the examination procedure (MAAF, 2006).

For these two reasons, the government has undertaken R&D of genetic technology. From 2001 to 2005, the NCSS undertook R&D aimed at combining DNA analysis technology with growth testing. As an example, the NCSS tried to combine the detection technology of induced genes with growth testing, using the blue-purple carnation developed by genetic recombination (Horiguchi et al., 2004) as the sample material. The NCSS has developed a database of genotypes of varieties collected for growth testing, as a reference for use in the examination of new varieties⁽²⁰⁾. Furthermore, MAFF, in its business guidelines for the NCSS⁽²¹⁾, directed NCSS to conduct R&D of DNA technology for the identification of plant varieties. The NCSS, in response to this directive, formulated a new policy to conduct such R&D, now part of the NCSS medium term plan⁽²²⁾ and annual plans⁽²³⁾.

4 DNA analysis resolves civil conflicts

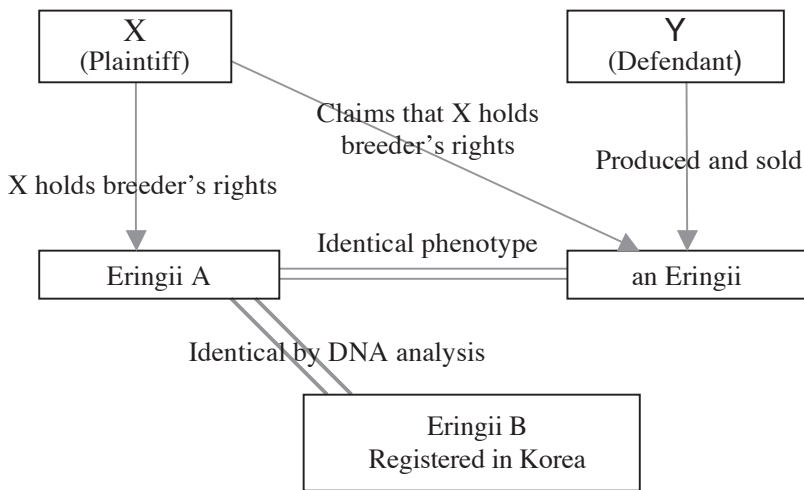
DNA analysis is often used to resolve conflicts about breeders' rights.

A judicial precedent exists (Intellectual Property High Court, 2006) for the use of DNA analysis in cases of breeder's rights. Figure 2 shows the relationship among interested parties. In this case, a holder of breeder's rights (plaintiff, appellant) over *eringii* (a species of mushroom) A sued a person who had produced and sold an *eringii* (defendant, respondent), for the infringement of the breeder's rights based on the Seeds and Seedlings Law, as both *eringii*s are identical in the phenotypic characteristics. The Intellectual Property High Court dismissed the appeal, stating that the breeder's rights over *eringii* A were invalid because *eringii* A is, by DNA analysis, identical to *eringii* B which had previously been registered in Korea. The points of dispute were whether DNA analysis data can be adopted in the case of dispute on plant varieties, and whether DNA analysis data is more important than the phenotypic characters. In the judgment paper, the court clearly stated that DNA analysis proved that these two *eringii* varieties were identical and that it was therefore meaningless to discuss their phenotypic characteristics, which can be influenced by growing conditions.

It is noticeable that the court considered the DNA analysis data more important than the phenotypic characters, giving little attention to the fundamental principle of the law under UPOV system.

In another case, DNA analysis was used to resolve a conflict between a holder of breeder's rights and a person who infringed those rights, without the need to go to trial. In 2001, the local laboratory in Hokkaido proved, by DNA analysis, that kidney beans imported from China were identical to kidney beans already protected by the breeder's rights held by the laboratory (variety denomination "Yukitebo"). The laboratory warned the importer, citing the DNA analysis data. The importer accepted the warning and negotiations between both parties led to a settlement. In response to a directive from MAFF following this case, the Bean Importers Association, of which the importer was a member, also subsequently agreed to undertake DNA analysis of the beans which they import. Thus, DNA analysis is now considered to be a de-facto standard method with which resolve civil conflicts regarding breeders' rights under UPOV system.

Figure 2. Disputed point in the trial (Use of DNA analysis in case of breeder's rights)



5 DNA analysis in the supporting system

MAFF and the NCSS are enthusiastic about activities that support the use of DNA analysis. Such activities include the standardization of DNA analysis methods for agricultural

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology (並河) products, the establishment of a DNA analysis service available to the public, and the introduction of DNA analysis to trade policy.

In 2003, MAFF issued a report on the standardized methods of DNA analysis for several agricultural products (MAAF, 2003). MAFF has since conducted or supported many R&D projects to establish standardized methods of DNA analysis for a wide range of agricultural products. Examples of the agricultural products for which standardized methods were established by 2006 include rice (more than 200 varieties can be identified), strawberries (more than 70 varieties), plums (more than 120 varieties), cherries (more than 100 varieties), pears (more than 100 varieties), apples (more than 80 varieties), and shiitake mushrooms (more than 140 varieties) (Takahashi, 2007). MAFF plans to further increase the number of standardized methods for each agricultural product, stating in a report recently issued that DNA analysis is a “decisive method with which to identify plant varieties” (MAAF, 2006).

The NCSS conducts a DNA analysis service for plant varieties which is available to the public^{(24) (25)}. In order to pursue this analysis service properly, the NCSS carries out several activities. Firstly, the NCSS studies and uses various conventional DNA analysis methods and has developed a database of DNA information on varieties registered under the law⁽²⁶⁾. Secondly, in 2007 the NCSS began an R&D program aimed at finding useful DNA markers for flowers, the R&D for which had so far been dominated by the private sector⁽²⁷⁾. Furthermore, MAFF has expressed the idea that in future, in order to extract the plant DNA, the NCSS should preserve a part of all plant bodies that are registered under the law, including vegetative reproductive plants (MAAF, 2006).

DNA analysis is also used in export promotion policies. MAFF promotes the export of agricultural products, seeds and seedlings, and this is likely to lead to the unauthorized growth of the relevant plants overseas in future. Therefore, the government is supporting R&D programs for DNA analysis technology for some agricultural products which are promoted for export, in order to prevent illegal importation of such products in future. In 2006, specific R&D programs for DNA analysis technology for gentian, chrysanthemum, lawn grass and groundnut were supported by the government (MAAF, 2006).

The abovementioned activities of MAFF and NCSS indicate that they expect and plan to use DNA technology more extensively in their administrative procedures and activities under the Seeds and Seedlings Law.

VI Discussion

1 Results of the analysis

The government has introduced DNA analysis in the administrative procedures and activities of Customs inspections, in the inspection of processed goods, in the settlement of conflicts about rights, and in the service to the public. The government is also moving towards introducing DNA analysis into the examination of new varieties of plants, although it maintains the principle of judging them by their phenotypic characteristics. This result shows that, through the introduction of DNA analysis into its administrative procedures and activities under the Seeds and Seedlings Law (domestic UPOV system), the government is considering both genetic structure and phenotypic characteristics.

2 Demarcation between the two systems

The Seeds and Seedlings Law, based on the UPOV system, literally considers the phenotypic characteristics but does not at all consider DNA (the “nucleotide sequence”) as a condition upon which breeders’ rights are granted. However, the government has recently introduced DNA analysis, which reflects “nucleotide sequence”, as part of its administrative procedures and activities under the law. The patent system considers both the phenotypic characteristics and “nucleotide sequences” as conditions under which patent rights for genes are granted. Consequently, both the Seeds and Seedlings Law and the Patent Law are becoming based on “nucleotide sequences” and phenotypic characteristics. The demarcation between these two systems is technologically becoming “blurred”.

The UPOV system literally protects varieties with special phenotypic characteristics. However, the system in effect protects “genetic information”, since the genetic information of the particular variety controls its phenotypic characteristics. The patent system for genes literally protects the chemical substances of polynucleotide. However, this system in effect also provides substantial protection of “genetic information”, as the genes carry genetic information embedded in chemical structure of polynucleotide sequence. It is intrinsic to the existence of each system to protect genetic information. They observe substantially the same thing, genetic information, from different viewpoints. Both have been shackled by conventional ideas about the protection of a material entity, either a phenotypic

Overlapping of intellectual property systems for plant variety as a result of advances in biotechnology (並河) characteristic or a chemical substance, and little consideration has thus far been given to the idea of protecting an immaterial entity, genetic information. It has recently become clear that these two systems are functionally and practically identical, as the relationships among phenotypic characteristics, nucleotide sequences and genetic information have been clarified. In 1991, when the current UPOV system was established, such relationships were not clear, and genetic engineering technology had not been well developed. Therefore, a system that observed genetic information through the “lens” of phenotypic characteristics, and a system that observed it in terms of nucleotide sequences, could coexist without overlap.

3 Integration of the two systems

The technological demarcation between the two systems will become increasingly “blurred” with further advances in genetic technology. The author estimates that DNA analysis will be included in the examination of all new plant varieties in the near future, and that this might soon supersede examination of phenotypic characters. At that point, these two systems will become effectively identical. The author believes that the UPOV system and the patent system for genes of plants might be integrated into one system which protects genetic information.

In Japan, each system was established independently, being driven by the needs of each related industries. According to Asano (1991), the Seeds and Seedlings Law was established in addition to the Patent Law because plant varieties developed by traditional breeders could not fulfil the conditions necessary to obtain patent rights, in particular the requirements of “novelty” and “reproducibility”. According to Hirai (2000), the patent system for genes was introduced, with little discussion, through successive administrative procedures and activities of the Patent Office in order to meet high-technology industries’ demand to develop a system to protect rights on chemical substances of polynucleotide. Both systems were established to meet the demands by each related industry, without prior rigorous theoretical discussion of the demarcation between the two. If such discussions were made, these two systems should not co-exist. There is no theoretical reason why these two systems should coexist.

Other reports support the author’s view. Hirashima (1996) and Aizawa (2002) both refer to the idea of establishing a new law or system to protect genetic information. They reached this conclusion by discussing the patent system for plant genes, whereas the author has

done so by discussing the UPOV system.

VII Conclusions

There are two important systems in place to protect the intellectual property associated with plants: the UPOV system and the patent system for plant genes. Legal matters, such as the scope of the protection, have dominated discussions of the relationship between the two systems. It has been concluded from these legal considerations that the demarcation between the systems is clear. However, technological matters, such as the methods and conditions of examination of new plant varieties, have not been adequately discussed.

This paper takes as a case study the administrative procedures of the government of Japan under the Seeds and Seedlings Law, and demonstrates that genetic technology is used in the various procedures of Customs inspections, in the inspection of processed goods, in the settlement of conflicts about breeders' rights, and in the service to the public. That is, the government is observing both the genetic structure as well as the phenotypic characteristics of new plant varieties.

Thus, both the Seeds and Seedlings Law, and the Patent Law consider both genetic structure and phenotypic characteristics, and the technological demarcation between these two systems is becoming "blurred". The increase in the international trade in plant varieties, together with the increase in filings of international applications for new plant varieties, will require an internationally standardized analytical technology that is not affected by natural condition, i.e., DNA analysis. Advances in the technology of genetically modified plants, and marker-assisted breeding technology, will require the UPOV system to introduce DNA analysis. Moreover, it will become increasingly necessary to use DNA analysis to resolve conflicts concerning the rights associated with essentially derived plant varieties. Therefore, the technological demarcation between the two systems will become increasingly "blurred".

It is intrinsic to the existence of both systems that they protect genetic information. Accordingly, the author considers that these two systems might be capable of integration into a single system that protects plant genetic information.

The author believes that extensive international discussion about the introduction of

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DNA analysis into the UPOV system will occur in the near future.

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Note

- (1) Director General for Customs Bureau, Ministry of Finance (hereinafter referred to as the Customs Bureau), Basic Notification on Custom Law 69-12-1-4-(1) (This notification is amended very frequently. This note shows the article number in the notification dated January 1, 2011).
- (2) Customs Bureau, Basic Notification on Custom Law 69-12-1-4-(2) (same as (1)).
- (3) Customs Bureau, Basic Notification on Custom Law 69-12-1-3-(1) (same as (1)).
- (4) Customs Bureau, Basic Notification on Custom Law 69-13-3-(2)-he-① (same as (1)).
- (5) Customs Bureau, Basic Notification on Custom Law 69-13-3-(2)-he-② (same as (1)).
- (6) Customs Bureau, Basic Notification on Custom Law 69-18-1 (same as (1)).
- (7) Custom Law, Article 69-18 (2).
- (8) Ministerial ordinance on inquiring of the NCSS about whether goods infringe the breeders' rights (dated March 1, 2006, and amended on July 22, 2009).
- (9) Certificate of Incorporation of the NCSS, Article 69-8 (dated April 2, 2001, amended on March 10, 2010).
- (10) MAFF, Middle-Range Business Guidelines for the NCSS (dated June 30, 2006).
- (11) Cabinet order on the Seeds and Seedlings Law, Article 2 (dated November 20, 1998, amended on October 3, 2007).
- (12) Notification from the Director General for the Production Bureau, MAFF (hereinafter referred to as Production Bureau), 2-1-(4) (17-Production-4731, dated November 30, 2005).
- (13) Production Bureau, 2-1-(4) (17-Production-4731, dated November 30, 2005).
- (14) MAFF, Middle-Range Business Guidelines for the NCSS (dated June 30, 2006).
- (15) NCSS, 2005 FY Annual Business Report.
- (16) NCSS, Medium-Term Plan (dated March 31, 2006, amended on March 31, 2008).
- (17) MAFF, Ministerial Ordinance to Enforce the Seeds and Seedlings Law, Article 11-2 (1) (dated

- December 3, 1998, amended on March 31, 2010).
- (18) Production Bureau, Method of Examining New Varieties (dated April 2, 2001, amended on April 1, 2009).
- (19) Division of Intellectual Property, Production Bureau, MAFF, Manual for Applicants for the Registration of a New Variety (dated October 1, 2009).
- (20) Certificate of Incorporation of the NCSS, Article 69-9 (dated April 2, 2001, amended on March 10, 2010).
- (21) MAFF, Middle-Range Business Guidelines for the NCSS (dated June 30, 2006).
- (22) NCSS, Medium-Term Plan (dated March 31, 2006, amended on March 31, 2008).
- (23) NCSS, 2006 ~ 2009 Annual Business Report.
- (24) Certificate of Incorporation of the NCSS, Article 69-4 (3)-3 (dated April 2, 2001, amended on March 10, 2010).
- (25) NCSS, Detailed Rules for Measures to be Taken Against the Infringement of Breeders' Rights (dated 3 April, 2006, 18-NCSS-51).
- (26) NCSS, Medium-Term Plan (dated 31 March, 2006, amended on March 31, 2008).
- (27) NCSS, 2007 and 2008 Annual Plan (dated 29 March, 2007, 18-NCSS-1077, and dated March 31, 2008, 19-NCSS-1210).

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