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DEVELOPMENTS IN AGRICULTURAL BIOTECHNOLOGY

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I. INTRODUCTION

Significant advancements are being made in agricultural biotechnology.[1] New advancements in genetic engineering and testing methods have resulted in easier identification of different plant varieties and have promoted the development of transgenic plants and animals.[2] The intellectual property

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1. Biotechnology is "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses." JACK R. KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 1492-2000 (1988) (using the Congressional Office of Technology Assessment's definition of biotechnology).

2. A transgenic plant is "a plant which is transformed when a gene taken directly from another plant or organism is physically inserted into it." John Schoenemann, *Transgenic Plants May Be In Your Future*, AMERICAN VEGETABLE GROWER,

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rights in the new processes and products of biotechnology can be protected. For example, plants are now subject to general utility patent, as well as Plant Patent Act, Plant Variety Protection Act, and trade secret protection. Courts have recently decided several important cases pertaining to the protection of plant varieties and processes.[3]

Government regulation of agricultural biotechnology continues to be an area of uncertainty. Although the United States Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration all have a hand in the current regulatory structure, the agencies' individual roles have not been well defined. The new administration, particularly Vice-President Albert Gore, has expressed an interest in reviewing the existing regulatory framework and potentially proposing changes in the present regulatory scheme.[4]

This Article will discuss recent developments in agricultural biotechnology. Additionally, the Article will discuss the applicability of patent and trade secret protection to agricultural developments and current government regulation of agricultural biotechnology. Finally, the Article examines the subject of future regulation.

II. Significant Developments in Animal and Plant Biotechnology

A. Animal Biotechnology

Developments in animal agriculture are proceeding at a somewhat different pace than developments in plant biotechnology.[5] Desired changes in animals can still be made rela-

Aug. 1992, at 21-22. *See also* Boyee Rensberger, *Technique May Fight Disease by Reversing Instructions to Cells*, Wash. Post, Jan. 4, 1993, at A3 (containing a description of how a transgenic plant is formed).

3. *See infra* Part III.B.

4. Vice-President Gore has shown a great interest in the subject during his terms in the Senate and in the House. In his recent book, Vice-President Gore proposed the development of a Strategic Environment Initiative to discourage and phase out older technologies. Gore also called for the development of a new generation of environmentally benign substitutes. Al Gore, Earth in the Balance 140, 319 (1992). *See also* Alex Barnum, *Biotech Poses Key Test for Clinton Administration: New Leadership Faces a Balancing Act Between the Environmental and High-Tech Sectors*, San. Fran. Chron., Jan. 4, 1993, at B1 (discussing possible action of Clinton administration in biotechnology industry).

5. John M. Czarnetzky, *Altering Nature's Blueprint for Profit Patenting Multicellular Animals*, 74 Va. L. Rev. 1327, 1329-30 (1988).

tively quickly through conventional breeding and selection techniques.[6] In just a few years, size, muscling, and conformation traits can be bred into large numbers of animals to significantly alter the attributes of any breed.

While advancement in the genetic engineering of animals has not yet progressed to the levels achieved in plant research, transgenic animals are on the horizon.[7] Ethical concerns that have slowed the short term progress may continue into the near future.[8] Among these ethical concerns are human control of life, maintenance of species integrity, and economic equity.[9] Because many of these arguments predate patenting animal technology it is unclear what, if any, new issues patenting will add to these ethical concerns.[10]

B. Plant Biotechnology

1. Identification and Labeling of Plant Varieties

The identification and labeling of plant varieties is an important issue for the seed industry, the government, and farmers.[11] Proper labeling is essential to maintain fair competition and to prevent misrepresentation of seed varieties.[12] The Federal Seed Act, enacted in 1939,[13] and regulations promulgated under the Act,[14] require labeling by varietal name. These reg-

6. Daniel D. Jones, *Genetic Engineering in Domestic Food Animals: Legal and Regulatory Considerations*, 38 FOOD DRUG COSM. L.J. 273 (1983).

7. In 1988, the United States Patent Office granted Patent No. 4,736,866, the first patent for a multi-cellular animal. The patent was granted to a team of researchers who had developed a genetically altered mouse to aid their research in breast cancer. *See* Czarnetzky, *supra* note 5, at 1327 (discussing the patenting of multicellular animals). *See also infra* notes 78-80 and accompanying text.

8. *See* Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597, 613-14 (1991); Czarnetzky, *supra* note 5, at 1328 n.5; Mark W. Lauroesch, Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 114-19 (1988).

9. *See* O'Connor, *supra* note 8, at 613.

10. *Id.* at 614.

11. *See* Roy G. Creech, *Federal Seed Program Review* 49 (United States Department of Agriculture, Final Report, Sept. 30, 1980).

12. Roy Creech notes that one problem in variety identification and labeling is that there is no agreement on what constitutes a variety. *Id.* Varietal mislabeling is not a new problem. For example, prior to the 1950's, hybrid seed corn varieties often were marketed under many names. After 1951, federal regulations required hybrid seed corn varieties introduced into interstate commerce to use only one varietal name for each variety. *See* 7 C.F.R. § 201.34(d)(6) (1992).

13. 7 U.S.C. § 1551 (1988).

14. 7 C.F.R. § 201 (1992).

ulations make the renaming of a variety previously marketed under another varietal name illegal.[15]

In the late 1970's, the United States Department of Agriculture (USDA) attempted to police varietal labeling by proposing what was commonly referred to as a "look-alike" program.[16] When the look-alike program was considered, the relative significance of mislabeling incidents in the seed industry—compared to other periods in the history of the industry—was subject to reasonable and legitimate debate. The program consisted principally of a visual appraisal to prevent varietal mislabeling in a number of agronomically significant crops.[17] The USDA's concern was that a number of the hybrids and open-pollinated varieties marketed under different varietal names were in fact the same varieties.[18] Some varietal mislabeling continued to occur[19] and the program ultimately failed, in part because it was based on "questionable assumptions and scientific procedures."[20]

2. *Transgenic Plants*

New techniques in genetic engineering have led to the introduction of transgenic plants.[21] The products of the new technologies appear to be close to commercialization. Calgene's FLAVR SAVR™ tomato is presently advancing through what may be the final stages of the Food and Drug Administration regulatory process.[22] Monsanto has entered into an agreement with Delta & Pine Land Company to commercialize its *Bt* cotton as the product enters the later stages of the Environ-

15. 7 U.S.C. §§ 1571(a)(1), 1571(d), 1596(a) (1988); 7 C.F.R. §§ 201.10, 201.12, 201.34(d)(2)(1992).

16. *See* Creech, *supra* note 11, at 49-52.

17. *See* Creech, *supra* note 11, at 49.

18. The use of primarily visual techniques in the evaluation process was vigorously opposed by the seed industry. Many of the major seed companies at the time argued that there were different strains or races having different physiological characteristics which should be considered different varieties, even though physical appearances were similar, if not identical. *See* Creech, *supra* note 11, at App. H.

19. *See, e.g.*, In Re Stauffer Seeds, Inc., 817 F.2d 47 (8th Cir. 1987) (finding varietal mislabeling in underlying action); Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., No. 81-60-E (S.D. Iowa 1987) (alleging varietal misappropriation).

20. *See* Creech, *supra* note 11, at 49. One of the problems with the program was that plants of the same variety may look different when subjected to different environmental circumstances. Likewise, different varieties may look the same. *Id.*

21. *See* KLOPPENBURG, *supra* note 1, at 16.

22. 57 Fed. Reg. 22,772 (1992).

mental Protection Agency regulatory process.[23] While the ultimate commercial impact of these initial products is unknown, the regulatory process for the introduction of new products is slowly being developed.

III. Intellectual Property Rights Protection

Developments in both animal and plant biotechnology have created many new issues involving the protection of intellectual property rights. Only recently have both animal and many previously unprotected forms of plant life been considered patentable subject matter.[24] However, the protection of intellectual property rights in animals and plants has developed differently.[25]

A. Animal Protection

Private breeding efforts with respect to many agriculturally significant animals have been quite public. Purebred breed association registries have been kept for many years. These registries record ancestral heritage information. In contrast, the seed and plant industry has developed much differently. Plant breeding efforts are often done privately,[26] and products and processes have been protected as trade secrets.

B. Plant Protection

1. Patent Protection of Plants

a. The Plant Patent Act

In 1930, the Plant Patent Act (PPA) was passed to provide patent protection to asexually reproduced plant varieties.[27]

23. 56 Fed. Reg. 65,073 (1991).

24. 35 U.S.C. § 101 (1988). *See generally* Cathy Musco, *Could the Patenting of Animals Lead the Island of Dr. Moreau to Your Backyard?*, 8 Temp. Envtl. Law & Tech. J. 119, 121-28 (1989).

25. Potentially patentable animals are likely to be transgenic animals produced via recombinant DNA techniques or through other applications of genetic engineering. *See* O'Connor, *supra* note 8, at 608. Transgenic animals are created by augmentation of the organism's naturally occurring DNA by addition of additional DNA from a source other than the parental germplasm. *Id.* The usual source of the additional DNA is another animal. *Id.*

26. While releases by public institutions have been an exception, even public plant breeding efforts have involved a greater degree of secrecy than has generally been present with animal breeding. *See* Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 425-26 (1989).

27. 35 U.S.C. § 161 (1988). Originally passed in 1930, the current version was

The legislation, however, was very limited and did not extend patent coverage to tuber-propagated plants, such as the potato and the Jerusalem artichoke.[28] The PPA further required only that an asexually reproduced plant be new and distinct.[29]

b. The Plant Variety Protection Act

In 1970, the Plant Variety Protection Act (PVPA) extended a new form of patent-like protection to sexually reproduced plant varieties.[30] Like the PPA, the protection afforded by PVPA is limited. PVPA protection does not extend to "fungi, bacteria, or first generation hybrids."[31] Unlike the PPA, the PVPA is administered directly by the USDA.[32]

The PVPA uses three criteria to determine the protectability of novel plant varieties: distinctness, uniformity, and stability.[33] If a plant variety is considered distinct, uniform, and stable, the USDA issues a certificate of protection for an eighteen year period.[34] The certificate of protection grants the breeder the right to exclude others from selling, reproducing, importing, exporting, or using the protected variety in producing (as distinguished from developing) a hybrid or different variety.[35]

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amended in 1954 and provides that discovered plant seedlings are patentable if reproduced asexually with characteristics distinct from other plants. *Id.*

28. *See generally* Seay, *supra* note 26, at 419-23. The Act was "limited specifically to plants and plant varieties which [had] already reproduced asexually." *Id.* at 420. A subsequent amendment excluded "plants found in an uncultivated state." *Id.* at 421.

29. 35 U.S.C. § 161 (1988).

30. 7 U.S.C. § 2402 (1988).

31. *Id.* § 2402(a) (1988). *See* Seay, *supra* note 26, at 423-25.

32. 7 U.S.C. § 2321 (1988).

33. *Id.* § 2401(a). The statute defines these criteria:

> (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 differenec (sic) 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.

Id.

34. *Id.* § 2483(b).

35. *Id.* § 2483(a). In addition, the owner may request that the certificate of pro-

The PVPA includes three exemptions not found in the PPA or the general utility patent statute:[36] (1) the crop exemption;[37] (2) the research exemption;[38] and (3) an intermediary exemption.[39] The most controversial of the three exemptions—the crop exemption—has been interpreted to exempt sales from one farmer directly to another.[40] In wheat, for example, the crop exemption has caused a significant transfer of genetic material to farmers who consequently do not need to re-enter the market to buy new seed each year.

The leading case decided under the PVPA is *Delta & Pine Land Co. v. Peoples Gin Co.*,[41] a case involving the construction of the crop exemption.[42] In *Delta & Pine*, Peoples Gin asserted that, as an agricultural cooperative, it acted as a mere agent for the member farmers' delivery, shipment, and transfer of Delta & Pine Land Company's protected Deltapine 41 cottonseed.[43] Thus, Peoples Gin argued its activities fell within the crop exemption.[44] The United States District Court for the Northern District of Mississippi agreed that Peoples Gin was the agent of its member farmers.[45] However, the court held that the exemption analysis did not end with the agent determination.[46]

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tection specify that in the United States, seed of the variety shall be sold by variety name only as a class of certified seed and, if specified, shall conform to the number of generations designated by the owner. *Id.* *See generally* Seay, *supra* note 26, at 424-25.

36. 35 U.S.C. § 101 (1988).

37. 7 U.S.C. § 2543 (1988).

38. *Id.* § 2544.

39. *Id.* § 2545.

40. Delta & Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012, 1016 (5th Cir. 1983). The court stated that this interpretation conforms with the Act's purpose while preserving the farmer's right to sell his seed directly to other farmers. *Id.* at 1016. A farmer is statutorily defined as "a person whose primary farming occupation is the growing of crops for sale for other than reproductive purposes." 7 U.S.C. § 2543 (1988).

41. 546 F. Supp. 939 (N.D. Miss. 1982).

42. 7 U.S.C. § 2543 (1988). Section 2543 provides in part:

> Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section . . . .

Id.

43. *Delta & Pine Land Co.*, 546 F. Supp. at 940-41.

44. *Id.*

45. *Id.*

46. Delta & Pine Land Co. v. Peoples Gin Co., 546 F. Supp. 939, 943 (N.D. Miss. 1982).

In construing the statute and the exemption, the court determined that if Peoples Gin were to fall within the scope of the exemption, the declared purposes of the Act would be frustrated.[47] The court distinguished between direct farmer to farmer sales and those assisted by the involvement of a third party.[48] The court held that the Act exempted only sales between farmers "without the intervention and assistance of independent agents to bring buyer and seller together."[49] Peoples Gin was also found in violation of section 2541 of the Act since its sales were not in compliance with Mississippi's strict seed labeling requirements.[50] Hollandale Seed & Delinting Company, a co-defendant in the case, was also found to have violated the Act because the variety was dispensed without notice to the purchasers that the seed was a protected variety.[51] The Fifth Circuit affirmed the district court's decision.[52]

Farmers continue to utilize the crop exemption, and disputes often arise over the exemption's applicability.[53] The dispute over the statutory crop exemption recently focused on the number of bushels a farmer could save and sell. In *Asgrow Seed Co. v. Winterboer*,[54] the Federal Circuit Court of Appeals held that the crop exemption did not impose a seed quantity unit upon the selling farmer.[55] The holding reversed the district court's interpretation which had imposed a quantity limitation on the farmer based on an extension of the policy arguments set forth in *Delta & Pine Land Co.*.[56] The Federal Circuit recognized that the crop exemption could extinguish the incentives of the PVPA.[57] Absent a quantity limitation, the court identi-

47. *Id.*

48. *Id.*

49. *Id.* at 942. *See also* 7 U.S.C. § 2543 (1988).

50. Delta & Pine Land Co. v. Peoples Gin, Co., 546 F. Supp. 939, 944 (N.D. Miss. 1982).

51. *Id.* Hollandale provided services for delinting, treating, and bagging the seed. *Id.* at 942.

52. Delta & Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012, 1017 (5th Cir. 1983).

53. *See* Seay, *supra* note 26, at 425.

54. 982 F.2d 486 (Fed. Cir. 1992).

55. *Id.* at 491.

56. Asgrow Seed Co. v. Winterboer, 795 F. Supp. 915, 920 (N.D. Iowa 1991). The district court decided that a farmer whose "primary farming occupation" was the "growing of crops for sale for other than reproductive purposes" had a limited exemption which entitled the farmer to save or sell only the number of bushels of soybeans required to plant that farmer's own acreage in a single year. *Id.* at 917-18.

57. *Asgrow Seed Co.*, 982 F.2d at 489, 491.

fied a number of other statutory requirements that still must be met for a farmer to take advantage of the crop exemption.[58] The court nevertheless felt compelled to rely on the statute's wording in determining that the Winterboers did not have a bushel restriction.[59]

Other areas of dispute arising under the PVPA relate to issues such as the availability of the Act's protection and competing rights to a protected variety.[60] However, most of the disputes to date have centered on the crop exemption.[61]

c. *The Jones Patent*

Disputes over patent rights and patent validity are not new in the seed industry. The first economically significant patent to affect the seed industry was the Jones patent, issued by the Patent Office in 1956.[62] The patent claimed a method of hybrid seed corn production that utilized genetic factors capable of restoring pollen fertility to the progeny of cytoplasmic pollen sterile strains.[63] The CMS/restorer system, the subject of the Jones Patent, incorporated cytoplasmic male sterility into the seed parent and restorer genes into the pollinator.[64] The

58. The court's analysis of the crop exemption defined seven express limitations that restricted a farmer's right to sell seed. The limitations are:

1) A farmer remains subject to infringement under § 2341(3)-(4);
2) A farmer may only save, use, or sell seed produced from or descended from seed obtained by authority of the PVPA certificate owner for seeding purposes;
3) A farmer selling a novel variety must primarily grow crops from that seed for consumption;
4) A farmer acquiring a novel variety must primarily grow crops from that seed for consumption;
5) A farmer who acquires a novel variety in a brown bag sale can neither save nor sell seed harvested from that seed;
6) The sale must comply with state laws; and,
7) A farmer cannot divert seed originally sold for consumption to planting purposes.

Asgrow Seed Co. v. Winterboer, 982 F.2d 486, 490 (Fed. Cir. 1992).

59. *Id.* at 491.

60. For consideration of other cases decided under the PVPA, see Public Varieties, Inc. v. Sun Valley Seed Co., 734 F. Supp. 250 (N.D. Miss. 1990) (holding that licensee lacked standing to bring action for alleged infringement); Heart Seed Co. v. Seeds, Inc., 4 U.S.P.Q.2d (BNA) 1324 (E.D. Wash. 1987) (enjoining defendant from further patent infringement); Bud Antle, Inc. v. Scattini Seed Co., 229 U.S.P.Q.2d (BNA) 547 (N.D. Cal. 1985) (holding that defendant can sell seed only on the condition that defendant not propagate the seed).

61. *See* Seay, *supra* note 26, at 425.

62. Jones Patent 2,753,663 (entitled Production of Hybrid Seed Corn).

63. *See generally* KLOPPENBURG, *supra* note 1, at 113-16.

64. *Id.*

application of the system had significant economic effect by eliminating the need for detasselling crews in hybrid seed corn production fields.[65] The resulting reduction of labor costs lowered the cost of hybrid seed corn production and allowed for higher profit margins.[66] By the mid-1960's much of the hybrid seed corn sold in the United States had incorporated the CMS/restorer process.[67]

Although the seed industry was using the CMS/restorer process, Research Corporation, the assignee of the patent by Jones, was unable to convince the industry to honor the patent and pay royalties. In 1963, Research Corporation filed suit in federal district court in Chicago to enforce its patent.[68] After litigating for a number of years, the parties eventually settled but only after extensive discovery had been taken and after Research Corporation had filed a class action antitrust suit against all of the companies in the seed industry who utilized the patent.[69]

Ironically, the patent litigation may have been responsible, at least in part, for the quick rebound the hybrid seed corn industry made after the Southern Corn Leaf Blight of 1970-1971.[70] On December 3, 1968, Research Corporation filed an-

65. *See* Marc Linder, *Crewleaders and Agricultural Sweatshops: The Lawful and Unlawful Exploitations of Migrant Farmworkers*, 23 CREIGHTON L. REV. 213, 215 (1989). Historically, seed companies employed local teens, college students, and migrant workers as their labor force. *Id.* at 215. The introduction of cytoplasmic male sterility eliminated the need for manual detasseling. *Id.* at 215 n.15.

66. *See* William L. Brown, *Hybrid Vim and Vigor: George Shull's Experiments With Inbreeding and Crossbreeding Corn*, 5 SCI., Nov. 1984, at 77 (noting that adoption of hybrid corn also added a value of several billion dollars per year to the farmer over the period of 1930-1979).

67. *See* KLOPPENBURG, *supra* note 1, at 113.

68. *See* Research Corp. v. Pfister Assoc'd Growers, Inc., 310 F. Supp. 1377 (N.D. Ill. 1970).

69. *See* Research Corp. v. Asgrow Seed Co., 425 F.2d 1059 (7th Cir. 1970). While under advisement, the case was consolidated with another infringement action on the same patent. *Id.* at 1059. The consolidation later resulted in class action certification. Research Corp. v. Pfister Assoc'd Growers, Inc., 301 F. Supp. 497, 498 (N.D. Ill. 1969) (certifying the case as a class action). On January 22, 1970, the Seventh Circuit Court of Appeals dismissed an appeal of a consent judgment. *Asgrow*, 425 F.2d at 1059 (dismissing appeal on grounds defendants failed to adequately object to the settlement).

70. An interesting aspect of the Research Corporation litigation is that much of the germplasm being used in the industry was T-cytoplasm material. *See generally* KLOPPENBURG, *supra* note 1. This material was later discovered to be susceptible to the Southern Corn Leaf Blight which decimated the corn crops in much of the Midwestern corn belt in 1970 and, to a lesser extent, in 1971. *See* Lucas v. Pioneer, Inc.,

other suit.[71] Funk Brothers was charged with returning to other parent lines and refusing to pay royalties despite a negotiated licensing agreement between Funk Brothers and Research Corporation for the Jones patent. Research Corporation alleged that Funk Brothers intended to switch parent lines before the settlement was entered and falsely represented in the licensing negotiations that Funk Brothers intended to continue use of the CMS/restorer process.[72]

d. The General Utility Patent Statute

Increasingly, the Patent and Trademark Office (PTO) has issued patents for hybrids, seeds, plants, plant parts, and parent inbreds. However, animal patents are still somewhat slow to issue.[73] While the celebrated Harvard Mouse patent was granted in April 1988,[74] almost five years passed without the issuance of another transgenic animal patent. The drought recently ended. On December 29, 1992, the PTO issued three new patents for genetically engineered mice.[75]

In 1980, the United States Supreme Court determined that a live, human-made microorganism was patentable subject matter under the general utility patent statute.[76] In *Diamond v. Chakrabarty*[77] the Court held that the living or nonliving character of an invention has no bearing on patentability.[78]

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256 N.W.2d 167, 171 (Iowa 1977) (farmers brought class action suits against seed companies in reaction to the corn blight). *See also* JACK DOYLE, ALTERED HARVEST: AGRICULTURE, GENETICS, AND THE FATE OF THE WORLD'S FOOD SUPPLY 1-15 (1985).

As a result of the Jones patent litigation, some in the seed industry, such as Funk Bros., may have decided to switch to germplasm resistant to the Southern Corn Leaf Blight before the disease compelled the change.

71. *See* Complaint, Research Corp. v. Funk Bros. Seed Co., No. 68 C 2336 (N.D. Ill. Dec. 3, 1968) (on file with the *William Mitchell Law Review*).

72. Complaint at 7-8, Research Corp. v. Funk Bros. Seed Co., No. 68 C 2336 (N.D. Ill. Dec. 3, 1968) (on file with the *William Mitchell Law Review*).

73. *See generally* Czarnetzky, *supra* note 5; O'Connor, *supra* note 8; Musco, *supra* note 24.

74. Leder et al. Patent 4,736,866 (entitled Transgenic Non-Human Animals) [hereinafter Harvard Mouse]. *See* Czarnetzky, *supra* note 5, at 1356-57.

75. 45 PAT. TRADEMARK & COPYRIGHT J. (BNA) 159 (1993) (describing the first animal patents issued since the Harvard Mouse patent). *But see* 45 PAT. TRADEMARK & COPYRIGHT J. (BNA) 347, 354 (1993). Senator Mark Hatfield has proposed a two-year moratorium for animal and gene patents, a proposal prompted in part by the three mouse patents issued by the PTO in December 1992. *Id.*

76. 447 U.S. 303 (1980).

77. *Id.* at 309-10. The general utility patent statute is located at 35 U.S.C. § 101 (1988).

78. *Chakrabarty*, 447 U.S. at 313.

Rather, the important distinction is whether the product was derived from human effort and meets the criteria of novelty, utility, and non-obviousness.[79]

The *Chakrabarty* decision first opened the door to the possibility of protection for both plant and animal life under the general utility patent statute.[80] While the decision reiterated the statutory requirements of utility and newness, *Chakrabarty* removed the restrictive subject matter limitations created by the PPA and the PVPA.[81]

Following *Chakrabarty*, the Court's interpretation of the general utility patent statute's relationship to the PPA and the PVPA was considered, by some, to be unclear. Finally, the issue was specifically addressed in 1985. In *Ex parte Hibberd*,[82] the PTO stated that the plant-specific statutes were not restrictions on the general utility patent statute and were not the exclusive forms of protection for plant life.[83] Two years later, in *Ex Parte Allen*,[84] the PTO further stated that the general utility patent statute's scope "clearly indicates man-made life forms."[85]

Shortly after *Ex parte Allen* was decided, the PTO published a notice in the *Official Gazette* stating that "nonnaturally occurring nonhuman multicellular living organisms, including animals, constituted patentable subject matter" within the scope of the general utility patent statute.[86] This announcement ultimately sparked the filing of a lawsuit by a group of individual farmers, animal husbanders and non-profit corporations.

In *Animal Legal Defense Fund v. Quigg*,[87] the plaintiffs alleged that the PTO violated the Administrative Procedures Act[88] by failing to provide for public notice and comments before issuing the notice.[89] The plaintiffs also alleged that the notice ex-

79. *Id.*

80. Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980).

81. In order to apply the general utility patent statute to human-made organisms, the Court offered a broad interpretation of the language of the statute. *Chakrabarty*, 447 U.S. at 310.

82. 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences 1985).

83. *Id.*

84. 2 U.S.P.Q. (BNA) 1425 (Bd. Pat. App. & Interferences 1987).

85. *Id.* at 1427.

86. 1077 Off. Gaz. Pat. Office 24 (April 21, 1987).

87. 710 F. Supp. 728 (N.D. Cal. 1989).

88. 5 U.S.C. §§ 551-59 (1988).

89. *Animal Legal Defense Fund*, 710 F. Supp. at 729-31.

ceeded the PTO's statutory authority.[90] The court disagreed, holding that the notice was interpretative of earlier PTO administrative decisions and court decisions and "thereby exempt from the public notice and comments requirement of the APA."[91] The court further commented that "because the PTO is authorized to issue [interpretative] rules" and because the notice "neither abridge[d] nor enlarge[d] the rights of anyone, the PTO could not . . . have exceeded its statutory authority in promulgating [the notice]."[92] The Court of Appeals for the Federal Circuit affirmed,[93] finding that, because the rule was deemed to be interpretive rather than substantive, public notice or comment was not required prior to promulgation.[94]

Other noteworthy cases concerning seed or animal products patented under the general utility patent statute have not yet materialized. However, some suits are beginning to emerge. In Florida, a patent suit for a tomato with long shelf life properties[95] is currently pending.[96] Another dispute that ultimately may prove significant is the interference proceeding which ICI Americas has instituted in the Patent Office to challenge Calgene's antisense patent.[97]

2. *Trade Secret Protection of Plants*

Pioneer Hi-Bred International, Inc. v. Holden Foundation Seeds, Inc.[98] is perhaps the most significant case involving the assertion of a trade secret theory. Pioneer's principal allegation was that Holden had misappropriated several of Pioneer's inbred lines.[99] The key parent line Pioneer appeared to be concerned about was the line designated "H3H."[100] Pioneer did not have

90. *Id.* at 729.
91. *Id.* at 732.
92. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728, 732 (N.D. Cal. 1989).
93. Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).
94. *Id.* at 931.
95. Nahum Patent 4,843,186 (entitled Long Shelf Life Heterozygous Tomato Plant).
96. Agricultural Seed Technologies, Inc. v. LSL Biotechnologies, No. 91-572-CIV-ORL-19 (M.D. Fla. 1991) (on file with the *William Mitchell Law Review*).
97. Hiatt et al. Patent No. 4,801,540 (entitled PG Gene and its Use in Plants). *ICI Challenges Calgene Plant Antisense Patent*, GENETIC TECH. NEWS, Aug. 1992, at 6, 6.
98. No. 81-60-E (S.D. Iowa Oct. 29, 1987) (Findings of Fact, Conclusions of Law and Decrees) (on file with the *William Mitchell Law Review*).
99. *Id.* at 11.
100. *Id.* at 16.

PVPA protection or any other form of patent type protection for H3H.[101] While no direct evidence demonstrated that Holden had misappropriated the line, the court observed that Holden had previously isolated Pioneer parent lines in seed production fields.[102] Based on that evidence and on conclusions that the court drew from the results of a series of electrophoresis and chromatography tests conducted during the litigation, the court concluded that Holden had, in fact, obtained Pioneer's H3H parent line through improper means.[103] Because no Plant Variety Protection or any other form of patent-type protection existed on Pioneer's parent inbreds, Pioneer asserted Lanham Act, trade secret, conversion, interference with business advantage, unjust enrichment, and unfair competition theories.[104] The court found for Pioneer on all claims but one.[105] The court ruled for Holden on the unfair competition theory.[106]

In finding Pioneer's trade secrets theory applicable, the court held that the "genetic messages" of Pioneer's parent inbreds were trade secrets.[107] The court acknowledged that the usual requirement under Iowa law—that the acquisition of a trade secret must be "as a result of a confidential relationship"—was not met but held that the tort of misappropriation of trade secrets could also focus on whether the secret was discovered by "improper means."[108] The court concluded that Pioneer had met its burden of showing misappropriation[109] and ruled that the burden shifted to Holden to show that either Pioneer's inbred lines were lawfully acquired or Holden's inbred lines "LH38," "LH39," and "LH40" were de-

101. *Id.* at 29.

102. *Id.* at 107.

103. Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., No. 81-60-E, at 54 (S.D. Iowa Oct. 29, 1987) (Findings of Fact, Conclusions of Law and Decrees) (on file with the *William Mitchell Law Review*).

104. *Id.* at 2.

105. Pioneer prevailed on the Lanham Act, trade secret, conversion, interference with business advantage, and unjust enrichment theories. *Id.*

106. Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., No. 81-60-E, at 106-07 (S.D. Iowa Oct. 29, 1987) (Findings of Fact, Conclusions of Law and Decrees) (on file with the *William Mitchell Law Review*).

107. *Id.* at 72. The genetic messages of H3H and H435Z7 did not exist outside of Pioneer's fields and the fields of its contractors. Evidence revealed that Pioneer has taken reasonable precautions to protect the secrecy of the genetics. *Id.*

108. *Id.* at 72-73.

109. *Id.* at 74.

veloped independently of Pioneer's "H3H" and/or "H43SZ7" lines.[110] The court concluded that Holden had not met this burden.[111]

On December 30, 1991, following a trial on the damage issue, the district court entered a judgment in favor of Pioneer in the amount of $46,703,230.[112] Post judgment motions are still pending, and appeals may ultimately be taken.[113]

The Board of Trustees of the University of Illinois v. Pioneer Hi-Bred International, Inc.,[114] involved a suit filed by the University of Illinois, DuPont, and Pfister against Pioneer, under the Illinois Trade Secrets Act and other theories.[115] The University of Illinois had entered into an exclusive licensing agreement with DuPont and Pfister under which the University granted to Dupont and Pfister the exclusive right to commercialize five high oil corn lines developed by the University.[116] Pioneer initially expressed interest in bidding for the exclusive license but later withdrew from the bidding process.[117] Pioneer continued to express interest in receiving the high oil lines and ultimately requested them from the University's Dr. Alexander.[118] Dr. Alexander agreed to send Pioneer three lines that had already been released by the Illinois Agricultural Experiment Station.[119] When the seed was forwarded to Pioneer, the three released lines were present.[120] However, five seed populations that were the subject of the upcoming exclusive license were also provided.[121] The University asserted that the release was a mistake and alleged that Alexander's authority to release the seed populations to third parties was restricted.[122]

110. Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., No. 81-60-E at 75 (S.D. Iowa Oct. 29, 1987) (Findings of Fact, Conclusions of Law and Decrees) (on file with the *William Mitchell Law Review*).

111. *Id.*

112. *See Seed Firm to Appeal Judgment*, CHI. TRIB., January 1, 1992 at C3.

113. *Id.*

114. Board of Trustees v. Pioneer Hi-Bred Int'l, Inc., No. 90-2038 (C.D. Ill. Jan. 31, 1990) (Complaint) (on file with *William Mitchell Law Review*).

115. *Id.*

116. *Id.* at 11.

117. *Id.*

118. *Id.*

119. Board of Trustees v. Pioneer Hi-Bred Int'l, Inc., No. 90-2038 at 10 (C.D. Ill. Jan. 31, 1990) (Complaint) (on file with *William Mitchell Law Review*).

120. *Id.*

121. *Id.*

122. *Id.* at 12.

On a motion for preliminary injunction, the court prohibited Pioneer from using, developing or distributing any of the high-oil seed or its progeny during the pendency of the litigation.[123] After an appeal from the injunction order was filed, the case was settled.

3. Product Liability Ramifications of Patent Protection

Transgenic plant patents have potential product liability ramifications. Thus, civil courts may ultimately play a significant role in regulation of the products of biotechnology.[124] While the scope of the civil courts' role is largely undetermined at the present time, disputes regarding products liability are almost certain to arise.

Product liability disputes may potentially arise where companies target their research efforts to develop insect and disease resistant plants. To the extent that research efforts successfully result in the issuance of either plant variety protection certificates or utility patents with claims directed to disease or insect resistant features, the companies developing the products will need to rigorously test their products before making any specific claims.

When a product is patented, the patentee receives a statutory right to exclude others from making, using or selling the patented product in return for public disclosure of the best mode of his or her invention.[125] Because the product is required to be capable of a written description,[126] an inventor necessarily sets forth statements that "describe" the invention in the application process.[127] After the patent issues, these statements become a matter of public record. Thus, if a transgenic plant is claimed to be resistant to a particular viral disease and a patent is issued for the product, a sale of the patented product would likely be accompanied with the description of the qualities and disease resistance features of the

123. Board of Trustees v. Pioneer Hi-Bred Int'l, Inc., No. 90-2038 (C.D. Ill. May 18, 1990) (Order on Plaintiff's Motion for a Preliminary Injunction) (on file with the *William Mitchell Law Review*).

124. For a discussion of future regulations, see *infra* Part.V.

125. 35 U.S.C. § 154 (1988).

126. *Id.* § 112.

127. *Id.* The statements include a written description of the invention as well as the manner and process of making and using the invention. *Id.*

plant as disclosed in the patent application.[128]

While disease "resistance" and disease "tolerance" are not new terms, these terms may take on a new meaning when used in connection with transgenic patented plants. The public may have exceedingly high expectations regarding the capabilities of the transgenic product.[129] Should these products fail to live up to their promised billing, grower suits can be expected.[130] If suits result, virtually unprecedented attention may be directed toward the validity of the underlying tests and research that support the data disclosed in the publicly filed patent applications.

At the time of the Southern Corn Leaf Blight in 1970 and 1971, major class action litigation was filed against the companies using the T-cytoplasm germplasm.[131] The only patent in existence at that time that might potentially have become involved in the litigation (it did not) was the Jones process patent on the CMS/restorer process of hybrid development. The Jones patent was only a process patent, not a product patent; the Jones patent did not contain any claims directed to disease resistance features. There were no publicly disclosed—and no publicly available—representations with respect to disease resistance to be found in any product patent filings. If product patents claiming disease or insect resistant features had existed, however, the litigation may have been somewhat more difficult for the seed companies to defend and may have required the utilization of other defenses.

Even if internally prepared scientific testing procedures are strictly followed, liability exposure can still be significant. This is best illustrated by a recent decision involving an onion hybrid.[132] In *Lutz Farms v. Asgrow Seed Co.*,[133] the Tenth Circuit affirmed a judgment of $2,931,254.96 against Asgrow arising

128. *See, e.g.*, U.C.C. § 2-313(1)(b) (1992). "Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." *Id.*

129. Already, the term "resistant" has been used to describe some of the products of biotechnology. *See* Notices, 57 Fed. Reg. 24,235-37 (1992).

130. *See, e.g.*, Lucas v. Pioneer, Inc., 256 N.W.2d 167 (Iowa 1977).

131. *See id.*

132. Lutz Farms v. Asgrow Seed Co., 948 F.2d 638 (10th Cir. 1991). A group of farmers brought suit against a seed seller for damages caused by the genetic defects in onion seeds that produced "double and misshapen onions." *Id.* at 640.

133. *Id.* at 638.

out of a case of unsalable double onions.[134] The court stressed the fact that Asgrow emphasized its genetic testing and quality control programs in its marketing efforts.[135] The court also noted that, in violation of its own internal procedures, Asgrow failed to test the pollinator seed parent of the seed sold to the Lutz Farms.[136]

As more plants are genetically modified to include resistance to particular insects, diseases, or herbicides, it can be reasonably anticipated that rigorous statistical testing will be required before the products are introduced into the marketplace. Whether government agencies, acting as independent third parties, will play a significant role in such testing will largely depend upon how the products are developed and promoted.

IV. Product Testing and Introduction

Congress has not enacted specific legislation to govern the products of biotechnology.[137] In its absence, products are being federally regulated by three separate agencies: the Animal and Plant Health Inspection Service of the United States Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration.

A. The United States Department of Agriculture

The USDA's Animal and Plant Health Inspection Service (APHIS) considers the source of its regulatory authority to be the Plant Quarantine Act of 1912,[138] the Federal Plant Pest Act of 1957[139] and the Federal Noxious Weed Act.[140] APHIS published regulations on June 16, 1987,[141] setting forth its field

134. Of the total amount, $1.2 million was allocated for pure economic loss. An additional $800,000 was assessed for punitive damages and another $425,000 for emotional distress damages. *Id.* at 639.

135. *Id.* at 640 n.1.

136. *Id.* at 647.

137. Although some bills to address genetically altered animal issues have been introduced into Congress, none have become law. O'Connor, *supra* note 8 (an overview of recent congressional action on genetically altered animals). *See also* Czarnetzky, *supra* note 5 (advocating the need for Congress to adopt patent laws to protect genetically engineered animals).

138. 7 U.S.C. § 151 (1988).

139. 7 U.S.C. §§ 150(aa)-(jj) (1988 & Supp. III 1991).

140. 7 U.S.C. § 2801 (1988).

141. 7 C.F.R. § 340 (1992).

testing permit procedure.[142] The APHIS procedure requires companies seeking to release any regulated article[143] into the environment to obtain a permit from APHIS prior to its release.[144]

The permit application is to be submitted at least 120 days in advance of the proposed release.[145] An initial review will be completed within thirty days of receipt of the application to determine whether the application was completed correctly.[146] The applicant will then be notified that the APHIS 120 day review period has begun to run.[147]

Prior to the expiration of the review period, the applicant will be informed whether approval has been granted or denied.[148] At a minimum, a granted permit is subject to the ten conditions set forth in the regulations.[149] If the permit is denied, the regulations provide for an appeal procedure.[150]

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142. *Id.* § 340.3 (1992).

143. *Id.* § 340 (1992). The term "regulated article" is defined as follows:

> *Regulated Article.* Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 of this part and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such as [sic] organism, or any other organism or product altered or produced through genetic engineering which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Id.

144. *Id.*

145. 7 C.F.R. § 340.3(b) (1992).

146. *Id.*

147. *Id.*

148. *Id.* § 340.3(e) (1992).

149. *Id.* § 340.3(f) (1992). Briefly, the ten conditions are

1. Proper maintenance and disposition.
2. Proper disposal and shipping material.
3. Separation from other organisms.
4. Confinement to specified areas.
5. Access to inspection.
6. Proper identification.
7. Prevention of accidental or unauthorized release.
8. Prevention of the spread of the plant pests.
9. Monitoring reports.
10. Notification in the event of:
    (i) Accidental or unauthorized release.
    (ii) Substantially different "characteristics" or "any unusual occurrence."

Id.

150. *Id.* § 340.4(g) (1992). The appeal must be submitted within 10 days after

Once a finding is made that no significant environmental impact will occur if the genetically engineered organism is tested in the field,[151] a notice is published in the Federal Register.[152]

The APHIS regulations list plant pests and exempted organisms.[153] A procedure is created under which a petition may be submitted to amend the list of organisms in Section 340.2 . . . by adding or deleting any genus, species, or subspecies."[154] The USDA publishes proposals to amend the APHIS regulations in the Federal Register and solicits comments from the public.[155] The Deputy Administrator issues a decision within 180 days of receipt of the petition to amend.[156]

On June 2, 1992, APHIS received a request from Calgene, Inc. for abatement of future regulation of the FLAVR SAVR™ tomato as a plant pest or as a "regulated article"[157] on the ground that the vectors used in producing the tomato were disarmed.[158] APHIS has indicated that, based on the reviews of a number of field tests of the FLAVR SAVR™ tomato and the information submitted by Calgene in its petition, APHIS believes that the tomato is not a plant pest and there is no reason to believe that it may otherwise present risk to nontargeted plants.[159] Thus, APHIS has indicated that the FLAVR SAVR™ tomato is not a regulated article under the APHIS regulations.[160]

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notification of denial and must "state all of the facts and reasons" why the applicant believes the decision should be changed. *Id.*

151. APHIS does not describe what a "significant impact" entails. Rather, APHIS requires that an organism does not "present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment." Notices, 57 Fed. Reg. 24,235 (1992).

152. *See, e.g.*, Notices, 57 Fed. Reg. 24,235-37 (1992).

153. 7 C.F.R. § 340.2 (1992).

154. *Id.* § 340.4(a).

155. *Id.* § 340.4(c)(2).

156. *Id.* § 340.4(c)(3). The petition will either be approved in whole or in part or denied in whole or in part. *Id.*

157. Regulation of the FLAVOR SAVR™ was promulgated under 7 C.F.R. § 34 (1992).

158. Notices, 57 Fed. Reg. 31,170 (1992). "Vector" describes the actions of small DNA rings, or plasmids, capable of replication. As plasmids can pass from one cell to another, they may be induced to act as vectors, or carriers, of the specified DNA material. *See* Czarnetzky, *supra* note 5, at 1332.

159. Notices, 57 Fed. Reg. 31,170 (1992).

160. *Id.*

B. *The Environmental Protection Agency*

The Environmental Protection Agency (EPA) considers the source of its authority for regulation of biotechnology products to be the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[161] and the Toxic Substances Control Act (TSCA).[162] FIFRA authorizes the EPA to restrict pesticides that present "unreasonable adverse" risks to the environment.[163] TSCA allows the EPA to prevent the manufacture or use of dangerous "chemical substances" not otherwise regulated if lack of prevention would present an "unreasonable risk of injury to health or the environment."[164]

On December 13, 1991, the EPA published notice that it had received its first application for an Experimental Use Permit for a transgenic plant pesticide.[165] The request, made by Monsanto, was for tests on several forms of the insect control protein delta-endotoxin[166] to be introduced into cotton.[167] Upon receipt of the request, the EPA solicited public comments concerning Monsanto's application.[168]

On April 10, 1992, after concluding that there was no fore-

161. 7 U.S.C. § 136(c) (1988).

162. 15 U.S.C. § 2601 (1988).

163. 7 U.S.C. § 136(a) (1988). "Unreasonable adverse" risks are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).

164. 15 U.S.C. § 2605(a) (1988). A "chemical substance" is defined as "any organic or inorganic substance of a particular molecular identity, including:

> i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
> ii) any element or uncombined radical . . . .

Id.

165. Notice, 56 Fed. Reg. 65,073 (1992). An experimental use permit will be issued only if the EPA determines that the applicant needs more data before a determination may be made about registration of a pesticide. 7 U.S.C. § 136(c) (1988). A pesticide must be registered by the EPA before sale or distribution. *Id.* § 136(a).

166. Delta-endotoxin is an insect control protein derived from a soil microbe. 56 Fed. Reg. 65,073 (1992).

167. Monsanto proposed to transfer the delta-endotoxin gene to cottonseed to produce a pesticide. 56 Fed. Reg. 65,073 (1992). The proposed testing of these genetically altered plants would include the following five experiments, designed to evaluate the performance of the expressed proteins against the pests:

> (1) economic threshold;
> (2) host plant resistance;
> (3) gene evaluations;
> (4) population dynamics studies;
> (5) threshold treatment determinations.

Id. In addition, breeding nursery and seed increase trials were to be conducted. *Id.*

168. 56 Fed. Reg. 65,073 (1992). The EPA determined that Monsanto's applica-

seeable significant risk to humans or to nontarget organisms from Monsanto's proposed field tests, the EPA issued an Experimental Use Permit.[169] The EPA indicated that the assessment was based solely on Monsanto's application for the permit.[170] The EPA again solicited comments from the public concerning the Monsanto application, stating that "eventual commercialization of Monsanto's transgenic cotton pesticide may raise other issues not addressed with this [Environmental Use Permit]."[171]

C. *The Food and Drug Administration*

The Food and Drug Administration (FDA) considers the source of its regulatory authority to be the Federal Food, Drug and Cosmetic Act (Act).[172] The FDA's interpretation of the Act treats all food products alike, whether the products result from traditional plant breeding methods, recombinant DNA[173] or other genetic engineering techniques.[174]

In May 1992, the FDA published notice of receipt of the first request for consultation concerning a new plant variety developed through recombinant DNA techniques.[175] The request concerned Calgene Inc.'s FLAVR SAVR™ tomato—a product claimed to exhibit improved fruit ripening and long shelf life

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tion may have been of regional and national significance, therefore, public solicitation of comments was mandatory in accordance with 40 C.F.R. § 172.11(a). *Id.*

169. 57 Fed. Reg. 21,655 (1992).

170. *Id.* The agency's decision was specifically based on the expectation that offsite movement of the expressed proteins would be minimal because of the limited acreage utilized and short duration of the field test. *Id.*

171. 57 Fed. Reg. 21,655 (1992).

172. 21 U.S.C. § 321(b) (1989). In addition,

> The Federal Food, Drug and Cosmetic Act (the act) provides the FDA with broad authority to ensure the safety and wholesomeness of food, empowering the agency to initiate legal action against a food that is found to be adulterated or misbranded within the meaning of the act. Consequently, firms frequently consult with the agency concerning potential safety and regulatory issues that may be associated with food products developed through new technology. FDA believes that such consultations are important for the agency to be knowledgeable about current methods of food production and to carry out its responsibility to protect public health.

57 Fed. Reg. 22,772 (1992).

173. Recombinant DNA results from the insertion into a DNA chain, through chemical or biological means, of a sequence not originally present in that chain. STEDMAN'S MEDICAL DICTIONARY 1331 (25th ed. 1990).

174. 57 Fed. Reg. 22,984 (1992).

175. Calgene's request was published separately at 57 Fed. Reg. 22,772 (1992) with a comment period that remained open through July 28, 1992. 57 Fed. Reg. 22,772 (1992).

properties.[176] Upon receipt of Calgene's request, the FDA solicited public comment on the request.[177]

V. FUTURE REGULATION

The future of biotechnology regulation is uncertain. In February 1991, the President's Council on Competitiveness issued a report regarding the continued deregulation of biotechnology.[178] This report recommended four principles to shape the development and streamlining of biotechnology regulation.[179] These principles were developed in an attempt to produce regulatory uniformity among the FDA, EPA and USDA.[180] The report of the Council on Competitiveness attempted to focus the scope of the agencies' oversight on "risk-based" regulation rather than "turf-based regulation."[181]

On May 26, 1992, Health and Human Services Secretary

176. 57 Fed. Reg. 22,772 (1992). Specifically, Calgene asked for an advisory opinion concerning whether FLAVR SAVR™ tomatoes are food and, therefore, subject to the same regulation as other tomato varieties. *Id.*

177. 57 Fed. Reg. 22,772 (1992). Subsequently, Calgene has also asked the FDA to review the Kanamycin-resistance marker gene and its protein (utilized in producing the FLAVR SAVR™ tomato) under the FDA's food additive regulations. *Calgene Seeks FDA Approval of Marker Gene Used in Tomatoes*, FOOD CHEMICAL NEWS, January 11, 1993.

178. PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

179. The four principles are:

> 1. Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product - not the process by which it is created. . . .
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> . . . .
>
> 2. For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare. . . .
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> . . . .
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> 3. Regulatory programs should be designed to accommodate the rapid advances in biotechnology. Performance - based standards are, therefore, generally preferred over design standards. . . .
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> . . . .
>
> 4. In order to create opportunities for the application of innovative new biotechnology products, all regulation in environmental and health areas - whether or not they address Biotechnology - should use performance standards rather than specifying rigid controls or specific designs for compliance.

Id. at 12-13.

180. Prior to the Council's report, the FDA had announced that it did not need to establish further regulatory procedures or requirements to review new biotechnology products. On the other hand, the EPA and the USDA had announced plans to develop further rules and guidelines for reviewing the products. *Id.* at 12.

181. *Id.*

Louis W. Sullivan announced a new policy stating that the FDA will regulate new varieties of whole foods developed through biotechnology by applying the same standards as those used in "traditional foods."[182] The FDA's policy describes the scientific basis for evaluating and ensuring the safety of new varieties of foods produced by any technique, including recombinant DNA and gene splicing processes.[183]

While the Council on Competitiveness appears to have had significant involvement in establishing the former administration's policy, President Clinton recently abolished the Council.[184] As a result, the future biotechnology regulatory structure is somewhat unclear. The subject of biotechnological regulatory processes will nevertheless almost certainly prove to be a significant issue for the new administration.

182. Notice, 57 Fed. Reg. 22,984 (1992). In its notice, the FDA also provided guidance for producers to follow "in determining whether their product [was] a candidate for food additive regulation" under § 409 of the Act and set forth criteria and analytical steps for producers to determine "whether consultation with FDA should be pursued to determine the regulatory status of the product." *Id.* at 22,990-91.

183. *Id.*

184. Stuart Auerbach, *White House Delays Leave Regulatory Policies Hanging*, WASH. POST, Feb. 3, 1993, at F1 (noting President Clinton abolished the Council on Competitiveness).