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MILT STOMBLER AS OF 10/08/87

START DATE: AUGUST 1986

3rd QUARTER INVENTION #	<u>1986</u> DIS	CLOSURE DATE	DISCLOSURES/VIABLE
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01-86-020 A		03-03-86	6/6
01 - 86 - 021 A	2	09-26-86	
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INVENTION #	DIS	CLOSURE DATE	
01-86-023 R		?	
01-86-024 R		10-13-86	
01-86-025 R		10-22-86	
01-86-026 R		10-17-86	
01-86-027 A		10-18-86	7/1
01-86-028 A		09-23-86 (a)	
01-86-029 R		11-20-86	
01-86-030 R		11-24-86	
01-86-031 A		07-10-86 (a)	
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01-87-001 R		2-04-87	
01-87-003 A		2-13-87	5/4
01-87-004 A		3-16-87	-7 -
01-87-005 A		3-24-87	
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2nd QUARTER	1987		
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01-87-006 R		2-18-85 - 8-13-87	(c)
01-87-007 I		4-09-87	
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01-87-016 I		*	
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7 I/4*	24.1%		
8 R	27.6%		
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CHARLIE GOODWIN AS OF 10/8/87

START DATE: FEBRUARY 1987

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The Challenge of Changing Technology to European Plant Breeders Rights in the 1990's

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Roger G. Ditzel and Robert E. Fissell University of California

Prepared for Presentation to the First International Symposium on Fruit Tree Nurseries Lleida, SPAIN

September 21, 1989

The Challenge of Changing Technology to European Plant Breeders Rights in the 1990's

Roger G. Ditzel and Robert E. Fissell * University of California

I Introduction

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We are most pleased and honored to be with you at this important conference, and with the prestigious speakers who are participating. It is a particular pleasure to again meet numerous previous acquaintances, many of whom have been highly supportive of the University of California in the United States and in Europe. We truly value your friendship, and thank you for the hospitality extended to us.

^{*} The views expressed in this paper are those of the authors, and not necessarily those of The Regents of The University of California

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We will present an overview of what we see as the exciting challenge to the future of plant breeding. The subject is of vital importance to not only breeders and nurserymen dealing in woody plants, but those involved with small grains, forage crops, and vegetables as well. As a result of developments in biotechnology, we will see major changes in agriculture over the next decade with the need for pesticides reduced, currently fallow land becoming productive and expensive laboratory developments overshadowing the traditional techniques of plant breeding.

There will be as substantial a change in technology as there will be in the market due to the finalization of the EEC. It is important that the governmental mechanisms for protecting the rights of breeders be responsive and anticipate these changes.

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Our view is that of a research university where an overriding objective is the advancement of knowledge, and change in the market place as a result of the broad use of that knowledge. Intellectual property rights afforded to inventors and plant breeders by variety protection and patents encourages such change. Those rights must be readily obtainable if they are to be of eventual benefit to us in the products we can buy at the market.

In this paper, we first review the types of plant variety protection available in the United States for cultivars, including utility patents dealing with plant subject matter. Second, we review the patent licensing programs of the University of California, a major technology generator, with particular emphasis on our world-wide

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licensing program for new asexually reproduced plant cultivars. We last address issues we believe are important to the effective development and rapid introduction of those cultivars. Two important references are cited in the Bibliography. Extensive background material and discussion about issues of concern here can be found in each of these excellent documents.

II Protection for Plant Breeders' Rights in the United States

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Until sixty years ago, no protection existed in the United States for any new or novel plant. The first protection came in 1930 when the traditional patent laws in the United States were modified to provide for "plant patents" (35 USC 161), which are limited to asexually propagated materials. They provide the breeder with the right to exclude others from propagating, using or selling the protected plant for a period of seventeen years. This law is administered by the Department of Commerce. Data with respect to the new variety, including a description detailing the novelty, is obtained by the breeder and included in the written application for patent protection. Unlike many other types of patent protection, the time required for issuance from the date of filing is relatively short, averaging from twelve to eighteen months.

Plants that are seed propagated, such as small grains, are protected in the United States under the Plant Variety Protection Act, which became law in 1970 and is administered by the United States Department of Agriculture. As in the plant patent program, there is

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no government testing. Protection for a period of eighteen years is relatively easy to obtain.

Traditional utility patents in the United States (35 USC 101) cover machines, methods and compositions of matter such as drugs that are new, useful and not obvious. Plants modified through biotechnology techniques are also subject to protection by such utility patents. This protection lasts for seventeen years and gives the patentee the right to exclude others from making, using or selling the invention. Protection was recently given in the United States to a mouse in which the inventor had introduced a new gene giving particular susceptibility to cancer. Such modified animals may not be patentable in Europe, but modified plants are patentable in both Europe and the United States if they meet the established criteria for such protection. For example, AgriGenetics obtained a utility patent in Europe for alfalfa with increased protein content.

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Protection for cultivars available in the United States roughly parallels that available in Europe through utility patents and under the International Union for the Protection of New Varieties of Plants (UPOV).

The incentives provided to a patent owner encourage individuals to spend their time and money, on a pure risk basis, to develop new and improved products, processes and plant varieties. In return for disclosing what might otherwise be kept as a trade secret, the inventor receives the incentive of a time-limited right to exclude

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others with respect to his invention. This often, but not always, gives one the exclusive right to practice that invention.

Patented inventions may involve only marginal improvements or encompass broad and exciting breakthroughs leading to new industries. The latter occurred over the last decade with biotechnology. Inventions made in biotechnology receive the same privilege under patent laws as do other technologies, with the inventor having an exclusive period in which to exploit that invention. The right to such exploitation can be passed to others through a license agreement. This system caused large amounts of risk capital to flow to biotechnology, and new products are being introduced to the marketplace each month as a result.

In the same manner, plant breeders have the incentive to improve cultivars and to earn the right to exclude others from propagating and selling their protected varieties. Breeders often license others to propagate and sell the new variety in return for a royalty payment for each unit propagated or sold. In all cases, complete information about the invention must be disclosed, and not kept as a trade secret.

Enforcement of these rights is a unique problem with plant varieties, since it is often expensive to prove that an infringement has occurred. While there are enzyme typing tests that prove what a variety is not, there is no reliable laboratory test to prove the varietal identify of a particular plant. This is particularly difficult in the strawberry market. Fortunately, experienced

-5-

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breeders, nurserymen and growers can distinguish between commercial varieties with a high degree of certainty. Scientific methodologies will probably be developed.over the next decade to provide even greater proof.

III The Licensing of Plant Cultivars by The University of California

The University of California is a major licensor of a wide variety of cultivars for the world-wide production of agronomic crops. That licensing is part of an extensive program of patenting and licensing technology to many sections of industry and agriculture.

The University of California consists of nine campuses including five medical schools, as well as the largest agricultural experiment station in the world. The campuses span a distance of a thousand kilometers north to south, and enroll 130,000 students. A State Constitutional Corporation, the University spends \$5.4 billion per year, of which \$1 billion is on research. The University is contractor to the United States Department of Energy for Lawrence Berkeley Laboratory, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory. These spend an additional \$2 billion per year, with much of this amount dedicated to research and development on energy and defense.

The University of California is a major research university, with advanced expertise in almost all fields of science and a world-wide

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reputation for excellence. It is within this setting that many new technologies have been generated. The pioneering Boyer-Cohen work in biotechnology was carried out at The University of California-San Francisco and Stanford University. That work was developed rapidly at the University of California. Many useful products have resulted, including recombinant hepatitis-B vaccine, human insulin, and growth hormones. Agricultural biotechnology has prospered at the Davis Campus.

Technology management and the licensing of inventions to industry and agriculture by the University of California has three interrelated objectives:

1. The development and distribution of the invention for the benefit of the public. We seek wide use of the results of University research. In the case of new plant varieties we encourage the distribution of relatively clean and healthy plant materials.

2. The motivation of faculty researchers and plant breeders. This occurs when their research results are further developed and made available to the public as consumer products.

3. The generation of royalty income paid by licensees for the use of protected University technology. We believe the University of California, as a public institution, should manage its intellectual property and receive payment for its value, as would be expected for the management of real estate as a public trust.

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3. The generation of royalty income paid by licensees for the use of protected University technology. We believe the University of California, as a public institution, should manage its intellectual property and receive payment for its value, as would be expected for the management of real estate as a public trust.

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Written descriptions of inventions arising as a result of University research are received from campuses at a central office, where they are evaluated for commercial potential, patented or otherwise protected in the United States and other countries, and licensed to industry. Licensing of new inventions often occurs long before patents issue.

Last year, over 350 inventions were reported by University researchers, and 186 United States patent applications were filed. United States patents were issued to the University on 87 inventions on earlier filed applications, of which ten were for plant cultivars. The University now holds over 700 issued United States patents and has approximately 550 licenses in effect. Of these licenses, some 350 are for plant varieties protected by United States plant patents.

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From \$0.7 million in 1979, the University's annual patent royalty income grew to \$9.8 million this year. Of this \$1.7 million was from plant patents, including \$1.4 million from strawberry patents. Over \$2.5 million was spent during the year to protect patent rights world wide. Those rights are assigned by employees to the University as a condition of employment.

The royalty income received is used to support further research in all fields, after the payment of costs and a share to employeeinventors, including plant breeders.

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Plant breeders at the University of California have developed many improved fruit and nut trees, strawberries, asparagus, rootstocks, grapevines, and other cultivars. Plant patents protect a total of 71 of these in the United States.

Table I lists those University cultivars currently protected in the United States. Testing of these cultivars by the breeders was carried out with the cooperation and good will of growers and nurserymen within the State of California. Grower groups often provide funding for research on cultivars and members of the industry graciously offer their time to serve on Advisory Boards.

Table I

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While the listed cultivars were developed to meet the needs of California agriculture, such improved lines often find usefulness wherever there is a similar mediterranean-type climate. Although fruit characteristics are not always predictable from one part of the world to another, a general pattern does exist. This leads to very strong interest in the results of University of California plant breeding by nurserymen and growers in many parts of the world. The time required to test and demonstrate commercial utility of a new cultivar lasts for years, or even decades in the case of fruit trees. Generally, extensive testing precedes the University of California's release of a new variety for commmercialization. Table II shows the history of developmental and testing time required for a number of our patented cultivars.

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Table II

Promising varieties under University testing are often sought by growers for their own use prior to release. In some cases the desire for propagating materials by others has been so great that we have experienced theft of those materials prior to formal release. Such theft is disconcerting to us, but undoubtedly has been experienced by plant breeders world wide. We pursue the perpetrators of such thefts.

Traditional breeding techniques have provided incremental improvements that have been adopted by farmers on a relatively slow and orderly basis. Biotechnology will make available important improvements not possible using traditional breeding. Because these improvements will offer more economic production, the market will demand faster introduction of these improvements.

A substantial amount of capital has been used at the University to develop and bring biotechnology to practical application. Industry and government have funded research designed to insert genes into plants and provide resistance to disease and drought, and to improve salt tolerance. A recent corporate advertisement described that company's use of biotechnology to provide plants with resistance to tobacco mosaic virus, attack by certain caterpillars, and to tolerance for broad spectrum herbicides. Research conducted at the University of Wisconsin and the University of California has led to

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the increased resistance of plants to freezing through the application to the plant leaf surface of genetically engineered bacteria which do not cause ice nucleation, and which replace the naturally occurring, ice nucleating bacteria on the leaf.

An example of cooperative work between an industrial company and the University of California is the use of regenerative techniques to implant a lepidoptera-resistant gene belonging to the company in a grapevine. We expect the new vine will be protected in the United States by a plant patent owned by the University and by a utility patent on the gene itself held by the company. As a result a grower will need a license from both the University and the company to use the new grapevine. Obviously, well designed licensing techniques and education will be required to prevent misunderstandings as these technologies are applied in practice.

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When a new cultivar is ready for commercial release, licensing in the United States is normally non-exclusive to all reliable nurserymen. Perhaps because of a large market with one body of law and a tradition of respecting patent rights, our domestic licensing can be conducted with little difficulty and at a low cost of administration. We wish that was true in every other country.

Outside the United States, licensing is conducted on opportunistic basis except where we can identify major business opportunities. We seek to obtain royalties where protection is available and the market size justifies the cost of that protection. Licenses are often exclusive for a country, and contain diligence provisions.

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California tax payers and growers who pay royalties in the United States believe that we have a responsibility to obtain a royalty outside the United States. In some countries this is difficult, but laws are slowly changing in our favor.

Protection for breeders rights is almost non-existent in Latin America. We have done no licensing in Russia, the Eastern block, or in China. Australia, with no protection for breeders rights until recently, has had an enlightened attitude and used plant quarantine regulations as a means of ensuring breeders a fair return for the use of their cultivars. Likewise, we have limited potential for licensing in Africa except for countries bordering the Mediterranean. Japan may offer significant opportunity for us in the future.

IV Issues and Concerns for the 1990's

Important horticultural improvements will occur as a result of the application of biotechnology to plant tissues. Improvements in yield, resistance to disease, reduced need for fertilizer, and other examples cited previously will have a substantial economic impact on the production of food and fiber.

Biotechnology research to make these improvements possible is being conducted at great cost and using advanced scientific techniques. Patents having substantial breadth of coverage will issue to those

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who have conducted that research. Patentees will have the exclusive use of their inventions for a limited period of time.

As a result of the insertion of new genes into known varieties, naming of cultivars will become an increasing problem. We may need new international protocols to prevent confusion. Perhaps strict notice requirements to indicate ownership of the intellectual property rights contained in various plant materials will be required. While UPOV regulations prohibit the trademarking of a name used as a protected variety, in non-UPOV countries trademarking varietal names is not uncommon. We need to promptly and thoroughly rethink the system of names relating to protected and unprotected varieties before changes in technology overwhelm our traditional ways. Perhaps genetic tagging can be used to positively identify the source of materials when new genes are introduced to plants, should future research make that feasible. Regardless of the solution, the problem is particularly difficult because it involves the resolution of conflicts between intellectual property laws and a separate body of trademark laws with international treaties involved in both areas.

Technology has also exacerbated the traditional problem of theft of propagating materials. A leaf or cutting representing propagating material carried from one continent to another by an individual aboard a jet aircraft is virtually undetectable. From that same material, advanced propagating techniques can produce plants that are true to type for further propagation to provide substantial numbers of plants in a short period of time. Even if border

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controls were effective in finding such materials, the problem of lack of specific technology to make positive identifications of the nature of the material and the owner would make such interdiction futile. Intentional misnaming of plant materials in international shipments for the purpose of unauthorized entry into another country will become a substantially greater problem with the increased value of plant material containing economically important genetic material introduced by advanced technology.

For these reasons it is important to plant breeders that each country in which there is a need for advanced genetic plant materials for commercial purposes have systems which allow rapid commercialization with effective protection of breeders' rights. Without such systems in place, the incentive will increase for the theft of advanced selections from one country to another. Rampant theft is in no country's long-term best interest. The increased use of trade secrets and the development of black markets are predictable outcomes unless legally effective and rapidly responsive protection systems are instituted.

The opportunity for member states of the EEC to encourage plant breeders to work on European problems is substantial. The Common Market promised for 1992 is eagerly awaited, but will bring greater incentives to plant breeders if the member states develop simplified and commonly accepted means for dealing with the procedural matters of examining and testing for new cultivars useful in one or more member states. Such procedures exist under the 1973 European Patent Convention for utility patents, resolving many

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procedural duplications which previously existed. The differences between EEC countries under UPOV are as troublesome as were the old national patent laws.

The cost and time required to obtain protection on cultivars in numerous countries in Europe are substantial impediments to breeders. As a result, informal arrangements often replace formal protection. This alone argues for an improved and faster system of protection.

The need to formally protect a new cultivar in every EEC member country adds to a breeder's costs. This need arises to prevent unauthorized propagation in every member state, even though the cultivar is grown for fruit production in only a few of the states. Without protection in each country, the uncertainty of law, and cost of finding infringers, (given the free movement of goods within the EEC), the breeder is left without economically enforceable rights in any EEC member state. This situation should not be allowed to continue.

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As an example we cite our experience with strawberries. The University has twenty-four patented varieties, generated through traditional breeding done by Royce Bringhurst and Victor Voth. A new series of strawberry plants has been released each five years for the past two decades. Twenty-one of these varieties have been successfully introduced and licensed in the United States. Over the last decade Spain has become a dominant factor in the production of strawberries. Variety protection for strawberries in Spain became

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available in March of 1989. However, without obtaining protection in every EEC member state, we could have difficulty preventing the unauthorized sale to Spanish growers of plants propagated in another member state.

The practical effect is that we have found it necessary to file for protection on each of five new varieties in each of eight EEC countries, for a total of forty separate applications. Many of these countries are requesting plants of each variety for examination. Table III shows the extent of the protection we have sought.

Table III

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The "research exemption" of UPOV Article 5.3 needs to be reevaluated in light of developments in biotechnology. That exemption allows use of any protected variety as an initial source of genetic material by other breeders. As a result, the breeder who introduces a new and useful trait at substantial cost by genetic engineering will be deprived of protection for that trait in similar cultivars in UPOV countries. In the lepidoptera-resistant grapevine example given earlier, exclusivity in Europe would be lost. Such a situation will not encourage private breeders to address and solve problems of particular importance to European growers.

The UPOV concept of National Lists for member states also needs reexamination. Any member effectively can deprive breeders of rights

-16-

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The UPOV concept of National Lists for member states also needs reexamination. Any member effectively can deprive breeders of rights

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otherwise available under UPOV, simply by not adding a particular plant type to its National List. Geographic shifts are occurring in agricultural production, often aided by changing economics and applied technology, such as tunnel production. Assuring the availability of breeders rights in each country for a greater number of crops would increase incentives, both in the traditional breeding and biotechnology areas, and prevent lack of protection when geographic production shifts do occur.

V Conclusion

Whether we like it or not, biotechnology is here to stay. It will have substantial impact on plant breeding and cause significant commercial dislocation in the distribution of plant materials. The nature of this technology argues against market fragmentation and for effective propagation and distribution systems. Indeed, the current trend of consolidation in the seed and nursery industries is undoubtedly being effected by the opportunities biotechnology holds for agriculture.

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As a result of existing testing and examination procedures, the incentive for plant breeders to introduce new materials into the EEC is not as great as we believe desirable. Greater incentive to breeders would result in earlier availability of varieties adapted to local needs. The EEC has a real opportunity to offer expanded incentives for plant breeders through a single, commonly accepted application and testing procedure. Advanced and expensive

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technology will be applied to European problems in a more vigorous way when the reward system reflects the contributions made by plant breeders. We urge you to review the certification and protection procedural matters in each of your countries, and to work towards a less complex system for the EEC.

As the European Economic Community becomes finalized in 1992 it will become a licensing area of greater interest to us. It is our hope that the size of the European market will convince European breeders and governments, nurseryman and growers that uniform, effective and timely protection for breeders rights is in their best interest.

We at the University of California are anxious to introduce new and protected varieties promptly into the EEC. Even more important we seek to continue the cooperative and productive scientific relationships between your industry, institutions such as IRTA, and our scientists.

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-18-

-18-

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TABLE I

UNIVERSITY OF CALIFORNIA PATENTED PLANT CULTIVARS

		Number of <u>U.S. Patents</u>
ASPARAGUS		4
AVOCADOS		3
CHERRIES		1
GRAPES		. 10
GRAPEFRUIT		2
OLIVES		2
PEACHES	,	8
PEARS		4
PLUM		1
ROOTSTOCKS		6
STRAWBERRIES		24
 WALNUTS		3.
OTHER		<u> </u>
	TOTAL	71

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TABLE II

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EXAMPLES OF TIME REQUIRED FOR TESTING AND PROTECTING CULTIVARS IN THE UNITED STATES

	Years Crossing to <u>U.S. Patent Application</u>	Months Application to <u>Patent Issuance</u>
ASPARAGUS	16	15
CHERRIES	19	17
TABLEGRAPES REDGLOBE CHRISTMAS ROSE CENTENNIAL	22 18 14	22 16 22
GRAPEFRUIT	27	22
PEACH FREESTONE DWARF	13 8	13 18
PEAR	23	22
STRAWBERRIES TUFTS DOUGLAS CHANDLER OSO GRANDE	7 4 5 6	29 13 19 20
WALNUT	12	10

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TABLE III

STRAWBERRY VARIETAL PROTECTION - OSO GRANDE SERIES EUROPEAN COUNTRIES

EEC Countries	UPOV	<u>Trademark</u>	
Belgium	X		
Denmark	х		
France .	x		
Germany, Federal Republic of	х		
Greece		X	
Ireland			
Italy	х		
Luxembourg			
Netherlands	х		
Portugal		x	
Spain	х	Х .	•
United Kingdom	X		
Other		÷	
Austria	-		
Finland			
Lichtenstein			
Norway			
Sweden			
Switzerland	×	,	

Sweden Switzerland

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TABLE III

STRAWBERRY VARIETAL PROTECTION - OSO GRANDE SERIES EUROPEAN COUNTRIES

E	EC Countries	UPOV	<u>Trademark</u>
	Belgium	x	
	Denmark	x	
	France ·	x	
	Germany, Federal Republic of	x	
	Greece		x
	Ireland		а. в. — ,
	Italy	х	
	Luxembourg		
	Netherlands	x	
	Portugal		X
	Spain	x	Χ
	United Kingdom	x	
<u>0</u>	ther		
	Austria		
	Finland		
	Lichtenstein		
	Norway		
	Sweden		. `
	Switzerland	x	2 .

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X

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Sweden Switzerland

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An Overview of Assessment Methods

March 1986

Prepared by

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Coopers & Lybrand and the Office of Productivity, Technology and Innovation U.S. Department Of Commerce



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