MARY MARY QUITE CONTRARY HOW DOES YOUR BIODIVERSE GARDEN GROW? AN OVERVIEW OF INTELLECTUAL PROPERTY PROTECTIONS FOR PLANTS IN THE UNITED STATES, EUROPE, AND JAPAN

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ABSTRACT

As we enter further into the boom of the biotechnology era, the role that plants play in our everyday lives continues to grow increasingly more important. This article seeks to provide a general outline of the protections available on a national, as well as, international level for new plant varieties produced through both genetic engineering processes utilized by the biotechnology field, as well as, the "older" methods, such as cross germination, splicing, etc. that are still successfully being utilized by the general scientific community. In the broadest sense this article is designed to help those who are unfamiliar with the protections available for new plant varieties better understand the minimal protections available in those countries that are signatories of the TRIPS-GATT treaty, as well as, the more specific systems of protection that are available in Europe, Japan, and the United States. This article is also designed to emphasize the industrially important role that securing protections for new plant varieties plays in the world of today, as well as, the world of tomorrow, on both a monetary, as well as, humanitarian level. As the advances made in the biotech arena offers new hope in erasing world hunger, sicknesses, such as AIDS, and pollutants resulting from various industrial processes, I can only hope that the world will continue to embrace, as well as, reinforce the plant protections that are currently available.

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MARY MARY QUITE CONTRARY HOW DOES YOUR BIODIVERSE GARDEN GROW?[1] AN OVERVIEW OF INTELLECTUAL PROPERTY PROTECTIONS FOR PLANTS IN THE UNITED STATES, EUROPE, AND JAPAN

JACQUELINE M. COHEN*

Once upon a time Mary Q. Contrary only had to worry about how the plants sewn in her garden grew. However, the role that plants play in agriculture, health, and manufacturing has rapidly grown and expanded,[2] and now Ms. Contrary must decide whether to protect the new plant varieties growing in her garden, or allow the new varieties to be appropriated and commercialized without remuneration for her efforts. Contrary Mary does not have time to dawdle. She must act fast.

The increasingly important role that plants play in our society is evidenced by the large percentage (an estimated 80%) of the world's population that depends on medicines derived from plants to treat their illnesses,[3] the growing trend to utilize plant resources instead of petroleum-based stocks as the primary source for manufacturing industrial materials,[4] and the astounding fact that approximately 90% of the world's dietary needs are met by just 20 cultivated crops.[5] With plant resources in such high demand, it was only a matter of time before scientists would discover a way to more efficiently and effectively meet the demands of our society.[6] Little did Watson and Crick know that the biotechnology field they fathered would lead to such a sea of change in the use and development of plants.[7]

Biotechnology has been the primary catalyst for this sea of change because it can be used to decode a plant's genetic blueprints, thereby enabling scientists to enhance crop productions with greater speed and accuracy than they previously could through selective breeding processes.[8] Discoveries that once took years or decades to uncover

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[1] *See Mary, Mary, Quite Contrary*, *available at* http://www.tudorhistory.org/poetry/marymary.html (last visited Mar. 15, 2003) ("Mary, Mary, quite contrary, How does your garden grow? With silver bells and cockle shells, and pretty maids all in a row.").

[2] *People, Plants, and Patents*, *at* http://idrc.ca/books/725/chap1.html (last visited Mar. 15, 2003).

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] Study released by The National Center for Food and Agricultural Policy in 2002 "found that six biotech crops planted in the United States — soybeans, corn, cotton, papaya, squash and canola — produced an additional 4 billion pounds of food and fiber on the same acreage, improved farm income by $1.5 billion and reduced pesticide use by 46 million pounds."

[7] *See generally* David S. Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373 (1998) (explaining how science changed farming techniques). The field of biotechnology was born in 1953 when J.D. Watson and Francis Crick discovered the double helical structure of deoxyribonucleic acid (DNA). *Id.* at 397. A DNA molecule is the molecule containing the hereditary characteristics that a plant or animal passes on from one generation to the next. *Id.* at 446 n.151.

[8] *Id.* at 398.

are now discovered in one generation.[9] Moreover, the ability to map a plant's genetic code has enabled biochemists to more rapidly determine whether a plant has any medicinal value.[10]

In the agricultural world, scientists are using biotechnology to create transgenic[11] plants that attain three primary goals.[12] First, scientists seek to increase the value that fresh produce has to consumers by creating plants that have desirable characteristics, i.e., tastier tomatoes,[13] potatoes having a longer shelf-life, etc.[14] Second, scientists are trying to create plants that enable farmers to produce larger crops without changing the conditions under which the plants are grown.[15] Finally, scientists attempt to increase plant resistance to weeds, insects, disease, temperature fluctuations, and drought.[16] Apparently scientists have enjoyed some success because since 1998 farmers have steadily increased the number of acres sewn with genetically engineered plants.[17]

In the industrial community, attempts are being made to replace petroleum as the primary raw material used to produce plastic with plastic-producing transgenic plants; to that end researchers have inserted a gene into mustard plants that makes plastic.[18] Researchers in the paper-making industry have been utilizing gene manipulation techniques to try and produce trees that have an increased cellulose content, the structural fiber used to make paper, while at the same time decreasing the amount of other components responsible for the pollutants that are produced when the trees are processed into paper.[19]

In the healthcare industry, biotechnology has reinvigorated the pharmaceutical industry's search for new plant-derived medicines.[20] By screening plants found in

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[9] *Id.*

[10] *Id.* at 426-27.

[11] A transgenic plant is a plant that has had non-indigenous DNA incorporated into it. *See* Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 43 n.27 (2001).

[12] *Id.* at 5.

[13] *Plant Biotechnology Timeline: Learn how technology has been used to improve the food we grow and eat, available at* http://www.whybiotech.com/index.asp?id=2157 (last visited Mar. 15, 2003). A bioengineered tomato having more flavor and a longer shelf life is approved by the FDA for sale in the United States and marketed under the trademarked name FlavrSavr. *Id.*

[14] *Id.*

[15] *Id.* Scientists use bioengineering techniques to successfully grow tomato plants in the salty soil that would normally cause their demise; a feat that researchers have unsuccesfully been trying to accomplish for 100 years via selective breeding processes. *See also* Kristen Philipkoski, *Modified Tomatoes Hold the Salt, at* http://www.wired.com/news/print/0,1294,45694,00.html (last visited Mar. 15, 2003).

[16] Mary Lynn Kupchella, *Agricultural Biotechnology: Why It Can Save the Environment and Developing Nations, But May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 724 (2001).

[17] *Id.* "In 1998, genetically engineered crops accounted for 25% of corn acreage planted in the United States, 38% of soy bean acreage, and 45% of cotton acreage, for a total of 45 million acres, an increase of 250% from 1997. In 1999, biotechnology plantings in the U.S. increased to 62 million acres." *Id.* Moreover, in 2000 farmers in 13 countries planted 109.2 million acres of land with bioengineered crops, a 25-fold increase over 1996. *Plant Biotechnology Timeline, supra* note 13.

[18] Lydia Nenow, *To Patent or Not To Patent: The European Union's New Biotech Directive*, 23 HOUS. J. INT'L L. 569, 576 (2001).

[19] *Id.*

[20] Tilford, *supra* note 7, at 428.

exotic places like the Brazilian rainforest and the mountains of Kenya, pharmaceutical companies have uncovered new medicines worth millions of dollars.[21]

This comment will provide an overview of plant variety protections available in Europe, the United States, and Japan. Part I of this comment will provide an overview of the relevant international treaties, and part II will address the mechanisms available in Europe, the United States, and Japan to protect plants.

I. PROTECTIONS AVAILABLE FOR NEW PLANT VARIETIES

Under the TRIPS (Trade-Related Intellectual Property) portion of the General Agreement on Tariffs and Trade (GATT), signatory countries must adopt either a patent system, or some other *sui generis* system of protection for new varieties of plant species.[22] A plant variety right is an intellectual property right in a new strain of plants that is similar to a patent.[23] This right gives the developer of a new species of plant the exclusive right to exploit her new plant for a limited period of time.[24]

One example of a *sui generis* system of plant protection is the Plant Breeder's Rights (also known as Plant Variety Protection (PVP)) system offered by the Union for the Protection of New Varieties of Plants (UPOV).[25] Operating under the umbrella of the World Intellectual Property Organization (WIPO), UPOV was originally established in 1961 primarily to protect new kinds of flowers and ornamentals.[26] This primary objective remains unchanged today, with roses and chrysanthemums being the most commonly protected plant species under UPOV.[27]

Plant Breeders' Rights are rights that the Member Countries of UPOV have incorporated into their national laws.[28] Once incorporated, the government can grant an exclusive right to the plant breeder enabling the breeder to exclude others for a limited time from either making, or commercializing the material from the breeder's protected variety of plant.[29]

There is a 1978 version of UPOV[30] and a 1991 version of UPOV[31] in effect today.[32] Both versions offer a *sui generis* system for protecting plants, but the

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[21] *Id.* at 428-29.
[22] *People, Plants, and Patents*, *supra* note 2.
[23] Timothy Millett, *The Community System of Plant Variety Rights*, 24 EUR. L. REV. 231 (1999).
[24] *Id.*
[25] *People, Plants, and Patents*, *supra* note 2.
[26] *Id.*
[27] *Id.*
[28] Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 136 (2000).
[29] *Id.* at 135-36.
[30] *See* International Convention for the Protection of New Varieties of Plants, Dec. 12, 1961, as revised at Geneva on Nov. 10, 1972, and on Oct. 23, 1978, and on Mar. 19, 1991, *available at* http://www.upov.int/en/publications/pdf/list_publications.pdf (last visited Mar. 15, 2003) [hereinafter UPOV].
[31] *See* UPOV, as revised at Geneva on March 19, 1991, *available at* http://www.upov.int/en/publications/pdf/list_publications.pdf (last visited Mar. 15, 2003).
[32] *People, Plants, and Patents*, *supra* note 2.

differences between the two versions are significant.[33] The European Union (hereinafter E.U.), United States, and Japan are all members of the 1991 version.[34]

Although the 1978 version provides more flexibility to signatory countries by allowing each individual country to select the range of plant species entitled to protection,[35] the 1991 version allows member states to provide more than one form of intellectual property protection to new plant varieties, i.e., a new plant variety inventor may be granted both a plant or utility patent and plant variety certificate.[36] The 1991 version, however, does not allow farmers, unless individual signatories adopt an exception, to save the seeds of a plant species protected by UPOV from one growing season for planting in the next, a right that is available under the 1978 version.[37] The minimum term of plant variety protection available under the 1991 version has been extended from 18 years to 25 years for trees and vines, and from 15 years to 20 years for all other species.[38] Moreover, the 1991 version extends plant variety protection to cover the crops harvested from the protected plant varieties, and provides an option to extend such protection even further to cover products made from the harvested crops.[39] Finally, the 1991 version incorporates a provision extending plant variety protection to varieties essentially derived from the protected variety.[40]

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[33] *Id.*

[34] *See States Party to the International Convention for the Protection of New Varieties of Plants, available at* http://www.upov.int/en/publications/gazette/pdf/pub422_24-10-02.pdf (last visited Mar. 15, 2003).

[35] *People, Plants, and Patents*, *supra* note 2. Under the 1978 version of UPOV, the individual member states define the plant varieties entitled to protection via their national laws, while the 1991 version of UPOV requires members to draft their national laws so as to cover plant varieties of all species and genera. *Id.*

[36] Millett, *supra* note 23, at 233 (explaining that the requirement under the 1961 version of UPOV, which only allowed member states to grant one form of protection for a new variety of plant, was relaxed in the 1978 version before completely being eliminated in the 1991 version).

[37] *People, Plants, and Patents*, *supra* note 2.

[38] Millett, *supra* note 23, at 233. The term under the 1978 version remains 18 years for trees and vines and 15 years for all other plant species. UPOV, *supra* note 30, art. 8.

[39] Millett, *supra* note 23, at 233 (explaining that such a provision "allows imports of harvests from protected seeds, [or products made therefrom], to be prevented").

[40] *Id.* (explaining that this provision was introduced into the 1991 version to protect plant breeders who use conventional breeding methods from losing their exclusive rights because a genetic engineer introduced a cosmetic change into the new variety just weeks after it was put into the stream of commerce).

II. MECHANISMS AVAILABLE IN THE EUROPEAN UNION, UNITED STATES, AND JAPAN TO PROTECT NEW PLANT VARIETIES

A. The European Union

There are three primary sources of law governing the protection of new plant varieties: 1) the European Patent Convention[41] (EPC); 2) plant variety protection certificates; and 3) the Biotechnology Directive[42] (Biotech Directive).

1. The European Patent Convention

The EPC was adopted in 1973 by the E.U. members in order to enable an inventor to obtain patent protection throughout the entire E.U. by filing a single patent application with a central authority.[43] The central authority administering the system is the European Patent Office (EPO). Although the grant of a patent by the EPO instantly creates a bundle of E.U. patents, the enforceability of the patent that is granted will be governed by the national laws of each individual E.U. member.[44]

Under article 53(b) of the EPC, plant varieties are excluded from patent protection.[45] Article 53(b) provides in relevant part: "European patents shall not be granted in respect of: (b) 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."[46] The EPC does not provide definitions for the terms "essentially biological" or "plant varieties,"[47] leading to uncertainty as to the extent of the prohibition on patenting plant varieties. The EPO has explained through Board opinions that "essentially biological" means that all steps which are essential to, and have a decisive impact on the final results of the claimed process, must be capable of being carried out without any human intervention.[48]

With respect to "plant varieties," the EPO Technical Board of Appeals, in *Plant Genetic Systems/Glutamine Synthetase Inhibitor*, construed the term broadly to include plants that had been genetically modified.[49] As a result, the EPO had to "suspend its previous practice of granting claims to genetically modified plants."[50]

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[41] Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC]. The members of the EPC are the fifteen E.U. member states, *see infra* note 57, as well as Cyprus, Lichtenstein, Monaco, and Switzerland. Gitter, *supra* note 11, at 43 n.133.

[42] Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 [hereinafter Biotech Directive].

[43] Nenow, *supra* note 18, at 583-84.

[44] *Id.* at 584.

[45] EPC, *supra* note 41, art. 53(b).

[46] *Id.*

[47] *Id.*

[48] *See* Nenow, *supra* note 18, at 587.

[49] Decision T356/93, *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, 1995 E.P.O.R. 357, 375, 380 (1995).

[50] Tim Roberts, *EPO: Patents - Patentability of Plants*, 22 E.I.P.R. N49, N49 (2000).

Discontent with the decision of the Technical Board of Appeals, Novartis appealed a test case involving transgenic plants to the EPO Enlarged Board of Appeals.[51] The Enlarged Board held that plants are not per se excluded from patentability under article 53(b).[52] Although the Enlarged Board held that the definition of a plant variety does include genetically modified plants,[53] they carved out an exception to the general prohibition on patenting plants.

The Enlarged Board held that the term "plant varieties" only encompasses claims drawn to specific plant varieties, and is not applicable to claims that encompass more than one variety.[54] The Enlarged Board's decision is designed (1) to prevent patents from being granted for specific plant varieties that can be protected by plant variety rights, and (2) to enable inventors to obtain patents directed at plant groupings because such plant groupings cannot be protected by plant variety rights (PVRs can only protect specific plant varieties).[55] A similar outcome would be reached under the provisions of the Biotech Directive, which will be discussed further infra, although the Board did not rely on the Biotech Directive in reaching its decision.[56]

2. Community Plant Variety Rights

In 1995, the European Union,[57] in conformity with the 1991 version of UPOV, adopted the Community Plant Varieties Rights[58] (hereinafter CPVR).[59] The CPVR system was adopted in order to enable a plant breeder to file one application and obtain protection for a new plant variety in the entire territory of the E.U.[60] Prior to the inception of the CPVR system, plant breeders wishing to obtain protection for a new plant variety in the entire E.U. territory had to file separate applications to each individual member state.[61]

The Community Plant Variety Office (CPVO), located in Angers, France, was established to administer the CPVR system.[62] The CPVO is required to accept all

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] Margaret Lewelyn, *The Patentability of Biological Material: Continuing Contradiction and Confusion*, 22 E.I.P.R. 191, 196 (2000).
[55] Roberts, *supra* note 50, at N49.
[56] *Id.*
[57] The European Union consists of the following member states, all of whom were affected by the enactment of the Biotechnology Directive: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, & the United Kingdom. *See* Gitter, *supra* note 11, at 43 n.4.
[58] Council Regulation 2100/94 of July 27, 1994 on Community Plant Variety Rights, 1994 O.J. (L 227) 1, amended by Council Regulation 2506/94 on Community Plant Variety Rights, 1995 O.J. (L 258) 3 [hereinafter CPVR].
[59] Millett, *supra* note 23, at 234.
[60] *Certificate of Community Protection for Plant Varieties, at* http://www.sib.it/engsib/nov_veg/cer_euri.htm (last visited Mar. 15, 2003).
[61] B. P. Kiewiet, *CPVO Papers, at* http://www.sib.it/engsib/nov_veg/cer_euri.htm (last visited Mar. 15, 2003).
[62] Millett, *supra* note 23, at 244.

applications and any other papers that are submitted in the official language of any of the E.U. member states.[63]

Under article 5 of the CPVR, a "variety" is defined as a "plant grouping within a single botanical taxon of the lowest known rank, which grouping can be defined by: the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged."[64] A "plant grouping" is further defined by article 5 as "entire plants or parts of plants as far as such parts are capable of producing entire plants."[65]

Moreover, a plant breeder will only be granted a CPVR if the variety is: 1) distinct, 2) uniform, 3) stable, and 4) novel.[66] A variety is distinct if, on the date the application is filed, the variety is different from any other variety then known.[67] A "uniform" variety is a variety that expresses the characteristics making it distinct with very little variation when propagated.[68] A variety is considered "stable" when the characteristics making it distinct do not change after repeated propagation.[69] A variety is considered "novel" if the CPVR application is filed within one year of the variety being commercialized in the E.U. and/or within four years (six years if a tree or vine) of the variety being commercialized outside the E.U.[70]

In order to obtain a CPVR, the applicant must be a natural or legal citizen or resident of either an E.U. or UPOV member state, or any other country guaranteeing reciprocal treatment to legal citizens or residents of E.U. member states.[71] The grant of community-wide protection lasts for 30 years for vine and tree species and 25 years for all other species.[72] These terms may be extended for up to five years for specific genera and species, and has been extended for potatoes because of their long breeding process.[73] The transfer or termination of a certificate of CPVR protection, transfers or terminates all Community-wide rights obtained thereunder.[74]

Under the CPVR system, E.U. members may continue to grant national plant variety rights.[75] However, the inventor of a new plant variety may not obtain a certificate of Community protection and a certificate of national protection in the same variety, the applicant must choose between national and Community rights.[76]

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[63] *Id.* at 245. As of May, 2001, the CPVO has received more than 12,600 CPVR applications. *Community Plant Variety Rights and New Apricot Varieties*, *at* http://www.cpvo.fr/news/apricot.pdf (last visited March 15, 2003).

[64] CPVR, *supra* note 58, art. 5.

[65] *Id.*

[66] CPVR, *supra* note 58, art. 6.

[67] *Community Plant Variety Rights and New Apricot Varieties*, *supra* note 63.

[68] CPVR, *supra* note 58, art. 8.

[69] *Community Plant Variety Rights and New Apricot Varieties*, *supra* note 63.

[70] *Id.*

[71] *Certificate of Community Protection for Plant Varieties*, *supra* note 60.

[72] CPVR, *supra* note 58, art. 19.

[73] Millett, *supra* note 23, at 242.

[74] *Id.* at 235.

[75] *Id.*

[76] *Id.*

Moreover, a plant variety protected under the CPVR system may not be the subject of any European or national patent.[77]

3. The Biotechnology Directive

On June 16, 1998, the E.U. enacted the Biotechnology Directive, which came into force on July 30, 1998.[78] The Biotech Directive was designed to:

> adapt European intellectual property rights to recent technological changes and to harmonize the domestic laws of the member states with the goal of creating the legal certainty required to draw the biotech industry into the European Union, ending the competitive disadvantage that separated the European Union from the United States.[79]

The Biotech Directive required each member state to enact national laws protecting biotechnological inventions[80] by July 30, 2000.[81]

Article 4.1 of the Biotech Directive, which is a mirror image of article 53(b) of the EPC, provides that "plant and animal varieties [and] essentially biological processes for the production of plants or animals" are not patentable.[82] However, this limitation is qualified by article 4.2 of the Biotech Directive, which provides that "plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."[83] The Biotech Directive

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[77] *Id.*

[78] Robin Nott, *'You Did It': The European Biotechnology Directive at Last*, 20 EUR. INTELL. PROP. REV. 347, 347 (1998). A directive is a law that establishes a specific goal which each member state must achieve, and although the goal itself is binding on each member state, the members are permitted to choose the method and, sometimes, the extent to which the announced goal will be implemented. Gitter, *supra* note 11, at 43 n.3. A regulation, on the other hand, is a law that not only establishes a particular goal to be achieved by each member state, but also dictates the method and extent of its implementation. *Id.* As a result, directives give member states the flexibility necessary to harmonize the national laws affected by their enactment. *Id.*

[79] Nenow, *supra* note 18, at 590.

[80] Biotech Directive, *supra* note 42, art. 1.1.

[81] Nott, *supra* note 78, at 347. However, "[a]s of September 2, 2000, only Denmark, the United Kingdom, and Austria had amended their national laws in accordance with the Directive." Gitter, *supra* note 11, at 43 n.20. On the contrary, the Netherlands, with the support of Italy and Norway, filed an action in the European Court of Justice seeking to have the Directive annulled, *Biotechnology Patents in Europe*, *at* http://www.sib.it/engsib/novita/pat/151001.htm (last visited Mar. 15, 2003), while the German and French lawmakers sought to have the Directive immediately renegotiated. Gitter, *supra* note 11, at 43 n.20. On October 9, 2001, the European Court of Justice ruled against the Netherlands finding that 1) a proper legal basis was used to adopt the Biotech Directive, 2) the Biotech Directive is not inconsistent with the laws pertaining to patentability of plants because no conflict is possible between the laws governing plant varieties and patents, and 3) the Biotech Directive does not impose a threat to human dignity and integrity, which is a general principle of E.U. law. *Biotechnology Patents in Europe*, *supra*.

[82] Biotech Directive, *supra* note 42, art. 4.1(a) & (b).

[83] Biotech Directive, *supra* note 42, art. 4.2.

introduced this exception to expressly allow claims directed at plant groupings, which cannot be protected by plant variety rights, to be patentable.[84]

Moreover, article 2.3 of the Biotech Directive adopted the definition of "variety" that is set forth in article 5 of the CPVR[85] (see section II.A.2 infra) to eliminate the uncertainty found in the EPC regarding the definition of a "plant variety." It is also important to note that the Biotech Directive and EPC operate independently of each other, with neither superseding the other.[86] As a result, a plant breeder seeking patent protection for a new plant variety would be well advised to apply directly to the countries that have adopted laws complying with the Biotech Directive.

B. The United States

Unlike the E.U., the United States does allow a plant breeder to obtain patent protection for a new plant variety. As a result, a plant breeder seeking protection in the United States can obtain 1) a plant patent, 2) a utility patent, or 3) plant variety rights.[87] The laws governing the three options available to plant breeders overlap and therefore "[a]ny attempt to obtain dual protection may be objected to on a double patenting grounds. . . ."[88]

1. Plant Patent

In 1930 the United States passed the Plant Patent Act to protect asexually reproduced plants.[89] The Plant Patent Act was established in order to give the agricultural industry the same opportunity to participate in the patent system that was offered to other industries.[90] Under the Plant Patent Act, a plant breeder may obtain patent protection for an asexually reproduced[91] plant variety that is distinct and new, and is neither a tuber propagated plant, nor a plant found in an

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[84] Llewelyn, *supra* note 54, at 193. *See also* Biotech Directive, *supra* note 42, recital 31 (stating that "[w]hereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants").

[85] Biotech Directive, *supra* note 42, art. 2.3.

[86] Nott, *supra* note 78, at 349 (explaining that the Biotech Directive is not directly applicable to patents granted by the EPO). *See also* Gitter, *supra* note 11, at 43 n.138 ("The governing bodies of the E.U. do not exercise any control over the EPC, and the EPO is not legally bound to follow the [Biotech] Directive.").

[87] Janice M. Strachan, *Plant Variety Protection: An Alternative to Patents*, *available at* http://www.nal.usda.gov/pgdic/Probe/v2n2/plant.html (last visited Mar. 15, 2003).

[88] 5 DONALD S. CHISUM, CHISUM ON PATENTS § 1.05[4], at *33 (2002).

[89] Kupchella, *supra* note 16, at 737. In fact, the United States is believed to be the first country to incorporate legal provisions for plant patents into their Patent Laws. *See also* 1 SINNOTT, BAXTER WORLD PATENT LAW & PRACTICE § 1.08 (2001).

[90] CHISUM, *supra* note 88, §1.05 at *1.

[91] MANUAL OF PATENTING EXAMINING PROCEDURE § 1601 (Aug. 2001). Asexual reproduction involves the propagation of plants by rooting of cuttings, by grafting, budding, layering, inarching etc., and does not involve the propagation of plants from seeds. *Id.*

uncultivated state.[92] A new and distinct plant variety expresses characteristics that distinguish it from other known varieties.[93]

Although the term "plant" was not defined in the Plant Patent Act, the Federal Circuit's predecessor, the Court of Customs and Patent Appeals explained in *In re Arzberger*[94] that the legislative history surrounding the Act clearly indicated the term "plant" was being used in its ordinary sense.[95] Accordingly, protection under the Plant Patent Act only extends to plants in their ordinary and common sense rather than their strict scientific sense.[96]

A plant patent only gives its holder the right to exclude others from 1) asexually reproducing the plant, 2) selling the asexually reproduced plant, and 3) using the asexually reproduced plant without the patent holder's permission.[97] Accordingly, a person who sexually reproduces a plant (that is, with seeds) which is protected under the Plant Patent Act does not infringe any rights of the plant patent holder.[98] The Plant Patent Act, therefore effectively excludes all plants from patent protection that are reproduced from seeds, as well as bacteria, fungi, and tuber propagated plants.[99]

In 1998, the Plant Patent Act was amended in order to extend plant patent protection to cover the "parts" of asexually reproduced plants.[100] This extension gave plant patent holders the right to exclude others from using, selling, and importing "parts" of an asexually reproduced plant.[101] However, the amendment is only applicable to patents issued on or after October 27, 1998.[102]

2. Utility Patent

Prior to 1980, a utility patent could not be obtained on plants under 35 U.S.C § 101 because it was believed that the patent protections afforded under § 101 did not extend to living things.[103] In 1980, however, the Supreme Court held in *Diamond v. Chakrabarty*[104] that living, genetically-altered microorganisms constituted patentable subject matter under Section 101.[105] In 1985, the holding in *Diamond v. Chakrabarty* was extended by the Board of Patent Appeals and Interferences in *Ex*

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[92] CHISUM, *supra* note 88, §1.05 at *1.
[93] *Id.; see also* 35 U.S.C. § 161 (2002) (providing in relevant part: "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 therefore . . . .").
[94] *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940).
[95] CHISUM, *supra* note 88, §1.05[1][b][i] at *5.
[96] *Id.*
[97] *Id.* at *1.
[98] *Id.*
[99] J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms,* 94 COLUM. L. REV. 2432, 2558 n.155 (1994).
[100] CHISUM, *supra* note 88, §1.05[1][d] at *17.
[101] *Id.* at *17-18.
[102] *Id.* at *18.
[103] Kupchella, *supra* note 16, at 737.
[104] 447 U.S. 303 (1980).
[105] CHISUM, *supra* note 88, §1.05 at *22.

Parte Hibberd[106] to include plants, plant seeds, and plant tissue cultures as constituting patentable subject matter under 35 U.S.C. § 101.[107] The United States Supreme Court's recent decision in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*[108] dispelled any questions that remained regarding the protectability of sexually reproduced plants under 35 U.S.C § 101. In *J.E.M AG Supply, Inc.*, the Supreme Court held that "[n]ewly developed plant breeds fall within the subject matter of § 101, and neither the PPA [Plant Patent Act] nor the PVPA [Plant Variety Protection Act] limits the scope of § 101's coverage."[109] As a result, "the United States offers perhaps the most comprehensive coverage to biotech inventions of any nation."[110]

3. Plant Variety Rights

In 1970, Congress passed the Plant Variety Protection Act (PVPA) in order to provide protection for the sexually reproduced plants that were expressly excluded from protection under the Plant Patent Act.[111] Congress enacted the PVPA in order to help the United States remain competitive in the agricultural arena because 1) the plant breeding technology had evolved from 1930 to 1970 allowing scientists to "replicate [sexually reproduced varieties] in ways that had previously appeared impossible" and 2) leading European countries had adopted *sui generis* systems of plant protection for new plant varieties.[112] On November 8, 1981, the United States became a member of UPOV, which required Congress to amend the PVPA in order to meet the minimum standards established by UPOV.[113] In 1994 Congress once again amended the PVPA in order to bring it into conformity with the 1991 version of UPOV.[114] However, the amendments made to the 1994 PVPA are applicable only to certificates that issue on applications filed after the effective date of the changes, and therefore the provisions of the 1970 PVPA remained applicable to all applications filed before 1995.[115]

The PVPA system is administered by the Plant Variety Protection Office (PVPO) within the Department of Agriculture.[116] In order to be protected under the PVPA, the plant variety must be new, uniform, stable, and distinct from all other varieties.[117] Fungi, bacteria, and first generation hybrids are expressly excluded from protection under the 1970 PVPA.[118] However, under the 1994 Act, first-

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[106] 227 U.S.P.Q. 443 (1985).
[107] CHISUM, *supra* note 88, §1.05 at *27.
[108] No. 99-1996, 2001 U.S. LEXIS 10949, at *1 (Dec. 10, 2001).
[109] *Id.* at *3.
[110] Kupchella, *supra* note 16, at 737.
[111] Reichman, *supra* note 99, at 2467.
[112] *Id.*
[113] CHISUM, *supra* note 88, at *2.
[114] *Id.*
[115] *Id.* at *19.
[116] Reichman, *supra* note 99, at 2468. The PVPA Office accepts approximately 270 applications per year and over 2,700 Certificates of Protection have been issued in over 100 crops by the PVPA Office since 1971. Strachan, *supra* note 87.
[117] Strachan, *supra* note 87.
[118] *Id.*

generation hybrids and tuber propagated varieties are eligible for PVPA protection.[119]

A variety is considered new if the variety has not been sold, used, or otherwise exploited in the United States more than 1 year prior, or in a foreign country more than 4 years (6 years in the case of a tree or vine) prior, to filing an application for protection in the United States.[120] A variety is distinct if it is "clearly distinguishable from any other variety" which is known at the time of filing.[121] A variety is uniform when "any variations are describable, predictable, and commercially acceptable."[122] A stable variety is one that remains "unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability" when reproduced.[123]

A Certificate of Protection remains enforceable for 18 years from the date of issuance, if governed by the 1970 Act, and 20 years (25 years for trees and vines) if governed by the 1994 Act.[124] There are two exceptions to a Certificate holder's rights. First, under the PVPA, farmers are allowed to save seeds from one planting year to the next either for use on their own farms, or to sell to their neighbors.[125] Second, scientists are allowed to conduct research using protected varieties without the Certificate holder's permission in order to promote the free exchange of germplasm within the scientific community.[126]

Unlike patents, the United States does not have to issue a Certificate of Protection to a foreign national unless a treaty requires them to do so.[127] If there is no treaty, the United States is only required to offer as much protection in the United States as the country where the foreign national is domiciled offers to nationals of the United States for the same plant genus and species.[128]

C. Japan

Unlike the European Union and the United States, Japan does not have a plant variety rights system, opting instead to offer only patent protection for new plant varieties under their national patent laws.[129] In 1981, Japan's Ministry of International Trade and Industry (MITI) recognized biotechnology as the key to the future success of Japan's industrial technology.[130] At that time, large Japanese biotechnology corporations were either acquiring, or licensing the technology of smaller U.S. and European biotechnology companies because Japan's own

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[119] CHISUM, *supra* note 88, at *20.
[120] 7 U.S.C. § 2402(a)(1)(A)(B)(i)(ii) (2001).
[121] *Id.* § 2402(a)(2).
[122] *Id.* § 2402(a)(3).
[123] *Id.* § 2402(a)(4).
[124] CHISUM, *supra* note 88, at *18, 29.
[125] Strachan, *supra* note 87.
[126] *Id.*
[127] CHISUM, *supra* note 88, at *19.
[128] *Id.*
[129] *See Outline of Industrial Property Systems, at* http://www.jpo.go.jp (last visited Mar. 15, 2003). *See also* 2A SINNOTT, BAXTER WORLD PATENT LAW & PRACTICE § APP 1.00, app. 1-4 (2001).
[130] Michael North, *The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies?*, 18 B.U. INT'L L.J. 111, 125 (2000).

biotechnology research and development efforts were very weak.[131] MITI was able to recognize that "the Japanese do not excel in the basic science research that remains so important to biotechnology," and enacted patent laws that would help strengthen and maintain the relationship between the large Japanese biotech corporations and the smaller foreign biotech companies.[132]

The Japanese Patent Office requirements for patenting living matter are similar to the requirements of the United States Patent Office.[133] The primary difference is the refusal of the Japanese Patent Office to grant patents on "processes in the fields of medicine, diagnosis, therapy, and pharmacology in which the human body is an indispensable element."[134] This difference has resulted in the exclusion of certain biotechnology inventions that are patentable in the U.S. from being patentable in Japan.[135] As a result, some U.S. patented inventions may have to be changed in order to come within the scope of Japanese patentable subject matter.[136]

Plant patents are specifically addressed by the Japanese patent laws in Chapter 2, "Biological Inventions," of the "Implementing Guidelines for Inventions in Specific Fields."[137] Section 3 of Chapter 2 deals with inventions of plants that relate to parts of plants, i.e., fruits, uses of plants, processes for creating plants, etc.[138] Section 3 does not pertain either 1) to undifferentiated plant cells, or plant tissue cultures (these inventions are addressed in Section 2 of Chapter 2), or 2) to matters involving plants that are related to genetic engineering (these inventions are addressed by Section 1 of Chapter 2).[139]

"In an application for the plant itself, the plant must be specifically defined in the claims."[140] If the application relates to a method for producing the plant, the claims must sequentially set forth the steps for producing the plant in a clear and succinct manner.[141] Additionally, if one of the steps used to produce the plant involves a selection based on characteristics, the characteristics necessary for the selection, as well as any environmental characteristics necessary and indispensable for the method of production must be disclosed.[142] In sum, all elements that relate to 1) the kind of plant produced, 2) the gene or special property which characterizes the produced plant, 3) the process for producing the plant, or 4) conditions needed for cultivation must be disclosed.[143] Moreover, in order for a new plant variety to be patentable, a person of ordinary skill in the art must be able to achieve the same plant variety that is disclosed in the patent when the claimed plant is repeatedly bred.[144]

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131 *Id.*
132 *Id.*
133 *Id.*
134 *Id.* at 125-26.
135 *Id.* at 126.
136 *Id.*
137 *Implementing Guidelines for Inventions in Specific Fields*, Ch. 2, *at* http://www.jpo.go.jp (last visited Mar. 15, 2003).
138 *Id.* at § 3.
139 *Id.*
140 Akira Kukimoto, *Patent Law*, 25 J. OF THE JAPANESE GROUP OF A.I.P.P.I. 170, 179 (2000).
141 *Id.*
142 *Id.*
143 *Id.*
144 *Id.*

III. CONCLUSION

As the role that plants play in our everyday lives becomes increasingly more important, the controversy over how to best protect plant resources will continue to be forced into the forefront. Regardless of the inevitable controversies lying ahead, one thing is certain, with biotechnology breakthroughs fueling the rapid discovery of new plant varieties, the E.U. must either increase the rate at which its laws are evolving to accommodate these biotech breakthroughs, or continue to lose big biotech business and their fortunes to the United States and Japan. Although the Biotech Directive and recent ruling by the EPO Board are steps in the right direction, there is still too much uncertainty in E.U. law regarding how the Biotech Directive and EPC laws will be harmonized and interpreted to enable the E.U. to successfully induce the billion dollar biotech industry to sew their resources in the fields of the E.U.