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UPOV

PLANT VARIETY PROTECTION

Gazette and Newsletter
of the
International Union for the Protection of New Varieties of Plants (UPOV)

No. 44 | June 1985 | Geneva

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NEWSLETTER

UPOV

This issue contains the first part
of the Records of a Symposium on

INDUSTRIAL PATENTS AND PLANT BREEDER'S RIGHTS -
THEIR PROPER FIELDS AND POSSIBILITIES
FOR THEIR DEMARCATION

held on October 17, 1984,
on the occasion of the eighteenth ordinary session
of the Council of UPOV*

* The Records have also been printed in English, French, German and Spanish in UPOV publications No. 342(E), (F), (G) and (S) respectively and may be obtained free of charge from the Office of the Union.

OPENING OF THE SYMPOSIUM

Jean Rigot*

I declare open this fifth Symposium organized by the International Union for the Protection of New Varieties of Plants (UPOV).

I bid a cordial welcome to each one of you. You are indeed all welcome in this WIPO building, which is also the headquarters of UPOV.

It is my hope that, by the end of today, and after having heard our guest lecturers and heard or taken part in the discussions that will follow the lectures, you will go away not only intellectually but also professionally satisfied, certain of being, from then on, better informed on the problem that is the subject of the Symposium, and better equipped to take a hand in the solution of the problem that concerns us all.

UPOV is an intergovernmental organization, and it was given a very precise task by the signatory States of the Paris Convention, namely:

- to assist the various countries in drafting and implementing, under the best possible economic conditions, and in respect of the greatest possible number of crops, legislation on the protection of new plant varieties;

- at the same time to promote an increase in investment in plant breeding and the spreading of interesting varieties.

Our Union is not, however, confined to the strict, mandatory or technocratic performance of the task thus entrusted to it. Its purpose is also:

- to inform the public concerned, whether researchers, breeders, lawyers or others, on all aspects and facets of breeders' rights and on everything surrounding those rights, and moreover:

- to inform itself and to gather opinions in order that its decisions may be right, appropriate to the circumstances, applied flexibly and well received, in order that they may have the full beneficial effect on the improvement of plant production, that is expected of them.

For the grant, or arrangement for the grant, of a right of strict ownership to the discoverer or creator of a new, improved variety, is in fact not the sole end of UPOV: it is only a means to an end. A means of increasing, throughout the world, the production of proteins and carbohydrates. And I use these words advisedly, my thoughts being especially on developing countries, some of which continue to suffer from serious shortages and even a total lack of foodstuffs, whereas Western countries have had to apply measures to ration or limit their agricultural and food output. In this disoriented world, there are those who have no money to provide for their essential nourishment, and those who no longer have enough food to give away. Indeed that is perhaps only one of the paradoxes of this end of the twentieth century, where everyone is trapped in an unprecedented economic crisis which is nonetheless unevenly suffered by the various peoples of the globe. Moreover, I take the liberty of repeating with some emphasis that the protection of plant innovations is in no way intended to limit their spread, in the sense of spreading into the developing countries, but quite on the contrary to promote access to innovations on the part of those and indeed all countries. That should be accompanied by safeguards assuring the creator of a fair return on his investment, which is the best incentive for progress.

When, during the last century, the Austrian monk Gregor Mendel discovered the laws of heredity, which were specified by the Dutchman De Vries, the German Correns and the Austrian Tschermak, he generated great hopes for the improvement of plants. Mass selection, which was somewhat empirical in character, was to be superseded by the genuine creation of plants, of new, improved varieties.

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* President of the Council of UPOV

The science of genetics came into being around 1900. It was to make it possible for the characteristics present in different parents, skilfully chosen and crossed, to be transferred to and combined in the offspring of the cross. This "manufacture" of new varieties was a revolution in plant breeding. It was moreover to be the cause of substantial progress in the effective yields of species of agricultural and horticultural plants.

And yet how many new paths have still been followed since that time!

Our breeders, their curiosity and haste ever growing, looked for ways of multiplying both the sources of new and different characteristics and the possibilities of combining them in one and the same individual, in one and the same parent. They also looked for ways of shortening the time then necessary for the creation of new strains. The period of about ten years required by the classical method to produce and market a new acquisition does indeed seem excessive compared with the five years during which a new cereal variety maintains its popularity today. This disparity certainly stimulated the creativity and inventive genius of our breeders.

In the 1930's, treatment with colchicine, which upsets mitosis, gave rise to polyploids and mutants.

The 1950's saw the explosion of mutation breeding.

Later, haploids were created; anther or ovule culture, or the treatment of cereals with the pollen of *Hordeum bulbosum*, brought haploids transformed into dihaploids. And so the time necessary for the production of homozygotes was already shortened.

Interspecific hybridization either *in vivo* or *in vitro* through the fusion of cells produced new plants. Triticale is perhaps the best known example of this.

Gametocides were to simplify hybridization and made it possible to benefit more easily from the heterosis effect.

In the wake of the progress made in plant physiology, biochemistry, microbiology and molecular biology, laboratories developed *in vitro* propagation. *In vitro* culturing of plant tissues, initiated with explants (fragments of stems, leaves, etc.) provided a new possibility for finding genetic variability in a certain number of agricultural and horticultural plants. Still more progress was thus made. Of course, *in vitro* culturing did not in itself create variability, as a meristem culture, for example, is no more than a method for the rapid vegetative micropropagation of a large number of plantules, which are refined exact copies of the donor plant.

Finally, under the heading of genetic manipulation, there appeared what one might be tempted to call open-plant operations, as researchers worked on the nucleus itself, extracting genes from or inserting genes in the chromosomes. To do this they secured the assistance of microorganisms, and manufactured chemical scalpels for whose use they also provided instructions.

This then was the long developmental path followed by breeding methods, which has brought us to a point of convergence determined by the product innovation in relation to the non-biological process innovation. For evolution and progress are going to continue and no doubt develop more new processes, and perhaps especially non-biological ones.

Are we at a crossroads of progress, or is this merely a turning-point towards the future? Is our present conception of plant variety protection going to have to change under the influence of evolution and progress? This Symposium should certainly provide at least the makings of replies to these questions.

From the mere witnesses to this progress that we have been up to now, we could tomorrow have to become its judges or arbiters, and have to draw up rules for the simultaneous protection both of the process and of the product. Should that happen, however, it could not happen without due account being taken of a certain number of postulates: a satisfactory balance has to be struck between means and requirements, and the situation has to be avoided where a small, all-powerful élite secures for itself all the profit from process innovations; finally nothing must hamper the development of new technology for the greater benefit of all mankind.

If UPOV recognizes and guarantees a right of ownership for the benefit of the breeder of a new variety, it would definitely have some difficulty in refusing the same right of ownership to the inventor of a non-biological process or tool, meaning in the latter case a grant of a patent.

However, as the means and the end are easily confused because one is the consequence of the other, the boundaries between the patent and the plant breeders' right have to be clear and unequivocal. That will be a first difficulty to overcome. Another will arise from the fact that work is being done on living matter, which reacts within itself and also to its environment, unlike inert industrial material. This characteristic will call for an accurate definition not only of the properties and characteristics of the process, but also of its side effects on the plant.

If for instance a gametocide, as a chemical agent, can help us convert a self-fertilized plant into a cross-fertilized one, we cannot disregard any side effects that it might have on female fertility or the morphology of the plant, nor can we disregard any mutagenic or polluting effect that it might have. And the user would have to know that.

Another example, which is perhaps just outside the purview of this Symposium: a plasmid carries information which has to do with changing either the structure of a protein or merely the protein level of the plant. That is all well and good, but there has still to be some assurance of the heritability of the message passed on.

In a word, the problem is certainly more complex than it seems at first sight, and its examination deserves very close attention on our part. That is the reason for this Symposium and for the participation of the four specialists whom we have invited, and whom I thank now for the insights that they will most certainly give us.

However, in order that everyone may benefit fully from the lectures and from the discussions that will follow them, we considered it essential to explain and define accurately the scope of this Symposium, the objective that it will be pursuing, the pitfalls to be avoided and the points to be clarified. Dr. Mast, Vice Secretary-General of UPOV, will make this introduction to the subject, and I have no doubt that he will do so with the very great competence that he has at his disposal.

Ladies and Gentlemen, I thank you for having kindly listened to these considerations of mine, presented by way of introduction.

[Original: French]

INTRODUCTION TO THE SUBJECT OF THE SYMPOSIUM

Dr. Heribert Mast*

Today's Symposium is devoted to the proper fields and the demarcation of two closely related types of rights which are granted under the legislation of a number of States, in particular the UPOV member States, namely plant breeders' rights and patents. There could hardly be a better place to discuss this subject than in this building, which is the international home of both types of rights.

Let me start with plant breeders' rights, the province of UPOV. They are granted, according to the UPOV Convention and the basic rules contained in it, to breeders of new plant varieties, at their request and for a limited time, and give them certain exclusive rights to the commercial production, offering for sale or marketing of the seed or other propagating material of their varieties. Plant breeders' rights do not normally extend to the final product or

* Vice Secretary-General of UPOV

plants of the variety intended for consumption, nor do they prevent anyone from using the new variety as an initial source of variation for the purpose of creating another variety and selling that other variety--except where there is repeated use, for example, as a parent line for a hybrid variety--a principle so unique and important that I wish to mention it here at the very beginning of my introduction. I should also mention that plant breeders' rights are granted for the new variety as such, not for the process used to breed it, and that they are granted when the following conditions are fulfilled: distinctness and novelty, homogeneity and stability.

In most countries plant breeders' rights are granted in the form of special titles of protection. When they were introduced some twenty or thirty years ago, special names, such as "certificate of plant variety protection," "certificat d'obtention végétale" or "Sortenschutzrecht," were coined in the languages of the countries concerned. In some States, however, plant breeders' rights are granted in the form and under the name of a patent. Those States have adapted their patent system to the special pattern of plant variety protection and to the basic rules contained in the UPOV Convention; they have included special rules in their patent laws and the patents which they grant for plant varieties are sometimes given the name "plant patents." These plant patents, as far as their legal effect and the conditions required for them to be granted are concerned, thus correspond more or less to the special titles of protection. However, there is one rather significant difference: plant patents, even though they are specially adapted to the UPOV Convention, are still more closely connected than special titles of protection with the other patents which, for the sake of clarity, we have called "industrial patents" in the title of this Symposium. Plant patents are granted by the same authority that grants industrial patents. Thereby, some guarantee is given against unsuitable overlapping since the same authority would surely hesitate to grant two exclusive legal titles for the same object. Historically, the reason why some UPOV member States decided to grant special titles of protection, and others plant patents, was a different one. States providing for plant patents were particularly concerned to ensure that the international rules governing patents should also apply to the rights they were going to grant for plant varieties.

Legal protection for plant varieties is a rather new development, having its origins in industrial patents. Such patents, the second type of right treated in this Symposium, have existed for a long time and most people are familiar with the general idea of the patent system, which is that the patents are granted for inventions--inventions of new processes, of new ways of applying those processes, of new products--and that they give the inventor an exclusive right under which only he, or others licenced by him, may use the invention commercially. Like plant breeders' rights, industrial patents are granted on request--this time that of the inventor--and for a limited period.

I said that patents were there before plant breeders' rights came into existence. It was indeed the plant breeders' rights system that separated from the patent system. If you will allow a botanical comparison, plant breeders' rights are a kind of mutant of the patent system.

Why did this separation happen? It was not intended at the beginning. For some decades, breeders of new plant varieties pursued in many countries a long and largely futile struggle to obtain the same type of protection as inventors were, as they saw, enjoying for technical inventions. Breeders wanted to have patents for new varieties, and in a number of cases they managed to obtain them, but only in very few cases did they manage to profit fully from their rights. More often than not, their patent applications were rejected or the patents proved to be worthless. It appeared that the patent system, as developed for technical inventions, was not fully suitable for this living, self-reproducing subject matter and the examination of this fact led to the creation of the above-mentioned type of protection which we nowadays call plant breeders' rights.

The separation was not achieved lightheartedly, and you might cite me as a witness for this. Those responsible in governments and parliaments were seriously concerned about that separation. There was a general fear that it might cause a disintegration of the patent system, and there was also a particular concern that dividing up the two fields might lead to double protection for inventions. Both types of protection, plant breeders' rights and patents, whatever their basic difference, were in many respects so very close to each

other that it was hard to conceive that titles of the two types could exist side by side in free competition. The lawmakers and the drafters of the relevant conventions rejected such a double protection by both types for one and the same variety and they did not even want to see both types of protection granted side by side for different varieties of the same botanical genus or species. In the latter case it was feared that double protection of varieties of one and the same botanical genus or species would cause confusion, disturbance of the market and general legal insecurity, and the lawmakers were not prepared to accept such insecurity.

As a consequence, the UPOV Convention of 1961 provided that plant breeders' rights could very well be granted in the form of patents or of special titles of protection and that even a mixed system was admissible; but at the same time it was clearly spelled out that for the same botanical genus or species only one form of protection can be provided under national legislation, and that is the rule up to the present day, if we forget for a moment about the possibility, introduced in 1978, to make a reservation in an exceptional case. No differentiation is made in that formula between industrial patents and plant patents. At the time when it was devised, law makers could not conceive that a patent office of a country, having adapted its patent law for the introduction of plant patents, could still grant for a plant variety an industrial patent instead of a plant patent. In accordance with the formula, a line was drawn between patents and special titles of protection in some patent conventions and national patent laws. Plant varieties were expressly excluded from--industrial--patent protection, and so were essentially biological processes for the production of plants, for special reasons which the lecturers will certainly explain in more detail. An exception was made, however, for microbiological processes and products thereof. Microorganisms were at that time of greater importance in the pharmaceutical world than in agriculture, and they were--and today still are--treated like chemicals. They were left to the patent realm.

This dividing line was very clearly drawn in the European Patent Convention, which was signed on October 5, 1973, in Munich. It was copied at the national level by a series of European States in their endeavour to adapt their national patent law to the European patent law they had created--and also because, at this same time, such a dividing line represented the modern trend--and the same formula was also copied by other States having no interest in the European patent system. Some European States applied this rule in a particular way, in that they excluded protection by industrial patents only for varieties of those botanical genera and species for which plant variety protection was (already) available. For the other varieties, patent protection was not expressly excluded in those States, but in at least one of them it was strongly underlined that this rule should not be construed as meaning that plant varieties were in fact patentable.

For some time it seemed that the dividing line introduced by the European Patent Convention would develop into a generally accepted international rule, and the best proof of this is that the World Intellectual Property Organization (WIPO) followed this principle when establishing the WIPO Model Law for Developing Countries on Inventions.

This sane and happy world--at least in Europe--of a fine equilibrium between industrial patents and plant breeders' rights, and of the well-established line of separation between them, has recently been disturbed by new developments, mainly by developments in the field of biotechnology, or at least by the discussion of the possibilities afforded by those developments. Biotechnology in itself is of course not new. If you so wish, you can classify the more or less traditional methods of breeding, such as selection, crossing, hybridization, use of natural mutation or artificial induction of mutation, as simple forms of biotechnology since they amount to human intervention in the propagation of living matter. In his introduction, Mr. Rigot, President of the Council of UPOV, has just given a good survey of the lines of development and the increased and ever accelerating use in recent decades of increasingly technical methods in plant breeding. However, for a number of years now, new developments in the field of biotechnology have been observable which might, in the not so distant future, put plant breeding on a completely new footing. "Genetic engineering" is the term which was coined to describe certain new methods for changing the genetic information of a plant by a kind of surgical or chemical intervention in the plant cell and its chromosomes, resulting, for example, in cell fusion or in a transmission of genetic material from cell to

cell by separating and recombining the DNA of two plant cells. These methods applied in laboratories are strongly reminiscent of the processes used in advanced chemical and pharmarceutical research, and the persons applying them are scientists and laboratory technicians. They work with test tubes, microscopes and high precision instruments, but still their aim is the same as that of the traditional plant breeder, namely to create a new plant with new valuable characteristics which can be transferred to the plants of subsequent generations. These new methods--so it is expected, hoped or feared--will permit the combination of genetic information from various plant varieties of different genera and species which so far it has not been possible to cross because of certain natural barriers, such as the barrier of sexual incompatibility. In addition, there are even hopes--and here again I can refer to the introductory remarks of Mr. Rigot--that it will be possible in the future to artificially produce genes and to introduce them into a plant, thereby changing the plant's genetic information. No great amount of fantasy is required to envisage a leap in the development of plant breeding--or what will perhaps be taking its place--a development of which today we can only dream.

And it cannot be denied that this development has already left the realm of dream and fantasy, the world of Jules Verne. Realistic scientists and technicians in universities, in very down-to-earth national and international research centers, such as the International Agricultural Research Centers that initiated the green revolution, and scientists, technicians and breeders in commercial enterprises, are examining how these new methods can be made useful for plant breeding, how they can be further developed and where priorities should be placed. Here, as everywhere, there are of course people with exaggerated fantasies, and it was just two years ago that Dr. Padwa, representing an American firm deeply involved in genetic engineering, warned in a UPOV Symposium against being deceived by "hallucinations of maize that whistles and radishes that ride bicycles." There is indeed sometimes a certain over-estimation of the true present potential of genetic engineering in the field of plant breeding, fostered to some extent by the general press and the popular scientific press as well as by some who try to obtain the necessary funds from both private and public sources for further research and development. Be that as it may, there is no doubt that the future has already started and the majority of plant breeders look forward with great expectations to the further development of genetic engineering.

What have UPOV and the subject of today's Symposium to do with that development? Certainly a great deal! The development, if full use is made of it for plant breeding, will have to be advanced by two groups of people. On the other hand, there will certainly be the plant breeders who will play an important role in this, in assessing the needs, in formulating the research aims and in bringing results achieved by scientists into practical use. In this respect I wish to refer again to the UPOV Symposium held two years ago in which Max Rives of the French National Institute of Agronomic Research (INRA) underlined the role and the continuing importance of the breeder. On the other hand, the basic research and a good part of the applied research will have to be done by researchers in scientific institutions, in public institutes, in university laboratories or in the laboratories of private enterprises. In fact, the development will thus rely on interdisciplinary and interinstitutional cooperation. There will furthermore be a need for investment of money and manpower. It is understandable that, in this context, it has been asked whether the incentives for research and development, which are one of the main reasons for having both a patent system and a plant variety protection sytem, are working to their full potential under the present rules of both systems, whether the patent law and the plant breeders' rights law need to be adapted and, in particular, whether the present demarcation line between the two systems is still correctly drawn. And yet it is also understandable that experts in plant variety protection are concerned that the guarantees that their system has created for further research and development and for a good balance between proprietary rights and the special needs of agriculture should not be sacrificed by any inconsiderate and premature shift in policy.

To answer these questions we first need to consider the true potential of genetic engineering and of other methods of biotechnology. We need to know where realistic appraisal ends and where science fiction begins, and we hope to hear some interesting remarks concerning this question from Sir Ralph Riley. I have been assured that we could not have made a better choice for a speaker on that subject.

Furthermore, we need to recall the essential aspects of the patent system, its legal nature, its application in the case of living matter under the rules presently in force and under some conceivable future rules, and its built-in limits. We know that patent law and living matter, and in particular patent law and plant varieties, did not always match well in the past and we need to know why. We need to know whether the reasons are to be found in the legal nature of the industrial patent system or only in an over-narrow application of it. Here we hope for some enlightening remarks from Professor François Savignon of Paris and Strasbourg, a man who was not only in charge of the French Patent Office for quite some time but whom I also know rather as a companion in the creation of the European Patent Convention and other conventions in which it was first dared to draw a dividing line between patents and plant breeders' rights, a man who is furthermore closely involved with the teaching of industrial property law and in basic studies devoted to that field.

We should certainly also hear more about plant breeders' rights, their legal nature and their present and future demarcation from patent law, and we would like to hear more about the principles that plant breeders would wish to have retained should the present demarcation line ever be changed. UPOV thought that it would be best to entrust the treatment of this topic to someone who is competent in questions of legal theory, who at the same time does not sit in the ivory tower of academic thinking but is confronted daily with practical work. Our choice fell on Dr. Peter Lange, legal advisor to a German breeding firm which, I am told, is the largest in the Federal Republic of Germany. Dr. Lange seemed to us not only to possess the necessary academic qualifications but also to have the advantage of representing a generation of young lawyers who see the current separation between patents and plant breeders' rights with fresh eyes and are not in danger of being biased, like a number of us, by their former involvement in creating this line.

Finally, we have on our agenda a further speaker coming from a far-away country, namely Japan. Japan, a UPOV member State for a few years now, has the reputation of being very open to ultra-modern developments and of making excellent use of the possibilities offered by the patent law. In addition, it is a country which is prominent in plant breeding and is on the way to building up plant variety protection as a useful resource for plant breeders and the seed trade. We were therefore very happy and felt honored at the same time that Professor Nobuo Monya of the Faculty of Law at Seikei University in Tokyo offered to inform us on the legal protection of achievements of biotechnology in Japan. There is another reason why we should look forward with special interest to the explanations that will be given by Professor Monya. Japan is a not a Contracting State of the European Patent Convention. It does not have a written rule separating patents and plant breeders' rights, though the separation in the past was the same as in the European States. Japan is thus one of the UPOV member States not tied to the formula introduced by the European Patent Convention.

Last but not least, I look forward to an interesting panel discussion on the solid basis of today's lectures. This panel discussion will certainly not be the last one on the subject. It will only be a beginning. Discussion on the questions of this Symposium will be continued in less than a month's time, in this building, in a Committee of Experts on Biotechnological Inventions and Industrial Property convened under the auspices of WIPO. There will certainly be further discussions in UPOV committees; the first ones will take place this November. There will be discussions in international non-governmental organizations in the field of plant breeding and the seed trade and in joint meetings between UPOV and those organizations. I hope that today we will lay the foundation stone for all these discussions and that they will be based on facts, on sober assessments, rather than on wishful thinking or fantasies.

Thank you, Mr. President.

[Original: German]

THE NATURE OF PATENTS OF INVENTION AND THEIR APPLICATION IN THE CASE OF LIVING MATTER

Professor François Savignon*

Abstract

Patents, as we know them today, are the result of a long process of development. Some of the principles on which they are based seem to be inseparable from their nature, whereas others have a relatively incidental relationship to that nature.

Consequently, the protection of inventions relating to living matter can be accommodated within established patent practice, to the extent that such protection is compatible with the basic principles, even if it is necessary, in order to take into consideration some special aspects of living matter, to adapt the provisions of current laws that are concerned with the incidental principles.

These should be considered to include, in my opinion, those provisions that exclude patentability of some inventions concerning living matter: new plant varieties, animal varieties and essentially biological processes for their production.

Everything connected with the transmission by inheritance, the scope and the modalities of the rights granted is also incidental to the nature of the patent system.

The irreducible content of the idea of a patentable invention, to combine Benkard's definition and the wording of the 'Red Dove' decision, seems to me to be that: "A patentable invention is an instruction for the systematic use of controllable natural means, leading each time to a usable result that does not constitute part of the prior art, whose realization could not be expected on the basis of the knowledge available to the average man skilled in the art."

Leaving to one side the requirements of novelty, inventive step and industrial applicability expressed in that definition, it becomes apparent that the heart of the problem is the reproducibility of the invention. Well, since it has been acknowledged that, for the purpose of protecting microorganisms by patents, the reproducibility inherent to the living nature of the protected matter can take the place of the reproducibility achievable by using the information given in the description, the basic impediment to the patentability of living matter has been circumvented.

It can therefore be concluded that all forms of life that result from actions applied systematically by man to natural elements are compatible with patent protection.

That is not to say that the national laws and international conventions that currently stand in the way of such protection do not represent a considerable impediment, nor that resistance on ethical grounds to the patentability of living matter is already a thing of the past. In fact, no value judgement can be drawn as to the comparative benefits of patent protection and protection by some special title.

The aim of the paper I have been asked to give, if I am not mistaken, is to present the basic features of patent protection to an audience versed in both the scientific problems of new plant varieties and the legal problems of protecting them by means of specialized laws, in order to furnish some of the elements for discussion in this Symposium.

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After setting out the essential features of patents, I will consider application of this type of protection to plants and, more generally, to living matter, since the leading decisions have often been taken in respect of applications that were not for plants.

The second part of my paper may be approached in two different ways: Firstly, a study may be made of the application of current laws to protection of inventions in the field of living matter. Such an undertaking is essential for assessing the extent to which the various existing patent systems may already, today, be applied to such inventions. Excellent studies have been devoted to this aspect[1] and the UPOV Secretariat has just distributed a useful survey.* It is also possible, and this is the approach I felt had to be adopted, to endeavor to make a distinction between that which is fundamental to patent law and that which is ancillary and could possibly be amended without necessarily going beyond the limits of patent protection. The advantage of making such a distinction lies, it would seem to me, in the possibility of envisaging the field of protectable inventions in a prospective manner, thereby giving the notion of patent its greatest possible extension. If, on the other hand, all the problems facing protection of inventions in respect of living matter caused by the laws of all the countries were to be handled in the same way, this would tend to make all those problems appear equally insurmountable.

The patent, as we know it today, is the result of a long evolution, which is clearly not finished yet, and study of that evolution enables the fundamental nature of this institution to be perceived more clearly. For example, the notion of usefulness, which at certain periods played an essential part in the granting of exclusive rights to inventors, has almost altogether disappeared from the patentability requirements, having been replaced by the test of the invention's economic success on the market.

I shall adopt the traditional division of the problems relating to patents: those that concern the acquiring of the patent and those that concern the rights of the patentee. In those cases where it is necessary to refer to a given law, reference will be made to European law, as established by the European Patent Convention and the Community Patent Convention which, beyond its own territory, has exerted a unifying influence on the domestic laws of numerous States.

The Grant of Patents

For a valid patent to be granted, it is necessary that it concern an invention, that the latter meet a number of requirements in respect of the prior art and that the means of carrying it out be made available to the public in such a way that a man skilled in the art can reproduce the invention.

The Invention

The word "invention" had a very broad meaning in earlier times, covering all new undertakings and in fact quite close to the modern word "innovation." At the time "invention" began to be used exclusively to designate a new solution to a technical problem, "invention" and "discovery" were frequently used as synonyms. Subsequently, the word "discovery" assumed its modern meaning of an act perceiving an object, a phenomenon or a relationship between phenomena, that already existed in nature prior to any human intervention.

It would seem that two observations must be made as regards the distinction, of fairly recent origin, between discovery and invention. The first is that invention borrows the elements of discovery and that this is indeed ever more frequently the case now that pure research and applied research constitute two activities of the same nature, based on the same knowledge of natural laws, closely bound up and even intermingled. The second is that not only does the description of a discovery not prevent a patent being applied for,[2] but also that it is indispensable to describe the discovery, as yet unpublished, on which is based the invention for which protection is sought.

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* The document referred to (SYMP/1984/4) will be reproduced in the next issue of Plant Variety Protection.

I would conclude that the sole operative criterion for distinguishing between a discovery and an invention is its industrial application, meaning that the subject matter of the invention may be produced by industry or used by it.[3] I would emphasize the alternative, and not cumulative, nature of the terms "produced" and "used."[4] It is sufficient that the subject matter of the patent be capable of being utilized within industry or be the marketable result of industrial activity. In this case, industry is to be understood in a very broad sense, covering agriculture in particular.

The most important restriction in respect of industrial application is that it implies operations that concern matter and/or energy; operations exclusively concerning information are as yet excluded.

An invention is new in respect of the state of the art and comprises inventive step. According to its broadest definition, the state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application.[5] An invention is considered to be new if it does not form part of the state of the art.[6] An invention is considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.[7]

Reproducibility of the Invention

The patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.[8] This definition in fact covers two separate requirements. The first, which is relatively trivial, is the requirement of intellectual honesty on the part of the author of the description who must reveal everything that he knows will be useful if the invention is to be reproduced by a man skilled in the art. The other, which concerns the very nature of the invention, requires that the result announced in the description, that is to say the industrial application of the invention, be repeated, if not every single time then at least with a high degree of probability, whenever a man skilled in the art follows exactly all instructions given in the description of the invention.

However, the patent offices have in practice ceased, for obvious reasons, to experimentally check themselves the reproducibility of inventions. In reaching his decision, the examiner bases himself on the information supplied by the applicant, who must, in particular, supply proof of experimentation, and on his own knowledge of the laws that govern the phenomena involved in the invention (thus are rejected, to take an extreme case, applications relating to "perpetual motion").

Having therefore surveyed what I consider the basic conditions to be satisfied by inventions eligible for the protection afforded by patents, I will now discuss their application to living matter.

It was long thought impossible to apply the notion of invention to living matter, despite the fact that in practice patents had been granted for yeast (e.g., the patents granted to Louis Pasteur in France in 1873 and also in the United States of America[9]). However this distinction between living matter and inanimate matter was borrowed from vitalism, a theory alien to the nature of patents. Today, it is no longer with us, and judgments from the highest courts in the Federal Republic of Germany[10] and the United States of America[11] have clearly acknowledged that the subject matter of an invention is patentable when it is living matter. What should we therefore think, in that case, of the exclusions contained in current legislation in respect of inventions concerning living matter? In my view, they are purely solutions of opportuneness. Exclusion from patentability of new plant varieties would seem to be clearly inspired, particularly in the French Law, by the wish to avoid setting up two competing schemes of protection for the same object.[12] The exclusion of new animal varieties[13] may be interpreted as reflecting moral preoccupations, the refusal to extend to higher animals, that no biological boundary separates from man, something that was previously reserved for inanimate matter. The exclusion of methods of treatment and diagnostic methods practiced on the human or animal body[14] corresponds to a code of medical ethics. These prohibitions, that are not universal, derive from principles that are alien to the nature of a patent. In my view, the European Patent

Convention derives this latter exclusion from the absence of industrial application in a most artificial way. If such industrial nature were obviously lacking in all interventions practised on the human or animal body, it would have been pointless to say so in an article of the Convention.

An interesting problem is raised by the exclusion of "essentially biological methods or processes for the production of plants or animals." That is, whether the fact of using a process in which nature plays the greatest part may be termed an "invention." This problem is closely linked to that of the patentability of organisms found in nature; a matter that is still hotly debated and to which therefore special attention must be paid. Contrary to the claims that have sometimes been put forward,[15] I do not feel that the existence of an inanimate body or of a living organism in nature or the existence of a "natural law" automatically makes such object or such law a part of prior art and therefore deprives a patent application of its novelty. Existence in nature cannot be assimilated to "that which has been made available" to the public; the word "made" would seem to imply human intervention, the form of which may certainly be very varied, but which is absolutely necessary to make it part of the state of the art. For a medicinal plant to be comprised within the prior art, it is probably not necessary for it to have been described as such in a scientific publication. The fact that it was known by Amazonian Indians would suffice. It may also be noted that if existence in nature were enough to make it part of the prior art, many inventions of the greatest importance would have been rejected as lacking in inventive step. Once the properties of the natural organism or of the natural law have been demonstrated, industrial applications appear obvious to the man skilled in the art. The greater part of inventions based on a discovery would be declared unpatentable!

In order for a natural "object" to form part of the prior art, it is necessary for it to have been made available to the public in the same way as for a technical creation.

Consequently, if natural "objects" are to be held to be non-patentable, it will not be for a general lack of novelty. It has been held that the simple fact of discovering a natural object lacked inventive step. However, if one considers the difficulties involved in research, separation, identification of the special properties that are to form the basis of industrial application, it would seem that the various criteria for establishing the existence of inventive step would most frequently be fulfilled in the case of the "invention" of a product existing in nature.

Nevertheless, one could acknowledge that the case, fairly unlikely as things stand at present, of an organism that was easy to recognize, possessing properties giving it an obvious industrial application, in which human intervention consisted in distinguishing that organism from those previously known (the prior art), could be held to involve an inadequate inventive step.

There would not seem any particular problem in applying the criteria of novelty and inventive step (non-obviousness) to biological processes (whether they be "essentially" biological or not). As far as application to living matter is concerned, the evaluation of novelty is often facilitated by applying taxonomic rules and criteria used by breeders to distinguish new varieties from the relevant "state of the art" (distinctness characteristics). As regards the requirement of inventive step in relation to living matter, it does not concern the living organism itself but the human intervention required to obtain it, whatever the process and identification of its special properties.

I will now take a look at the most important question of reproducibility of inventions in respect of living matter. If we consider firstly the case of biological processes, it would seem that for those processes where the outcome appears hazardous, insufficiently regular, to the examiner or to the judge required to pronounce on the validity of a patent, the process claim will be refused, as will therefore the product obtained by means of the process.

Such was the gist of the decision taken by the Federal Supreme Court of the Federal Republic of Germany as regards reproducibility in the well-known case of the "Red Dove."[10] It is generally acknowledged that the various interventions falling under the term of genetic engineering possess a greater degree of reproducibility than those that are "essentially biological," such

as the hybridization described in the red dove application. However, it would seem to me that this is more a question of the individual case than the nature of the method. It is for the applicant to show that the process taught by his application comprises sufficient reliability.

As far as living organisms are concerned, patentable as such or as a means of carrying out a process, the initiative taken by American applicants in depositing microorganisms with the public collections to remedy the problem of disclosing in written form the means of reproducing an invention was approved in 1970 by the Court of Customs and Patent Appeals. This change in the thinking of the courts, that has now become generalized and is regulated by an international Treaty,[16] represents a capital turning point. If it is accepted that the reproduction of the characteristics of living matter, claimed in a patent application, may be achieved by multiplying the living organism instead of resulting from the sole intervention of a man skilled in the art following the teaching contained in the patent application, there is no reason to refuse to extend this method beyond the field, already very broad, of microorganisms. Obviously, considerable difficulties will face the generalization of a method that consists in meeting the reproducibility requirement by means of deposits in collections of living organisms that are accessible to the public. These difficulties may derive from the nature of the living organisms involved or from economic factors. But, as already mentioned at the beginning of this paper, I am ignoring those difficulties that do not derive from the nature of patents.

An important question is that of the material kept in the collection for reproducing the characteristics claimed in the patent application. It must be remembered that a patent application contains "claims," that is to say a number of statements by means of which the applicant defines and sets out the limits of the features of the invention for which he seeks protection. It is on the basis of these claims that the examiner and the judge will assess patentability. Therefore, in the case of a living organism, it is not necessary that all features of the deposited material be maintained in the collection, but only, and this is sufficient, that the features claimed in the application be preserved to satisfy the reproducibility requirement.

Conclusion as Regards the Conditions for Obtaining a Patent.

I would like to propose the following definition, borrowing that of Benkard, but slightly amended to take into account the "Rote Taube" decision:

"A patentable invention is an instruction for the systematic use of controllable natural means, leading each time to a usable result that does not constitute part of the prior art, whose realization could not be expected on the basis of the knowledge available to the average man skilled in the art." If we accept that the reproducibility of the heriditary characteristics, inherent in living matter, may remedy the lack of reproducibility using the instructions provided in the description of the invention, it would seem that neither biological processes nor living organisms should be excluded, as such, from patent protection.

However, I would not like to give you the impression that I consider the obstacles that I have held to be ancillary to the nature of a patent, to be easy to overcome for all that.

Considerations alien to the basic nature of patents may form unavoidable obstacles, either moral or economic or even arising out of practical difficulties of application. The problem of amending legislative provisions must also be taken into account since some of these are quite recent and, in the case of international conventions, require a consensus of the authorities of a number of countries. Without doubt, in opposition to these curbs, two factors acting towards adaptation of the patent system to the new technologies must be taken into account, particularly as regards inventions in the field of living matter. The first of these factors is the activity of the companies that are developing and using the new technologies; the rapid progress of microbiological inventions must be linked to the interest shown by powerful branches of industry. The second element is the ingeniousness of lawyers who frequently succeed in causing case law to evolve, whenever the statutes do not formally prevent it from so doing, in order to keep the patent institution aligned with its highest aim, "to promote the progress of science and the useful arts."

The Patent Granting Procedure

So far we have dealt solely with the conditions an invention is required to satisfy if it is to be eligible for a patent. However, certain aspects of the procedure must also be considered since they pose special problems in the case of inventions in the field of living matter. I have already referred to the claims, which play an essential part in the procedure, and I shall now restrict myself to two questions, that of examination and that of availability to the public.

Examination of Patent Applications

Following a formal examination, which need not concern us here, patent applications are subject in most of the major granting procedures to a substantive examination in respect of the patentability requirements. For the examination of novelty and inventive step, it is essential that the offices should know the state of the art, that they should possess highly qualified staff capable of assessing the differences between the application and the prior art. Although patent offices have begun to adapt as regards microorganism inventions, such is not generally the case for inventions concerning higher plants, without speaking of other forms of life.

Availability to the Public

If the invention can be entirely disclosed in such a way as to satisfy the reproducibility requirement, by a combination of texts and drawings, it is made available to the public through the publication of the application and of the granted patent or of the patent alone. Obviously, in this case, persons who wish to reproduce the invention have frequently to make considerable effort, particularly since they do not have the know-how accumulated by the inventor during the development of his invention.

The innovation constituted by the deposit of microorganisms with approved institutions has considerably changed the meaning of availability to the public.

The furnishing of a sample microorganism to interested persons--generally the inventors' competitors--places them in a favorable sitution compared with disclosure by publication since all that part of the invention that comprises the production of the microorganism is automatically furnished to them. The fact that it is possible for someone who has received such sample microorganisms to obtain derived cultures, distinct from the deposited strain, but nevertheless comprising its useful features, has led to changes in practice and in the regulations, as yet still fluid, as a result of which those to whom samples are furnished are likely to be required to enter into a strict commitment as regards the transmission, export or use of samples. These conditions would also apply to derived cultures. The European Patent Convention lays down in its amended Rule 28 that between first publication of the European patent application and granting of the patent, the applicant may require communication of samples only to an "independent expert" who will carry out the checks and make the experiments requested by the third party, without communicating the sample to him.

From the point of view of procedure, the deposit of a microorganism with an institution would seem to represent an indispensable yet unfortunate remedy for the impossibility of using the normal channels for communicating all the information necessary to reproduce the invention.

Rights Afforded by a Patent

Whereas the law governing the granting of patents is determined above all by the features of the inventions that are to be protected, the rights afforded to the patentee are influenced above all by the economic system applying in the country granting the patent.

A distinction may be made between the rights of the inventor and those of the owner of the patent.

The inventor has primarily a moral right that is imprescriptible and inalienable, but which may be no more than the right to be designated as such in the patent. He also has economic rights, but these may be assigned either before the patent application is filed (except in the United States of America) or after filing. Many laws give the employer of a salaried research worker the right to a patent, subject to varying conditions which frequently comprise the salaried inventor's right to remuneration, but without rights in the exploitation of the invention. The situation of the salaried inventor in such cases is similar to that of the owner of a Soviet inventor's certificate (or of similar titles issued in other socialist countries), who also has a right to monetary advantages, but has no right in the exploitation of the invention.

The owner of the patent, whether the inventor or his successor in title, has a right which is often formulated as the right to prohibit any third party, during a limited period of time, from accomplishing any act of exploitation of the invention. The longest term currently found in practice is twenty years as from filing of the application, without the possibility of extension. This is a provision, however, that has varied a great deal throughout the history of patents; certain national laws still today comprise a system of prolongation.

The acts that are prohibited for unauthorized third parties comprise, in the case of a product patent, the manufacture of the patented product (in the case of living matter this may be understood as the production), the selling or offering for sale, use or importing or stocking for purposes of production or manufacture. Acts that are accomplished for purposes that are not essentially economic, either privately or experimentally or for the execution of a medical prescription for individual purposes are not covered by this prohibition. As far as process inventions are concerned, prohibition concerns the use of the process, its offering for sale and acts carried out on the product obtained directly by means of the patented process.

A most important aspect of the rights afforded by a patent is that known as "exhaustion of the patentee's rights." Basically, exhaustion of the patentee's rights means that once he has put the patented article (product covered by the patent or product obtained directly by means of the patented process) on the market, he may no longer use his right to oppose subsequent acts carried out by third parties without his authorization. For example, if he has sold patented articles after having manufactured them, he may no longer oppose their resale or their utilization.

The problems of applying these principles, affecting the rights afforded to the owner of the patent, to living matter stem mainly from the fact that for inventions concerning inanimate objects the prohibited productive act must be repeated by the third party for each item that is produced, whereas the existence of a self-reproducing product increases the risk of infringement once the patentee has marketed the patented living matter. The reversal of the burden of proof, requiring the defendant in infringement proceedings to prove that he has obtained the new product, covered by the patent (for example, a directly protected living organism), by means other than those covered by the patent, would ease the task of the plaintiff; it could be automatic in cases where the defendant had received a sample of the living organism.

General Conclusion

One may already consider the development of industrial applications of biotechnology to be one of the major features of industrial evolution. The question that arises is whether this development is going to take place anarchically, to the sole advantage of the most powerful, or within the framework of a balanced system of protection for the creators and innovators, taking into account the interests of their competitors and of the community.

Coordinated development does not necessarily mean standardized development. If one accepts the arguments I have put forward in this paper, it would seem that no category of invention in the field of living matter may be necessarily excluded from patentability. However, it is possible that certain creations in the field of living matter would be more easily or more effectively protected by specific procedures, for example in the case of plant varieties bred by "traditional" means, whereas others may fall more readily under patent protection. It is probable that protection for processes, in so

far as they possess a sufficient degree of reproducibility, could be found within this group. Finally, in a field that is still in a state of scientific flux, it would seem prudent to leave scope for case law to evolve at the same time. One may well ask whether it would not be preferable to give an inventor the choice between a number of systems of protection rather than drawing rigid boundaries between systems that are mutually exclusive.

It would seem to me worthwhile to endeavor to construct new interconnections, new combinations uniting both patents and plant breeders' rights.

However, there I feel I am heading towards a field onto which the participants in this Symposium should cast the light of their conclusions.

[Original: French]

NOTES

1 Sidney B. Williams, Jr., Intellectual Property Aspects of Plant Variety Genetic Engineering: View of an American Lawyer. UPOV Symposium, 1982

Peter Kreye, Intellectual Property Aspects of Plant Variety Genetic Engineering: View of a European Lawyer. UPOV Symposium, 1982

Beier F.K., Crespi R.S., Straus J., Patent Protection and Biotechnology: an International Analysis. Organisation for Economic Co-operation and Development. Paris, 1984

2 European Patent Convention (EPC) Art. 52(3)

3 EPC Art. 57

4 Mousseron J.M., Traité des brevets; Vol. I: L'obtention des brevets, No. 218. Paris, Librairies techniques, 1984

5 EPC Art. 54(2)

6 EPC Art. 54(1)

7 EPC Art. 56

8 EPC Art. 83

9 Federico P.J., Louis Pasteur's Patents. Science, No. 86, 1937, p.327

10 Beier et al., op. cit., Annex C1

11 Beier et al., op. cit., Annex C9

12 Article 7: "The following shall not be patentable ... plant varieties belonging to a genus or species enjoying the protection established by Law No. 70-489 of June 11, 1970, on the Protection of New Plant Varieties"

13 EPC Art. 53(b)

14 EPC Art. 52(4)

15 Edelman B., Vers une approche juridique du vivant. Dalloz, 1980, chronique, page 329

16 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977

THE NATURE OF PLANT BREEDERS' RIGHTS (PLANT VARIETY PROTECTION LAW) AND THEIR DEMARCATION FROM PATENTABLE INVENTIONS

Dr. Peter Lange*

Abstract

A. Introduction: Historical development of breeder's rights

B. Main Part:

I. The Nature of Breeder's Rights as Special Protection Rights
On the basis of the International Convention for the Protection of New Varieties of Plants (Convention) and the European Patent Convention (EPC) special requirements exist for the following criteria:

- Invention/Discovery
- Progressivity/Inventive step
- Maintenance breeding
- Reproducibility
- Industrial applicability

II. Content of Breeder's Rights; Scope of Protection

III. Prohibition of Double Protection

IV. Attempt at Demarcation of Inventions in the Patent Field from Breeder's Rights, Choosing an Invention of Genetic Engineering as an Example

Article 53(b) EPC

No patent for

1. plant varieties
2. essentially biological processes for the breeding of plants

Patentable, therefore:

a) essentially technological processes for the breeding of plants
b) microbiological processes or products obtained with the help of these processes

At a) The immediate product of a technological process for the breeding of plants, according to Article 64(2) of the EPC, cannot be a variety.

At b) Can a product obtained with the help of a microbiological process be a plant variety? Answer: No, because:

1. varieties are generally excluded from the patent protection and
2. the product of a microbiological process cannot be a variety.

C. Conclusion:

Possibilities of demarcation demonstrated with the help of the example of the transformation of a protected gene into a variety.

I. The process patent does not extend its scope to the propagating material of the variety (because it is not the immediate product; otherwise there would be a violation of the prohibition of double protection).

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II. **The product patent of a gene itself is not a juridical part of the variety, because it is excluded by definition and because the basic principles developed for alloys and synthetic compounds lead to the conclusion that the public interest in having an unrestricted commercial trade in the variety is predominant. Result: The propagating material of the variety with an artificial gene is therefore freely available to every breeder for his breeding work, quite apart from the fact that after the plant material has been commercialized with the agreement of the patent owner the patent right has been exhausted.**

A. INTRODUCTION: The Development of Plant Breeders' Rights

For some centuries now, the creators of new, progressive objects, designs and processes have had the possibility of protecting their "inventions", for a limited period of time, against copying or unauthorized exploitation by others. The earliest known instrument was the Venetian Statute of Inventions of 1474, the so-called Parte Veneziana, and not the more familiar English Statute of Monopolies of 1624, although the latter did in fact exert a much greater influence on the development of patents.[1]

Testimonies in the field of plant breeding are of much more recent date,[2] and understandably so, since systematic creation, that is to say the breeding of new plant varieties, began only in the last century. Thus, in our field of plant breeding the first testimony that can be cited is an edict promulgated by the Papal States in the year 1833[3] under which anyone discovering a natural product or introducing a new agricultural species was to obtain for a limited period of time an exclusive property right therein. Just as the above-mentioned Parte Veneziana had no noticeable influence in the field of technical inventions, likewise this edict remained without effect in the field of legal protection for plant breeders. Plant breeders' rights did not develop until our century, and are therefore still very recent. Nevertheless, they do have--like everyone else--their ancestors. Who were then the mothers of plant breeders' rights? I intentionally speak of "mothers" and not "fathers" since in conventional breeding the mothers play a much greater part than the fathers, even if this is to be changed by genetic engineering processes. In my view, plant breeders' rights have had two mothers:

1. public seed and plant variety law and
2. industrial property rights (particularly patent law).

This I will explain, using the example of developments in Germany. As from 1895, systems of seed testing and seed approval were introduced in Germany, to be carried out on a voluntary basis by the professional, self-administrated organizations, which were extended in 1919 by the introduction of variety examination by those same organizations. The demand for statutory regulation of consumer protection in Germany led to a draft, submitted in 1929, for a seed and plant material law.[4] The first part of this draft was entitled "protection of the breeders." However, the draft statute was never to become law. In the mid-thirties, an official system of variety examination was introduced in Germany and the approval of varieties regulated. However, the system no longer contained the notion of protecting the breeders, but was simply limited to public law trade provisions, particularly as regards the protection of seed users. The result was to oblige breeders to attempt to obtain protection for their breeding work through competition law, patent law or trademark law. Indeed, as from the beginning of the thirties, over 100 new plant varieties managed to obtain patent protection in Germany. Patent law practice offered the choice of process patents, application patents and product patents. However, the patent law approach to the further development of breeders' rights was not a particularly even one. On the contrary, it was decidedly stony. There were two reasons for this:

First, there was political resistance to extension of patent protection to the agricultural field. It was feared that such an extension of industrial property to original production would bring plant breeding to a halt. This criticism resulted in numerous breeders withdrawing the patent applications they had already filed--which they nevertheless maintained in many cases abroad.

Secondly, and this would seem to me a weightier reason, patent protection in the field of plant breeding, that is to say in the field of biological material, proved unsuitable in a number of ways. Amongst many others, mention might be made here of the difficulties experienced in the granting procedure, particularly in meeting the requirements of repeatability, industrial applicability and inventive step; difficulties with which applications for genetic engineering processes will also be faced.

Additionally, the physical configuration of patent law is not well adapted to plant breeding since the scope of its protection is too narrow in some respects and is too broad in others, that is to say it does not sufficiently fulfill the requirements demanded of an adequate system of breeders' rights. We will have to return to this point in more detail.

More recent developments in plant breeders' rights, beginning after the end of the war and reaching a first summit with the conclusion of the International Convention for the Protection of New Varieties of Plants in 1961 and the birth of specialized national laws for the protection of new plant varieties, do not need any particular presentation before this audience. However, the following may be said from the point of view of the plant breeder:

We as breeders, who are judged each day on whether we can offer new, improved or more advanced varieties, are quite open-minded and, by nature, we believe in progress. Innovations in no way put us on the defensive, even in the field of patents. Quite the contrary. We indeed support the demand that an intellectual effort must be capable of appropriate economic exploitation through adequate protection. In this way, patent protection, just as variety protection, plays an important part in promoting the development of innovation and in furthering economic growth and the competitiveness of the undertakings involved. Nethertheless, in view of various innovations in fields which are closely related to plant breeding--particularly, for instance, in the fields of applied molecular biology, that is to say that of the so-called "green genetic engineering"--it is important to identify ways in which such innovations can be meaningfully protected, what the scope of their protection should be and how possible conflicts between patents and breeders' rights should be solved.

In this area, we are but at the start of a breathtaking development, which, although it will not replace traditional plant breeding, may be most helpful in supplementing it. Therefore, we as breeders in particular, must realize that patent law, as already once in the past, may again help us.

In the following, I will attempt to point to possible solutions from the angle of a legal practitioner. This can but constitute an initial attempt since very few decisions have been taken by patent offices and practically no case law as yet exists. What I have to say will basically refer to the International Convention for the Protection of New Varieties of Plants (Convention) and the European Patent Convention (EPC). National patent laws--including in particular that of the USA--can of course only be referred to by way of example.

The best way of approaching the solution of a problem is to begin by dissecting it, particularly in order to show up differing opinions, or to be more precise in this case, differences between fields of law, even if we are all quite aware that the points in common are by far the most numerous. However, the problems to be dealt with in this case can only be solved meaningfully if the differences are made quite clear. This I intend to do by describing the special nature of plant breeders' rights.

B. MAIN PART

1. The Nature of Breeders' Rights as Special Protection Rights.

I intentionally use the term breeders' rights since the Convention also does this; in Article 1(1): "The purpose of this Convention is to recognize and to ensure to the breeder of a new plant variety or to his successor in title a right" or in the first sentence of Article 2(1): "Each member State of the Union may recognize the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent."

The term breeders' rights was not chosen without some thought. It indicates that an author's right in the broadest possible meaning of the word is involved, that is to say, in particular, an industrial property right. A further aspect is the fact that breeding, and therefore also breeders' rights, contrary to technical inventions, may in principle also cover discoveries and do indeed cover them. Discovery in this context is to be understood as the identification of properties or phenomena that, although unknown, already objectively existed in nature. Invention, on the other hand, is understood as the purposive solution to a given problem using technical means.[5] What does this mean?

A protracted and lively discussion has taken place in the field of patent law on the question of whether a discovery was to be equated with an invention. Earlier patent laws, such as the American Patent Act of April 10, 1790, or the French Law of January 7, 1791, have defined the subject matter of patent protection as "INVENTION OR DISCOVERY" or "TOUTE DECOUVERTE OU NOUVELLE INVENTION" and thus equated the two terms. Nowadays, however, such is no longer the case. Under the laws of most countries, discoveries as such enjoy neither copyright law nor patent law protection. Thus, Article 52(2)(a) of the 1973 European Patent Convention (EPC) stipulates that discoveries shall not be regarded as inventions.

Contrary to patentable inventions, discoveries may also qualify for plant breeders's rights. All varieties in whatever form they have been developed, qualify for protection. Article 6(1)(a) of the Convention reads "Whatever may be the origin, artificial or natural, of the initial variation from which it has resulted, the variety must be clearly distinguishable."

The breeding activity that is to be promoted is to be found here in the intuitive recognition of the special properties, thus presupposing considerable specialized knowledge, as may be clearly seen from the example of the identification of spontaneous mutations--so-called sports--or of particularly valuable types that have either fallen into oblivion or have never been recognized.

The need to extend plant breeders' rights to such discoveries requires no further justification. Indeed, it already constitutes one of the basic differences from inventions within the patent law meaning.

According to the first sentence of Article 2(1) of the Convention any member State may recognize breeders' rights by granting either a special title of protection or a patent. The Convention thus gives a choice between:

- a special title of protection (plant breeder's right) or
- a patent.

Both forms of protection must fulfill the requirements laid down in Article 6 of the Convention, that is to say: distinctness, novelty, sufficient homogeneity, stability, variety denomination. This list is an exhaustive one as shown by the first sentence of Article 6(2) of the Convention. This means that no further material conditions for granting protection may be required by the member State. This also applies, as mentioned, for breeders' rights given in the form of a patent which, to distinguish it from a general patent, should preferably be referred to as a "plant patent." In addition, the above-mentioned forms of protection for breeders' rights must satisfy the content or minimum scope of protection set out in Article 5(1) of the Convention and may even grant, under Article 5(3), rights which extend beyond that minimum, particularly as regards the commercially marketed product. A number of the member States have availed themselves of this possibility, as for example France and Switzerland.

As a result, a number of special features exist in comparison with an invention:

a) Novelty/Inventive Step

A new invention can only be patented if it comprises the necessary inventive step. However, the patent law terms of novelty and inventive step are rarely adequate to describe breeding activities. This has led to the above mentioned requirements for protection which have been modified in relation to patent law. Notions such as "distinctness" "sufficient homogeneity" and "stability" are much more appropriate to biological material which, contrary

to a technical invention, is subject to natural variations and to continuous changes. Even the notion of novelty in the Convention allows the flexibility that is necessary in this case.[6] The "advantage" or "inventive quality" of a new plant variety is frequently to be found solely in the fact that this is different (as in the case of ornamentals) or in the selection of relatively obvious parent lines without an "inventive step" in its usual patent law interpretation. This does not mean, however, that breeding does not constitute a creative activity. Quite the contrary. Even the breeding of a new plant variety that differs from known varieties solely in its color constitutes an enriching creative activity. It is simply that the patent law definition of inventive step does not suit plant breeding.

b) Maintenance Breeding

A further special feature of plant breeding activities is constituted by maintenance breeding. This notion is completely alien to patents. A technical invention exists within the meaning of the definition reproduced above. It is subject to no change, indeed it must be unchanging since otherwise the "adequate solution of a specific problem" would be in jeopardy. Breeding, on the other hand, requires continuing maintenance work--of varying intensity depending on the type of plant--otherwise the result of the breeding is lost. Transposition of these inherent plant breeding requirements to patents would demand grounds for nullity that are alien to patent law, that is to say the loss of inherited stability.[7]

c) Reproducibility

Reproducibility is a requirement that is specific to an invention. It means that an invention must be described in such a way that it can be used by other persons skilled in the art. This feature has to be required in the case of an invention since to forgo reproducibility would in fact mean forgoing the requirement of the teaching that enriches technology and thus also mean extending patent protection to discoveries.[8] If the requirement of reproducibility were extended to new plant varieties, it would mean that only those results of breeding could obtain protection that could be reproduced. Apart from the fact that such is impossible in many cases, this would lead to an artificial distinction that was not technically appropriate since it would depend on hazard. In any event, contrary to technical inventions, breeding does not at all need the requirement of the "enriching teaching" particularly since as already mentioned above, discoveries are indeed a part of breeding. In this connection, it should be particularly emphasized that the product of a breeding invention, if I may coin the term, as a whole carries within itself the propensity to reproduction. A pound of a chemical substance remains a pound. A pound of a new potato variety, however, may be the basis for countless reproduction stages.[9]

d) Industrial Applicability

The industrial applicability or usefulness required in the case of an invention is not identical with "commercial importance." In the case of a technical invention, it denotes the capability of being produced in an industrial establishment or of being used technically in industry. To demand the same quality in respect of plant breeding would be pointless. Indeed, the result of a breeding process--once completed--is generally that it becomes superfluous thereafter.[10] The economic pointlessness of utilizing the process is inherent in the majority of cases. In exceptional cases, the breeding process can be commercially applicable where its repetition is economically justified. Such is the case, for instance, where the properties obtained are not stable or the breeding process has to be repeated for each generation, as in the case of hybrid breeding, in order to obtain the same properties.

II. Content of Breeders' Rights; Scope of Protection.

For the breeder, the content of his rights and the scope of protection are much more important than all we have mentioned so far. This is the very essence of breeders' rights. Article 5(1) of the Convention has the following to say: "The effect of the right granted to the breeder is that his prior authorization shall be required for

- the production for purposes of commercial marketing
- the offering for sale
- the marketing

of the reproductive or vegetative propagating material, as such, of the variety.

The effects of the breeder's right therefore extend to two types of utilization, namely

1. commercial production and
2. commercial marketing (including offering for sale) of reproductive and vegetative propagating material of the protected variety.

The subject matter of protection is thus the propagating material of the variety. If one wishes to compare this with possible categories of patent, one may think of a product patent but not of process or application patents. Process claims are not covered by plant breeders' rights, indeed no particular need has been felt so far.

The term propagating material used above is not defined in the Convention, a simple statement is made that whole plants are also included (second sentence of Article 5(1)). This term will certainly have to be interpreted very broadly in order to cover all the material which may be used to produce new plants that is to say: seed, plants, parts of plants--and also in the present state of the art individual plant cells. The notion of propagating material therefore also comprises a subjective element.

This also means, however, that plant breeders' rights do not relate to use of propagating material in the consumer sector. Contrary to patents, plant breeders' rights concern only the production stage, i.e. the commercial production of the propagating material plus its commercial marketing within this stage. Nevertheless, this is not a lower level of protection.[11] Indeed, it becomes obvious on closer inspection that the scope of protection under plant breeders' rights in fact goes further on account of the subjective element contained in the notion of propagating material. Whereas a patent owner has no further say once the patented product has been put on the market with his permission--that is to say the patent rights have been exhausted--plant breeders' rights are only exhausted in respect of further commercial marketing of the actual propagating material. However, the breeders' rights are regenerated as soon as the propagating material is used for further propagation or when the material obtained in such a way is commercially marketed. This again is a special feature of plant breeders' rights, that again possess the flexibility needed in this context. A further particularly important special feature is contained in the first sentence of Article 5(3). This sentence reads: "Authorisation by the breeder shall not be required either for the utilisation of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties." Contrary to patent law, the Convention here makes the breeder who creates a new variety by using protected varieties for crossbreeding or as initial material for obtaining either random or planned mutations, independant of the plant breeders' rights in the varieties utilized. This principle is essential to plant breeding since, contrary to inventions, breeding always bases itself on something that exists already and it is therefore absolutely essential that there should be freedom to make use of material. The sole limitation on this principle is given by the second sentence of Article 5(3) of the Convention which requires the breeders' consent when repeated use of the variety is necessary for the commercial production of another variety. These are well known cases, particularly that of hybrid breeding.

This special feature of the lack of a system of dependency in plant breeders' rights also derives from the nature and necessities of plant breeding. Again, in this case, there can be no question of a lower level of protection. Nevertheless, it does once more make it obvious that plant breeders' rights constitute a specific system of protection whose flexibility is tailored to the needs of plant breeding--it is indeed a system of protection that is made to measure!

III. Prohibition of Double Protection

As a result, in a way, of these special features, the second sentence of Article 2(1) of the Convention contains a prohibition that one could refer to as the prohibition of double protection. This means that a member State may not grant both types of protection for one and the same botanical genus or species. This Article was maintained even after accession by the United States of America. However, the possibility was created, in Article 37 of the Convention, for countries that had previously afforded the possibility of double protection, to maintain such double protection by means of a notification. This special ruling, although it had its purpose in facilitating the accession of certain countries, should not, however, lead to dropping the prohibition of double protection altogether, as is sometimes proposed by commentators.[12] This prohibition of double protection was not introduced just by chance.[13] It simply states that in addition to a special form of protection such as variety protection, no other form of protection (plant patent) may be afforded for the same botanical genus or species. In this connection, it should be remembered that a plant patent must also satisfy the requirements of Article 6 and that the granting of this form of protection may not be made dependent on further requirements. If we look more closely at the above-mentioned proposal to discard the prohibition of double protection, it will be seen that the intention in reality goes further. The purpose would seem, in view of the patent protection sought in those quarters for genetically engineered plant breeding, to obtain an additional possibility of protection of plant varieties under general patent law and not in fact under the special plant patent that is concerned by the prohibition of double protection.

However, this would mean--whether it be a cumulative or an alternative possibility--that the special features referred to above in respect of plant varieties could no longer be applied. It would mean, in particular, that plant varieties protected in such a way, contrary to Article 5(3) of the Convention, would no longer be freely usable for further breeding work. The proposal to remove this prohibition on double protection would in fact therefore mean that the exemption from patentability in respect of plant varieties contained in Article 53(b) of the EPC would be lifted. For the reasons given above, such an act cannot be contemplated.

IV. Attempt at Demarcation of Inventions in the Patent Field from Breeders' Rights, Choosing an Invention of Genetic Engineering as an Example

a) Article 53(b) of the EPC[14]

This Article of the EPC, already mentioned above, contains a delimitimg clause.[15] Corresponding provisions are also to be found in the national patent laws. Article 53(b) of the EPC contains certain exceptions to patentability. Of these exceptions, the following are of interest for our study:

European patents are not granted in respect of:

1. plant varieties
2. essentially biological processes for the production of plants.

This provision is not applicable to microbiological processes or the products thereof.

Each of the words quoted from Article 53 must be read most carefully:

1. Plant varieties (the emphasis is on varieties!) are simply excluded from patent protection.[16] This goes further that in many national patent laws,[17] since the latter frequently only exclude those varieties that may be protected by a special law--that is to say that are included in the relevant list of species.[18] Other varieties, not covered by a special law, remain patentable under the national patent laws, although for the reason already mentioned above this remains more or less a theoretical possibility.

2. Essentially biological processes for the production of plants are likewise excluded from patent protection. It is noteworthy that use has been made of the term "plants" and not that of "plant varieties." This means that processes that are not essentially

biological (i.e. that are technical) for the breeding of plant varieties cannot be patented. This also means, on the other hand, that essentially technical processes for the production of plants are patentable. In order to distinguish between essentially technical and essentially biological processes, reference should be made to Guidelines for Examination at the European Patent Office, particularly Chapter IV 3.4 Part C.[19]. The yardstick here is the extent to which man intervenes technically in the process. It will be necessary to devise additional criteria of demarcation. However, I do not consider this matter to be so important. More important for us as plant breeders is the statement that plant varieties as such are excluded from patent protection. Breeding processes that make use of genetic engineering methods are only patentable under the EPC in those cases where they constitute:

a) essentially technical breeding processes that are generally applicable and do not serve solely for the breeding of one variety and

b) microbiological processes or the products thereof.

In order to distinguish between biological and microbiological processes the corresponding criteria must likewise be established. The European Patent Office's Guidelines are altogether scanty in this respect. However, it will have to be assumed that genetic engineering processes are extensively of a microbiological nature since they frequently utilize microbiological knowledge and microorganism techniques and produce new microorganisms. Indeed, according to the quoted Guidelines, plasmids and viruses[20] also constitute microorganisms (not plant cells, however!). Nevertheless, even this demarcation between biological and microbiological processes would not seem so important.

More important is the question whether a plant variety can also be a product obtained by means of a microbiological process within the meaning of the EPC. For me, this is not possible, on the following grounds:

1. According to the EPC, plant varieties are generally excluded from patent protection.

2. The second part of Article 53(b) of the EPC simply follows on from the first part which refers to essentially biological processes and says that, on the contrary, microbiological processes and the products thereof are patentable. This does not mean, however, that plant varieties are also to be encompassed. The possibility of creating an independent product patent for plant varieties was certainly not intended here. Admittedly, the formulation of the second part of Article 53(b) is not altogether unequivocal. A number of the national patent laws, e.g. the second sentence of Article 2(2) of the German Patent Law, are clearer in this respect.

3. The product of a microbiological process can indeed in my view not be constituted by a variety, but at best non-specific plants or parts of plants that have been treated or created in a specific way. Plant material or propagating material of a variety, on the other hand, represents more since it presupposes a degree of individuality distinguishing it from other varieties. Thus, there is a difference between the products of processes (including plants, parts of plants and propagating material of plants) and plant varieties and their propagating material that must be made. Indeed this very difference has been drawn in exactly that way by the Technical Board of Appeal of the European Patent Office in a number of recent decisions.[21]

b) The Effect of Protection for Processes under Article 64(2) of the EPC

Similar considerations must also apply to the legal effect of protection for a process laid down in Article 64(2) of the EPC, that is to say its extension to products directly obtained by the process. (This legal effect of process protection is to be distinguished from the so-called product patent!)

This effect first presupposes that the patented process is indeed applied. Further, only the direct product is covered. In the case of a breeding process or of a genetic engineering process, this can only concern the direct result of breeding, that is to say at best the plants of the F_1 generation but not the results of further propagating steps, that is to say the propagating material of a variety as described above[22].

C. CONCLUSION

When looking at the results of this tentative demarcation, we will see that within the area of the Paris Convention and of the EPC there exist hardly any points of contact, let alone possible cases of collision, between a patented invention in the field of plant breeding or of genetic engineering and plant breeders' rights. At most, such points of contact could be conceived in the field of microbiological processes and their products, particularly in those cases where the interpretation I have advocated is not adopted. However, this interpretation is indispensable for the plant breeder. If it were possible to protect plant varieties by means of a product patent, the further development of the specialized legislation of the UPOV countries which, as explained above is tailored to the needs of plant breeding, would be jeopardized. The prohibition of double protection would thus be undermined.

I will now take a look, using a practical example, at how the boundary could be drawn between patent law inventions and breeders' rights in accordance with my interpretation:

Assuming the gene responsible for resistance to a fungus has been isolated. Let us further assume that it has been possible to obtain a product patent for this gene and, additionally, a process patent for its incorporation, by means of a suitable vector, into the plant material of a variety. (However, I consider this highly unlikely in the European legal context since such an application for a patent would come across the problems of discovery/invention, novelty, reproducibility and also industrial applicability.) The actual result could be that, with the aid of the gene and of the process, propagating material of a new, (because distinguishable) variety could be produced. The legal consequence would be that without the consent of the patentee no one would be authorized to use the patented invention, that is to say:

- "to fabricate, to distribute, to utilize or to hold the gene for the aforementioned purposes,

- to utilize the process or to offer, to distribute, to utilize or to hold for the aforementioned purposes the direct product of the process."

However, such an invention is only of use to the patentee if it is patented, assuming that he does not wish to hold it as a reserve patent. Exploitation is of particular value to the patentee when the gene is not incorporated in random plant material but in the propagating material of an individual variety. What happens then? What becomes:

(i) of the process patent?

(ii) of the product patent relating to the gene?

The first question has already been given an extensive answer. The protected process for isolating or incorporating the genes maintains its full scope of protection--it does not extend, however, to the propagating material of the individual variety.

The second question is considerably more interesting. Can the gene constitute a legal element of a variety? Would it continue to be protected as such and can the patentee influence the marketing of the propagating material of the variety or even prevent breeders from using material of a variety for their breeding activities? In my view, the answer to this question is no, for the following reasons:

Although the patented gene can be an "element" of non-specific plant material or perhaps an element of a quite specific plant, it cannot, from a legal point of view, be an element of a quite specific individual variety since this is already excluded on terminological grounds (a material object, that is to say a gene, cannot be an element of an immaterial object, that is to say a variety). Additionally, the creation of an individual variety necessitates further propagation steps. However, this would far exceed the notion of "directness" which--as is to be explained--would have to be applied in this case.

Even if the gene were to be understood as a legal element of a variety, the patent law principles, in respect of the conjunction or mixing of one patented product with another protected or even unprotected product, would

have to be applied. According to those principles, the protection of the incorporated product (of the gene) does not, however, simply come to an end.[23] The protection for the product also extends further than the protection for the "direct product of the process" since the notion of directness is lacking in this case. Nevertheless, the principles developed in respect of the scope of protection for the "direct product of the process" are to be applied. This means that the decision must take into account the question of appropriate remuneration for the "inventor" of the incorporated gene and of the general interest in unhindered trade in the variety.[24] This decision falls clearly in favor of the general interest in unhindered trade. Indeed, this must be so since the special provision contained in Article 5(3) of the Convention has to be taken into account. This Article 5(3) attaches a particular importance--as described above--to use of the variety for breeding purposes unhindered by protection rights. In this case, contrary to patent law, public interest has prevailed over the individual interest. Indeed, this is also regulated in a similar way in the American Plant Variety Protection Act of which Section 114 reads: "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act." It is therefore to be noted that in the case of propagating material of an individual variety, the patent protection of the gene is no longer effective.

Thus the propagating material of the variety is freely available to any breeder for his breeding activities, quite apart from the fact that once the plant material has been marketed with the consent of the patentee, the patent rights would be exhausted. This means that although the patentee can decide whether the subject matter of the invention may be marketed, subsequent acts of utilization, particularly further propagation of the material, are no longer subject to his control. The object that was protected has become common property and the patent rights have been used up.[25]

Thus, if the inventor of the gene or of the incorporation process wishes to claim this subsequent utilization for himself, he is obliged to make use of variety protection. He will therefore also find a suitable form of protection but, of course, would have to satisfy the requirements of these special rights. This, in my opinion, is quite justified. There is indeed no need for patent law protection of the product in the form of the variety!

To conclude, the following remark must be made: The ongoing discussion on the patentability of genetic engineering processes and the products thereof was foreshadowed by the discussion in the thirties of our century at the time demands were made for a plant patent, except that today we have a "plant patent" of that kind in the form of a proven system of special rights. This we should not call into question, particularly since it is tailored to the special needs of plant breeding, as is indeed also admitted by critics of the prohibition of double protection. On the other hand, the solution I have proposed also satisfies the justified desire for protection on the part of inventors of genetic engineering processes and products.[26]

[Original: German]

NOTES

1 Beier, "Wettbewerbsfreiheit und Patentschutz," GRUR 1978, pp. 123-132 (p. 123, Note 1)

2 Lessmann, "Der Schutz von Pflanzenzüchtungen im deutschen Recht," DB 1980, pp. 577-580; Wuesthoff, Sortenschutzgesetz, 1977, p.37

3 Festschrift "Bundessortenamt heute," Hanover 1982, p. 1

4 GRUR 1930, p. 244, p. 300

5 Beier/Straus, "Der Schutz wissenschaftlicher Forschungsergebnisse," Verlag Chemie 1982, p. 14

6 Hesse, "Zur Patentierbarkeit von Züchtungen," GRUR 1969, pp. 644 et seq. (p. 651)

7 Hesse, loc. cit. p. 651

8 Hesse, loc. cit. p. 648

9 Wuesthoff, loc. cit. p. 37

10 Hesse, loc. cit. p. 649

11 Thus, however, Straus, "Patentschutz für gentechnologische Pflanzenzüchtungen? Zum Verbot des "Doppelschutzes" von Pflanzensorten," GRUR INT 1983, pp. 591 et seq. (p. 595)

12 Straus, loc. cit. p. 597; although no explicit demand is made that the prohibition of double protection be lifted, this nevertheless emerges from the context of the article.

13 Thus, however, Straus, loc. cit. p. 596

14 Article 53(b) of the EPC corresponds to Article 26 of the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27.11.63 (GRUR INT 1964, p. 259)

15 Compare Kreye, "Intellectual Property Aspects of Plant Variety Genetic Engineering: View of a European Lawyer" in UPOV Records of a Symposium held on 13.10.82 in Geneva, pp. 63 et seq.

16 See "Guidelines for Examination at the European Patent Office" Part C, Chapter IV, p. 28 (the products of microbiological processes are excluded here however)

17 See Wuesthoff, "Biologische Erfindungen im Wandel der Rechtsprechung," GRUR 1977, pp. 404 et seq.

18 As, e.g. the German Patent Law, Article 2(2)

19 see Guidelines referred to in note 16, above, p. 32

20 see Guidelines referred to in note 16, above, p. 20

21 Decision of the Technical Board of Appeal 3.3.1. of the European Patent Office of 26.7.83, reference T. 49/83, GRUR INT 1984, pp. 301 and 302. "The subject matter of the claims is not an individual variety of plant distinguishable from any other variety, but the claims relate to any cultivated plants in the form of their propagating material which have been chemically treated in a certain way. However, Article 53(b) EPC prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety." [The Decision will be reproduced in the next issue of Plant Variety Protection].

22 See also Hesse, loc. cit. p. 650

23 Bruchhausen in Benkhard, Patentgesetz, 7 Ed. 81, Art. 9, Note 30 a), p. 342

24 Bruchhausen, loc. cit. p. 342

25 Hesse, loc. cit. p. 651

26 Straus, loc. cit. p. 594

DEVELOPMENTS IN BIOTECHNOLOGY - DREAM OR REALITY

Sir Ralph Riley*

Abstract

It is now six years since the Research Council for which I work in the United Kingdom initiated its coordinated program in plant genetic manipulation. Programs in several other countries commenced at about the same time. The UK program is carried out in several research institutes and by related groups in universities, and remarkable successes have been achieved in the scientific understanding necessary to create the plant biotechnology that will ultimately be used in cultivar production. As a result of the work in Western Europe, North America and Australia there is now reasonable understanding of the structure of plant genomes. We know how to incorporate alien genetic information into plant chromosomes, at least in certain special model systems, in a way that can lead to the expression of characters novel to recipient plant species.

From this it is clear that a practically usable biotechnology will probably be ready for exploitation in plant breeding before the 1990's. However, as seen from our present position there are likely to be two constraints on its widescale exploitation. These arise first because of the lack of knowledge on how the cells of several economically important crop species can be handled in culture using an effective vector system with which to incorporate foreign DNA. Secondly, while there is considerable understanding of the Mendelian genetics of economically significant characters in the major crop species there is very little understanding of the metabolic processes between the gene and the final phenotype. Consequently, we do not know how to isolate the genetic material determining attributes that could beneficially be transferred between species. Considerable gaps in our knowledge of plant biochemistry need to be filled before the dream of a useful technology can become a reality. Effort should, therefore, now be increased in research on the intermediary metabolisms of plants.

As I looked around this splendid room for the first time I saw the bust of Aristotle presented by the Greek Government. The quotation from Aristotle on that bust reads: "The best method of investigation is to study things in the process of development from the beginning." I am not able to begin from the beginning but you, Mr. Rigot, did describe in your opening remarks some of the beginnings of plant breeding. I am going to pick up the process of the development of plant breeding from the time when genetic engineering became a potentiality.

With the help of a slide I shall compare what has happened in the development of genetic engineering with the contemporaneous development of a plant variety, the winter wheat variety 'Avalon', which was developed by my colleague Mr. John Bingham at the Plant Breeding Institute in Cambridge from a cross made by him in 1969 between two existing wheat varieties. The variety was added to the Recommended List of the National Institute of Agricultural Botany in 1979. Part of the graph illustrates the build-up of sales of seed of 'Avalon' to the point where, by 1983, it was occupying about a quarter to a third of the acreage of winter wheat grown in the United Kingdom (see figure 1). The other part shows what was happening over the same period to the development of genetic engineering.

In the year after the first cross was made to develop 'Avalon', the first restriction enzymes were isolated. These enabled DNA to be broken in such a way that the broken ends were left in a form which enables the insertion of new pieces of nucleic acid which have been broken in the same way and have matching ends. The consequence was that new DNA molecules could be made and

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the first recombinant DNA molecules were created in 1972. Genes for nitrogen fixation were cloned in bacteria in 1977, sequencing techniques were developed and in the United Kingdom, as in many other countries, a program was commenced in 1978, or thereabouts, to study whether these forms of recombinant DNA technology could be applied to the transformation of plant varieties. In 1979/80, plant DNA was cloned in bacteria for the first time and in 1983, for the first time, in three laboratories in various parts of the world, foreign genes were incorporated in plant cells and expressed in those cells (see figure 2). Therefore, over the period of the development and utilization of the winter wheat variety 'Avalon', the whole process was invented, of changing DNA, of learning how to incorporate that DNA in plant cells and to have it expressed.

Whether plant biotechnology may be a dream or a reality depends entirely, I think, on the time scale over which you wish to consider the process. I shall compare later what has been happening in these fields with what has happened in the uptake of other new ideas and their incorporation as products, as new plant varieties.

Before I turn to that question, however, let me just say what some of the new developments are and give you some impression of them. The examples I have chosen are mostly drawn from the work of my colleagues in the United Kingdom. This is merely because I happen to know more about that work and to have available illustrations which will enable you better to appreciate what has happened. I illustrate first the process of incorporating in yeast the gene from wheat determining the enzyme alpha amylase (see figure 3). It proved possible to isolate the alpha amylase gene because in wheat grains the production of the messenger RNA which determines the production of alpha amylase can be stimulated in the aleurone cells by the application of gibberellic acid. So the RNA for wheat alpha amylase was isolated. The RNA was copied into DNA and incorporated in a bacterial plasmid and was then incorporated in a yeast plasmid. The appropriate signal sequence was also needed: it is the beginning of the protein of the enzyme and contains the instruction that the enzyme is to be exported from the cell. A determinant of expression was also needed. This work has resulted in the production of a form of yeast which is able to ferment all the way from starch to alcohol. This is merely a demonstration of the way in which we are able to transform cells and I should point out to you that yeast is a fungus, which is quite close to a plant in the structure of its nucleus, the structure of its cell walls and in many aspects of its physiology.

Now I would like to talk about similar work being done with plant cells. This is the work primarily of Dr. Bevan at the Plant Breeding Institute in Cambridge. He uses a plasmid from a bacterium called Agrobacterium tumefaciens, which is normally pathogenic, causing tumors to develop on the plants that it infects. The tumor-forming capacity is determined by a plasmid which the bacterium carries. As a result of work in the United States of America, Belgium and other places, it is known that the transformation of the plant cell to become tumorous involves the incorporation of part of the DNA of the plasmid into a plant chromosome. What Bevan did was to take the DNA region of another bacterium coding for resistance to the antibiotic kanamycin and associate it with an appropriate regulatory sequence. This construct was subsequently transferred to the Agrobacterium plasmid, which was then used to infect plants. I show you cells of a tobacco plant, transformed in this way so that they contain the gene determining resistance to kanamycin. They are being grown on a culture medium which contains the antibiotic, by which they are not affected; on the other hand, in another culture untransformed cells are killed. The work of Schell and his colleagues shows that this foreign information--resistance to kanamycin--is incorporated in the chromosome, can be transmitted sexually and is inherited like a normal mendelian character. Thus it is possible to incorporate entirely foreign information in plants and for those plants to behave in an essentially normal way. I will come back to that in a moment but it is very much like the model which Dr. Lange presented to us of the foreign disease resistance gene incorporated in a plant.

But the application of plant biotechnology is not only going to be helpful to breeders by enabling them to have access to new characters. It can be used in the technology of breeding without necessarily changing the structure of the plants concerned, for example by detecting in plants the presence of viruses. This process makes use of the sap of individual plants which is applied to cellulose filters and these filters are incubated. At the same

time, the nucleic acid of particular viruses has been cloned and cultivated as DNA in Escherichia coli, another bacterium. This complementary DNA (cDNA) can then be exposed to the sap which has been applied to the filters. The cDNA corresponding to the virus can be made radioactive and it will associate with the RNA of the virus. Where the virus is present in a plant, the association of the virus-equivalent DNA with the virus present in the sap will show up autoradiographically on the filter (see figure 4). The illustration shows the use of the test for detection of potato leaf roll virus and of potato virus Y.

Coming back to my description of the history of DNA technology (figures 1 and 2) you will remember that plant genetic engineering of this kind has been under way since about 1978. We already have potato plants transformed by A. tumefaciens DNA, we have genes of foreign origin incorporated in plant cells in many laboratories and in some laboratories the demonstration that those alien characteristics are inherited in an essentially simple and mendelian way. The phrase in the title of my talk, "Dream or Reality," is therefore appropriately cautious, I think, but it need be cautious only in terms of the time scale for its ultimate impact cannot be doubted.

Expectations should not be exaggerated, but they are real and what I should like to do now is to compare what may happen in this technology with what has happened in another plant breeding technology, related particularly to sugar beet. Sugar beet in Western Europe has been much affected by the application of novel kinds of breeding. Most of the sugar beet varieties that we grow in Western Europe are triploid, monogerm and hybrid. All of these novel characters have been introduced essentially in the 1970's or at least have been brought into wide-scale use in the 1970's. Let me take the three attributes one by one. They are triploid, that is to say they are artificial polyploids. Polyploidy was discovered in 1917. In 1937, for the first time, Blakeslee and others demonstrated that by using colchicine it was possible to increase artificially the chromosome numbers of the treated plants and their descendants to induce polyploidy. In 1938, for the first time, Schwanitz produced a tetraploid sugar beet, using colchicine, but polyploids in sugar beet did not come into widespread cultivation until the 1970's. Thus, there was a thirty year development span between the first recognition that colchicine could be used to double chromosome numbers and to get that idea applied to the sugar beet crop on a wide scale. Almost all sugar beets of the world are now monogerm. Monogerms were first described in 1934 in the Soviet Union. They were rediscovered in 1948 by Savitsky in the United States and it was the mid 1970's before monogerms were in wide-scale use in cultivation. That is a twenty-five year time span. As far as hybrids are concerned, I suppose, the value of maize hybrids was recognised in the 1920's and 1930's and they were in wide-scale use in the United States by the mid 1930's. In 1942, the first male-sterile sugar beet was discovered by Owen and the potentiality for hybrid variety production was recognized. By the late 1960's or early 1970's, hybrid varieties were getting into use; in other words a twenty-five to thirty year period of development.

What I am saying to you is that the pay-off period for the introduction of new ideas into plant breeding is prolonged. We should not therefore be impatient that the new ideas that have been developing in plant breeding research over the last five or six years have not led us to be further advanced than we are. If we apply a time scale to uptake similar to that which I have described to you for sugar beet, we ought to have varieties resulting from the kinds of manipulations that molecular biology now makes available to us ready for use by the turn of the century. That time scale may be foreshortened because of the enormous effort which is being made in it not only in public-sector laboratories but also in the private sector in the northern hemisphere.

Already, we are beginning to see the application in a very significant way of tissue culture methods to some crops. The one that I am most familiar with is the oil palm. We may expect replantings in major plantation areas of the world to be made with material cloned from the superior genotypes which exist only as isolated trees in current plantations, where extreme genetical heterogeneity obtains and where every tree is probably genetically different from all the others in a plantation. This probably is going to transform the capability of oil production from the oil palm.

What are the constraints which may limit the likelihood of uptake of molecular biological technology in plant breeding? There are two that I am most anxious about. One is the difficulties that those who work in this field

face in dealing with the cells of monocotyledonous plants, which are much less easy to manipulate and less easy to transform than are those of some dicotyledonous crop species. But I suspect that this may only require a concentration of effort. A particular difficulty is that the A. tumefaciens vector is not one which we are aware of thus far as having an applicability to monocotyledonous crops such as the cereals. There are those who are beginning to suggest that whilst cereal plants may not be infected by A. tumefaciens to form tumors, nevertheless they may still on some occasions be transformed by it. This is an active field of study at the present time but we desperately need advances here if biotechnology is to extend to those important crops.

The second anxiety is the grave ignorance of many aspects of plant biochemistry. The science of biochemistry has developed essentially using microorganisms and the cells of animals as experimental systems. The cells of animals have been used primarily because cell culture has long been readily possible; this knowledge was needed to practice medicine. But it is only recently that plant cells have been cultured effectively. There must be concentration on understanding the intermediary metabolism of plants. For example, there is no knowledge of the steps between the action of a mendelian gene determining disease resistance in a plant and the expression of that resistance. To isolate such a gene it will be necessary to know what the first products of the gene are and what its intermediate products are. This is an area to which, as far as I am able as a scientific administrator, I am directing a particular effort at the present time.

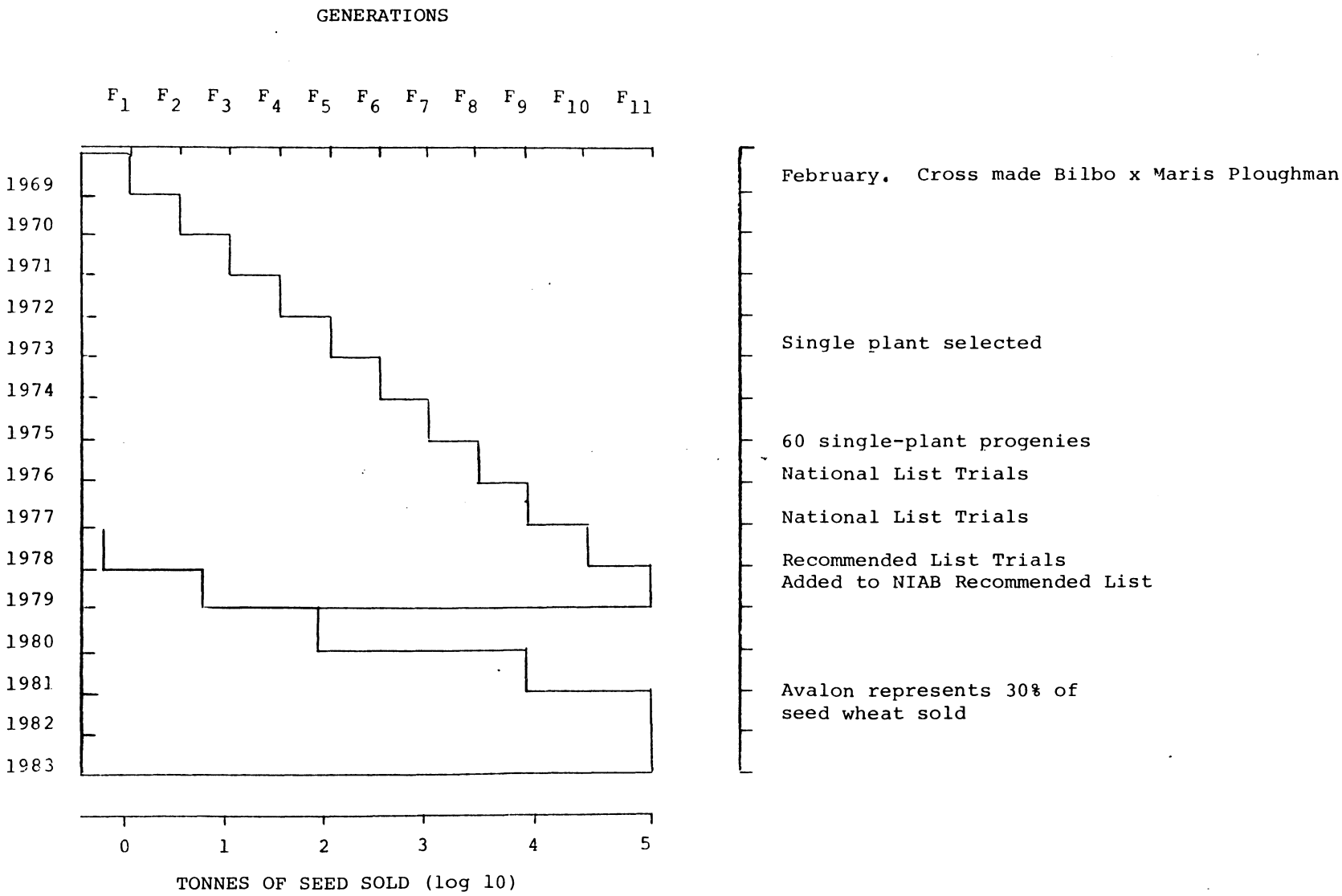
What about the prospects? Recognising what the President of the Council of UPOV said about the unsatisfactory nature of food production in many of the developing parts of the world, we nevertheless have an excess capacity to produce crops in much of the northern hemisphere. There is more sugar and starch and some kinds of vegetable protein than we know what to do with. Agriculture has a marvellous capacity for the production of dry matter. We might therefore contemplate using that production capacity in some other way. If a kanamycin resistance gene can be put into a plant cell there is no reason why the genes for human growth hormone, for insulin, for many other kinds of product should not be put into plants so that the sun's energy can be used to produce fine chemicals. Separation of those simple proteins from plants should present no greater problem than separation in most microbiological fermentation systems, especially after discounting the energy costs of production.

All of us who are concerned with the administration and conduct of agriculture must concern ourselves about what we are going to do with this tremendous industry in the future and there is no reason why we should not contemplate in the beginning of the next century the kind of transformation which can only come from the application of biotechnology. Finally, since this Symposium is discussing patent protection and plant breeders' rights, we may expect in the future that some of the secondary products of plants will be produced from plant cells in culture. I said that crops might be used to produce, for example, human growth hormone. There are many crops which are already used for such unusual processes. We produce rubber as a secondary product, we produce digitalis, morphine, quinine and many other unusual products, making use simply of the plants which nature has offered to us, which by chance happen to have available in them products useful to man. Biotechnology will enable new plant products to be tailored but the stimulus of property protection may be needed to make the necessary investment worthwhile.

[Original: English]

THE DEVELOPMENT OF THE PBI WHEAT AVALON

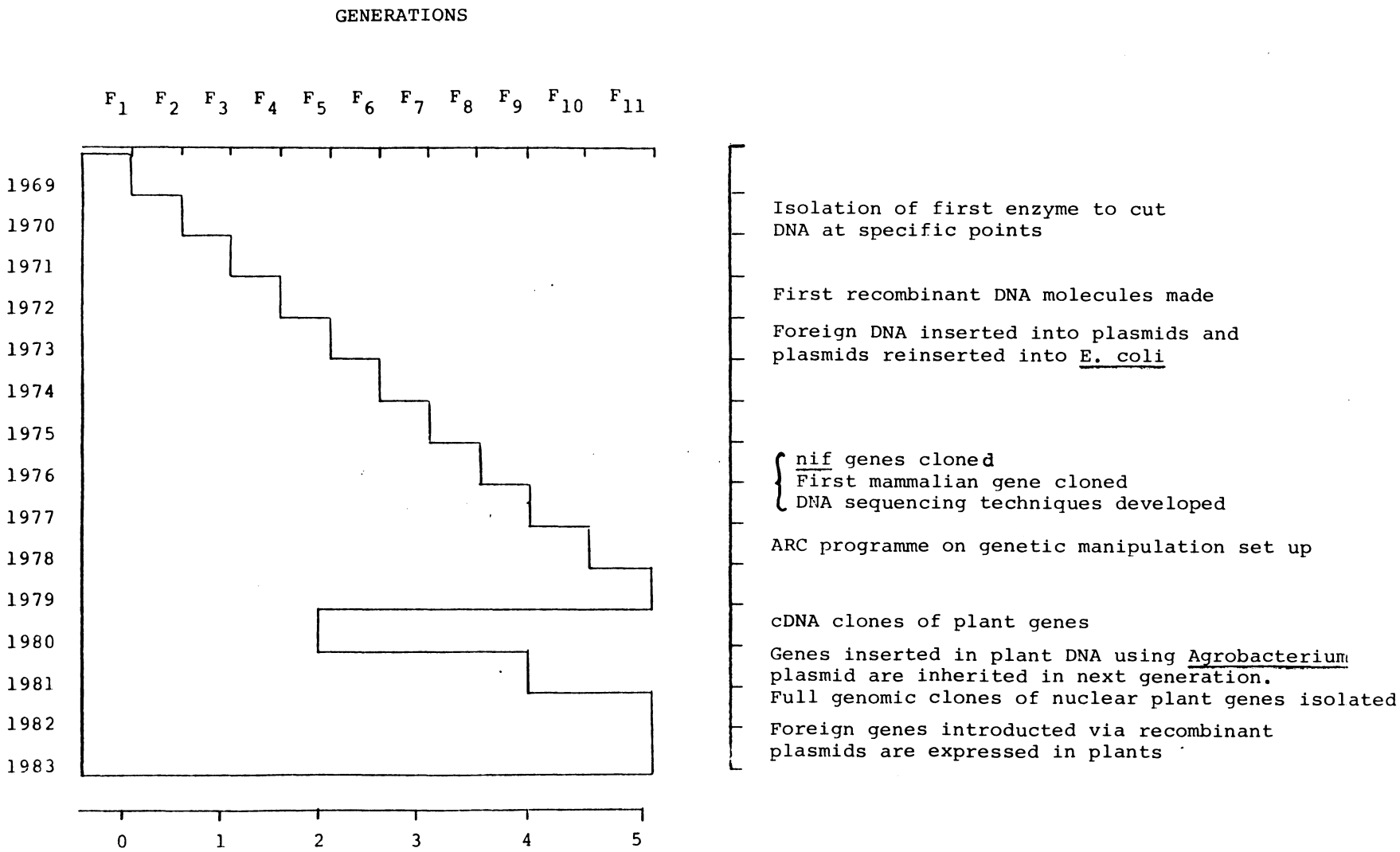
Figure 1



Reproduced with the kind permission of Dr. R.B. Flavell

THE DEVELOPMENT OF RECOMBINANT DNA TECHNOLOGY

Figure 2



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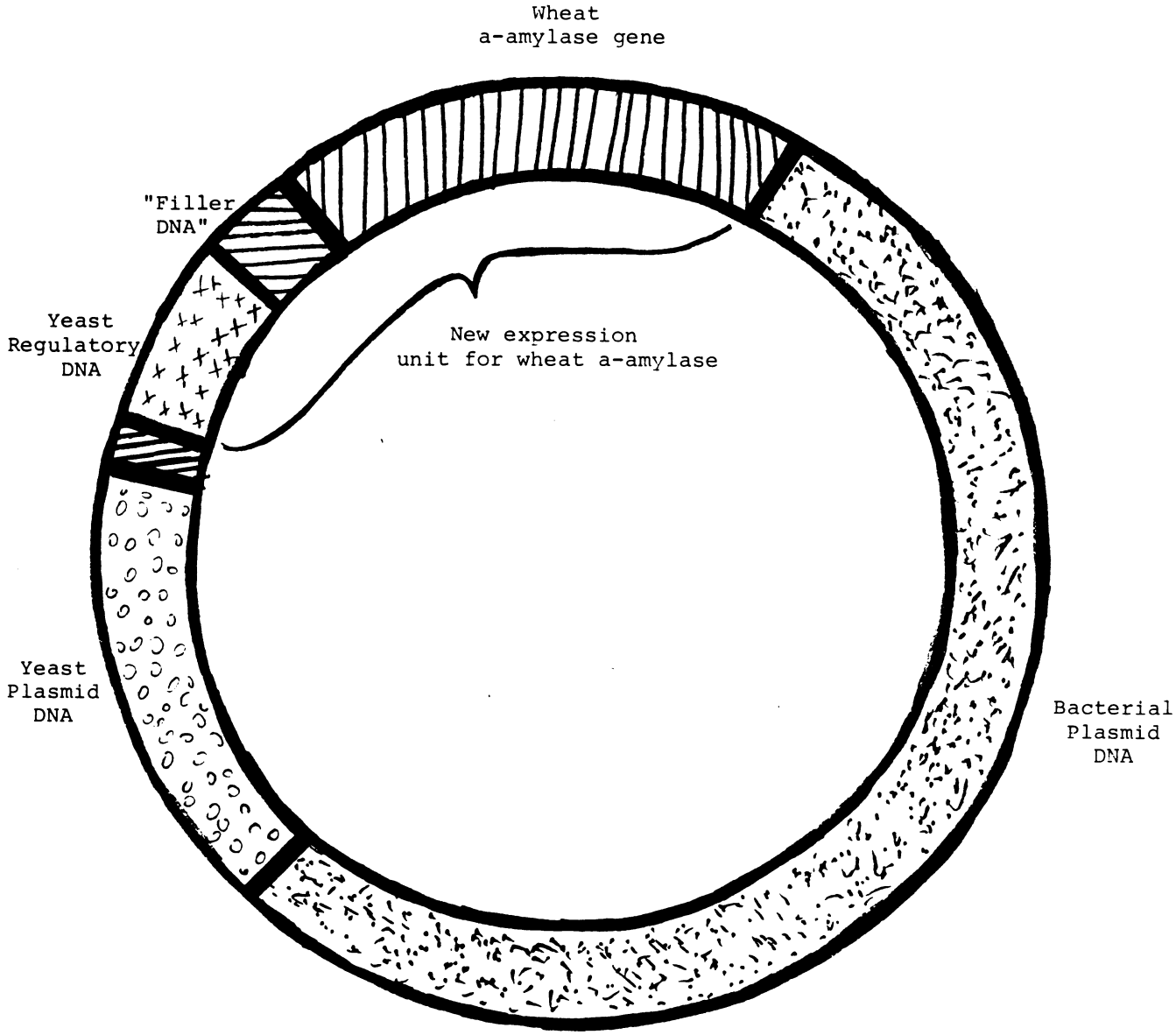
DEVELOPMENT OF STARCH DEGRADING YEASTS USING

GENETICALLY ENGINEERED PLANT GENES

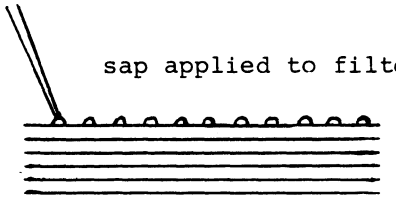
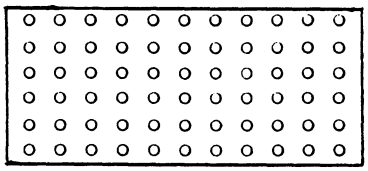
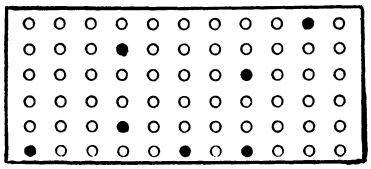
Figure 3



Vector constructed for insertion into yeast to
achieve replication and expression of wheat a-amylase gene

Reproduced with the kind permission of Dr. D.C. Baulcombe

Figure 4

	PROCESS	DURATION
1	Sap squeezed plants	30 sec per sample 1000 per day 100% operator time
2	 sap applied to filter	250 per hour 2000 per day 100% operator time
3	 Filter dried and baked	2 hours 2 min operator time
4	cDNA clone labelled by nick translaBion	3 hours 30 min operator time
5	Filter sealed in plastic bag and incubated with labelled probe	36 hours including prehybridisation 15 min operator time
6	Non-hybridised DNA washed away	1 h 15 min operator time
7	 Autoradiography	2 hours - 1 wk 30 min operator time

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THE LEGAL PROTECTION OF ACHIEVEMENTS IN BIOTECHNOLOGY, AS SEEN BY A JAPANESE LAWYER

Professor Nobuo Monya*

Abstract

Recent developments in biotechnology are remarkable. In the near future, the creation of various kinds of new plant varieties by new breeding techniques will no longer be a dream.

In Japan, plant varieties and breeding processes are theoretically protectable under the Patent Law. From the practical point of view, however, plant varieties are not protectable, because of the special nature of the subject matter. For this reason, the Seeds and Seedlings Law was enacted and Japan became a member of UPOV.

In Japan, "plant varieties or essentially biological processes for the production of plants" are not excluded from patentability and, in addition, provisions establishing a preferential status for a patent right for a breeding process, which is not a patent right for a plant variety itself, are contained in the Seeds and Seedlings Law.

However, patent rights for breeding processes are actually very rare and, furthermore, as those provisions are unreasonable in view of the legal nature of the rights, they must be interpreted and administered in a restrictive manner.

In the future, given its developments, the way in which achievements in biotechnology are to be protected will be problematic. At that stage, it is to be expected that a proper demarcation between the two protection systems will be established, taking into account the special nature of plants, to exclude double protection. This problem should be solved on the basis of internationally harmonized principles.

1. Introduction

Recently, with the remarkable developments in biotechnology, several achievements in wide-ranging fields such as pharmaceuticals, energy, foodstuffs, fodder and waste matter disposal have been reported.

In the field of plant breeding, breeding processes using biotechnology have been spotlighted in addition to cross-breeding methods and mutation-breeding methods. Because plant cells, unlike animal cells, possess totipotency, a plant cell can regenerate a complete plant from a somatic cell hybrid, created by means of cell fusion, or from a recombinant, created by means of genetic recombination. These techniques, along with the tissue culture technique, constitute the major new breeding techniques using biotechnology.

The cell fusion technique can fuse cells from completely different kinds of plants beyond the scope of ordinary cross-breeding. However, up to now, only interspecific cell fusion (e.g. *Nicotiana tabacum* x *Nicotiana spp.*) and intergeneric cell fusion (e.g. Pomato: Potato x tomato; Carrot (*Daucus carota L.*) x Parsley (*Petroselinum crispum Nym.*)) have been reported.

Recombinant DNA technology has so far been applied only to microorganisms. On the other hand, in higher plants, in which mechanisms of expression and regulation of genetic information are more complicated, clarification of the gene map and its corresponding phenotypic characteristics has just started.

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Although the new breeding techniques using biotechnology are just beginning, several new microorganisms have been created and the creation of various new plant varieties as well is no longer a dream. Taking into account the world food crisis, multiple applications of the new breeding techniques using biotechnology are expected in the plant breeding field.

From a legal perspective, the requirement of repeatability for the invention of a plant variety or breeding process can be fulfilled by these developments in biotechnology. Accordingly, in Japan, "plant varieties or essentially biological processes for the production of plants"[1] are not per se excluded from patentability. Protection under the Patent Law, in addition to the protection for plant varieties which already exists under the Seeds and Seedlings Law, (i.e. double protection) is therefore theoretically possible.

In the remainder of this talk I will consider the legal problems which should be anticipated in Japan in connection with these new plant varieties and breeding processes.

2. The Relationship between the Seeds and Seedlings Law and the Patent Law

In Japan, the Ministry of Agriculture, Forestry and Fisheries and the Patent Office reached agreement that even though plant varieties were theoretically protectable under the Patent Law, such protection would not be practical because of the special nature of the subject matter and the less strict requirements for protection contained in the draft of the Seeds and Seedlings Law. Based upon that agreement, the Seeds and Seedlings Law was enacted by amending the Agricultural Seeds and Seedlings Law (Law No.115 of 1947).[2]

For the same reasons, Japan subsequently became a member of UPOV on the assumption that only the Seeds and Seedlings Law would secure to plant breeders the rights provided for in the UPOV Convention.[3]

As stated above, protection of plant varieties and breeding processes would not be practical under the Patent Law. Furthermore, providing in the Patent Law that plant varieties and breeding processes are excluded from patentability would create difficult problems in sharing jurisdiction between the agricultural policies of the Ministry of Agriculture, Forestry and Fisheries and the policies of the Patent Office relating to industrial property rights. For these considerations, such a provision was not included in the Patent Law.[4]

On the contrary, a provision establishing a preferential status for a patent right for breeding processes over the plant variety protection right under the Seeds and Seedlings Law (Seeds and Seedlings Law, Section 12-5(2)(v)) and a provision restricting the effect of the plant variety protection right after the expiry of the patent right (the same law, Section 12-5(2)(vi)) were included in the Seeds and Seedlings Law [5] in response to a request from the Patent Office at the time of enactment of that Law.

Taking note of these circumstances, as Japan has not used the notification procedure provided for under Article 37 of the UPOV Convention, it is conceivable that there are some problems concerning Article 2 of the Convention, which prohibits double protection.

In the light of the foregoing, I will discuss the problems presented by the Patent Law and the Seeds and Seedlings Law.

3. Problems in the Patent Law

a) Inventiveness

Differing from the situation under the Patent Law of the United States of America,[6] the question whether the subject matter of a patent is a living organism is not relevant under the Patent Law of Japan. Consequently, the patenting of plant varieties and breeding processes is theoretically possible, as described above.

However, in Japan the requirement of repeatability of an invention has been applied to breeding processes,[7] as is also the case in the Federal Republic of Germany.[8] Such a requirement is a matter of course since the distinction between an invention and a mere discovery without any originality, such as a natural mutation, is maintained in the Patent Law. As a result, patents on plant varieties and breeding processes are effectively precluded.

Even though the gene map of a plant and its corresponding phenotypic characteristics will be clarified by future developments in biotechnology, it will still not be easy for a breeding process to satisfy the repeatability requirement (namely, to qualify as an invention) because of the instability of gene expressions, which originate inevitably from living organisms and do not derive from external effects.

b) Patentability of an Invention

For a patent to be obtained, an invention must satisfy the requirements of industrial applicability, novelty and inventive step (Patent Law, Section 29).

Industrial applicability indicates that the invention can be carried out repeatedly and continuously through industrial operation; this is not a requirement for the products of the invention. Therefore, by analogy, this requirement can be applied to a process of breeding but not to the reproduction or multiplication of the product after the completion of the original breeding process, i.e. the "invention".[9] In this sense, it is as difficult to qualify the patentability of a plant variety as it is to qualify its inventiveness. Furthermore, the reproduction or multiplication of plants would not usually be carried out through industrial operation, except in the case of hybrid varieties.

Next, novelty must be examined and this involves essentially the differences in gene arrangements. Since it is difficult at this moment to examine directly the different gene arrangements, they are examined through the observation of the morphological, physiological and ecological characteristics, which are the expressions of the differences in gene arrangements.[10] However, as such visible or performance characteristics are governed not only by gene arrangements but also by environmental factors, it will be difficult to obtain an absolute and clear answer from such examinations.

Inventive step means the degree of difficulty of creating a process of breeding in the light of publicly known techniques. An inventive step is not a matter of the color or the shape of plant varieties. Moreover, as a publicly known technique is variable and uncertain, assessment of the inventive step is extremely difficult. Consequently, the standards drawn up by the Patent Office in Japan for the examination of new varieties of plants do not refer at all to how to examine for inventive step, in spite of the fact that many pages in other industrial property examination standards refer to the procedures for determining this inventive step. For this reason, the Director-General of the Department of Appeals of the Patent Office has said that the standards for the examination of new varieties of plants are incomplete.[11]

c) Description and Application

As is commonly known, a patent right is granted in return for disclosure of the invention. This is a fundamental principle of the patent system. Thus, the invention should be disclosed in the patent description in such a manner that it may easily be carried out by any person skilled in the art to which the invention pertains (Patent Law, Article 36(4)).

As far as an invention exists in respect of a process of breeding, the process should be fully disclosed in the patent description in such a manner that it may easily be carried out by any person skilled in the art to which the invention pertains, whether the patent claim is for the breeding process or for a plant variety *per se*. Similarly, if the parental varieties are not known, the method of obtaining them should also be described.[12] Unless all of the foregoing is fully disclosed, nobody except a person who possesses the results of the breeding can carry out the invention.

In plant breeding, factors such as mutation, selection by technicians using personal skills (selection process), and the color and flavor of the plant occur and it is extremely difficult to describe them all precisely, whereas this can be done for machinery. Consequently, it is almost impossible that ordinary skilled persons will be able to carry out the invention, based only on the description of the invention, with sufficient likelihood of success. The view might thus be asserted that these factors would require some limitation of the requirement for disclosure of an invention in the case of inventions concerning plants, as in the United States Patent Law.[13] In that case, however, depending on what is limited and the extent to which it is limited, a patent right could be granted to a product which is produced by the breeder by means of a breeding process that cannot be repeated by ordinary skilled persons because instructions on the breeding process cannot be given. Such limitation would go against a fundamental principle of the patent system and, therefore, is not reasonable.[14]

In the field of inventions of microorganisms this problem has been solved by depositing microorganisms in culture depositories (Patent Law Enforcement Regulation, Section 23(2); Budapest Treaty, Article 3). However, no similar expedient is presently available for plants. As the cultivation methods differ considerably from plant to plant, it will be difficult to establish and carry out a similar system for plants in the future.

The requirements that drawings included as supporting documents in an application under the Patent Law must be drawn in thick Indian Ink and that coloring of drawings is prohibited (Patent Law Enforcement Regulation, Section 5, Form 17, Remark 3) have been softened under the standards for the examination of new varieties of plants. If it is necessary, colored drawings or color photographs are accepted as reference materials.[15] However, it is impossible to differentiate the characteristics of plant colors by means of colored drawings or color photographs. Also, it is quite questionable how such colored drawings included as reference materials would be judged in a case of infringement of a patent right.[16]

Furthermore, the concept of one invention per patent application is extremely narrow in Japan. Each plant variety, however, has numerous characteristics such as plant type, plant height, thickness of stem, stem color, leaf shape, phyllotaxis, leaf color, flower shape, flower color, flower size, flowering time, disease resistance, heat tolerance, insect resistance, and so on. Chemical substances also have many characteristics, but the characteristics of plants are very different from a qualitative point of view. Which plant variety should be considered as one invention is an unsolved question. In considering this question, the question of the identity of each plant variety has to be distinguished from the question of the identity of each invention.

d) Effect of a Patent Right

As plants are self-reproducing, quite unlike industrial materials, the range of effect of a patent is not clear in Japan.

The effect of a patent right for breeding processes extends to the use of the breeding processes and the plants bred by the breeding processes (Patent Law, Section 2(3)(iii)). However, the patent right does not extend to the plants reproduced or multiplied from the patented plants. The difference in treatment is due to the fact that the reproduced or multiplied plants result from a method that differs from the patented breeding process.[17]

While it is conceivable to cover the reproduction or multiplication processes by formulation of a claim which unites the breeding processes and reproduction or multiplication processes in one, as in the Federal Republic of Germany, an examination would then be necessary to determine whether an invention is able to exist in the reproduction or multiplication processes of the plants in relation to their self-reproducing nature and, if an invention is considered to exist, an examination would be necessary to determine whether there is an inventive step in the process.

We must next consider whether the effect of a patent right for a plant variety *per se* extends to such activities as the "manufacturing", use or marketing of the plant variety (Patent Law, Section 2(3)(i)). Here, although

"manufacturing" includes all kinds of breeding processes, it is not clear whether it includes reproduction or multiplication. For hybrid varieties (F_1), it would be of no advantage if "manufacturing" included reproduction or multiplication. But in other cases, a patent right for a plant variety is not useful unless the reproduction or multiplication is included in "manufacturing"[18] because obtaining the plant variety by reproduction or multiplication is easier and more practical for a third party than by means of the breeding processes. For this reason, United States Patent Law contains a separate provision relating to "reproduction" (United States Patent Law, Section 163), apart from the Section of the said Law which deals with manufacturing activities. However, no similar provision exists in the Patent Law of Japan at present.

Even if reproduction or multiplication is included in the "manufacturing" of plant varieties, it is considered that the effect of the patent right would not extend to legally purchased material relating to the patent (the principle of exhaustion of the right afforded by the patent).[19] Accordingly, in the absence of a particular provision to the contrary, the effect of the patent right may not extend to such activities as cultivation, seed production, multiplication, marketing, etc. by a person who legally purchases material relating to the patent.[20]

e) Summary

The principal problems in the Patent Law for plant varieties and breeding processes at the present time in Japan are as I have described. Although plant varieties or essentially biological processes to produce plants are technically not excluded from patentability under the Patent Law, from a practical point of view they are not protectable by patent at present. In the future, given further developments in biotechnology, problems such as difficulty of recognition of inventiveness and the requirement for disclosure of the invention may be solved. However, as long as problems such as the acceptability of drawings attached to the description, the unity of the invention and the effect of the patent right are not solved legally, it can be said that the resolution of the problem of granting patents for plant varieties and breeding processes will not make progress in Japan.

4. Problems in the Seeds and Seedlings Law

As previously described, the Seeds and Seedlings Law establishes a preferential status for a patent right for a breeding process over the plant variety protection right under the Seeds and Seedlings Law (as to the patentability of plant varieties *per se*, there are no similar provisions because plant varieties are not protectable by patent from a practical point of view). The Seeds and Seedlings Law also contains a provision which restricts the effect of the plant variety protection right after the expiry of the patent right for a breeding process.

The provision relating to the preferential status has resulted from the provision in the Patent Law which provides that the effect of the patent right for a process to produce a material extends to the material itself produced by that process (Patent Law, Section 2(3)(iii)) and also from the provision contained in the previous Law (Agricultural Seeds and Seedlings Law) which provided for a similar preferential status. The other provision is said to have merely resulted from applying a general principle of the patent system because of the existence of the first provision relating to the preferential status.[21]

However, considering the fact that the Seeds and Seedlings Law, like the Patent Law but unlike the Copyright Law, grants an absolute exclusive right (Seeds and Seedlings Law, Section 12-5(1) and(3); UPOV Convention, Article 5(1)) and the theory of industrial property laws, the foregoing provisions must be interpreted in a restrictive manner, in line with the provisions relating to determination of the effect of absolute exclusive rights under industrial property laws.

a) Preferential Status for a Patent Right Concerning Breeding Processes

According to Section 12-5(2)(v) of the Seeds and Seedlings Law, a patentee of a breeding process is preferred, with respect to a plant variety to be produced by such a process, to the holder of the plant variety protection right registered under the Seeds and Seedlings Law, regardless of the filing date of the patent application.

However, a dispute between the patent right and the right legally similar to the patent right (the plant variety protection right) should be treated as similar to a case of interdependence of patents. Accordingly, the preferential treatment accorded to the patentee in Section 12-5(2)(v) should be interpreted restrictively, to apply only to those who apply for the patent before the date of the application for registration of the plant variety.[22]

Furthermore, patent protection for a breeding process should not extend to the later generations reproduced or multiplied from the plant material obtained directly by means of the patented breeding process, as previously mentioned.[23] Consequently, the priority provided for in Section 12-5(2)(v) should be interpreted in a restrictive manner to cover only the activities relating to the particular plant material obtained by using the patented breeding process.

b) Treatment after the Patent Right for the Breeding Process has Expired

It is reasonable to interpret Section 12-5(2)(vi) of the Seeds and Seedlings Law in the light of the two restrictions described above in relation to Section 12-5(2)(v) of the said Law.

In similar situations, where one of two conflicting absolute exclusive rights has expired, industrial property laws provide as follows: in the case where a patent right attaching to a patent application made before the date of an application for registration of a design is in conflict with the design right granted to the application, the patentee and the licensee(s) of the patent right are able to enforce the design right within the scope of the patent right even after the expiry of the effective term of the patent right (Design Law, Sections 31 and 32; Patent Law, Sections 81 and 82).

The relationship between the patent right and the plant variety protection right, which has a proprietary nature legally similar to that of a patent, should be interpreted consistently with the above provisions. Consequently, Section 12-5(2)(vi) should be interpreted restrictively to permit only the patentee and the licensee(s) of the patent right, even after the expiry of the effective term of the patent, to use the conflicting registered plant variety protection right within the scope of the patent right.[24]

5. The Problems to be Solved in the Future

At the time of the enactment of the Seeds and Seedlings Law in 1978, the Ministry of Agriculture, Forestry and Fisheries and the Patent Office agreed to keep in close contact in order to administer the Seeds and Seedlings Law and the Patent Law with the understanding that protection for plant varieties under the Patent Law did not yet exist and would not exist in the future.[25]

However, the application for the invention relating to a pentaploid mugwort was granted publication in 1983 by the Patent Office. The Japan Seed Trade Association consequently filed an objection to the grant of a patent in respect of the application. The publication of this application is based on the fact that the application for the patent right was filed in 1977, before the enactment of the Seeds and Seedlings Law. However, should the patent right be granted, the various problems described above will arise in relation to the Patent Law and the balance between the two systems.

In the future, given its developments, the way in which achievements in biotechnology are to be protected will be problematic. At some stage, it is expected that a proper demarcation between the two protection systems will be established, based on mutual consent and cooperation between the Ministry of Agriculture, Forestry and Fisheries and the Patent Office, and taking into

account the special nature of plants and the requirement to exclude double protection. These problems should be solved on the basis of internationally harmonized principles.

[Original: English]

NOTES

1 Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Article 2; Convention on the Grant of European Patents (EPC), Section 53(b); WIPO Model Law for Developing Countries on Inventions, Section 112(3)(ii); Patent Law of the Federal Republic of Germany, Section 2(2); Patent Law of France, Section 7(c)

2 Stated by Ichiro Nakagawa, Minister of Agriculture, Forestry and Fisheries (Transactions of the Standing Committee on Agriculture, Forestry and Fishery of the House of Councillors, June 16, 1978, p. 2)

3 Stated by Mitsuaki Sato, Director, General Administration Division, Department of General Administration, Patent Office (Transactions of the Standing Committee on Foreign Affairs of the House of Representatives, April 9, 1982, p. 27)

Stated by Takashi Mogushi, Director-General, Cabinet Legislation Bureau (Transactions of the Standing Committee on Budget of the House of Representatives, March 2, 1984, p. 14)

4 Stated by Masao Beppu, Director, Section IV, Cabinet Legislation Bureau (Transactions of the Standing Committee on Agriculture, Forestry and Fishery of the House of Councillors, June 16, 1978, p. 5)

5 The Seeds and Seedlings Law, Section 12-5(2):

"Notwithstanding the preceding subsection, a person referred to in the following paragraphs may perform in the course of business the acts specified in the relevant paragraph:

...

(v) a person who has a patent right on the method of breeding a registered variety, or a person who has an exclusive license or a non-exclusive license with respect to that patent, and who produces the whole or a part of the plant by the method coming under the said patent--acts referred to in each paragraph of the preceding subsection ["working" under the Seeds and Seedlings Law], performed in respect of the whole or a part of the said plant;

(vi) a person who, after the expiry of the patent right referred to in the preceding paragraph, produces the whole or a part of a plant by the method coming under the patent in the said paragraph--acts referred to in each paragraph of the preceding subsection ["working" under the Seeds and Seedlings Law], performed in respect of the whole or a part of the said plant;

..."

6 Diamond v. Chakrabarty, 206 USPQ 193 (1980)

7 Standards for the examination of "New Varieties of Plants" (1975), 3.11(1)

8 Decision of the German Federal Supreme Court (Bundesgerichtshof - BGH) of March 27, 1969, in the "Rote Taube" (Red Dove) case, GRUR 1969, p. 672 et seq. Decision of the BGH of March 11, 1975, in the "Bäckerhefe" (Bakers' Yeast) case, GRUR 1975, p. 430 et seq.

9 Stated by Yuusuke Hiraki, Appeals Examiner, Patent Office, at a symposium on patent protection of new varieties of plants following the enactment of "the Seeds and Seedlings Law" between the Patent Office and the Plant Patents Committee of the Society of Patent Attorneys (Kin'ichi Ikenoya "Plant Patent and Protection of New Varieties of Plants (3)" Patent vol. 32 (1979), No. 3, p. 31)

10 Standards for the examination of "New Varieties of Plants" (1975), 2(2), 3.31(1)

11 Stated by Akira Yonekura, Director-General, Department of Appeals, Patent Office ("Symposium on plant variety protection legislation, in particular on the Seeds and Seedlings Law (I)" Jurist vol. 683 (1979), p. 22)

12 Standards for the examination of "New Varieties of Plants" (1975), 3.11(1), 3.32(2)

13 United States Patent Law, Section 162

14 Decision of the BGH of March 27, 1969, in the "Rote Taube" case, GRUR 1969, p. 674

15 Standards for the examination of "New Varieties of Plants" (1975), 3.332(3)

16 Masami Hanabusa, "Inventions concerning New Varieties of Plants," Tokkyo Kanri vol. 26 (1976), No. 7, p. 690

17 Yuusuke Hiraki, "Concerning the so-called Plant Patent (4)," Tokkyo Kanri vol. 26 (1976), No. 4, p. 328

18 Yuusuke Hiraki, "Concerning the so-called Plant Patent (1)," Tokkyo Kanri vol. 23 (1973), No. 5, p. 510

19 Decision of the Osaka District Court of June 9, 1969, "Precedents in civil administrative case law relating to intellectual property law," vol. 1, p. 160

20 Tetsuo Tomita, "Patent Rights for Plant Varieties," Tokkyo to Kigyo vol. 86 (1976), p. 24

21 Stated by Eiichi Hasegawa, Director, General Administration Division, Department of General Administration, Patent Office ("Symposium on plant variety protection legislation, in particular on the Seeds and Seedlings Law (II)," Jurist vol. 684 (1979), p. 132)

22 Stated by Nobuo Monya (see p. 133 of publication cited in 21, above)

23 see 17, above

24 see 21, above

25 see 2, above

CALENDAR

UPOV Meetings

June 5 to 7 Hanover (Federal Republic of Germany)	Technical Working Party for Agricultural Crops (Subgroup on June 4 at the same place)
June 19 to 21 Aarslev (Denmark)	Technical Working Party for Fruit Crops (Subgroup on June 18 at the same place)
June 25 to 27 Aarslev (Denmark)	Technical Working Party for Ornamental Plants and Forest Trees (Subgroups on June 24 at the same place and at Aars, Denmark)
July 9 to 12 Cambridge (United Kingdom)	Technical Working Party for Vegetables (Subgroup on July 8)
October 14	Consultative Committee
October 15 and 16	Meeting with International Organisations
October 17 and 18	Council
November 12 and 13	Technical Committee
November 14 and 15	Administrative and Legal Committee

Symposia

August 12 to 16 Wageningen (Netherlands)	International Symposium on the Taxonomy of Cultivated Plants

1986

February 17 to 20 Lincoln (New Zealand)	Department of Scientific and Industrial Research (DISR) Plant Breeding Symposium

The International Union for the Protection of New Varieties of Plants (UPOV)--an international organization established by the International Convention for the Protection of New Varieties of Plants--is the international forum for States interested in plant variety protection. Its main objective is to promote the protection of the interests of plant breeders--for their benefit and for the benefit of agriculture and thus also of the community at large--in accordance with uniform and clearly defined principles.

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The International Union for the Protection of New Varieties of Plants
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The price per issue is 2 Swiss francs, to be settled on invoice by payment to our account, No. C8-763.163/0 at the Swiss Bank Corporation, Geneva, or by deduction from the subscriber's current account with the World Intellectual Property Organization (WIPO).