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PLANT VARIETY PROTECTION

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CONTENTS

Page

NEWSLETTER

UPOV

This issue contains the Records of a Symposium on

GENETIC ENGINEERING AND PLANT BREEDING

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GENETIC ENGINEERING: A NEW TOOL FOR PLANT BREEDERS

David J. Padwa*

Summary

Insights deriving from recent developments in biology and biochemistry enable workers in the area of crop improvement to increase their understanding of genetic events at the molecular and cellular levels, instead of being confined overwhelmingly to the level of whole plants and plant populations.

Ultimately, an understanding of fundamental genetic mechanisms will lead not only to more effective plant breeding as practiced in the classical sense, but will also generate a complement of new genetic tools which permit the breeder to synthesize new genomes (both nuclear and cytoplasmic) in a manner and at a rate not previously thought possible. The power of the emerging new genetic technologies, however, depends upon their proper use within the context of sound plant breeding strategies and emphasizes the central strategic role of the modern plant breeder.

In this field we are entering a critical period where applications of the technologies are just now being convincingly demonstrated and where we are achieving a better understanding of some of the limitations which may be inherent in the techniques. If even the more conservative projections of the value of plant genetic engineering hold true, there will be a dramatic impact on world agriculture and especially on the seed industry.

It is indeed an honor for me to address you on the subject of Genetic Engineering here at the headquarters of the International Union for the Protection of New Varieties of Plants.

I myself find that the phrase "genetic engineering" is a troublesome one. If by genetic engineering we mean the use of certain enzymes to cleave or cut certain extra-chromosomal elements in bacteria, the term may have very little to do with plant breeding; if, on the other hand, we use it as a popular synonym to include the whole arsenal of tools that are available to biologists from biochemistry, through molecular and cellular biology, the term is so broad as to be nearly useless and possibly misleading.

But the fact is that the very methods of creating new varieties, as well as the kind of novelty created, may in fact some day exceed the original meaning of the founders of this Organization. The frontiers of genetic science are changing at a noticeable rate and many of the approaches used now in the transformation of single cell microorganisms may be useful in the future for transforming higher organisms and higher plants.

The subject of genetic engineering, unlike say chemical engineering or mechanical engineering, invariably excites a special response in the average person--a combination of curiosity and a certain metaphysical awe that scientists are capable of playing with the basic building blocks of life. It excites latent fears we have of laboratory monsters and of Faustian bargains with the devil.

Actually, molecular and cellular biologists are rather modest persons and the work they are conducting promises to be of major social and, I would say, philosophical importance to humanity. Their work touches upon all living processes, especially the process of reproduction, and certainly extends to the plant kingdom.

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Plants, of course, are in some ways an ideal laboratory subject for the biologist. They can be dissected, smashed, centrifuged, without protest or guilt. Plants nourish our scientific appetites as they do our aesthetic and alimentary appetites. Humanity has been tinkering with plants for the length of its existence and the analysis of food crop fossils is a routine part of archaeology. Some varieties of plants have been so thoroughly domesticated over thousands of years that they could no longer survive as species without annual human intervention. The maize plant is one such common example of genetic engineering of long duration.

The profession of crop improvement is a venerable one, with its roots buried in the prehistoric period. We tend sometimes to forget that time itself is a tool of crop improvement; we occasionally ignore the nearly invisible increments of progress that agriculturalists have made over millenia.

Most of the improvements whose fruits we enjoy today were produced empirically, with very little in the way of scientific explanation. Mythology and aesthetics were the frameworks. Moreover, this vast process of acquiring agricultural knowledge did not proceed under conditions of day to day urgency. The knowledge involved generations, not seasons. There is every reason to believe that the greatest advances in knowledge took place under conditions of leisurely observation rather than panic-driven necessity. Let us not forget that the pumpkin was used as a musical instrument, as a rattle, long before it was used as a foodstuff.

Now it is little more than a century since Gregor Mendel laid the foundations of systematic botany, since Louis Pasteur showed us that there are worlds within worlds, and since Friedrich Miescher first gave name to the substance he called "nucleic acid". From that time to this, in the life of species, has been the twinkling of an eye.

However, we are now living in an age of instant gratification, and we tend to lose sight of the fact that an incremental improvement of say half of one percent annually in crop productivity is cumulatively dramatic over the centuries. We crave much bigger leaps on a year-to-year (even month-to-month) basis. This lust for the dramatic is a folly, and ultimately produces an apocalyptic mentality which, of course, can contribute nothing to the process of developing useful new varieties of plants.

I put it to you that we are being seduced and betrayed by the expressions "Genetic Engineering" and "biotechnology". Those of us who recognize that the sexual life of plants is an archaic subject can continue about our work, and we shall absorb the new findings of biological science in a reasoned manner and with a much truer perspective.

I do not, of course, mean to trivialize the findings of modern biology and the potential they hold for agriculture. The seedsman, after all, is simply selling DNA. He is annually providing farmers with small packages of genetic information, and it stands to reason that advances in our understanding of genetic phenomena are likely to have some major impact on our profession.

Modern biological science seems to permit us to look at plants in a new way, so that we can ask: "how do plants grow?" instead of "how to grow plants." Historically, we have looked at plants in terms of ecotypes and phenotypes. We have worked in the past on the genetics of plant populations. Crop improvement correctly utilized the approach of the whole plant.

Within the last generation we began to focus on various plant organs and tissues and, more recently, on cellular and molecular approaches. It seems clear that the component physiological processes of agronomic or horticultural traits in a plant are a series of biochemical events which are under genetic control. Knowledge in this area assists us in understanding the developmental basis of these events and holds promise of practical utility.

Just possibly, we are entering upon an age when the electrophoresis gel, the chromatograph and the culture flask may begin to substitute for the flower pot, the greenhouse and the field plot. But our ability to move our understanding of plants from taxonomy towards modern experimental science should not deceive us with hallucinations of maize that whistles and radishes that ride bicycles.

Rather than gigantic "breakthroughs" we are likely to continue making gains in crop improvement in an incremental fashion. If we can take the roughly 1 percent annual increase in agricultural productivity which genetics may rightly claim over the last fifty years and increase it over the next fifty years to something as much or as ambitious as 2 percent we shall have done something very remarkable and dramatic indeed. I, for one, believe it will be done.

By referring to agricultural productivity I do not mean to focus exclusively on the tonnage of physical biomass produced per hectare. I think we shall start to focus more on a definition of productivity which relates to the net income of farmers and the use of modern science to reduce the cost of producing food, most notably by genetically displacing various capital-intensive inputs such as chemicals.

Modern molecular and cellular genetics may very likely generate valuable new forms of variability in plants. Typically, these will be seen first in the form of single plants, in single pots. The task of making new and useful products from such developments will continue, in my opinion, to fall upon the plant breeder, the seedsman and the nurseryman. The so-called revolution in the biological sciences intersects and merges with the long and illustrious tradition of crop improvement and cannot do without it.

Continuity of experience will be the key to commercial and practical success in my opinion.

And this mention of commercial success brings us to the question of proprietary rights in the world of crop improvement. As I have said before, crop improvement is an archaic human activity whose very nature is pre-industrial. Even in modern times plant science research has largely been supported by the public sector and private proprietorship in the world of crop improvement is a subject that has been with us only recently, as the membership of UPOV knows full well.

Biological proprietorships do not need a treaty organization and hybrid plants provide a form of economic protection that is actually more effective than the patent system. We should logically expect modern biology to give us new methods of generating and creating hybrids. Obviously they must benefit farmers.

The patenting of plant varieties is only another variation of a global system of intellectual and intangible property protection. At the root of this system lies the concept of supporting a very limited monopoly, the social benefits of which outweigh the liabilities. There are those who detest monopolies in any form (except perhaps where the monopoly is held by a political entity) and who not only think with Proudhon that 'property is theft', but that genetic and/or intellectual property is a theft of the worst kind. There are those who think that the sale of hybrid seeds, which is a form of biological proprietorship, is a crime against nature, but paranoia exists in all cultures. This is not the place to rebut such ideologies. We should be mindful, however, that biologists, and plant scientists in particular, are relatively new to the system of legal rights in intangible property which has served to stimulate invention and has demonstrated its social utility.

There are very obvious economic and social limits to the system of breeders' rights, and the real proprietorships will continue to derive from competitive quality and cost-effective production as well as from a service-based approach to marketing. Modern genetics will actually help the seedsman in reducing the cost and the time required for production and development of new varieties. A system of breeders' and inventors' rights is an intelligent and creative approach to innovation and success in the age-old process of crop improvement.

[Original: English]

THE SCIENTIFIC BACKGROUND OF GENETIC ENGINEERING: CURRENT TECHNOLOGIES AND PROSPECTS FOR THE FUTURE

Robert H. Lawrence, Jr.*

Summary

Plant genetic engineering, in a general sense, is a large array of recently developed genetic technologies which can logically be applied to plant breeding and thus to the development of new plant varieties. These genetic technologies have also been shown to have promise in their application toward improving methods of seed production.

The science that forms the framework upon which these genetic technologies are being built is based mainly in cellular and molecular biology. In the cellular area an experimental basis can easily be traced back to the turn of the century (Haberlandt, 1902, for plant tissue culture and Klercker, 1892, for protoplasts). However, many of the molecular concepts and techniques have been developed during the past decade.

Advances in both areas are now proceeding at a very rapid pace and the two areas are being appropriately utilized in combination to reveal a more fundamental understanding of plant genetics as well as to provide powerful methods of genetic manipulation.

In the cellular area, discussion will focus primarily on the methods of protoplasts, cell, and tissue culture and how these methods are being used in somatic cell genetics to generate somatic hybrids/cybrids, mutants for specific traits, somaclonal variants, etc.

In the molecular area, recombinant DNA technology will be discussed in the context of plant gene isolation, modification, transfer and expression.

In any attempt to adequately cover such a broad topic as the one chosen for this presentation, one must either speak at the rate of a high speed computer or merely attempt to highlight the important aspects of genetic engineering in the context of plant breeding and the seed trade. Fortunately for you and the interpreters I have chosen the latter.

It was my understanding while preparing this presentation that the audience would be composed of technical and non-technical agricultural experts from both the public and private sectors of the seed trade. I have structured my talk to achieve a level of general understanding and must, therefore, request tolerance from those scientists who fear over-simplification. I hope I have judged the audience properly.

It is said that nothing great is ever achieved without enthusiasm. Interest in genetic engineering of plants has generated a surge of new enthusiasm in agriculture. However, when discussing the newly emerging genetic technology within the context of plant breeding, it is essential that we do not get carried away with our enthusiasm. We must instead temper our enthusiasm with a realistic consideration of the practical capabilities <u>and</u> limitations of the technology. Nonetheless, I surmise that hindsight will show that we underestimated the true potential of this technology.

The science that forms the framework upon which genetic engineering technologies are being built is based mainly in cellular and molecular biology. It is not limited to molecular biology. Advances in both areas are now proceeding at a very rapid pace and, in combination, are achieving a more fundamental understanding of plant genetics, biochemistry and physiology. Additionally, and of particular interest to this symposium, these technological advances provide powerful methods of genetic manipulation to the plant breeder in the development of new varieties.

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Let us now briefly examine some of the more prominent current technologies and consider the prospects for the future. In doing this the audience will no doubt generate ideas and questions concerning commercial application to plant breeding and to the protection of intellectual property. This should hopefully generate interesting and productive discussion.

My presentation will focus mainly on the cellular aspects of genetic engineering which I believe are nearer to practical application, with respect to time, than the molecular aspects.

Cellular Biology

In the field of plant cellular biology perhaps no other single development generated more research activity than the ability to culture plant cells and tissues *in vitro*. It is based on a very simple concept, developed by Gautheret in the late 1930's, of culturing and manipulating plant cells and tissues in a fashion similar to that practiced with microbes. Since the early experiments with carrot and tobacco, a large body of knowledge has been compiled that demonstrates the use and value of cell and tissue culture technology for: (1) *in vitro* cloning of plant genotypes; (2) mutation and selection for the generation of new genotypes; (3) protoplast isolation, fusion, and culture to achieve asexual hybridization between sexually incompatible genotypes; (4) generation of new genetic variability via spontaneous somatic cell variation; (5) establishment of host cells for genetic transformation by exogenous DNA; (6) generation of haploids and dihaploids via anther or pollen culture; (7) production of secondary metabolites *in vitro* (which will not be covered in this presentation); and (8) many basic studies in plant biochemistry and physiology. Before examining these cellular technologies and how they relate to plant breeding, let us briefly review a few of the basic components of plant cell and tissue culture techniques.

Plant Cell and Tissue Culture Techniques

Cultures are initiated from cells or tissue excised from a plant, treated in a manner to destroy surface contaminants, and then handled aseptically from that point. Although practically any living plant cell may be used to initiate cultures, the genetic stability of tissues varies and certain ones are more likely to be void of internal contaminants. Generally, the apical meristem is the preferred explant.

Breeding programs that use field selections to establish cultures must rely on intensive field pest management to avoid endogenous microbial contaminants. The explant tissue is placed on an appropriate culture medium, (either liquid or solidified with agar), which contains various nutrient formulations. Hormones are used to control growth. Much of the success in cell culture research depends upon the development of proper media formulations, which many consider an art.

Where cell cultures are desired, media formulations are used to cause a proliferation of cells to grow from the explant tissue in the form of a callus mass. These cells, which are clonally derived from the original tissue, are removed and placed on fresh media every 2 to 4 weeks. This technique allows the tissue to be maintained by subculturing for long periods of time. When liquid media is used, a suspension of cells is formed which is composed of both single cells and cell aggregates (approximately 10^5 to 10^7 cells per milliliter).

The capability to reduce the study and manipulation of plants down to the cellular stage is of obvious value to the fundamental study of plants. However, plant cells possess a unique ability which is in large part responsible for much of the excitement shared by the plant geneticist for this technology. Plant cells in culture demonstrate a phenomena called totipotency. That is, individual cells or groups of cells can be induced to develop into intact plants. This phenomena, which is fascinating to work with in the laboratory, is obviously very significant to applied genetic studies. It permits cultured cells to be manipulated so that intact plant genotypes can be developed for genetic analysis and practical use in breeding programs. Additionally, *in vitro* cloning of plants via cell and tissue culture techniques is now an important method of asexual reproduction.

The regeneration of plants from cells in culture can be achieved via two routes. The first of these, organogenesis, involves the development of shoots from cell masses. These shoots are excised and placed on a rooting medium for the development of intact plants. In the second route, called embryogenesis, somatic embryos are formed from cells in culture which develop in a manner identical in most respects to zygotic embryos in seeds. The induction and regulation of regeneration is primarily accomplished by the manipulation of media factors, especially hormone composition and balance. Regardless of the method of regeneration, the in vitro formed plants must be carefully phased through a hardening-off process in order to withstand greenhouse or field conditions. Depending on the in vitro system and the plant species, normal plants are produced which follow a complete life cycle through to seed production.

In practice, therefore, the in vitro system for plants may involve a full cycle of plants to cells and back to plants. This sequence can be successfully achieved for an ever-increasing number of species, although there are some notable exceptions, such as soybeans which are very difficult to regenerate from established cultures. In addition, a common problem in developing practical and reliable in vitro cloning systems for crop species is that methodologies which work for one genotype may not be effective for another genotype of the same species. This genotype dependency in culture requires a great deal of empirical media tailoring and unfortunately demands a great deal of the research effort in this field. Obviously, a clearer understanding of regeneration mechanisms is needed.

In Vitro Cloning

One of the most obvious and commonly used features of plant cell and tissue culture technology is in vitro cloning or asexual propagation of plants. I will be brief here since so much is written about this topic which is used even now as standard propagation procedure for numerous commercial horticulture operations. There are however, several direct applications of in vitro cloning which will significantly impact on plant breeding and the seed trade.

Seed production from cloned parental lines is particularly attractive for certain crops, e.g., the Brassicas, where maintenance of the parent lines is costly and difficult. As in vitro cloning systems improve, I anticipate that the use of clonally produced parental lines for foundation or commercial seed production will become more widespread. Further, it will influence the types of breeding strategies developed for many different crops. When developing cloning systems for use in seed production, it is extremely important that genetically conservative methods be used to ensure a high degree of genotype fidelity. Considering the current state-of-the-art, axillary bud multiplication is the best guarantee of genetic stability. Recent studies, however, indicate that somatic embryogenesis may also serve as a potential system for achieving genetically stable lines and also represents the more cost effective approach.

Cloning of plants for mass production for direct sale is a second area which may significantly impact on the seed trade in the future. Large scale in vitro cloning is now commonly used for ornamental plants where vegetative propagation is normally practiced. However, it is clear that cloning technology is rapidly advancing to the point that it may become economically feasible to apply this procedure to crops normally propagated by seed. This type of system would require a very high level of multiplication and very low production costs. For this type of application, somatic embryogenesis, one of the two methods of regeneration, is ideal. Large numbers of cells are produced in culture, embryos induced, plated out, and transplants produced. Production technology for such a system would need to address several critical problems related to the biological constraints, e.g. genetic stability, developmental synchrony, and transplant survival.

The economic interest needed to stimulate such an application might involve competition with high priced hand-pollinated vegetable hybrids, or the production of hybrids which are not commercially available due to mating system constraints. The plant breeder would find such a system attractive since breeding could focus primarily on generation of valuable individual genotypes, which would then be reproduced by in vitro cloning.

Somatic Cell Genetics

The experimental capabilities afforded by plant cell culture methodologies now make plant cells amenable to the type of genetic studies common to microbiology. A key step in this process is the ability to develop cell clones and eventually plants from single cells. In successful systems, single cells derived from cell cultures, protoplasts, or gametes (such as pollen) multiply to form a small aggregate clone which may be induced to form an embryo, produce callus or suspension cultures, or to form shoots. Plants derived from these single cells have the potential to maintain the genotype originally represented by the single cell.

The efficiency of scale makes somatic cell genetics an interesting approach for the plant breeder. A small flask of suspension cultures might contain over 100 million cells which, if altered genetically by mutation, would represent a large number of unique genotypes. However, a system that permits desirable genotypes to be selected from these populations requires very high plating efficiencies. These selected mutant or variant colonies must then be efficiently regenerated to form whole plants which can be subjected to genetic analysis to be successfully used in a breeding program.

A distinct advantage of a somatic cell genetics system is the ability to directly select for desirable phenotypes by adding selective pressures to the plating medium. This can be in the form of inorganic or organic compounds (such as high salt or toxins) or by use of environmental constraints (such as high or low temperature). There are, however, some serious problems in the method itself which must be addressed.

Although suspension cultures are commonly used, rarely is a stable suspension culture composed of single cells rather than aggregates. This basic limitation creates difficulties in selecting variant or mutant cells from a population since chimerism of the aggregate may obscure the trait. In addition, there is a tendency for cells in culture to adapt to the selection conditions. This adaptation (as an acquired genetic trait) may be lost in the regenerated plant or not genetically transmitted through seeds. Such traits are often called epigenetic traits and would not be of value in a breeding program.

A second limitation with respect to the selection for useful agronomic traits is that the method is more suitable for simple genetic traits rather than complex multigenic traits, such as yield. The most critical limitation, however, is that selection of traits at the cultured cell level can only be for those traits which are expressed at the cellular level. Not all traits expressed by the whole plant (e.g., tuber size, leaf shape, stalk strength, grain quality, etc.) are expressed in culture. We also have a poor understanding of the genetic components of many whole plant traits. Thus, devising cell selection schemes for these traits is quite difficult. To further complicate the issue, not all traits expressed by cultured cells are expressed by the whole plant.

All is not bleak, however. Successful generation of new genotypes with specific traits is achievable. Notable examples of such traits are salt tolerance, herbicide resistance, pathogen toxin resistance, and nutritional quality. With further development of techniques and a better understanding of the biochemical and genetic mechanisms of plant traits, we can anticipate that somatic cell genetics will become a common and important tool for the plant breeder.

Somatic Cell Hybridization

In plant breeding, sexual hybridization is used for crop improvement by generating new gene combinations which can then be manipulated and evaluated according to established breeding procedures. The main limitation to sexual methods of crossing is interspecific and intraspecific incompatability. Since valuable gene pools exist in wild or related species it is important to establish methods of circumventing the sexual barriers. Somatic cell hybridization by protoplast fusion has been shown by many laboratories to be a solution to this problem and represents a powerful means of introducing new genetic information into a species.

Protoplasts are cells stripped of their cell walls and consist of protoplasm bounded by the plasmalemma or cell membrane. They are isolated from plant tissues (most commonly leaf tissue or cell cultures), by enzymatically digesting the cell wall in a medium containing cellulase, hemicellulase, and pectinase. Following wall removal the protoplasts are filtered and washed to remove debris and the enzymes. The isolated protoplasts may then be either directly cultured by suspension in a growth medium or fused with protoplasts from another preparation, perhaps from another species or another genus. The latter is achieved by adding a fusogen (fusion inducing agent) to the medium. Polyethylene glycol in the presence of a high concentration of calcium ions is one example; electrical induction of cell fusion is another.

In the presence of the fusogen, physical contact occurs between the cell membranes followed by a loss of membrane continuity along the area of agglutination. This forms one cell containing the two nuclei (which also may fuse) and a mixture of the two cytoplasms. The latter event, cytoplasmic mixing, is unique to somatic cell hybridization. It represents perhaps the most critical aspect of cell hybridization technology. Sexual hybridizations are uniparental pairings, with the maternal parent contributing the cytoplasmically inherited genes, contained in the mitochondria and chloroplasts. In the biparental combining of cytoplasms from cell fusions, new combinations of nuclear and cytoplasmic genomes can be created and genetic recombination of organellar genes may occur.

Fused cells are called homokaryocytes if both are from the same genotype; and heterokaryocytes if fusion partners are from different genotypes. Where fusion occurs to form a mononuclear hybrid cell, the term synkaryon is used. Cybrids are formed when an enucleated protoplast (one from which the nuclear genome has been removed) or a subprotoplast (one that does not contain a nucleus) is fused with another protoplast. A cybrid thus has the nuclear genome of one parent and the cytoplasms of both parents.

Following fusion, the protoplasts are grown in an enriched medium which induces cell wall formation and cell division leading to the development of an aggregate from which callus or cell suspensions can be developed, which will hopefully form a regenerated plant. The sequence from fused protoplasts to plant is difficult to achieve in many species, especially the cereal crops, but is essential if the practical value of somatic hybridization is to be realized.

Selecting the heterokaryocytes or somatic hybrid plants from the population of homokaryocytes and parental lines is achieved by either visual/physical means or by growth characteristics based on genetic or physiological complementation. Recently a procedure was developed which uses fluorescent-activated cell sorting to select heterokaryons containing the two distinct fluorescent labels of the parent lines.

The number of plants fused from somatic cell hybridization that have been successfully grown and genetically characterized is quite small and concentrated in the solanaceous species. The major limiting factors relate to the difficulty of regenerating plants from protoplasts and in the chromosome instability resulting in the variable loss of chromosomes. However, based on reports to date, somatic cell hybridization may indeed offer a unique method of nuclear gene introgression and will probably find early commercial value in the manipulation of cytoplasmic genetic elements such as those involved in cytoplasmic male sterility.

Somaclonal Variation

Many of the uses of plant cell and tissue culture discussed to this point, rely on genetic stability. The appearance of genetic variability in culture, called somaclonal variation, would appear to be undesirable and to need to be controlled or avoided. Recently, however, somaclonal variation has been recognized as a valuable source of variation with commercial value, e.g. as demonstrated for sugar cane and potato. In potato, numerous plant clones established from protoplasts, called protoclones, were observed to possess a wide range of variability for yield, disease resistance, and other traits. Similar types of studies involving protoclones or clones generated from cell cultures, suggest that some of the variation may pre-exist in the original explant tissue. The majority of the variation, however, is induced in some way by the culture process itself. Indeed, some media are even suspected of being mutagenic. The genetic mechanisms responsible for this variation are not well documented. Suspected mechanisms are: karyotype changes, chromosome rearrangements, transposable elements, gene amplification, and somatic crossing over. When combined with a rapid method of selecting and screening for agronomic traits, somaclonal variation may add still another tool to assist the plant breeder in generating a broader array of genotypes for particular applications.

Dihaploids from In Vitro Culture of Anthers and Pollen

The use of haploids and dihaploids is not new to plant breeders and geneticists who have for many years found applications in genetic studies and examined their potential for accelerating breeding programs. Recent advances in the generation of large numbers of haploid and dihaploid plants from anther cultures and microspores of various crop species have stimulated a much closer examination of dihaploid breeding theory.

The generation of homozygous lines by haploid doubling has application to self-pollinated crops for rapid pure-line development and for inbred-line development for hybrids of cross-pollinated crops. The value of these applications in plant breeding, however, is highly dependent on the particular crops and breeding strategy employed. Perhaps Mr. Rives will address these matters in his presentation.

Applications of Molecular Biology

The methods of genetic modification that we have discussed so far have obvious near-term applications in plant breeding. They seem crude, however, in comparison to the more precise techniques which are being developed in molecular biology. A detailed description of the various molecular techniques, based in large part on recent developments in recombinant DNA technology, will not be attempted in this presentation. In brief, however, these methods comprise molecular techniques to identify and purify genes from one organism and to prepare them for transfer to another organism, which is then transformed with the isolated genes. This ability to manipulate DNA was made possible by the discovery of several classes of enzymes, perhaps the most useful being the restriction endonucleases, which have the ability to cut double-stranded DNA at particular nucleotide sequences, resulting in a series of well-defined pieces which have sticky ends. These pieces of DNA, perhaps containing a gene of interest, can be covalently linked in the presence of the enzyme DNA ligase with other DNA molecules containing similar sticky ends. Using these and other enzymological tools such as DNA polymerase and reverse transcriptase, it is possible to construct, or engineer if you wish, vectors in the form of plasmids containing specific genes. These vectors are used to transfer the genes to a host cell which, for this presentation, would be a plant cell in culture or perhaps a protoplast.

These molecular techniques are rapidly advancing our understanding of the molecular basis of genetic events. On a practical level, however, molecular techniques have led to the ability to transfer specific genes from one organism to another. Transformation of plant cells by insertion of foreign genes is still in the "model system" stage. For broad application to crop plants several important areas of research must be developed. Plant genes selected for manipulation must be identified and isolated to permit detailed molecular characterization, including an understanding of the regulation of expression of the gene. Transfer vectors containing the gene of interest must be developed which can reliably transform the plant host cell. Stable integration of the transferred gene into the host genome must occur in a manner that does not interfere with the expression of essential host genes and that permits the proper expression of the transferred gene. The host cell system must be one that, following transformation, is capable of regenerating plants which retain the transferred gene. Sexual transmission of the gene is the final requirement and allows standard breeding procedures to be used to further exploit the use of the inserted gene.

A plant transformation system which meets all of the requirements has yet to be developed. A pessimist would say we have a long way yet to go. I believe we have come a long way. Reliable gene transfer systems for plants are inevitable. Their proper use, along with cellular genetic technology, adds an awesome perspective to the power of modern plant breeding.

In concluding, I would like to acknowledge the success of plant breeders throughout the world in applying genetic sciences in combination with those difficult-to-describe intuitive abilities that have significantly advanced the field of crop improvement. Their work has lightened the burden of satisfying daily nutritional needs for many of the world's people. The challenge of crop improvement, however, is like our appetite--it will be there day after day and must be constantly nourished with new contributions evolving from the research laboratory. These contributions, however, will only have impact through the close collaboration between the plant breeder and the research scientist. Efforts to enhance this collaboration should be a high priority for both the public and private sectors of agriculture.

[Original: English]

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Having delivered the above lecture, Dr. Lawrence indicated his willingness to receive any immediate questions arising from it.

A report of the questions asked and answers given is reproduced below:

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Dr. Böringer said that, although he was no specialist in that field, he had two very technical questions to put. The first concerned somatic hybridization. He was interested to know why, as explained by the lecturer, it was more difficult to achieve fusion of the somatic cells in some species than in others. That was his first question.

Dr. Lawrence replied that the problem was neither in the isolation nor in the fusion of protoplasts. As far as he was aware all plants could be used for the isolation of protoplasts and the enzymes used to remove the cell wall were effective on all plant cells. Once one had the naked cells and put the fusogen in the culture media, any cell could readily be fused. Regenerating the cell wall and then establishing a culture that could be regenerated into a plant from that clone of cells, however, did pose problems. It was particularly unfortunate that, in that respect, the cereal crops, which provided food for such a large part of the world's population, were one of the most difficult groups of plants to deal with. The legumes had also been very difficult to work with as far as regeneration was concerned. One of the most readily cultured plants at the cellular level, for example, was the soya bean. It grew very fast, and was very easy to manipulate at the cellular level, but it was extremely recalcitrant to regeneration. The possibilities for using somatic cell hybridization as a method of crop improvement for such species were currently limited. However great strides had been made and to stay within the boundaries of Switzerland, Ingo Potrykus and his colleagues at the Friedrich Miescher Institute in Basel, for example, had made great advances with maize and the regeneration of certain genotypes from protoplasts.

Dr. Böringer spoke again to put his second question in respect of tissue culture. The lecturer had reported that problems also arose for differing genotypes of the same plant variety. It would be interesting to learn whether the reasons for that were known. He was aware that in some species the proportion of mutations varied when using tissue culture. He wondered whether there existed background information that would explain the phenomenon.

Dr. Lawrence replied that there was a great deal of background information, but not enough. He could give two examples. In maize, there were certain inbreds used in the production of hybrids, which could be established in culture and regenerated readily. There were very closely related inbreds that crossed readily with those inbreds, but did not readily form plants in culture. Why that should be so was not well understood. In tomato, however, for certain genotypes the capability to regenerate in culture was obviously related to the level of endogenous hormones in the plant tissue. Plants containing obviously high levels of auxins regenerated more readily under certain media conditions. There was a real need to understand the genetic basis of regeneration. Although it was an extremely difficult mechanism there were some exciting model systems. The celery and carrot systems that he had described were systems where a cell suspension could be induced to form embryos in just a few days. It was possible by a hormone change to set off a series of developmental events leading to embryos. It was to be hoped that investigation of those that did not regenerate might lead to an understanding of the genetic mechanisms involved. It was obviously a serious limitation to the use of somatic hybridization to have one genotype that generated plants well, while the other did not. When protoplasts from those two genotypes were fused one might not get regeneration. That risk limited the gene pool to which the technology gave access.

Professor Kåhre said that he would first like to thank Dr. Lawrence very much for a most interesting lecture and survey. Secondly, he wished to state that the International Board for Plant Genetic Resources (IBPGR) was very much interested in the technology described by Dr. Lawrence. Last year, it had set up at the international level a special tissue culture working group, which had recently met in the United States of America. IBPGR looked forward to the implementation of that group's recommendations, for example, in relation to biochemical markers and disease indexing. IBPGR had two specialists in those fields, Dr. de Langhe from Belgium and Dr. Peacock from Australia. All germplasm had to be well described. That was a matter of great interest to both IBPGR and UPOV. IBPGR considered that its work with descriptors was only a start and that sooner or later gene symbols would be needed. Work on the genic and biochemical levels would probably have to be accelerated. Priorities were under continuous review in an effort to keep pace with developments. IBPGR would very much welcome thorough collaboration from all sides.

Mr. Jenkins, noting the difficulties that were experienced in protoplast regeneration in cereals, asked Dr. Lawrence whether he would like to comment on the possibilities of micro-injection of DNA into the egg nucleus.

Dr. Lawrence said that one way of circumventing the difficulty experienced in forming cell walls from cereal protoplasts was to only partially digest the cell wall in the first place. In that way it was possible to preserve a framework for the cell wall to recomplete itself. Organelles from other plants, or perhaps another protoplast, or perhaps isolated exogeneous DNA, could then be introduced into the partially stripped protoplast, either by micro-injection or by some other physical method. Work in this area was being done at Stanford University in the laboratory of Dr. Walbot. Some other interesting methods were being investigated, but he would not go into more detail since the Symposium was principally concerned with intellectual property rights.

Dr. von Pechmann took up Dr. Lawrence's remark that considerable success had already been achieved in that field. He had a very simple, if not to say primitive, question in that respect which was whether that success had already led to new breeding results, whether a new tomato variety or a new cereal variety had already been bred in practice using those methods, with characteristics that were better than those of varieties produced by traditional methods such as crossing.

Dr. Lawrence said in reply that there were numerous examples, but they were at different levels of development to that of a commercial hybrid or a commercial variety. He wished to cite the work of Dr. Shepard at Kansas State University. Dr. Shepard had used the system of potato proto-cloning to develop a wide range of variability in that normally vegetatively propagated plant. Numerous genotypes expressing variant traits had been tested extensively with breeders and with plant pathologists, and several new genotypes or varieties were being developed. Before they could be released, however, they would have to be tested for a long period. Dr. Lawrence said he thought that perhaps that pointed to a very important aspect of such work. New genotypes developed by such techniques would not be overnight successes, except perhaps in the laboratory, because the farmer needed a reliable genotype, proven under a wide range of conditions to express, for example, a trait for resistance to a pathogen. Dr. Shepard's work was, however, a particular example where a great deal of promise had been shown.

Professor El-Fiky said that from his own experience, particularly in grapes, there were many problems attached to the use of somatic embryogenesis techniques, such as abnormality of the somatic embryo formation and genetic instability inside cell suspensions. He thought that further academic studies about the reasons for genetic instability inside cell suspensions would be helpful, before extending the application of those techniques.

Dr. Lawrence remarked that Dr. Indra Vasil at the University of Florida had reported on the use of somatic embryogenic systems with cereals. According to the results of field tests the material produced had shown itself to be extremely genetically stable with high phenotype and genotype fidelity. Dr. Lawrence said that some of his own studies with celery had indicated that somatic embryogenesis, if properly approached, represented a genetically stable method of reproducing or cloning a specific genotype. Much depended on the methods of multiplying the cells in culture rather than on the genetic stability of the original explant tissue. Dr. Vasil, for example, had been able to isolate, on the basis of the morphology of the cells, some cell lines that were genetically stable and formed embryos, and others that were faster growing but that were genetically unstable and did not form embryos. Dr. Lawrence agreed that caution was needed in the use of somatic embryogenesis as a means of mass cloning, especially if the cloned plants were to be used as parents for hybrids. Then, genetic stability and high genetic fidelity were essential. In the production of plants for direct use, however, such as cloning a hybrid lettuce plant, some lack of phenotype stability could probably be afforded, since what was being looked for was an overall increase in population uniformity and population performance.

INTELLECTUAL PROPERTY ASPECTS OF PLANT VARIETY GENETIC ENGINEERING: VIEW OF AN AMERICAN LAWYER

Sidney B. Williams, Jr.*

Summary

The nature of modern genetic engineering technology both in general application and application to plant varieties will provide many real challenges for the intellectual property lawyer. These include input as to whether or not protection should be sought under specific plant variety protection laws, general patent laws or the law of trade secrets. In making the decision of what form of protection should be sought there must be a determination of what is the important invention; i.e. the variety, a genetic component, a vector system or a specific breeding technique and combinations thereof.

Another challenge will be the drafting of agreements that clearly define the rights and obligations of the parties during their relationships with each other. Such relationships include those between universities, governments and private industry and those between employers and employees.

Finally, because of the newness of and controversy surrounding some of the technology and the fact that it can be utilized in helping produce the world food supply, intellectual property lawyers will have a role in the development of socio/economic policy considerations.

I. INTRODUCTION

I am here today to give you an American lawyer's view of the Intellectual Property Aspects of Plant Variety Genetic Engineering. It seems appropriate to characterize my comments as a "view" because of the relative newness of the

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technology and the corresponding absence of case law, outside of the Chakrabarty case, about which I will have more to say later, and of other legal precedents in this field.

Even before the emergence of the new technology there was and still is very little in the way of legal precedents relating to the protection of plants. I should further like to refer to this technology as the new genetic engineering because plant breeders are genetic engineers by definition. Of course, the new genetic engineering on plant varieties involves a combination of traditional plant breeding techniques with the relatively new developments in molecular biology, tissue culture and recombinant DNA.

Does the application of the new technologies to plant breeding and production present different "intellectual property" legal problems than the traditional technology? This is a query I wish to explore with you during my comments. In an attempt to answer this question, I have divided my presentation into the following areas:

Protection of Plant Varieties in the United States of America

The Impact of Modern Genetic Engineering

Subject Matter for Protection

Industry/University/Government Relations

II. PROTECTION OF PLANT VARIETIES IN THE UNITED STATES OF AMERICA*

In the United States of America there are two statutes that provide specific patent-like protection for plant varieties. They are the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. In addition, the case of Chakrabarty v. Diamond, decided by the Supreme Court in 1980, suggests the possibility of protecting plant varieties under the general patent law. Trade secret law, which evolved from Court decisional law, offers a fourth alternative for the protection of plant varieties. The importance and implications of each mode of protection will be discussed in this paper.

A. Plant Patent Act

History and Purpose of the Plant Patent Act - The original Plant Patent Act,[1] the Townsend-Purnell Act, was enacted in 1930. The Act, as originally passed, provided patent protection for plants that are asexually reproduced. It was amended in 1953, when the general patent law was codified[2], to provide protection of newly found plants in a cultivated state.

Standards of Patentability - For plants to be patentable under the Plant Patent Act, they must be novel, distinct, unobvious and asexually reproducible. An excellent discussion of the standards of patentability is contained in Yoder Bros. v. California-Florida.[3] Also see a paper presented by Byrne.[4]

Distinctness - Characteristics that have been utilized to establish distinctness include "habit", "immunity from disease", "soil condition", "color", "flavor", "productivity", "storage qualities", "perfume", "form", and "ease of asexual reproduction".

Unobviousness[5] - Unobviousness as it relates to plants appears to depend upon a characteristic being totally different from that found in similar existing varieties or upon the magnitude of the differences between a characteristic and that found in similar existing varieties. In suggesting how the standard of unobviousness might be applied to a plant variety, the Court in Yoder[6] relied upon the concept of invention. In analogizing the plant patent application with those relating to chemical compounds the Court equated invention with an unexpected change in characteristics as follows:

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* This portion of my comments is a modified version of parts of an article prepared for the "European Intellectual Property Review" (EIPR). See Securing Protection for Plant Varieties in the USA, Williams, Vol. 3, Issue 8 of EIPR (August, 1981).

"...If the plant is a source of food, the ultimate question might be its nutritive content or its prolificacy. A medicinal plant might be judged by its increased or changed therapeutic value. Similarly, an ornamental plant would be judged by its increased beauty and desirability in relation to the other plants of its type, its usefulness in the industry, and how much of an improvement it represents over prior ornamental plants, taking all of its characteristics together."[7]

Asexual Reproduction - Asexual reproduction, which includes tissue culture, has always been a requirement of the Plant Patent Act.[8] When the law was enacted it was felt that the only way to insure reproduction true to form, was asexually. However, this feeling has changed as is made evident by enactment of the Plant Variety Protection Act, which provides for protection of plants reproduced sexually (by seed).

Plants Excluded from Protection - The term "plant" in the Act is used in its common usage and not in a strict scientific sense, and therefore does not include bacteria.[9] Tuber propagated plants are excluded from protection.[10] It would seem that any number of plants would fall under this definition; however, the only varieties to date affected by the exclusion are Irish potatoes and Jerusalem artichokes. Efforts have been made in the past to remove the exclusion,[11] and they will no doubt continue in the future.

Plants may also be excluded on the basis of the environment in which they are discovered. For example, if seedlings are found in a cultivated state they are protectable; if in an uncultivated state, they are not protectable.[12 13]

Content of a Plant Patent Application - The application must be filed in duplicate. If the Patent and Trademark Office wants a report regarding the novelty and distinctness of the variety in question,[14] it will send the second copy to the Agricultural Research Service Unit of the Department of Agriculture. A plant patent application must contain the same parts contained in a utility patent application; namely, a petition, specification, claim and oath.[15] However, there are some differences between what is required in the two types of applications as will be pointed out below.

The specification must contain as complete a description of the plant as reasonably possible but it does not have to meet the enablement and disclosure requirements of the general patent statute.[16] Breeding history should be disclosed when known. If the plant was reproduced by seed and only then reproduced asexually, the name of the seed parent and pollen parent should be disclosed. If it is a newly found plant the location and character of the area where found should be clearly described.[17] Also, the method of asexual reproduction should be disclosed. As a result of the recent adherence of the United States of America to the Convention administered by the International Union for the Protection of New Varieties of Plants (UPOV), the application must set forth the variety denomination.[18]

It is extremely important that the plant's characteristics and its differences from existing varieties be described and that ample information be supplied to allow a comparison of the characteristics with those of existing varieties.[19] If color is an important characteristic of the plant, the drawing must be in color and the color designated in the specification.[20] In designating colors, reference may be made to recognized color charts or dictionaries.

Only one claim is allowed in the application, whereas general patent applications may contain a multiplicity of claims.

The oath must contain an averment that the applicant has asexually reproduced the plant for which a patent is being sought.[21] Therefore, there can be no constructive reduction to practice under the Plant Patent Act.[22] Also, a statement that the plant was found in a cultivated state must be contained in the oath if it was newly found.[23] The latter statement is necessary because 35 U.S.C. 161 excludes protection of plants found in an uncultivated state.

Scope of Protection - A plant patent gives its owner the right to prevent others from asexually reproducing the patented plant and/or selling or using the plant so reproduced.[24] However, the question of whether derivation is an element of plant patent infringement remains an unsettled issue.

There is a line of cases that support the proposition that the infringer of a plant patent must not only copy the plant but must also derive the copy from patentee's stock.[25] Dicta in Pan American Plant Co. v. Matsui,[26] however, support the proposition that derivation is not required.

To date, the Plant Patent Act has been used primarily to protect ornamental plants. However, there are many food crops protected by plant patents.

B. Plant Variety Protection Act

History and Purpose of the Plant Variety Protection Act - The Plant Variety Protection Act of 1970 provides patent-like protection in the United States of America for the latest legislatively-recognized form of intellectual property (plants reproduced by seed).[27] It represents the culmination of an effort by many people in the seed industry to provide incentives for private industry to conduct research and breed novel varieties from seeds.

The Plant Variety Protection Act is modeled along the lines of our patent laws and is similar to many of the plant breeders' rights laws of Europe. Its purpose is to promote progress in agriculture by providing plant breeders with a limited exclusive right on new sexually reproduced plant varieties in exchange for the plant breeders' disclosure of the variety and how to reproduce it.[28]

Standards of Protectability - Standards of protectability are set forth in Section 2402(a) of the statute.[29] They are novelty and sexual reproduction.

Novelty - To meet the standard of novelty, a variety must (1) not be barred by any of the activities set forth in Sections 2402(a)(1), (a)(2) and (a)(3);[30] and (2) be distinct, uniform and stable.[31]

(1) Novelty Defeating Activities

(a) The variety was a public variety before the applicant's date of determination, being the date at which the applicant himself considered the variety to be distinct, uniform and stable.

(b) The variety was a public variety more than one year before the application.

(c) Available to workers and described in a printed publication in this country before the applicant's date of determination.

(d) Available to workers and described in a printed publication in this country more than one year before the application for plant variety protection.

(e) Applicant or his proxy filed for protection in a foreign country for same variety more than one year before filing in the United States of America. This provision is similar to 35 U.S.C. 102(d), except that it does not require that the foreign application has materialized into a patent.

(f) Another breeder has an earlier date of determination and has either obtained a plant variety protection certificate, has been continually engaged in development for commercialization, or has published a description of the variety within six months of the date of determination.[32]

This provision is similar to 35 U.S.C. 102(g), since it requires that the breeder with the first date of determination take steps to show that there is no intent to abandon, suppress or conceal the variety.

The one year statutory bar may be extended by the Secretary of Agriculture for a reasonable period of time.[33]

(2) The other components of novelty, distinctness, uniformity and stability are defined in Section 2401(a).

To the writer's knowledge there have been no court interpretations of the term "distinctness" under the Act. However, based upon legislative history and a definition adopted by the Court in the Yoder case (a plant patent case),[34] whether or not a distinctive characteristic is superior or inferior to those of existing varieties is immaterial.

Sexual Reproduction - Sexual reproduction (by seed) is another standard of protectability.

Varieties Excluded from Protection - First generation hybrids, fungi and bacteria are not eligible for protection.[35] Before the 1980 amendments went into effect, six species--okra, celery, tomatoes, peppers, carrots and cucumbers--were excluded from protection under the Act.[36]

Filing the Application

Where to File - Applications for a Plant Variety Protection Certificate are filed with the Plant Variety Protection Office in Beltsville, Maryland. This office is a unit of the Livestock, Poultry, Grain and Seed Division, Agricultural Marketing Service of the United States Department of Agriculture.

Fees - The cost for the filing, examination and issuance of a Plant Variety Certificate is presently $750.

Content of Application[37] - An application for a Plant Variety Protection Certificate consists of a completed application form (OMB No. 40-R3822) and accompanying affidavits. These forms, requiring the following information, can be obtained from the Plant Variety Protection Office.

1a. Temporary designation of variety
1b. Variety name
2. Kind name
3. Genus and species name
4. Family name (botanical)
5. Date of determination
6. Name 7. Address 8. Telephone number
9. Form of applicant's organization, if not a natural person
10. State of incorporation
11. Date of incorporation
12. Name and mailing address of applicant's representative before the Plant Variety Protection Office
13. List of exhibits submitted
14a. Whether or not the variety is to be sold by variety name only as a class of certified seed
14b. Whether variety is to be limited as to number of generations
14c. Number of generations limited beyond breeder seed
15a. Statement as to whether applicant has filed for protection of variety in other countries[38]
15b. Statement as to whether foreign rights have been granted on variety
16. Whether applicant agrees to have name and address published in Official Journal
17. Declaration that viable sample of seed will be furnished with application and that sample will be replenished upon request; statement that variety meets conditions of 7 U.S.C. 2401 and that applicant is entitled to protection provided by 7 U.S.C. 2402[39]

Term of Plant Variety Protection - When originally enacted in 1970, the term of protection was set for seventeen years. However, recent amendments to the Act increased the term to eighteen years.[40]

Priority Contests - There are three procedures set forth in the Plant Variety Protection Act for handling applications simultaneously submitted and covering the same variety.[41]

The Plant Variety Protection Office may:

(1) initiate a priority contest; the proceedings will be similar to those under 35 U.S.C. 135 (Interference Rules--interferences are used to determine inventorship in conflict patent situations) and are governed by Rules 180.205 to 180.222 of the Rules of Practice;

(2) issue a certificate on the application having the earlier filing date; or

(3) issue a certificate naming alternate owners; if two certificates for the same variety are issued to different parties, either party may seek determination of the true owner by civil action.[42]

Reexamination - The Act provides for reexamination of an issued certificate if written notice setting forth facts which may affect the protectability of the variety is filed with the Secretary of Agriculture within five years after issuance of the certificate.[43] This section is analogous to the Patent Reissue[44] and Reexamination[45] provisions, except that it is not applicable for the full life of the certificate. Under this provision, the Plant Variety Protection Office is authorized to conduct interparty hearings.[46]

Scope of Protection - A plant variety protection certificate gives its owner the right to prohibit others from selling or offering the variety for sale, importing or exporting it, sexually multiplying it for marketing, using it for producing another variety, and inducing others to perform any of the infringing acts.[47] Most of these acts are similar to acts that would constitute infringement under the patent laws. There are, however, differences between the plant variety protection and the patent laws. The major one is that acts of infringement can occur under the Plant Variety Protection Act prior to issuance of the certificate. Specifically, the statute states that the acts outlined in Sections 2541(1) through 2541(8), if performed by others after the novel variety has been distributed with notice required under Section 2567, constitute infringement.[48]

The Grandfather Clause - If another breeder develops the protected variety more than one year prior to the time the certificate holder files his application, that other breeder cannot be prohibited from reproducing and selling the variety.[49] This Grandfather Clause is similar to rights granted to prior inventors under patent laws in many European countries.

Other uses of the variety that are excused from infringement are those falling under the Seed Saving and Crop,[50] Research[51] and Intermediary Exemptions.[52]

The heart of the remedy afforded by a plant variety protection certificate is the right to keep others from using or selling the variety for reproductive purposes. Even though the statute only provides protection for sexually reproduced varieties, it is an infringement to perform any of the acts enumerated in utilizing an asexually reproduced version of the variety, except when the act is performed in pursuit of a valid plant patent.[53]

The Plant Variety Protection Act has a compulsory license provision that can be invoked when "the Secretary determines that it is necessary to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair."[54]

Effect on the Plant Variety Protection Act of the Adherence of the United States of America to the UPOV Convention - At the present time the Plant Variety Protection Act does not contain all of the UPOV Convention novelty provisions. The UPOV Convention prohibits the protection of a variety if it has been sold or marketed in a foreign country more than four years prior to the time an application for protection has been filed. This type of provision is not presently in the Plant Variety Protection Act.

C. General Patent Statute[55]

35 U.S.C. - In Chakrabarty v. Diamond, the United States Supreme Court held that the patenting of an invention is not prohibited merely because the invention consists of a life form.[56] This decision provides a basis for seeking protection of plants under 35 U.S.C. 101. The argument for seeking protection under 35 U.S.C. 101 is particularly compelling in the case of plants excluded from protection under either the Plant Patent Act (tuber-propagated plants), or the Plant Variety Protection Act or in the case of hybrids of varieties that are not readily reproduced asexually.[57]

At least two general patents covering plant products have been issued by the Patent and Trademark Office. These patents were issued prior to the Chakrabarty case. However, the United States Patent and Trademark Office has indicated that it will grant general patents on sexually reproduced varieties if they meet the general law's standards of patentability. In this regard it should be noted the United States Department of Agriculture does not feel that Chakrabarty provides a basis for granting general patent protection for plant varieties.

A process utilizing genic male sterility in the production of hybrid maize is described in United States Patent 3,861,079. The patent contains product-by-process claims but it also contains a product claim that has no process limitation which reads as follows:

> "An isolated stock of maize seed which upon growth yields a population of maize plants displaying genic male sterility in a proportion to the total plant population greater than would, owing to the recessive character of the genic hereditary factor responsible for the display of such male sterility, occur naturally, said stock having a greater than 50 percent proportion of maize seed homogeneous for male sterile alleles at a selected male sterile gene locus."

United States Patent 4,143,486 contains product-by-process claims to hybrid wheat. Product-by-process claims are utilized when the product can only be adequately described by reciting the process utilized to prepare the product. Both of these patents contain detailed descriptions of how to breed the varieties.

For a variety to be patentable under the general patent statute it must be useful, novel and unobvious. In addition, the application for it must meet the disclosure requirements of 35 U.S.C. 112.[58] The utility requirement should present no problems since most plant varieties for which protection is sought are either ornamental or useful for producing food or fiber. The novelty requirements are identical to those for plant patents.[59]

Unobviousness, unlike novelty is not absolute, and therefore its application requires an analysis of the prior art, the difference between the prior art and the invention, and the level of skill in the art. Such an analysis was made in the Yoder case.[60] Thus establishing unobviousness, which is similar to the European Patent Law concept of "Inventive Step" will be limited only by the imagination of the plant breeder and his lawyer.

Satisfying Disclosure Requirement of the General Patent Statute - Unlike provisions in the Plant Variety Protection Act and the Plant Patent Act (which require that applicants only describe how to produce their varieties to the best of their ability), a utility patent will require a complete description of the variety and how to breed it. The following approach is suggested for complying with the disclosure requirements of 35 U.S.C. 112.

If the analogy between patents on microorganisms and plants is valid, it is probable that the disclosure requirement can be met by depositing propagating material at a public depository.

Seed could be deposited at a public depository in a manner similar to those cases involving microorganisms.[61] In the case of hybrid varieties reproduced by seed, the specification should state that samples of the seed parent and the pollen parent have been deposited at a depository and contain a description of how the two parent seeds are bred. If a non-hybrid variety is involved, only the seed for which protection is being sought need be deposited. Still another method of meeting the disclosure requirement for a nonhybrid would be to place the variety on sale prior to filing the case.

If the variety is capable of being reproduced asexually (cloned) the specification should (1) state that a sample of the propagating material has been deposited at an appropriate depository before or at the time of filing of the patent application, or (2) contain a description of the technique for accomplishing the asexual reproduction. It should be mentioned that plans have already been developed for providing depositories for propagating material for some vegetatively reproduced varieties.[67] However, it is not certain that they will be available for storing varieties covered by patents.

If a plant is reproduced by breeding commercially available varieties, the varieties and where they can be obtained should be set forth in the specification in the same manner that the starting materials utilized for preparing chemical compounds is set forth in chemical applications.

Advantages of Patenting Plants under 35 U.S.C. 101

General Patents v. Plant Patents - The use of general patents for the protection of plants would seem to be especially appropriate now that modern genetic engineering and recombinant DNA are being applied more and more to breeding and production of plants. While there is a question as to whether derivation is an element of plant patent infringement, it is probable that derivation would not be an element of infringement of a general patent containing claims to a variety. Also, protection would not depend upon the method of reproduction as is the case with both plant patents and plant variety protection.

The use of general patents will also afford the opportunity to claim multiple forms of and subcombinations of the plants. For example, one could claim the seed, the whole plant and/or parts of the plant such as the fruit and/or leaves in the same application. In addition, the possibility of claiming multiple varieties in a single patent could be advantageous in reducing expenses resulting from maintenance fees.

General Patents v. Plant Variety Protection - Protection of hybrids and fungi is available under 35 U.S.C. 101 and not under the Plant Variety Protection Act. Also, the protection of seeds and varieties reproduced thereby under 35 U.S.C. 101 provides a basis for UPOV participation of sexually reproduced varieties since 35 U.S.C. 102 novelty provisions are compatible with UPOV Convention novelty provisions.

The Plant Variety Protection Act does not provide for the protection of multiple varieties by a single certificate.

Moreover, in interpreting general patents courts can apply a principle called "The Doctrine of Equivalents."[63] Under this doctrine an invention that is not identical to that covered by the patent in question, can nevertheless be held to infringe if it does the same thing in substantially the same manner as the patented invention. This doctrine, while applied frequently in mechanical infringement cases, has also been applied in chemical cases. The leading decision is the Graver case.[64]

Disadvantages of Patenting Plants under 35 U.S.C. 101

Disclosure requirements for obtaining both plant patents and plant variety protection certificates are less stringent than those for obtaining a utility patent. Some may consider it an advantage to utilize the plant variety protection route since there is no unobviousness standard to meet. It also could be argued that granting general patent protection would be contrary to Congressional intent since there is no farmer's or research exemption in the general statute. There is, however, a narrow judicial doctrine of experimental use in general patent law.

D. Trade Secret Law

Except for laws that deal with the submission of data and other information to the Federal Government there is no Federal legislation in the United States of America that provides protection for trade secrets. Consequently, the law governing the protection of secret proprietary information is based primarily upon State law. Over the years, there has been a continuing debate as to whether State trade secret law is preempted by Federal patent policy. However, the Supreme Court appears to have settled this problem in the Kewanee Oil Case,[65] where it held that patents and trade secrets can be alternate forms of protection for the same subject matter.

Unlike patent laws whose purpose is to encourage disclosure of technology, the value of trade secrets resides in the ability to maintain secrecy of the technology. Thus if one is able to reverse-engineer a product, the value of the technology as a trade secret has been destroyed.

The use of trade secrets to protect varieties is not new to the seed and ornamental plant industries. Protection of the parents has been and will probably continue to be the favored method of protecting hybrids. However, as tissue culture techniques improve, there may be a need to resort to general or plant patent protection of hybrids.

It is probable that protection by trade secret will be a useful tool for protecting plant varieties and plant breeding that employ the emerging technologies of tissue culturing, cell fusion, molecular biology and recombinant DNA. The use of trade secrets will be a particularly viable alternative to patents and plant breeders' rights where products are difficult to reverse engineer or where processes and techniques constitute the invention. In view of the fact that patents covering processes in general present difficult problems of enforcement, trade secret protection should always be considered.

The use of trade secrets to protect inventions resulting from university/industry agreements present difficult problems. I will talk more on this during my discussion on industry/university/government relations.

Another problem in the trade secret area results from the relatively small number of people trained in the new genetic engineering technology and their ability to move from job to job. This problem creates a need for employment agreements that protect employers from the appropriation of trade secrets, while at the same time allowing employees the ability to take advantage of career opportunities.

III. THE IMPACT OF MODERN GENETIC ENGINEERING

In the United States of America, intellectual property lawyers are seriously concerned about the area of new biotechnology and the extent to which changes in approach are necessary in order to protect it.

Certainly in the area of chemical products the ability of certain microorganisms to reproduce themselves and to reproduce at extremely fast rates presents a different challenge than the technology where products are made by multi-step processes utilizing various starting materials. How does this present a problem? With a traditional chemical compound a patent would prevent others from using the compound no matter how it is prepared. Chemical compounds, however, generally require complicated processes to produce them. When the invention is a plasmid or vector and samples have to be deposited to meet the disclosure requirements of 35 U.S.C. 112, the public would have access to the microorganism. Since the microorganism is self-replicating, the patentee loses some degree of control over it. This will be an important area of concern in the application of modern genetic engineering to plant breeding, as we shall see in my discussion of "Subject Matter for Protection."

There were and still are concerns over the possible harmful effects of the new technology. These include escape of pathogenic mutants into the atmosphere; cloning of human beings; and the irreversible alteration of human genetic characteristics. The promulgation of National Institute of Health (NIH) guidelines on genetic engineering and the absence of any untoward events has helped to erode these concerns.

Furthermore, the eligibility of technology for protection should not be determined by its potential misuse or catastrophic effect. As pointed out in the Chakrabarty[66] case, the safe use of technology is a legitimate area for the enactment of safety legislation. In making this point the United States Atomic Energy Act was referred to. The Atomic Energy Act sets up stringent rules governing the use of atomic energy. However, it does not make inventions relating to atomic energy ineligible for patent protection.

During hearings in 1979 and 1980 on amendments to the Plant Variety Protection Act, voluminous testimony was presented against the concept of providing patent-like protection for plants. Expressed were two concerns involving the narrowing of the plant germ-plasm base, which would result in a threat to the world food supply, and a monopolization of the food supply by certain multinational companies. However, proponents of the amendments argued successfully that plant variety protection in itself would not lead to the results forecast by the opponents of the legislation.

Since the use of modern genetic engineering will require a combining of classical plant breeding and molecular biology techniques, tissue culturing and recombinant DNA, there will be a great demand for lawyers trained in these disciplines so that they can draft various legal documents which will define relationships between industry and society, between industry and the government, with respect to the new technology. Such documents will include patents, plant breeders' rights, licenses and other agreements.

IV. SUBJECT MATTER FOR PROTECTION

Important subject matter for protection in the area of modern genetic engineering includes, but is not limited to:[67]

A. New varieties produced by transferring genetic material from one species to another

B. Parts of plants

C. Specific breeding techniques

1. Tissue culture
2. Transfer of genetic material
   (a) protoplasm fusion
   (b) recombinant DNA

3. Regeneration of whole plants

D. Products useful as genetic engineering tools

1. Vectors
2. Genes isolated from plants
3. Adaptors
4. Promoters
5. Microorganisms that are species specific
6. Cell lines

E. Testing and assay techniques

A. New Varieties

Whether produced by classical breeding techniques, genetic engineering or combinations thereof, new varieties will be protectable under the various United States plant protection statutes. The type and degree of protection, however, will depend upon the nature of the invention. Moreover, the difficulty of obtaining protection will depend upon which type of protection is sought. I would rank the various forms of protection in reverse degree of difficulty of obtaining, as follows: trade secret, plant variety protection (plant breeders' rights), plant patents and general patents.

Parenthetically, it should be remembered that the standards which have to be met in obtaining general patent protection are novelty, unobviousness and the description requirement. Therefore, in presenting the best case for patentability one must be prepared to submit deposits to meet the description requirement or, conversely, be prepared to describe in great detail and accuracy so as to enable another to reproduce the invention. The description requirements of plant patents and plant variety protection certificates are not as stringent as the requirements for utility patents. Trade secret protection merely requires maintenance of secrecy.

B. Parts of Plants

In the United States of America as well as in many other countries, there is a question whether parts of plants are the proper subject matter of plant variety protection. The most widely discussed example of this question arises with respect to the importation of cut flowers. It is probable that, in the future, the reproduction of ornamental plants by their flower will be part of the technology. This technology should allow the protection of parts of plants for which no protection is now available or is questionable.

There are many in the United States of America who feel that the protection against importation of asexually reproduced plant varieties is provided for under the Plant Patent Act. I share this view. It is also felt by some that an advantage of protection under the general patent statute is the possibility of claiming multiple aspects of an invention. Therefore, under this statute one could claim the whole plant, a bud, the flower and the seed in the same application.

The importation of flowers of an asexually reproduced variety covered by a plant variety protection certificate would constitute an infringement of the certificate.

Another possibility is to obtain an exclusion order from the International Trade Commission (ITC) under the Tariff Act of 1930.[68] This statute provides sanctions against importers using unfair trade practices where such practices injure or tend to injure a domestic industry that is being run economically and efficiently.[69]

The ITC statute can be applied even though the imported goods are not patented if they are prepared by a process patented in the United States of America.[70] Since plant patents are in the nature of process patents (asexual reproduction), shipment of cut flowers from a plant claimed in a United States of America plant patent could be the basis of a finding of an "unfair" trade practice.

C. Specific Breeding Techniques

1. Tissue Culturing - New and unobvious methods for tissue culturing are protectable under the general patent statute. This technique has already been used successfully to propagate some vegetable crops, fruit and nut trees, fruit and berries, foliage, flowers, ferns and bulbs, and it is becoming a commercially important method in the United States of America.[71]

Starting tissue would also be protectable under the Plant Patent Act if it could be used to generate whole plants. Of course, the use of trade secrets would be another means of protecting new tissue culture techniques.

2. Transfer of Genetic Material - It will be important to protect new vector systems that are useful in transferring genes and other genetic material from one plant to another. The systems which will be composed of vectors, genetic material and specific techniques should be protectable under the general patent statute. A specific example would be a method for the transfer of bacterial-nitrogen-fixation genes to plants.

3. Regeneration of Complete Plants - As we are all aware, it is one thing to alter cells by cell fusion and/or transfer of genetic material but it is a different matter to have the characteristic engineered for expressed in the whole plant. Therefore, novel and unobvious techniques developed for the regeneration of whole plants will be the proper subject matter of general patents. Improved and innovative techniques for tissue culturing, cell fusion and gene transformation would all fall in this category.

Complete regeneration of plants from tissue culture has been accomplished with some species of ferns, strawberries and trees.[72] Undoubtedly as the new techniques are perfected, the capability of regenerating additional species will increase. Such new techniques, and the various substances and tools used in them, will be subject matter for general patent protection.

D. Products Useful as Genetic Engineering Tools

Products, other than plant varieties and parts thereof, could be the proper subject matter of general patents and would fall into two classes: (1) those that are isolated from naturally occurring substances; and (2) those that have been subjected to genetic engineering. For products in the first category to be patentable, the applicant must overcome the "Product of Nature" argument.[73] Products in the second category would be patentable subject matter under Chakrabarty if they met the requirements of novelty and unobviousness.

1. Vectors - Vectors useful for the insertion of genetic material into plants can be claimed per se under the general patent statute if they meet the criteria of usefulness, novelty and unobviousness as well as comply with the

disclosure requirement. The basis for patentability could include being especially effective in some species or being capable of greatly speeding up the period needed to reproduce. Examples of vectors that could be patentable include plasmids, viruses and bacteria.[74]

2. Genetic material isolated from plants - A more controversial subject is the possibility of patenting specific genetic material isolated from plants. Examples of such genetic material are nitrogen-fixation, photosynthesis, protein-enhancing and herbicide-resistant genes.

3. Adaptors - DNA or components thereof that assist transferred genetic material in adapting to the new environment could be patentable: for example a DNA sequence that enables foreign nitrogen-fixation genes to adapt to a variety.

4. Promoters - DNA or components thereof that promote the expression of transferred genetic material. For example, a DNA sequence that would enhance the expression of photosynthesis in a plant that has received foreign DNA.

5. Microorganisms that are especially useful in modifying certain species of plants.

6. Cell Lines - Examples of cell lines that could be patentable are those that would lead to unexpected results in protoplast fusion. A controversy has arisen in the United States of America over the proprietary rights in a cell line useful in the production of interferon.[75]

E. Testing and Assay Techniques

Techniques and assays useful in the identification, comparison and quantification of the genetically engineered materials will provide a fertile ground for the solicitation of general patents.

V. INDUSTRY/UNIVERSITY/GOVERNMENT RELATIONS

At this juncture, I would like to raise the important question: "How will the traditional relationships between the plant variety industries, universities and governments be affected by the emergence of modern genetic engineering?"

A. University/Government

Changes in the relationships between universities, other non-profit organizations and the United States Government will probably be due more to legislation than to the nature of the inventions that result from modern genetic engineering. In December 1980, Public Law 96-517 was enacted. This allows universities, other non-profit organizations and small businesses to take title to inventions that result from government-sponsored research and development. The law provides for the first time a framework for the formulation of a unified government patent policy. Consequently, the question of who may take title under government-sponsored research can be decided on a more consistent basis. The government, however, as it did under its ad hoc patent policy still retains so-called "march-in rights".[76]

It would not appear that the nature of the technology would necessarily alter the relationship between government and universities in any substantial fashion.

B. Government/Industry

Under the present law, any change in relationships between the Federal Government and industry will depend upon the size of the business. If the business is classified as large then its relationship with government will continue to be governed by the government ad hoc patent policy.[77] On the other hand, if a business is classified as a small business (500 employees or less)[78] then its relationship with the government will be governed by Public Law 96-517. As with the case of university/government relationships, it is probable that the modern genetic engineering technology will not present additional legal problems between businesses and governments.

C. University/Industry

The relationship that presents the greatest challenge to intellectual property lawyers and others dealing with modern genetic technology is the proper role of industry and universities in their dealings with each other. These roles are complicated by many factors including those due to the differing organizational objectives of universities and private business. Let us briefly look at a few of the different objectives and how they affect an institution's approach to intellectual property.

The university has as one of its basic objectives, the search for truth. In the area of research and development this means basic research.

A for-profit organization has as its primary objective, the profitable provision of a product or service that is desired by customers. This requires that at least a major portion of research be conducted with the goal of producing a tangible product or service.

A university has as an objective training of its students in various disciplines.

Universities encourage their researchers to publish and disseminate the results of research.

Businesses view the results of research as proprietary data and strive to delay publication of results until patent or plant variety protection applications are filed or to avoid publication and/or dissemination of the results of the research if they are not patentable but are considered valuable enough to retain as trade secrets.

The primary job of university professors is to educate, motivate and train their students. However, due to the shortage of personnel trained in both traditional plant breeding and modern genetic engineering, many professors having such training are occupying roles both at the university faculty and as participants in business enterprises.

In joint industry/university projects there is concern that industry's desire for tangible results would impinge upon the university's goal of using the research as a teaching tool.

What, then, is the role of the intellectual property lawyer in helping to resolve some of the conflicting objectives of universities and private enterprises without compromising the role of either?

The first is to encourage a frank exploration of conflicting interests of universities and private enterprises.

Secondly, the lawyer should be prepared to draft agreements so that they clearly define obligations and rights that are consistent with the objectives of both parties. Specifically, such agreements should include, among other items, the following:

(1) Provisions setting forth which party will own rights to a variety and/or technology utilized in its development.

(2) A clear publication policy should be defined. One approach is to give the business a definite period to evaluate for patentability or protectability and to have the university or the business file for a patent or plant breeders' rights. If the technology is not protectable by patents or plant breeders' rights, then a negotiated manner of treating technology only protectable by trade secret should be set forth in the contract.

(3) Provisions defining which part of industry funds are for (a) basic research for which no exclusive rights may be obtained, and (b) applied research for which exclusive rights may be available.

VI. CONCLUSION

In summary, the nature of modern genetic engineering technology, both in general application and application to plant varieties, will provide a serious challenge for the intellectual property lawyer. Such a lawyer will have to decide whether or not protection should be sought under specific plant variety protection laws, general patent law or the law of trade secrets. In addition to deciding which form of protection should be sought there must also be a determination of what the important invention is; i.e. the plant variety, a genetic component, a vector system or a specific breeding technique.

Another important task will be the drafting of documents between universities and private industries that clearly define the rights and obligations of each during their relationship with each other.

Also, in view of the relatively small number of people trained in the new genetic engineering, especially in the plant breeding area, employer-employee contracts must be carefully drafted to protect the legitimate interests of both.

Finally, the assortment of issues raised by the new genetic engineering technology will provide a continuing challenge to industry, government, universities and other institutions involved in the development and commercialization of plant varieties.

FOOTNOTES

1 46 Stat. 376

2 35 U.S.C. 161 _et seq._:

Section 161. _Patents for Plants_

"Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of title." (Amended September 3, 1954, 68 Stat. 1190).

"The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided."

Section 162. _Description, claim_

"No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

"The claim in the specification shall be in formal terms to the plant shown and described."

Section 163. _Grant_

"In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced."

Section 164. _Assistance of Department of Agriculture_

"The President may by Executive Order direct the Secretary of Agriculture, in accordance with the requests of the Commissioner, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Commissioner, officers and employees of the Department."

3 Yoder Bros. v. California-Florida Plant Corp., 193 USPQ 164 (5th CA-1976): 35 U.S.C. 102 and 103

Section 102. Conditions for patentability; novelty and loss of right to patent

"A person shall be entitled to a patent unless--
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
(c) he has abandoned the invention, or
(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
(f) he did not himself invent the subject matter sought to be patented, or
(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other" (Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; November 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691).

Section 103. Conditions for patentability; non-obvious subject matter

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

4 Byrne, N.J., "Plant Breeders' Rights Law in the United States of America", a paper presented to the British Association of Plant Breeders on July 31, 1980

5 While there is no standard of unobviousness in European plant breeders' rights, it is possible that a similar principle is contained in the UPOV question of minimum distance.

6 See note 3, Supra

7 See Note 3, Supra

8 Asexual reproduction means reproduction other than by seed (grafting, budding, cuttings, layering, division and the like) Kim Bros. v. Hagler, 120 USPQ 210 (S.D. Cal. 1958)

9 In re Arzenberger, 46 USPQ 32 (CCPA 1940)

10 Senate Report accompanying S.4025, Report No. 315, 71st Congress, 2nd Session:

"EXCEPTION OF TUBER-PROPAGATED PLANTS

The bill excepts from the right to a patent the invention or discovery of a distinct and new variety of a tuber-propagated plant. The term "tuber" is used in its narrow horticultural sense as meaning a short, thickened portion of an underground branch. It does not cover, for instance, bulbs, corms, stolons and rhizomes. Substantially, the only plants covered by the term "tuber-propagated" would be the Irish potato and the Jerusalem artichoke. This exception is made because this group alone, among asexually reproduced plants, is propagated by the same part of the plant that is sold as food."

11 S.1447; introduced during the 86th Congress, 1959

12 35 U.S.C. 161, Supra

13 Ex parte Foster, 90 USPQ 16 (P.O. Bd. of Appeals, 1951)

14 35 U.S.C. 164, Executive Order No. 5464, October 17, 1930; 37 CFR 1.163(b)

15 "...The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided." 35 U.S.C. 161, Supra

16 Ex parte Solomons et al., 201 USPQ 42 (PTO Bd. of Appeals 1978);
37 CFR 1.162 and 1.163(a)

17 See note 16, section 1.163(a)

18 United States submitted documentary acceptance to Secretary-General of UPOV in late 1980; effect of adherence on United States plant patent law will be discussed later in this paper.

19 In re Greer, 179 USPQ 301 (CCPA 1973);
In re Jessel, Duffet and Mix v. Newland et al., 195 USPQ 674 (PTO Bd. of Interferences 1977)

20 37 CFR 1.165(b)

21 37 CFR 1.162

22 Dunn v. Ragin v. Carlile, 50 USPQ 472 (PTO Bd. of Interferences 1941)

23 See note 21, Supra

24 See note 2, Supra, Section 161

25 Cole Nursery Company v. Youdath Perennial Gardens Inc., et al., 31 USPQ 95 (N.D. Ohio 1936);
Kim Bros. v. Hagler, see note 8, Supra
Armstrong Nurseries Inc., v. Smith et al., 120 USPQ 220 (E.D. Tex. 1958);
Yoder v. California-Florida Plant Corp., see note 3, Supra

26 Pan American Plant Co. v. Matsui, 198 USPQ 462 (D.C. N. Calif. 1977)

27 7 U.S.C. 2321, et seq.

28 Plant Variety Protection Act, see note 27, Supra, Preamble:

"An act to encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest."

29 7 U.S.C. 2402

Section 2402. Right to plant variety protection; plant varieties protectable

"(a) The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor, subject to the conditions and requirements of this title unless one of the following bars exists:

(1) Before the date of determination thereof by the breeder, or more than one year before the effective filing date of the application therefor, the variety was (A) a public variety in this country, or (B) effectively available to workers in this country and adequately described by a publication reasonably deemed a part of the public technical knowledge in this country which description must include a disclosure of the principal characteristics by which the variety is distinguished.

(2) An application for protection of the variety based on the same breeder's acts, was filed in a foreign country by the owner or his privies more than one year before the effective filing date of the application filed in the United States.

(3) Another is entitled to an earlier date of determination for the same variety and such other (A) has a certificate of plant variety protection hereunder, or (B) has been engaged in a continuing program of development and testing to commercialization, or (C) has within six months after such earlier date of determination adequately described the variety by a publication reasonably deemed a part of the public technical knowledge in this country which description must include a disclosure of the principal characteristics by which the variety is distinguished."

30 7 U.S.C. 2402(a)(1), (a)(2) and (a)(3)

31 7 U.S.C. 2401(a):

"(a) The term 'novel variety' may be represented by, without limitation, seed, transplants, and plants, and is satisfied if there is:

(1) Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example, milling and baking characteristics in the case of wheat) as to which a difference in genealogy may contribute evidence, from all prior varieties of public knowledge at the date of determination within the provisions of section 2402 of this title; and

(2) Uniformity in the sense that any variations are describable, predictable and commercially acceptable; and

(3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its essential and distinctive characteristics with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed."

32 See note 29, Supra, section 2402(a)(3)

33 7 U.S.C. 2402(b):

"(b) The Secretary may, by regulation, extend for a reasonable period of time the one year time period provided in subsection (a) of this section for filing applications, and may in that event provide for at least commensurate reduction of the term of protection."

Public Law 91-577, Title II, Sec. 42, Dec. 24, 1970, 84 Stat. 1542.

34 See note 3, Supra

35 See note 29, Supra, section 2402

36 Public Law 96-574, removing exclusion of the six species, was signed into law on December 22, 1980.

37 7 U.S.C. 2422; Rule 180.10 of "Regulations and Rules of Practice Under the Plant Variety Protection Act" (hereinafter referred to as "Rules of Practice").

38 Rule 180.7(b) - Statement of Applicant, Rules of Practice

39 Rule 180.7(a) - Statement of Applicant, Rules of Practice

40 See note 36, Public Law 96-574, Supra

41 7 U.S.C. 2502

42 7 U.S.C. 2504

43 7 U.S.C. 2501

44 35 U.S.C. 253

45 H.R. 6933; signed by the President in December of 1980

46 See note 43, Supra, section (c)

47 7 U.S.C. 2541:

"Infringement of plant variety protection

Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 2567 of the title:

(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

(2) import the novel variety into, or export it from the United States;

(3) sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or

(4) use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or

(5) use seed which had been marked "propagation prohibited" or progeny thereof to propagate the novel variety; or

(6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or

(7) perform any of the foregoing acts even in instances in which the novel variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or

(8) instigate or actively induce performance of any of the foregoing acts."

48 See note 47, Supra; section (5)

49 7 U.S.C. 2542

50 7 U.S.C. 2543

51 7 U.S.C. 2544

52 7 U.S.C. 2545

53 7 U.S.C. 2541(7):

This is a rather anomolous provision since it suggests that it is possible to obtain a valid United States plant patent on a variety that is already protected by a plant variety protection certificate.

54 7 U.S.C. 2403

55 Title 35 of the United States Code Annotated

56 Chakrabarty v. Diamond (Commissioner of Patents and Trademarks), 206 USPQ 193

57 See notes 2 and 13, Supra

58 35 U.S.C. 112, first paragraph:

Section 112. Specification

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims, particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof. (Amended July 24, 1965, Public Law 89-83, sec. 9, 79 Stat. 261; November 14, 1975, Public Law 94-131, sec. 7, 89 Stat. 691)."

59 See note 3, Supra

60 See note 3, Supra

61 The Plant Variety Protection Office has an agreement with the National Seed Laboratory under which the Laboratory accepts and stores seed samples required to be furnished under the Plant Variety Protection Act. It would seem that a similar arrangement could be worked out between the Laboratory and the Patent and Trademark Office. The address of the Laboratory is:

United States Department of Agriculture
Science and Education Administration
Agriculture Research, Western Region
National Seed Storage Laboratory
Colorado State University
Fort Collins, Colorado

62 Brooks et al., "A Plan for a National Fruit and Nut Germ Plasm Repository,", Hort. Science, Vol. 12(4), August 1977.

One repository has been opened at the Agricultural Experimental Station in Davis, California, and another will be opening in the near future at the Agricultural Experiment Station in Corvallis, Oregon.

The American Type Tissue Culture Collection will accept frozen tissue cultures. The address is:

American Type Tissue Culture Collection
12301 Parklawn Drive
Rockville, Maryland 20852

63 This doctrine also contains some elements that are similar to those of the concept of minimum distance.

64 Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co., 339 U.S. 605, 608

65 Kewanee Oil v. Bicron Corp., 416 U.S. 470, 474 (1974)

66 See note 56, Supra

67 Several commentators have suggested potential patentable subject matter resulting from genetic engineering. See A.R. Whale "Patents and Genetic Engineering", a paper presented at the 26th Annual Conference of the Intellectual Property Division of the John Marshall Law School, Chicago, Illinois, February 18, 1982; A.P. Hallum, "Patenting the Results of Genetic Engineering Research", Banbury Report No. 10, pp. 73-83, paper from a conference held in October 1981 at Cold Spring Harbor Laboratory; Bertram Rowland, "Are the Fruits of Genetic Engineering Patentable?", Banbury Report No. 10, pp. 143-147 (1981).

68 Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337 et seq.)

69 19 U.S.C. 1337. Unfair practices in import trade.

"(a) Unfair methods of competition declared unlawful.- Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are hereby declared unlawful, and when found by the President to exist shall be dealt with, in addition to any other provisions of law, as hereinafter provided."

70 19 U.S.C. 1337a

71 Impacts of Applied Genetics: Microorganisms, Plants and Animals, United States Office of Technology Assessment, Chapter 8, pp. 140-145 (1981).

72 See note 67, Supra, pp. 146-148

73 It is generally held in U.S. patent law that "products of nature" are neither patentable subject matter under 35 U.S.C. 101 nor novel under 35 U.S.C. 102.

74 It has been reported that Ti-plasmids of Agrobacterium tumefaciens, cauliflower mosaic virus and several other substances have been used in genetic transformation in plants. Gamborg, O.L., "New Hybrid Plants"; Hall, T.C. et al., "Enhancing Protein Quality and Quantity"; and Bevon, M., et al., "Agrobacterium tumefaciens - Tumor Inducing Plasmids or Genetic Engineering Vectors in Plants." See Vol. V, pp. 29, 36 and 68 respectively, of the International Conference of Genetic Engineering, sponsored by the Battelle Memorial Institute on April 6-10, 1981 in Reston, Virginia.

75 Hoffmann-La Roche v. Regents of the University of California v. Genetech, Inc., Civil Action No. C80 360, AJZ (D.C.):

The facts of the case are as follows. Two researchers at the University of California succeeded in developing a cell line. They subsequently sent the cell line to a researcher at the National Cancer Institute (NCI). The researcher at NCI discovered that the cell line was capable of producing interferon and subsequently made the line available to Hoffmann-La Roche and Genetech. Through recombinant DNA techniques Hoffmann-La Roche produced modified cell lines from the California cell line that exhibited a greater capacity to produce interferon. The University of California alleges that it had a proprietary right in the cell line and that Hoffmann-La Roche and Genetech had misappropriated. This case has the promise of providing guidance in the area of ownership of cell lines and other genetic material. Also, it could establish criteria for how much change is required in a cell for it to be characterized as a different cell.

76 "March-in rights" provide the government with a royalty-free, non-exclusive license to an invention.

77 There are several bills pending in Congress that would allow large businesses to acquire title to inventions resulting from government-funded research. They are H.R. 4564 and S. 1657.

78 37 Code of Federal Register, Part 1, effective as of October 1, 1982.

[Original: English]

* * *

Having delivered the above lecture Dr. Williams indicated his willingness to receive any immediate questions arising from it.

A report of the questions asked and answers given is reproduced below:

* * *

Mr. Fikkert said that he wished to ask a question about the interrelationship between plant patents, general patents and plant variety protection certificates. He wished to know whether Dr. Williams considered that the granting of a general patent for a variety of a species or genus for which protection was available under one of the other two systems would be in conformity with the UPOV Convention. Mr. Fikkert said that he had particularly in mind the last sentence of Article 2(1) of the UPOV Convention, where it was stated that "nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species."

Dr. Williams replied that he was familiar with that sentence. Although there might seem to be some inconsistency he believed that Article 37(1) of the UPOV Convention provided the United States of America with an adequate basis for granting such protection.

Dr. Lange subsequently asked a complementary question as regards the competitive relationship of the various laws that applied in the United States of America. He would have been interested to know what had to be taken into account for the application in each case, and then also what the scope of protection was for each of the titles of protection granted. If he had understood correctly, it was possible under the system applicable in the United States of America to submit an application in respect of both generatively and vegetatively propagated varieties either under the Plant Patent Act or the Plant Variety Protection Act. A further question was that of competition with the general Patent Act, particularly when considering the new processes that had been developed in the field of genetic engineering. In his opinion, that posed the question of the scope of protection of a process patent. There also arose the necessity of regulating the matter of collision between the existing protection rights themselves and between them and a process patent. He would like to limit himself to that question to begin with.

Dr. Williams said in reply that he thought that it was necessary to keep in mind with all three of the statutes that, even though they might appear to conflict with each other, the substantive issues of novelty still had to be dealt with. For something to be considered as new, it had to meet certain criteria. As far as choosing between the two special laws was concerned, he thought that a major question would be whether it was more obvious to reproduce the variety sexually or asexually. Looking at the matter from the plant patent standpoint, if someone applied for a plant patent after a certificate had been issued, Dr. Williams thought that if there was an obvious way to reproduce the variety asexually then that particular application would face great difficulties under the plant patent statute. As for the process patent, even though the plant patent was similar in nature it did not afford equivalent protection. He therefore believed that the breeder should have an avenue to apply under the general patent statute. Breeders must remember, however, that they would definitely have to meet the standards of patentability for obtaining a process patent. Those standards would be guided by the general patent statute, and they were more difficult to handle.

Dr. Lange further said that he had another question in that context. It concerned the Copyright Act. He had heard that legal writers in the United States of America had proposed an extension of the Copyright Act. That would create yet another type of protection for genetic engineering processes. He would like to know how things stood.

Dr. Williams replied that Dr. Lange's question had been raised in several articles. Dr. Williams thought that there might be slight problems with such an approach. One would be treating the genetic code as an expression of an idea and claiming copyright in that expression. He wondered what the situation would be if someone extracted part of that genetic code, put it in something else, and used it. He thought that the question whether that was "fair use" would come up. The copyright holder would then have to face the fact that fair use, under the copyright statute, was a way of using something without its infringing.

Dr. von Pechmann had a question that was directed less towards the lecturer than towards the UPOV Secretariat. In view of the fact that genetic engineering was opening up many new possibilities in the field of plant breeding and that, in fact, genetic engineering was chemistry, basically pure biochemistry, but in part also molecular chemistry, the question arose whether the second sentence of Article 2(1) of the UPOV Convention, which had already been mentioned by one of the speakers, still corresponded to requirements. It was a fact that in a UPOV member State, either a patent alone or plant breeders' rights alone could be granted for a variety of a given genus or species. Since, however, the innovations developed with the help of genetic engineering were in fact inventions of a purely chemical nature, it seemed therefore logical that the whole matter should form part of patent law rather than of plant variety law. He wondered whether the UPOV Secretariat had already considered the need for a revision of that Article of the UPOV Convention.

Dr. Mast commented that it would indeed first be better to wait and see what subsequent developments brought and in any case what emerged from the rest of the discussions in the Symposium. In his opinion, it was necessary to consider the matter in depth before asking for a revision of agreements and laws. In the case in point, it would first be necessary to see what happened in Europe. From what he had heard, the European Patent Office and also the domestic European Patent Offices had received numerous patent applications for biotechnical inventions, in respect of which no decisions had as yet been taken. An attempt had been made in the European Patent Convention, and in the numerous domestic European patent laws that had been revised in recent years, to draw a clear line between technical inventions that had access to patent protection and the breeding of new plant varieties that was covered by plant variety protection. He referred to Article 53 of the European Patent Convention, which excepted plant or animal varieties or essentially biological processes for the production of plants or animals from patentability, and to the substantially identical Article 2(b) of the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, which permitted its contracting States to include in their national patent laws exceptions that corresponded to Article 53 of the European Patent Convention and of which many States had availed themselves. His view was that it would be better to wait and to see whether that provision was not adequate to find a reasonable solution to the possible conflict between the various rights. The fact that UPOV, not only the Secretariat, but also the Council, was taking the matter seriously was proved by the choice of topic for the Symposium. In any event, UPOV was taking the matter very seriously and was keeping a close eye on developments.

Mr. Royon said that he wished to add a remark to Mr. Fikkert's intervention. It seemed to him that, at least for asexually reproduced plants, which were very broadly covered in the United States of America by the Plant Patent Act, the reply could be that in Article 2(1) of the UPOV Convention it was not specified whether the patent mentioned was a plant patent or a general patent.

Mr. Royon then asked Dr. Williams whether he could elaborate on the controversial debate regarding the protectability of cut flowers imported into the United States of America. Had Dr. Williams said that the application of general patents might provide a solution?

Dr. Williams replied that the point he had been trying to make was that if in a general patent he claimed a rose, having given an adequate description of the rose plant, and then in a sub-claim he claimed a flower cut from the rose plant described in claim 1, it would be just like having a machine and a sub-component of the machine in the same patent. In that way one would provide protection for the cut flower.

Mr. Rigot asked for clarification regarding what was protectable by patents. He had noted from what Dr. Williams had said on that subject the catch words "transfer of genetic material" and "vector". Mr. Rigot said that he thought that two distinct things were involved, namely a process and a means or stage. For him a process was a method leading to something concrete and usable, and he believed a method, in that sense, to be patentable. He considered a vector to be a priori a means or stage in a process, a means that might be used in different processes. What he wished to know was whether such a means or stage was also patentable.

Dr. Williams said that he would try to answer by analogy. In a process for making say sulphuric acid one had to go through several stages, including the manufacture of an intermediate product. Processes for making sulphuric acid were already known, but if someone came up with an intermediate product that would increase the yield by 95%--and that would be something exceptional--that intermediate product would be protectable per se. By analogy, if someone came up with a vector that could be used to insert some DNA material into a particular plant and as a consequence a benefit could be obtained in one rather than several years, then he would say that that vector was a useful product, bearing in mind the definition of "usefulness" under the general patent statute, and that the vector could be part of a patentable process as well as being patentable itself.

Mr. Simon, referring to Dr. Williams' earlier remarks regarding the relationships between universities, industry and government, said that he would like to hear Dr. Williams' opinion on the problems that might arise between American universities and research institutes in other countries. How did he see the question of free exchange between scientists engaged in basic research?

Dr. Williams said in reply that, as far as the application of genetic engineering technology was concerned, he was not sure that he saw any additional problems in the plant breeding industry vis-à-vis that relationship. He thought that university people were going to talk to one another anyway and that there would be an exchange of information. As a lawyer, his only counsel would be that if there was a potential for proprietary information then efforts should be made to protect it. The nature of the technology might be such that, as in other areas, there might be things that would have to be cleared, for example, through the Department of Commerce. Present developments suggested to him that there would be more of a getting together, and he did not see any real problems regarding exchange of information.

Dr. Leenders said that he would like to put a hypothetical question. If someone had obtained protection for a plant breeding method under the general patent statute in the United States of America, which included publication of the method and which might include protection of the product produced by applying that method, and if, a little later another breeder submitted for protection under the Plant Variety Protection Act a variety he had bred by applying the patented method, could the owner of the patented method go to court and ask for the plant variety protection certificate to be annulled, or could he demand a royalty?

Dr. Williams replied that the question had not been litigated in the United States of America. He thought, however, that according to basic patent principles, such as the principle of the dominating patent, that a valid method claim for producing a variety would dominate protection subsequently granted to a variety by the Plant Variety Protection Office. The question could be raised that these were two different statutory rights. Provisions for plant variety reproduction and production schemes had, however, been a part of the general patent law for a long time. From a practical point of view, and as a lawyer approaching a situation like that, he would start talking about a licence, rather than start litigating.

Mr. Skov said that he wished to refer to an article published in the September 1982 issue of the OECD Observer. He had found that article very interesting and had already discussed it with Dr. Williams. The article contained a certain passage on which he would welcome Dr. Williams' comments.

Dr. Williams said in reply that the passage in question was concerned with the potential conflicts arising in the relationships between universities and industry, and in the handling of information. He agreed that this was a most difficult problem but thought that it could be resolved, simply by attempting to understand the various roles of the various institutions. He believed that industry recognized the role of the universities and the need to disseminate information. He also believed that universities recognized the need to capitalize on new proprietary rights. It seemed, therefore, that the line that had to be drawn would be a compromise. There might be a slowing up in the dissemination of information, but that should not be for an unreasonable length of time. Dr. Williams thought that the solution he would propose would be to develop a procedure for reviewing proprietary information, for determining whether or not protection should be sought and, in that way, for looking at the possibilities of publication. Another aspect of the problem, in his opinion, was that there were areas of basic research, the results of which really should be made available to industry and to various non-profit units. In such areas he could see that there should be no exclusive licences, and maybe no licences at all. But where solutions to specific problems were being sought, he thought that it would be unrealistic to expect any industry to invest huge sums of money in a project without being able to retain proprietary rights, and in many cases, exclusive proprietary rights.

Dr. Feistritzer said that he wished to refer to a practical situation regarding the relationships between public and private institutions, a situation that might have some implications for international agricultural research centers. If a private breeder who had done some final selection work on an advanced line developed by a public institution requested protection for the resulting variety, how would such a request be handled in the United States of America?

Dr. Williams replied that if Dr. Feistritzer was referring to the possibility of obtaining an exclusive right in such a variety, then he thought it was clear from American policy with respect to small businesses, non-profit institutions and universities, that such an arrangement was possible, probably on a more limited basis than say the full life of the patent or the plant variety protection certificate. He had in mind Public Law 96-517. That statute was very much related to small businesses, and one of its effects was that anyone wishing to give an exclusive licence, particularly to a large business, would have to undergo a very stringent review.

Dr. Mastenbroek said that he had been told that nowadays the technique existed to construct in the laboratory, by purely chemical means, a chemical substance that, after having been incorporated into a plant, was multiplied by the plant just like a natural gene, and that acted as a gene in a physiological sense. If such an artificial gene, supposing that it was not known and could thus be considered new, could be protected by a patent because it was a chemical substance, would it still be protected by that patent after being incorporated into a plant? If that was the case, that plant, contrary to the provisions of the UPOV Convention, would not be freely available for use by plant breeders aiming to produce additional genetic variability and new varieties. Although such a gene in an individual cell or in cell lines would be patentable in accordance with existing patent legislation, as a plant breeder, he was therefore opposed to patentability of a gene present in a plant or in part of a plant.

Dr. Williams said in reply that Dr. Mastenbroek had raised an interesting question. He was not sure that Dr. Mastenbroek would not get some agreement with some American breeders on whether or not one should be able to patent germ-plasm *per se*. If general patent protection could be provided on germplasm, then he thought that there would be some conflicts. He believed that he had referred earlier to the fact that certain exemptions were provided for under some statutes that were not provided for under the general patent statute. Therefore, he did not think that the matter would be limited to the question of genes, particularly where food crops were concerned. Conflicts might arise not just vis-à-vis UPOV, not just vis-à-vis a particular law, but between laws within one country as well, and he had to admit that he did not know how the courts would handle such conflicts. It was necessary to recognize that there were two stages in protection. One was the granting process where the granting office considered whether the subject matter was proper; the other process was where the courts had to interpret the law.

Dr. Williams said that he did think that patents would be granted on genes in the United States of America. He believed that, in the light of terms of its general patent principles, there would have to be a clear statement as to whether or not genes should be protectable absolutely or only on some restricted basis. He thought that a distinction would have to be made between a gene that had been modified by some type of human activity and one that had simply been isolated. The *Chakrabarty* case, which he had mentioned earlier, dealt with a bacterium that had been modified by human intervention. On the other hand, someone applying for a general patent for an isolated gene would have a tough problem with the 'product of nature' principle. For example, if that gene did nothing different than it did in its original environment, then he thought that there would be a patentability problem. If the applicant could in some way demonstrate, however, that the isolated gene behaved differently when put in an isolated environment or in some new type of environment, then that gene might be potential subject matter for patentability.

INTRODUCING NEW TECHNOLOGY TO PLANT BREEDING

Max Rives*

Summary

Plant breeding more often than not requires an increase in the frequency of favorable alleles of large numbers of genes with small individual effects. It makes use of identifiable genes that admit of Mendelian analysis in specific cases (disease resistance) or in the case of certain species like the tomato.

In order to achieve its aims, plant breeding makes extensive use of phenomena associated with meiosis and reproduction systems: genetic recombination in the conventional sense, consanguinity or hybridization within or between species, either for the analysis and measurement of genetic variability, or for exploitation in varieties, mainly in the form of heterosis.

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> The new technology resulting from developments in molecular biology and plant physiology, in particular everything concerned with in vitro culture, is therefore of varying interest according to the strategies and objectives of plant breeding, inasmuch as it can be a more efficient and faster means of accomplishing them.
>
> The constant endeavor to obtain homozygous genotypes, which are the factor determining the reproducibility of the varieties based on them, causes considerable interest to be focused on the techniques for the production of haploids (androgenesis, gynogenesis, etc.).
>
> The opposite concern, namely that of obtaining hybrids at will, explains the interest shown in techniques for the production and regeneration of protoplasts, especially after fusion, and all the more so since the first experiments have revealed hitherto unsuspected phenomena.
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> Micropropagation is an invaluable tool either for the true-to-type multiplication of genotypes as varieties or for that of parent material for hybrid or synthetic varieties.
>
> Too little research has been carried out as yet on the new type of variability that often appears after the use of in vitro culture for any pronouncement to be made on its potential practical value.
>
> Breeders are bound to be wary of any projects for breeding at the in vitro cellular stage. They are not convinced of the need for them, their efficacy or of the stability of their results.
>
> The use of monogenes may be considered as a means of exploiting male sterilities or morphological characteristics, in which case conventional techniques are quite sufficient, or as a means of using resistance of the vertical type, but bitter experience has taught pathologists and breeders to beware.
>
> Under present circumstances gene transfer, even though it is already possible with dicotyledons at least, cannot be regarded as more than an interesting curiosity for the breeder.
>
> The breeder is extremely interested on the other hand in the progress that is beginning to be made in the understanding of the phenomenon of genetic recombination (in the conventional meaning of crossing over): he sees it as an ever tighter bottleneck constricting the funda- mental approach to breeding, which involves increasing the frequency of favorable alleles of very numerous genes.

Plant breeding has been defined by Gallais (in a personal communication) as "the set of transforming operations that make it possible, from a group of individuals not having all the qualities at the required levels, to produce a new group of reproducible individuals, namely the variety, which represents progress in certain characteristics as a means of complying ever better with the needs of mankind."

Plant breeding is essentially based on three branches of genetics: evolutionary genetics, population genetics and quantitative genetics.

These are little known disciplines to anyone other than the specialists, particularly the last-mentioned, which is the most important but which often puts off the uninitiated on account of its unattractive mathematical connotations.

The three disciplines provide a theory for the interpretation of the concrete results of the very numerous breeding experiments that have been made during the last forty years, mainly in the United States of America. They are beginning to provide INRA in particular with the basic material for the assembly of resolutely innovative breeding plans, which perhaps could usefully be placed among the new techniques involved here.

Whereas the media have had much to say for some twenty years about molecular genetics or molecular biology, nucleic acids, genetic recombination in the sense of molecular biology, splicing, to use the correct English term, and gene transfer, I have no knowledge of articles addressed to the public at large, like those we read every week in "Le Monde" and "Die Welt," that deal with breeding theory and quantitative genetics. That is a pity, as it would have informed the public that, while the molecular biologists were making very remarkable progress, the more modest protagonists of these other disciplines were also making remarkable progress, and I feel that a comparison may be made between, on the one hand, the progress of quantitative genetics and its applications in a breeding theory and, on the other, the progress of molecular biology. What does that mean? It means that by making it possible to predict the genetic benefit of a breeding operation conducted according to different systems, or different strategies adopted by the breeder, this breeding theory enables the breeder to select the best, not only in the absolute sense but also in terms of the biological constraints of his species and in terms of his own constraints, namely the need to ensure his own livelihood and balance his firm's year-end accounts. I regard that as considerable progress in relation to thirty years ago, when plant breeding was carried on in a rather hit and miss way in the knowledge that everything would work out in the end, but when it was quite impossible to quantify what was going to happen.

Given the more restricted terms of reference of this Symposium, we shall keep in mind the fact that this breeding theory interprets observation of the evolution of genetic variability (which is the breeder's raw material) under the influence of breeding as being the result, in the population he is improving, of an increase in the frequency of favorable genes, favorable alleles of genes, situated in a large number of loci.

That number is a large one. But what does all this mean? Perhaps the most impressive experiment in plant breeding that has ever been undertaken is that of the University of Illinois at Urbana. In 76 generations (this year it will be 82 or 83), to give an idea of the efficacy of plant breeding, the researchers at Urbana actually achieved a genetic gain of more than twenty times the standard deviation of the original population for maize grain protein content. Just imagine, those of you who are breeders, what that really means; you others can take our word for it, it is just immense. The analysis of these observations made by Dudley (1976) shows that the gain is due to a relatively modest increase (from 0.25 to about 0.5) in the frequency of favorable alleles for 30 to about 150 genes.

Let us above all note that such a variation of frequency in such a large number of loci entails a still greater number of "effective" recombinations as defined by Hanson (1959), in other words crossings-over in the sense given them by conventional genetics, taking place in the heterozygous areas of the genome.

Analysis of measurable genetic variability by means of quantitative genetic techniques makes it possible today for breeding theory to propose means of optimizing breeding plans: it makes it possible to calculate, according to measurements of genetic parameters in a population, the genetic gain expected from any strategy combining breeding plans, methods for the breeding of populations and processes for the extraction of varieties, and thus to select the best strategy, due account being taken of the constraints associated with the biology of each species as well as of those imposed on the breeder by the means at his disposal.

It must not be forgotten however that, with certain species, notably the tomato, breeding is extensively based on monofactorial genetics. Also, it often happens that certain characteristics under monogenic or oligogenic control are invaluable to the breeder: we would mention the case of the gene that eliminates erucic acid in rape, and those that govern male sterility in conjunction with certain cytoplasms in a large number of species.

I am not pretending to overlook disease resistance genes. They are indeed useful as long as they escape the bypass phenomenon analyzed by Van der Planck (1963) under the name of vertical resistance. Breeders have learned, however, as a result of many rude awakenings, just how precarious the immunity thus conferred by monogenes actually is. They now therefore resort as systematically as possible to what is called stable resistance (or horizontal resistance, to use Van der Planck's expression); that is a characteristic that derives from the same theories as any other polyfactorial quantitative characteristic, and therefore from the same breeding strategies (Rives, 1977).

Breeders have often attempted to make use of other monogenes, but apart from those whose use I have mentioned in connection with species like the tomato, which more often than not are "normal" genes and which above all have to be rearranged in an appropriate manner, disappointments have usually been in proportion to the degree of desired effect on the metabolism of the plant: the best known is undoubtedly the "opaque 2" gene in maize: it increases the lysine content of the grain, and it was hoped that this would improve its nutritive value; however, when introduced into high performance genotypes, its effect is to reduce their yield by 15%, making specific breeding necessary afterwards to restore the appropriate genotypical context around it, which in turn restores in its presence a metabolism free of the profound disturbances caused by it.

This very sketchy picture of the genetic conditions that provide the setting for plant breeding gives us a basis on which we can attempt to evaluate any chances that genetic engineering may have of contributing to its progress.

We should say at the outset that the breeders who have studied the machinery of molecular biology and its practical applications are highly sceptical, for the reasons that I have already explained, regarding the prospects for gene transfer in higher plants: a recent survey conducted in the United States of America (Menz and Neumayer, 1982) among maize breeding specialists shows that not one of them considers genetic engineering, of the five types of biotechnology proposed, likely to have any significant effect on maize breeding before the year 2000. It is not that the transfer of genes is in principle impossible. Indeed, it has already been achieved in tobacco, by the use of _Agrobacterium tumefaciens_ and its Ti plasmid. Yet the list of obstacles to be overcome before this manipulation can be made into a tool suitable for everyday use is an impressive one; I shall not even speak of the difficulties directly attributable to molecular biology: identification, in eukaryotes, of the required sequences, transcription and translation of those sequences and sending their products off in such a way that they find the right path in the host cell through a system of regulation that is often totally new to them. In fact, the most serious problems seem to be that of expressing foreign sequences in the differentiated systems of a pluricellular organism and that of the metabolic price of that expression, if it is achieved. Before reaching that stage, however, it has to have been possible to regenerate whole plants on the basis of the transformed cells; this can be clearly seen in the case of the transfer of the phaseoline gene, which is the reserve protein of the bean, to sunflower cells: no one has yet succeeded, to my knowledge, in regenerating a whole plant. It is thus still unknown whether the phaseoline gene is prepared to express itself in a whole sunflower plant, or what the relative yield of such a transformed plant would be.

It should not be deduced from what I have just said that I am sceptical of genetic engineering as a matter of principle; it is just that I am afraid that the unreasonably optimistic promises made by some sellers of molecular biology, and above all, to be quite frank, by some sellers of shares in genetic engineering firms, will result in a correspondingly greater disappointment for the public, and consequently serve to increase that public's mistrust and even hostility towards research and science in general.

Yet, genetic engineering can provide plant improvement with new tools for inclusion in the array that it has already borrowed from a number of disciplines and is using with some success.

For instance, researchers at the Plant Breeding Institute (PBI) in Cambridge (United Kingdom) make use of radioactive probes to identify and locate allogenic sequences introduced into the genome of the species as a result of interspecific crossing (for instance, rye sequences in wheat).

Analysis of the genomes of cellular organites, chloroplasts and mitochondria by means of restriction enzymes has made spectacular progress possible; for instance, by showing the reality of recombination between genomes of cellular organites caused by fusions of protoplasts. It has enabled the breeder to predict the possibility, which was realized very quickly afterwards, of separating chlorophyll deficiency and male sterility in rape, which until then had always gone together, by identifying the former with a variation in the chloroplastic genome and the latter with a variation in the mitochondrial genome. This is extremely important in practical terms, because we now have available a male sterility in rape that works and will no doubt continue to work well, inasmuch as we know that it does so in other respects and that, once freed of its chlorophyll deficiency, it will certainly be very useful. I feel that this is a fairly convincing example of the rapid, immediate practical usefulness of the tool or tools that molecular biology and the various forms of biotechnology, especially in vitro culture techniques, place at the disposal of plant breeding . I think that they will become even more efficient, and a corresponding degree of credence will have to be attached to genetic engineering and its use.

This recombination phenomenon is extremely important, because it makes it possible to generate new genetic variability. And up to now we have not had any means, apart from crude, brutal mutation, of altering the genetic information of mitochondria. Now we have such a means; we have not yet mastered it fully of course, but we do have it.

Genetic engineering can assist plant breeding by contributing to the knowledge of reserve proteins, which are tied in the case of wheat, for example, to the adaptation of the flour of the different varieties to panification methods, which one calls quality; for it is beginning to be understood not only that their structural diversity is associated with hereditary factors traceable by electrophoresis and controllable by the usual techniques of Mendelian genetics, but actually what peculiarities of their structure are related to their more or less favorable properties in the dough. As a complement to their chemical analysis or mapping, a study of the DNA sequences that control them might one day simplify research into them.

It is also beginning to be realized that breeding acts not only on the substitution of certain alleles of structural genes for others, but also on that of the regulatory genes; breeding thus acts not only by altering the specific activity of enzymes, but also by causing their quantity to vary; in addition it can be shown (Hedrick and McDonald, 1980) that the property of dominance is much easier to explain in connection with regulatory genes than in connection with structural genes. Now breeders know that dominance and interaction between genes (which are typically regulating phenomena) are the basis of heterosis, which is the central phenomenon for all plant breeding. Molecular biology has already provided interesting models of heterosis in polymeric enzymes or enzymes with different function optima according to their structure, with the heterozygote being thus placed in a more advantageous position in relation to its environment than the two corresponding homozygotes. By clarifying the regulatory machinery of eukaryotes, it would no doubt make highly useful direct applications possible, but it would also provide sounder foundations for the modelling of genetic variability as observed in plant breeding, and that would be extremely welcome. The present limits of quantitative genetics are mainly those due to the imperfect nature of its model of observable genetic variation.

Finally, there is an area in which molecular biology has kept a low profile, namely that of recombination in the conventional sense of the term, which is to be found in the diploid cell at meiosis, and which is associated with crossing over. The sheer number of models of the purely molecular phase of recombination, which is no doubt much the same in the various types of organism, itself gives a good indication of the seriousness of the problem. However, more than the purely molecular machinery of splitting the DNA molecule and putting it together again in the recombined form, it is no doubt the various associated processes that really control the frequency of recombination in eukaryotes, unlike what happens in bacteria. Now as I said earlier it is this very frequency that limits genetic progress, in that it obstructs the rearrangement of favorable alleles, which is the sole factor determining the success of breeding. It is a question of the structures that define the homology of the sequences (or is it the sequences that determine the homology of the structures?), the enzymatic framework for the reciprocal recognition of those structures, the anatomical framework that surrounds DNA at the time of pairing off during the prophase, and the nucleosome structure associated with the histones as much as the structure of the synaptonemal complex.

A moment ago I said how much genetic progress in breeding depended on the frequency of the chromosomic recombination of favorable alleles; meiosis is accompanied, on average, by just one split per chromosome in an organism like maize. It is not difficult to imagine the increase in efficiency that any increase in this frequency would bring about for the breeder.

One is bound to conclude that there is an urgent need to remedy the lack of reciprocal communication and sharing of knowledge that prevails among breeders and molecular biologists. The former more often than not suffer from a dramatic lack of any training in biochemistry, while the latter lack knowledge of conventional and quantitative genetics (suffice it to mention, for instance, that it took until the second edition of "Molecular Biology of the Gene," by Watson, for an exposition to be made of the laws of Mendel.)

With the best will in the world, that is bound to lead the former to the blinkered incredulity (or alternatively unblinking enthusiasm) of the person who does not understand, and the latter to totally unrealistic fancies, like the plan to create drought-resistant varieties of lucerne by transferring to it the proline accumulation gene from Klebsiella.

I have deliberately confined my theme to genetic engineering in the strict sense, in order to remain within the terms of reference of this Symposium, but my title spoke of "new technology," in other words everything that today is placed under the heading of biotechnology.

It has to be said that plant breeding not only expects much of the new technology, but in fact has already begun to use it. This is notably true of haploids. It is also true of the fusion of protoplasts, because, as I mentioned, this technique enabled Pelletier and his team to separate male sterility and chlorophyll deficiency in rape.

Yet the case of haploids seems to me to illustrate the very pragmatic approach adopted by plant breeding specialists; the first practical uses are no doubt those of Chase (1952) on maize; spontaneous haploids were used, and the new technology consisted in sorting them rapidly by means of a genetic marker; this method, in spite of some success, did not become widespread. It has long been known that, when a seed has twin embryos, one of them is often haploid. The first systematic use of this phenomenon on any noteworthy scale was made in France by Thévenin (1968), on asparagus: again it was a case of detecting spontaneous haploids. It was only after Bourgin and Nitsch had obtained the first haploids produced by androgenesis in vitro (1961) that breeders began to wonder about the optimization of plants with Pelletier and Feyt. The production of haploids in wheat, which was achieved simultaneously by Picard (1972) and Chinese researchers, certainly contributed much towards promoting reflection on the subject. It was not until the first wheat haploids appeared that everyone really began to wonder what in fact was going to be done with them. This question seemed at the outset to be utterly irrelevant (haploids being in any case so useful), but eventually, when the reasoning of quantitative genetics was applied, and also whatever was known of the behavior of wheat haploids, it was realized that the answer was by no means obvious. I am now in a position to tell you, for instance, that the two schools of thought that I know to have applied themselves to this question, the French, namely my colleagues at INRA, and researchers at the Plant Breeding Institute (PBI) in Cambridge, were by no means of the same opinion on where the use of haploids belonged. We tend to think that it is very early on in the breeding process--as from F1, or at the latest F2--whereas the British prefer to leave it until F3 and perhaps even as far on as F4. It is my view that quantitative genetics and well conducted tests will enable us to decide where to put haploids.

However, the very low success rate of androgenesis, while causing new work to be undertaken in an attempt to improve it, has above all delayed its use in practice. Other routes have been sought, and they have led among other things to gynogenesis. But it is the use of haploidization by elimination of paternal chromosomes as a result of the crossing of cultivated barley with Hordeum bulbosum that, by achieving high success rates, has made it possible both to put them into general use in practice and also to present in its proper perspective the problem of the introduction of the haplo-method in plant breeding. A team of researchers at the University of Guelph in Canada has noted--and is in the process of publishing a whole series of articles to show--that the use of haploids, while naturally being of interest for the manufacture of varieties or of lines in cross-fertilized plants for subsequent use in hybrids, also makes it possible to analyze genetic variability with a view to predicting and optimizing breeding plans in a way that cannot be matched by any other means.

It can now be said that, by deriving haploids from a population of crosses that one wishes to use, one can gain invaluable information on the structure of the genetic variability within those crosses, which makes it possible to determine which have a chance of producing promising varieties for the future, and which have no such chance, and perhaps even how one should proceed in order not only to extract good new varieties from them but also to continue by way of recurrent breeding to improve the population from which they are derived. So there is an example of a use of biotechnology that goes far beyond the hopes that were placed in it, by providing possible new applications that had not even been suspected previously.

In these examples we have above all to note the extremely pragmatic character of plant breeding as a discipline; no tool is ever used otherwise than for its tested practical usefulness: in our example a haploidization technique is used because it has finally met the requirement of a sufficient success rate, but also without genotypical discrimination; and yet it would be a mistake to think that because he is very strict on a criterion of this kind, the breeder is incapable of evolving: the truth is that the fact of having this technique available has immediately triggered reflection, not only on the optimization of its introduction, but also on the new possibilities that haploids offer analysis in quantitative genetics (Choo, 1981).

This is another way of saying that plant breeding does not believe in miracle cures, wherever they may come from, but rather is quick to seize every opportunity of improving its efficiency, wherever that opportunity may come from.

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[Original: French]

* * *

Having delivered the above lecture, Dr. Rives indicated his willingness to receive any immediate questions arising from it.

A report of the questions asked and answers given is reproduced below:

* * *

Dr. Böringer felt that, although the contributions by Dr. Lawrence and Mr. Rives had sounded so different, they were in fact, in agreement on one point. Dr. Lawrence had ended his lecture with an appeal to the molecular biologists and biotechnologists to work together with the practical plant breeders. Mr. Rives, on the other hand, had started from practical plant breeding as carried out hitherto, and, against that background, had put the question of what molecular biology and biotechnology could offer to plant breeders. He would be interested to learn of Mr. Rives' views on the cooperation between the various disciplines in practical plant breeding, in respect of France--since Mr. Rives was director at INRA--and if possible, would like Mr. Rives to say something about what was going on in other parts of the world, not to say the rest of the world.

Mr. Rives said in reply that he thought that the first step towards practical cooperation between molecular biologists and plant breeders should be for each to get to know the other. They frequently met in a corridor or on the campus, but without really exchanging ideas. A little effort was needed on both sides to understand what was going on and, at least, to understand each other's terminology. His earlier emphasis on the meaning of 'recombination' had been intentional. Molecular biologists and plant breeders should be given every opportunity for discussion and to show one another their work. For such exchanges to be effective the molecular biologist had to meet the plant breeder in the field, where his plants were, and the plant breeder had to meet the molecular biologist in his laboratory, where his bench was, rather than at formal symposia at which each delivered lectures. Mr. Rives believed that it would be a great step forward for each to understand what made up the daily work of the other. Plant breeders would be amazed to learn that molecular biologists, instead of working yet again with the tobacco plant, had at last begun using some cultivated species which, although it might not interest them, did at least interest their breeder colleagues. On the other hand, plant breeders had to be able to evaluate what could be done by molecular biologists. Those without that knowledge either saw the molecular biologist as a good-for-nothing or as someone who would bring them the moon the next day. Mr. Rives thought that both attitudes were wrong. To be able to properly evaluate the potential of molecular biology one had to make the effort to achieve a rather thorough understanding of what it was, what it did, what were its tools, its principles, its approach and possibly even the difficulties of handling it.

Professor El-Fiky felt that most of the audience would be disappointed by what Mr. Rives had said. Throughout the world, and particularly in the developing countries there was a struggle between conventional plant breeding and the new technology of genetic engineering. In deciding whether the new technology was more useful or not there were two factors; one was money and the other was time. If it was decided that conventional plant breeding was useful, was it useful for developed countries or for developing countries? He did not know the extent of the audience's knowledge about genetic engineering, but it should be clear that there were still many problems to be solved even in tissue culture, let alone in genetic engineering. Two points had to be stressed. First, there was a need for basic research to identify the real problems and to find out how to solve them. That research, which was a matter for universities or other specialist institutions, had to precede direct application of the new technology to agriculture. Secondly, what was the situation if developing countries wanted to use the new technology? Should they wait or should they just start?

Mr. Rives said that Professor El-Fiky's question was extremely interesting. First, he thought that developing countries could, and already did benefit from the considerable improvements made in conventional plant breeding techniques. There were several centers in the world at which modern ideas were applied in the breeding of new varieties. A number of varieties of maize, wheat, potato and especially rice had been developed, and these, in the aggregate and in spite of the odd accident along the way, had improved agricultural productivity in numerous developing countries.

Mr. Rives said that his reply to the question whether a developing country had to wait for the biotechnology to become available for use, or whether it should try to begin at once to get involved, was that it should get involved immediately. A developing country should have advanced industries alongside those engaged in urgent, practical work. The more it could equip itself with its own laboratories, with its own national programs, with targets to reach out for, the more easily it would succeed in developing itself in research matters. He recalled having given a course in 1970 at the University of Havana in Cuba, when things were at their lowest ebb. A man called Shapiro, who was famous at that time as the discoverer of the operon 'lac', was working there in a small molecular biology laboratory. One might have asked oneself if the Cubans really needed to be working in molecular biology at that time. He thought the answer was yes, and events had proved that to be the case. That laboratory, like others, had served as a beacon for Cuban agronomic research in general, which was at a relatively high level. Mr. Rives was therefore of the opinion that it would be wrong to think that a developing country should be deprived of a technique because that technique was ambitious. Two years ago he had taken part in a Franco-African molecular biology course at Monastir in Tunisia. Molecular biologists from about a dozen African countries were brought together and the course had been very interesting and of an extremely high level. He had had great difficulty in understanding all that had been said there.

INTELLECTUAL PROPERTY ASPECTS OF PLANT VARIETY GENETIC ENGINEERING: VIEW OF A EUROPEAN LAWYER

Peter Kreye*

Summary

(i) Description of plant breeders' rights and of European patents as far as plant varieties and procedures for the breeding of new plant varieties are concerned.

(ii) Possibilities of protecting inventions in the field of genetic engineering by means of a European patent:

(a) patentability;

(b) scope of protection;

(c) infringement and its prosecution.

(iii) Influence on plant breeders' rights of European patents granted in the field of genetic engineering:

(a) present situation;

(b) developments to be expected.

(iv) Working of European patents granted in the field of genetic engineering.

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I

1. In their lectures, Dr. Padwa, Dr. Lawrence and Mr. Rives have pointed most impressively to the manifold possibilities offered by genetic engineering for the breeding of new varieties of plants. It should be clear to all interested parties that we stand but at the beginning of a new development whose outcome and implications can hardly be forecast at this point in time. Just as in the development of this technology, we are also taking an untrodden path when trying to assess, from a legal point of view, whether and how this technology is to be protected and the effect it will have on the existing protection of plant varieties. As Dr. Williams rightly pointed out in his lecture, despite the existence of a few court decisions[1], it is not yet possible to give a definitive assessment in respect of the United States of America, and, in any event, future developments must be awaited.

In taking up a position on this question as a European, I base myself on the German plant variety protection law since this corresponds, as a result of the International Convention for the Protection of New Varieties of Plants, in all relevant points with the plant variety laws of the European countries of UPOV. As regards the patent law aspect, I base myself on the Convention on the Grant of European Patents of October 5, 1973, to which practically all European UPOV member States have acceded; since they have adapted their national patent legislation to that Convention it seems that there is no need to discuss separately the national patent legislation of the individual European member States.

2. The International Convention and the individual national plant variety protection laws have created a right that, in contrast to the previously known patent rights, is more suited to the special requirements of plant breeding and to the interests of the breeders. The plant variety protection law affords protection to varieties of species contained in the list of species, in the form of a substantive right, related to the variety, under which the owner alone has the right to produce for purposes of commercial marketing and to market propagating material of the variety. I do not wish to enter into more detail here as regards the additional protection for ornamental plants. Before granting breeders' rights a growing trial is carried out so that when the application for protection is filed and the breeder's right is granted, the actual configuration of the variety is recorded. On the other hand, the breeding method used by the breeder, and which has made it possible to breed a variety that is new, stable and homogeneous, is not directly involved in variety protection.

3. Already, before the possibilities of genetic engineering and its effect on plant breeding were known, the question of possible patent protection for new varieties of plants and/or breeding processes was extremely disputed.[2] Even after the entry into force of the International Convention and of the national plant variety protection laws, this is still the case for those species that are not included in the relevant list of species.[3] My feeling is, that under the still current provisions of the German patent law, an effective patent was only possible for new plant varieties and breeding processes where the breeding method--and not the propagation method--of the plant that had been bred was repeatable, as disclosed in the patent specification.[4]

Following the grant of the first United States patents for genetic engineering processes, that is to say No. 3.813.316 to Chakrabarty and No. 4.237.224 to Cohen and Boyer, although these do not directly concern plant breeding, the interest in patent protection for such technologies has been created and initial discussions have already taken place.[5] Those discussions have become more intense following publication of European patent application 81303287.7.

We may agree with Vossius[6] that inventions in the field of genetic manipulation can also be patentable in respect of plant breeding on condition that they meet the requirements of the European Patent Convention. European patents are granted, in principle, for inventions that are new, that involve an inventive step and that appear to be industrially applicable, although the European Patent Convention does provide for a number of exceptions to this principle. As far as the subject of interest to us here is concerned, such an exception is provided for in Article 53(b) of the European Patent Convention, which reads as follows:

"European patents shall not be granted in respect of:

...

plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

An initial explanation of that provision is given, in addition to the actual wording, in Chapter IV.3.4, Part C of the Guidelines for Examination at the European Patent Office, issued by the General Secretariat of the Council of the European Communities in 1976, as follows:

"Article 53(b)

3.4 Also excluded from patentability are "plant or animal varieties or essentially biological processes for the production of plants or animals". One reason for this exclusion is that, at least for plant varieties, other means of obtaining legal protection are available in most countries. The question whether a process is "essentially biological" is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded. To take some examples, a method of crossing, interbreeding, or selectively breeding, say, horses, involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a method of treating a plant or animal to improve its properties or yield or to promote or suppress its growth by some mechanical, physical or chemical process-- e.g. a method of pruning a tree--would not be essentially biological since, although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.3)."

Section 3.5 of the same chapter is also important. It reads as follows:

"3.5 The exclusion referred to in the preceding paragraph does not apply to microbiological processes or the products thereof. Thus, patents may be obtained not only for processes involving microorganisms, but also for microorganisms themselves (as well as inanimate products) when produced by a microbiological process. In the case of microbiological processes particular regard should be had to the requirement of repeatability, as mentioned in item II, 4.11."

The following picture therefore emerges. According to the European Patent Convention, plant varieties are basically not patentable, whether or not contained in the list of species of the individual UPOV countries. The same applies to breeding processes that are essentially of a biological nature. Patentability is exceptionally admitted for breeding processes that are not essentially biological and for microbiological processes and their products.

We may assume, along with Bossung[7], that when agreement was reached on the European Patent Convention the question of patent protection for plant breeding processes was not given more positive attention, despite the knowledge that the International Convention for the Protection of New Varieties of Plants, that was already available, would not provide comprehensive protection, since patents were considered a less suitable type of protection for such inventions and, in addition, it was not wished to place the extra burden of this thorny problem on the already difficult negotiations leading up to the conclusion of the European Patent Convention.

A breeding process utilizing genetic engineering is therefore patentable under the European Patent Convention solely when it is not essentially of a biological nature or if it constitutes a microbiological process.

Doubt may be expressed as to whether the above-mentioned European patent application corresponds to the exceptions referred to. As felt by Crespi[8], it would seem very doubtful whether the content of the application can be considered not essentially biological. My own personal view is that Claims 1 to 18 and 20 are in fact biological processes. Although the meristematic propagation process claimed in Claims 19 and 21 may be deemed non-biological, it does not serve for breeding but only for propagation. It is not possible to regard it as a microbiological process either and the subject matter of both these claims would therefore appear to be non-patentable.

Quite apart from the eventual fate of the above-mentioned European patent application, we must assume that the marked activity of big firms in the field of genetic engineering will lead to the grant of European patents for plant breeding processes within the foreseeable future, in so far as these refer to essentially non-biological processes or to microbiological processes.

A further obstacle to the recognition of genetic engineering processes as patentable inventions is inherent in the requirement that they must be repeatable and in the fact that the applicant is required to prove, for example in opposition proceedings, that his invention is realizable and repeatable. Reference may be made here to Chapter V 4.3. of the Opposition Guidelines contained in the Guidelines for Examination at the European Patent Office already referred to. In one limited field of microbiology, that of microorganisms, it is possible to deposit microorganisms, and thus to obviate the need to prove repeatability. This does not mean, however, that proof of repeatability no longer has to be furnished in the case of microbiological processes for plant breeding.

Although there seems reason to have considerable doubt as to the effectiveness of the German applications and patents granted so far--corresponding experience being lacking for the European patent--since the repeatability cannot indeed be guaranteed, it would not seem out of the question that future inventions and the European patent applications for them could satisfy this requirement of repeatability.

II

I should now like to make some brief comments on the formalities of the granting procedure for European patents.

On receipt of the patent application, a simple examination as to form takes place in respect of various formalities, which are of no particular interest here. Once the application has survived this formal examination, it is then published without an examination of patentability, in particular of novelty, having been carried out. Generally, publication does not take place until the search report has been received, although prior publication is permissible. In the case of the application referred to above, publication was made before a search report had been received. On receipt of the search report, the applicant requests examination of the patent application. It is only after such examination that the decision on granting is taken.

It must be pointed out in this context that, as far as I am informed, no search report has as yet been received for the patent application I have referred to and it has therefore not yet been examined. For this reason, I do not wish to enter here into the numerous objections in respect of the claimed lack of novelty that were published in the August 1982 issue of the journal "Nature."[9]

As regards the scope of protection of a European patent in the field of plant breeding, it should be pointed out that in the case of non-microbiological processes that are protectable, that is to say in the case of those that are not essentially biological, such protection covers exclusively the breeding process and prohibits its repetition, but not generally the product of the breeding process as in the case of variety protection, that generally affords protection to the commercial production and the marketing of propagating material or, exceptionally, the final product in the case of ornamental plants in France. Although Article 64(2) of the European Patent Convention protects a directly obtained product, this requires that the protected process has been used in accordance with its intended purpose in obtaining the product. Additionally, those concerned disagree as to what constitutes the direct product of a breeding process, particularly when propagating processes follow the breeding process.[10] The case is different for microbiological breeding processes where the product, that is to say the new variety, is also protected.

III

Although it is not yet possible to foresee when and in what form European patents will be granted for genetic engineering processes for plant breeding, the question already arises of the effect such patents will have on the existence and further development of the protection afforded to breeders by plant variety protection law. A distinction should be made in future between microbiological processes, which also afford protection to the product, and other processes which, in order to be patentable, may not be essentially biological.

1. To begin with the latter type, it is only the process that enjoys protection, as described above, and not the variety as such, except in so far as it is a direct product of the process, meaning that no overlapping with plant variety protection is evident.

2. In the case of genetic engineering based on microbiological processes, however, things are different. Since, in this case, direct protection is given to the product, that is to say the variety, a situation may arise in which it is possible to obtain for one variety both plant variety protection for the variety and a European patent for its microbiological breeding process. This situation is in contradiction with Article 2 of the International Convention for the Protection of New Varieties of Plants, according to which member States may provide only one possibility of protection for a variety.

In that event it will become necessary to limit either the European Patent Convention and the national patent legislation or the national plant variety protection law in order to avoid such parallel protection. In view of the positive experience which plant breeders have had with national plant variety protection laws in the UPOV countries, I can but recommend that protection under the European Patent Convention of varieties bred by a microbiological process be excluded from now on, inasmuch as the varieties belong to species included in the lists of species to which, in one or several UPOV member States, plant variety protection is applicable.

IV

We all hope that genetic engineering inventions will prove of great utility for the further development of plant breeding. As regards the exploitation of these inventions, thought should be given to the following aspects. Genetic engineering developments, which regularly require high financial investment, can only be promoted if the research and development firm is sure that it can obtain a corresponding return on successful developments to cover its development costs and also a fair share in the profits realized by users of the invention.

The European plant breeders, who are mostly medium-sized firms, have so far had to defend their plant variety rights against the less developed countries with the arguments I have stated, and they are of the opinion that agreement has been reached on that basis. They fear, however, that in future genetic engineering for plant breeding will be dominated by financially strong firms and that there will be a danger of detrimental monopolies being exercised. I feel, however, that the developments that have so far taken place in the United States of America have shown that fair agreements can be reached between owners of patents and those who need to use those patents.[11] The same should also be possible in Europe. The introduction of compulsory licenses would raise considerable difficulties and should therefore be avoided, as far as possible.

Finally, I can see a very clear possibility of the national plant variety protection rights in the UPOV countries being able to continue their existence together with the expected European patent applications for breeding processes and that neither of these two forms of protection need be impaired by the other.

FOOTNOTES

1 Decision of the Supreme Court of June 16, 1980, in the case of Diamond v. Chakrabarty, GRUR Int. 1980 p. 627 et seq., with an annotation by Bodewig, p. 631 et seq.; Ein wichtiger Schritt zur Anerkennung der Patentfähigkeit von Mikroorganismen in den USA, GRUR Int. 1980, p. 16 et seq.

2 Hesse, Zur Patentierbarkeit von Züchtungen, GRUR 1969, p. 644, with further references.

3 Benkard, Patentgesetz, 7th edition, note 15 regarding Section 2 of the (German) Patent Law, with further references.

4 BPatGE 17, p. 181 et seq. - African violets.

5 E.S.C. Conference, London, September 30, 1982, The Genetic Manipulation of Plants.

6 Vossius, Patentfähige Erfindungen auf dem Gebiet der genetischen Manipulationen, GRUR 1979, p. 579 et seq.

7 Bossung, Erfindung und Patentierbarkeit im europäischen Patentrecht, Mitt. 1974, p. 121 (pages 123 et seq.)

8 Paper read at the Conference listed at 5 above.

9 Volume 298, August 26, 1982.

10 Hesse, op cit., p. 650; Heydt, GRUR 1969, p. 674 (page 676).

11 v. Dungern, Zur Praxis der Lizenzvergabe für gentechnologische Erfindungen in den USA, GRUR Int. 1982, p. 501 et seq.

[Original: German]

REPORT OF DISCUSSIONS

prepared by the Office of the Union
and approved by the speakers

1. The lectures were followed by a lively discussion which was presided over by Dr. W. Gfeller, President of the Council of UPOV. Dr. Gfeller was assisted by a panel comprising the five lecturers (Dr. D. Padwa, Dr. R.H. Lawrence, Jr., Dr. S.B. Williams, Jr., Mr. M. Rives and Dr. P. Kreye) and Dr. H. Mast, Vice Secretary-General of UPOV.

2. The President said that he was sure that he could speak for all the delegates in thanking the lecturers for their interesting and thought-provoking papers, and for their willingness to respond to a number of very specific questions. He then invited questions to the panel.

3. Dr. Böringer referred to the conclusion drawn by Dr. Kreye that the European patent and the breeders' patent under the UPOV Convention could indeed cohabit. Although he was certainly no specialist in the European patent, he nevertheless wished to ask whether it was not indeed possible that a conflict could arise. He wished to give the following example of a European patent granted for an ornamental plant variety which, as far as he understood it, did not exclude protection of cut flowers, and indeed Dr. Williams had said the same thing in respect of the United States of America. The protection right under the UPOV Convention varied in such a case. There were countries, like France and Switzerland and some others, where the final product such as cut flowers were included in the protection, but, as an example, such was not the

case in the Federal Republic of Germany. He asked whether that did not constitute in fact a conflict or did he see things wrongly.

4. Dr. Kreye replied that he had indeed said, towards the end of his lecture, that for the present he saw no probability of conflict, but developments had only just begun and it was therefore quite conceivable that at some point in the future a conflict situation could arise. Such had indeed already been referred to and Dr. Mast had already taken up a stance. As far as the example of ornamental plants was concerned, he could make two comments: as yet he knew of no ornamental plant patent that could be really valid since ornamental plants in particular failed to meet the requirement of repeatability. Although more than 100 patents had been granted in the Federal Republic of Germany for ornamental plants, this was generally considered to have been a great mistake. Those patents should never have been granted. It was of course a different question to decide what should be done with the cut flowers. There was in fact a specialist in that matter amongst those present, namely Mr. Royon. He would say, however, that the problem of protecting the final product had very little to do with the subject matter of the Symposium. In any event, he foresaw no conflict situation for ornamental plants.

5. Dr. Mast added that, in his opinion, after having being involved for many years in the preparation of the European Patent Convention, the granting of European patents for plant varieties was quite out of the question. There was no European patent protection for a plant variety as such and there was also no European patent protection for essentially biological processes for breeding plants. Protection was therefore only available for essentially non-biological processes for breeding plants and a patent granted for such a process would also include the product that was directly produced with the help of the process and, as already mentioned, it would have to be a process that was not essentially of a biological nature. It would be interesting to see how the European Patent Office was going to interpret this demarcation formula in respect of inventions in the field of genetic engineering. Dr. Mast repeated at that point that the provision of the European Patent Convention he had referred to had found its way into most of the domestic patent laws in Europe, although in some cases with certain restrictions. It had also been included in the WIPO Model Law for Developing Countries on Inventions. Finally, it was likewise to be found in the Regulations under the Patent Cooperation Treaty (PCT). Thus, that formulation that was intended to demarcate patent law and plant variety law, was either applicable or at least a guideline throughout extensive parts of the world, but despite that had not as yet, as far as he was aware, achieved recognition in the United States of America.

6. Mr. Fikkert said that he did not fully agree with Dr. Kreye's assessment that he did not foresee any clash between patents and plant breeders' rights in Europe. Mr. Fikkert thought that the example given by Dr. Böringer was perhaps not the best, since as far as cut flowers were concerned the situation under plant breeders' rights was almost the same as that which might exist under patents. From his understanding of patents, he foresaw two areas where there might be a clash. In the first place, there was the question of protection of the final product, and by that he meant, for instance, the protection of barley destined for the brewery. The second area of concern to him was the right of a breeder to use protected varieties belonging to other breeders in the creation of new varieties. Those two points, as far as he could see, were of major concern and might lead to clashes between the two systems of protection.

7. Dr. Böringer agreed that Mr. Fikkert had convinced him that he had perhaps not expressed himself clearly. His intention in referring to cut flowers could have also been fulfilled by wheat or barley. Thus, if a European patent for an essentially non-biological process could lead to substantive protection for the final product, it appeared to him to constitute a conflict with breeders' rights as laid down in the UPOV Convention. Perhaps there was still some time to reflect on this possible conflict. He himself, however, could as yet see no solution.

8. Dr. Padwa said that he would like to make two comments. First, he would predict that the phrase or the concept of something being "essentially biological in nature" was a swamp from which it would take many years to emerge. He believed that many modern biologists now felt that the ghost of vitalism had been laid to rest about the turn of the century, and that the distinction between what was living and what was non-living raised non-scientific issues, issues that might in fact very well be non-legal issues as well. He suspected

that something that was a very difficult metaphysical (but non-scientific) problem was really being handed off to the lawyers. The second point that he would like to make, and he could not speak to the European experience, was that it was his understanding that the distinction between receiving a plant variety protection certificate and obtaining a product patent on a plant in the United States of America had to do with the degree of novelty that existed in each specific case. (He remarked that he used the word "patent" as it was used under the broad meaning of the U.S. Patent Code, and not in its more limited sense of the Plant Patent Act of 1930.) Plant breeders, for example, were accustomed to generating new varieties all the time. They used traditional means to do so and the degree of novelty that they achieved was probably adequate to receive a variety protection certificate, but was probably not sufficient to receive a product patent. On the other hand, a biotechnologist might in some non-classical way, such as using a vector or micro-injection, insert new genetic material and alter the genome of a plant in such a way as to say confer herbicide resistance upon the plant. That was not out of the question. If that variety, which incorporated a gene or genes for herbicide resistance, was protected under the plant variety protection system, then all other plant breeders, public and private, could legitimately use the material in their own breeding programs and, to the extent that the gene or genes for herbicide resistance were incorporated in other people's material, other people could then presumably get plant variety protection. Dr. Padwa said that he believed, however, that the doctrine of product patents was that if a product patent was issued on that genetic material, then breeders who attempted to use it as parental material for their own breeding program would be precluded from obtaining a patent on any resulting variety, because their material would contain the fruits of a product patent. That, he believed, was essentially the difference in outcome between product patents and plant variety protection in the United States of America.

9. Dr. Williams felt that Dr. Padwa had outlined very well the conflict situation that was under discussion. The question was how to approach it. Dr. Williams said that he believed, as he had indicated earlier, that in the United States of America, the problem was going to arise mostly in relation to food crops. From reading the legislative history one got an idea that there was some concern about food crops being subjected to patent protection. As far as the question of experimental use was concerned, the doctrine in the general patent area was certainly not as broad as that in the plant variety protection area. He had to say that he did not know what decision the courts would take in the face of a claim by a plant or general patent holder that he did not want any use of his germ-plasm and that he had every right to it under the general patent statute.

10. Dr. von Pechmann returned to the example given by Dr. Böringer and observed that the question whether a cut flower could be protected by means of a patent or not only occurred in cases where protection could be applied for the process for producing the flower, that is to say when the subject matter of the invention was a process. He illustrated his point with the example of an invention consisting in a process for producing a blue rose by means of hydroculture characterized by the addition of substance X to the nutritive solution. That process also gave protection to the rose in the form of a cut flower since it constituted the product of the process. In the case of the blue rose it was not of course a new genetic variety, since the addition of the substance had to be continuous in order to obtain the blue color for each individual rose. A different example could be chosen however. It could be assumed that the invention consisted in chemically influencing the gene by allowing material to have an effect on the cell components and thus lead to a permanent blue coloration. If such a process was repeatable, that is to say could be imitated at any time, it would also be patentable in his view. The inventor would therefore obtain protection for a new variety having the genetic characteristic of producing blue rose petals. This could of course lead now to some conflict since the inventor could apply to the plant variety offices for variety protection for the rose. Equally, no-one could prevent the inventor from filing an application with the European Patent Office since it would indeed be a purely chemical process, a process to influence the genetic structure which, as had already been said, would be repeatable. Thus two parallel protection rights would exist for the same variety and the question would then arise of how that could be made compatible with Article 2 of the UPOV Convention.

11. Dr. Leenders said that he also wished to comment on the example given by Dr. Böringer. Dr. Leenders believed that there was a difference between the case of roses and that of barley or any other agricultural crop. He thought

that the whole audience would be aware that the requirements under patent law for stability, homogeneity etc. were much stronger than under plant variety protection law. That, in fact, was one of the reasons why special plant variety or plant breeders' rights laws had been introduced.

Dr. Leenders believed that a method could be protected under the European Patent Convention, provided the method was not biological in nature. The question was whether the end product could be protected. He thought that to be very doubtful because, by its very nature, a product such as barley might not satisfy such requirements as stability and reproducibility, which requirements were different under plant variety protection law and patent law.

12. Dr. Mast said that he would like to add something to what had been said so far. Two exclusive rights could exist in the same product: the European patent for a procedure, extending to the immediately produced product, and plant breeders' rights. Dr. von Pechmann had mentioned one case. Although that case was conceivable, until now it had been an abstract case. One should wait to see whether such cases really did occur, because on the one hand the question arose whether a given procedure was patentable, and on the other hand the question arose whether the product, namely the plant variety, was really eligible for protection under the plant variety law of a country. Even if such cases did occur they would not lead to an absolute legal catastrophe. In the field of intellectual property it was possible for two exclusive rights to exist in the same product or in the same procedure. Under patent law it was not unusual to have for the same product or for the same procedure two patents, one being dependent on the other. The only consequence was that everybody using such a procedure or product, or both, needed the authorization of the holders of both exclusive rights.

Dr. Mast believed that it could be seen from the European Patent Convention and from the European national patent legislations that both the Convention drafters and the European legislators had, as he had mentioned earlier, tried to avoid that situation, thinking it to be undesirable. He thought, however, that even if it could not be excluded, that did not necessitate a change. Such a need would only arise if cases became very common, if they appeared daily, or at least weekly or monthly. In addition, he thought that little was to be gained by changing the UPOV Convention or the national plant breeders' rights laws, because the desired change could only happen in the field of patents. The separation which the drafters of the European Patent Convention had tried to achieve was on the patent side. The only reference in the UPOV Convention was the provision--in Article 2(1)--that there should not be two forms of protection for one and the same botanical genus or species. It remained to be seen whether that provision would be interpreted as covering patents of procedure that led, mainly as a result of the scope of protection afforded to them, to protection of the product also.

13. Dr. Williams said that he would like to follow up what Dr. Mast had said. The need to live with dual types of protection for the same item certainly occurred in the United States of America. Dr. Williams wished to draw the audience's attention to the case of ornamental designs for manufactured articles. There was a statute called the design patent statute. The old copyright statute had contained a section that also provided protection for that same design as an expression of authorship. The United States Court of Customs and Patent Appeals had distinctly held that having one form of protection would not prevent having the other, and there really had not been a large problem with that.

14. Mr. Skov, expressing shock at what he had heard, said that he wished to refer to Article 5(3) of the UPOV Convention, where it was provided that "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." He believed that it had been the philosophy of the drafters of the UPOV Convention that genetic material belonged to mankind as such, and could not be appropriated in such a way that others were excluded from using it. He now saw that there might be possibilities in that direction, and that really shocked him.

15. Mr. Hutin said that he would like to continue in the same vein. With reference to Dr. Padwa's intervention, the reasoning of which he had well understood, he would like to have Dr. Padwa's reaction to the following thoughts. No reference was made in a plant variety protection certificate to the way in which the variety had been bred. Consequently, the holder of a plant or product patent would have to challenge the application for a certificate and

would have to furnish proof that his patented variety had been used in the breeding of the applicant's variety. It therefore seemed obvious to Mr. Hutin that all that was necessary to get round the patent was to produce an intermediate line in a country where no patent existed. The applicant could then say that his source had not been the patented plant but another plant, which he could moreover produce in evidence and which was not covered by a patent. Mr. Hutin considered, therefore, that the thought of being able to control the use by other breeders of patented material was somewhat illusory.

16. Dr. Padwa said in reply that there might very well be ways of actually putting so-called fingerprinting or marker materials into genetic material. In that way it would be possible to identify derived materials. What he had been trying to suggest previously was that plant variety protection relied on obvious means to produce new varieties, whereas patent product protection involved the use of non-obvious means and afforded a higher and tighter degree of protection; unlike variety development, something patentable involved a novel invention.

Dr. Padwa said that he also wished to respond to the comment about genetic material being the heritage of all humanity. He certainly did not wish to sound like a monopolist, but he thought that comments of that kind were perhaps more suited to a literary club atmosphere. One could equally say that words and/or music "belonged to all mankind" and that there should therefore not be any copyright on literary or musical materials. One could even say that the realm of ideas in the 'noosphere' was in fact so great that it too was the heritage of all humanity and that we should not have any such things as patents at all. The fact was that legislators and politicians of every shade and description had worked out a fragile balance in trying to see what the trade-offs were, what the benefits and what the liabilities were. He thought that man was proceeding cautiously, with very tentative knowledge, and that it was probably better not to strike emotional cords about plant material and to realize that there were practical benefits in rewarding invention.

17. Mr. Duyvendak said that he would like to comment on what Dr. Padwa had just said. Mr. Duyvendak thought that there was a very clear parallel between plant breeders' rights, where a whole combination of genes was being protected in the form of a plant variety, and copyright, where a whole combination of words was being protected in the form, for instance, of a book. The use of the words to make a new book was free and, under plant breeders' rights, the use of the genes to make a new plant variety was also free. The difficulty was that if certain genes were patented as such, and if the number of patented genes was very great, many possibilities would be blocked. One could avoid words or find alternatives for them. With genes the situation was much more difficult because the number of chromosomes was very limited. Breeders did not have the enzymes Mr. Rives asked for to speed up the number of recombinations. They had to live with a very small number of chromosomes, and therefore the use of genes should be free like the use of words.

18. Mr. Royon said that the remarks made and the fears expressed by some speakers had caused him to feel that the glossary issued to participants might usefully have been complemented by a small glossary of basic terms relating to patent and plant variety protection legislation. He believed that it was essential to emphasize two things.

First, one had to distinguish on the one hand between patent protection for a process, as existing in patent laws and which it was wished to call upon for the protection of some of the highly sophisticated techniques that had been mentioned and, on the other, protection of the 'product', which was possible either, in some countries, by filing an application for a patent--that was the case especially in the United States of America--or by filing an application for a plant variety protection certificate, say for varieties developed by classical plant breeding methods. Mr. Royon believed that there could be a risk of boundary conflicts in a country such as the United States of America, which had legislation that was dualist and extremely flexible.

Secondly, he thought that it was necessary to adjust what had been said about the European patent. At times in the discussion it had been treated as if it were equal to an American patent. It was necessary to emphasize, he believed, that the Munich Convention on the Grant of European Patents did not aim at the granting of a supranational title, but simply at establishing a unified procedure for the examination of patent applications. European patents granted on the basis of such applications divided into a number of national titles. It was at that moment that one was faced by the possibility, or for that matter the impossibility, of conflicts between the two systems of law, the patent law and the plant variety protection law. Mr. Royon said that he wished to note his belief that if the Munich Convention had excluded plant varieties from its orbit at a particular moment, then it had done so principally because the protection of plant varieties had been a question that was evolving in very many countries and the situation had not been very clear. It had not done so in order to preclude new varieties of plants from patentability as such. The French laws on patents and on new varieties of plants, for example, clearly provided that for species not yet covered by the 1970 law on new varieties of plants it was possible to apply for protection under the law on patents.

Mr. Royon said that he had considered it important to emphasize the problem of terminology since it seemed to him that the risks of conflicts and the fears raised should not be as intense as had been suggested.

19. Mr. Skov said that he wished to add a few words to his earlier remarks about freedom of access to genetic material and to Dr. Padwa's comments thereon. Mr. Skov said that he was convinced, from his work in defending plant breeders' rights, that if the necessary balance between rights and duties was not established, then the task of protecting the varieties that one wanted to protect in order to further agriculture would never be accomplished.

20. Dr. Mast concluded by returning to his earlier words with which he had spoken against dramatizing the situation. He qualified his statement, however, by explaining that his tranquilizing words had of course only referred to the situation that existed within the purview of the European Patent Convention and of the majority of domestic European patent laws. Where that Convention and the national European Patent Laws aligned on it were of application, he was able to reassure Mr. Skov since, under those laws in the case of new plant varieties the product was covered by the protection only where they were produced by an essentially technical process, which was surely a rare case and indeed one that only affected biology marginally. The bypassing of Article 5(3) of the UPOV Convention was therefore not so serious in that case. Dr. Mast continued by saying that, on the other hand, he was not so sure that no grounds for fear existed in the majority of non-European countries. If he kept returning to the compromise contained in Article 53 of the European Patent Convention, it was because it would be a good thing at the present time to remember the rule of demarcation set out there and to help ensure that it was correctly interpreted by the various authorities and courts since that clause had indeed been accepted in numerous laws throughout the world and also in a number of international conventions. It was therefore a formula that had been recognized throughout large areas of the world. If it was possible to achieve reasonable results on such a reliable basis in a number of UPOV member States--and he held that expectation to be fully realistic--it could be hoped that such decisions would also be copied in further parts of the world. He was indeed convinced that such a process would have to constitute the first step. Only once that had been done, could a call be made for revision of the Convention or action by the legislator.

21. The President closed the Symposium by again expressing his appreciation of the lectures given and by thanking all who had participated in the discussions.

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VIII. OFFICE OF UPOV: A. Bogsch (Secretary-General); H. Mast (Vice Secretary-General); M.-H. Thiele-Wittig; A. Heitz; A. Wheeler

CALENDAR

1983

UPOV Meetings

September 21 to 23 Rome (Italy)	Technical Working Party for Fruit Crops (Subgroup on September 20)
September 27 to 29 Conthey (Switzerland)	Technical Working Party for Ornamental Plants and Forest Trees
October 3 and 4	Technical Committee
October 11	Consultative Committee
October 12 to 14	Council
November 7 and 8	Administrative and Legal Committee
November 9 and 10	Meeting with International Organizations

Meetings of Other International Organizations

July 17 to 22 Munich (Federal Republic of Germany)	International Association of Horticultural Producers (AIPH), Congress
November 7 to 11 Quito (Ecuador)	Tenth Panamerican Seeds Seminar

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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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