A Review of U.S. Intellectual Property Law Applicable to Inventions in Biotechnology: U.S. Intellectual Property Law Continues to Demonstrate Its Adaptability to New Technology

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A REVIEW OF U.S. INTELLECTUAL PROPERTY LAW APPLICABLE TO INVENTIONS IN BIOTECHNOLOGY: U.S. INTELLECTUAL PROPERTY LAW CONTINUES TO DEMONSTRATE ITS ADAPTABILITY TO NEW TECHNOLOGY

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I. INTRODUCTION

Intellectual property is a generic term for intangible personal property that includes patents, trademarks, copyrights, and trade secrets.[1] For innovative businesses, intellectual property may be the most valuable assets, more valuable even than the factory and equipment. For biotechnology companies, intellectual property is often essential to financing and survival. Intellectual property has always been important to agriculture;[2] much of the new agricultural equipment of the nineteenth century that made agricultural expansion into the Great Plains possible was subject to patent protection.[3] According to many commentators, intellectual property is key to innovation and economic prosperity.[4] Without the protection of intellectual

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1. *See* IRAH H. DONNER, PATENT PROSECUTION: PRACTICE & PROCEDURE BEFORE THE U.S. PATENT OFFICE 10-11 (2d ed. 1999).

2. *See* John H. Barton, *Introduction: Intellectual Property Rights Workshop, in* INTELLECTUAL PROPERTY RIGHTS: PROTECTION OF PLANT MATERIALS 13, 14 (P. Stephen Baenziger et al. eds. 1993).

3. *See* ALLAN G. BOGUE, FROM PRAIRIE TO CORN BELT: FARMING ON THE ILLINOIS AND IOWA PRAIRIES IN THE NINETEENTH CENTURY 148-50 (1963).

4. *See* FRED WARSHOFSKY, THE PATENT WARS: THE BATTLE TO OWN THE WORLD'S TECHNOLOGY 5-6 (1994).

property, companies could not profit from their research and development, and might have their good name, which they had spent years developing, plundered by imitators selling inferior products. This Article will provide a general introduction to intellectual property and issues specific to agricultural biotechnology. It will explore the question of whether existing intellectual property law is up to the job of providing protection for innovation in biotechnology; some commentators have suggested that current intellectual property law is lacking in this regard.[5]

II. UTILITY PATENT PROTECTION

Congress has authorized the U.S. Patent and Trademark Office ("Patent Office") to issue a patent to any person who invents a product or process that is novel, nonobvious, and useful.[6] Although the inventor may assign patent rights to her employer or others, the application for patent protection must be made in the name of the actual inventor.[7] Such patents are often called utility patents[8] to distinguish them from special types of patents discussed below. Numerically and economically, utility patents are by far the most important type of patent.[9] For a product or process to be novel it must be new, meaning that no other person has made, sold, or published a description of the product or process prior to the application.[10] The Supreme Court has determined that a living organism or a part of a living organism may be patented.[11] Indeed, many patents have been granted for genes of particular organisms.[12] Some plant varieties, like Roundup Ready® soybeans and Bt cotton, now contain patented genes.[13] In addition to patenting genes

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5. *See* Kenneth G. Chahine, *Enabling DNA and Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation*, 25 AIPLA Q.J. 333, 369-70 (1997).

6. *See* 35 U.S.C. §§ 101-102 (1994); 35 U.S.C. § 103 (1994 & Supp. IV 1998).

7. *See* 35 U.S.C. § 111 (1994). Where large teams of researchers collaborate, as is usually the situation with research in biotechnology, determining inventorship may be an issue. *See* Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F.3d 1223, 1226-27 (Fed. Cir. 1994).

8. *See* Donner, *supra* note 1, at 4-5 (stating the requirements for a utility patent are that an invention must be new, functional, and useful).

9. *See* Martin P. Hoffman, *Design Patents/Trademarks/Other Types of Product Protection*, SE 44 ALI-ABA 161, 163 (2000), *available in* 2000 WL, TP-ALL.

10. *See* 35 U.S.C. § 102.

11. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980); PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY 225-27 (1999). The United States granted a patent on a living organism to Louis Pasteur in 1873; however, despite this precedent, the U.S. Patent and Trademark Office developed the practice of not granting claims to living organisms that resulted in the Chakrabarty litigation. *See* GRUBB, *supra*, at 225-27.

12. *See* GRUBB, *supra* note 12, at 224-25. A gene is a component of the genetic code of an organism. *See* WEBSTER'S DICTIONARY OF THE ENGLISH LANGUAGE 395 (1988).

13. *See Australia Slow On Genetics*, THE CANBERRA TIMES (Austl.), May 25, 1998, at 8A, *available in* LEXIS, Newspaper Stories, Combined Papers (discussing Monsanto's patent of the Bt gene); Repps Hudson, *Seeds Sow Court Case in NE, MO.*; *Soybean Holding Practice is Tested*, ST. LOUIS POST DISPATCH, Sept. 21, 1997 at 1E, *available in* LEXIS, Newspaper Stories, Combined Papers (discussing Monsanto's patent on Roundup Ready® soybeans).

and entire organisms, biotechnology companies may also obtain patent protection on the equipment and processes developed to create novel genes and organisms.[14]

Patent protection is available for those inventions that are new or novel.[15] An important limitation on the availability of patent protection is that the inventor must file a patent application with the Patent Office within one year of the first commercial use (known as the "on-sale bar") or publication of the invention.[16] Because a patent is entitled to a presumption of validity, one who seeks to prove the invention was either anticipated by another or is subject to the on-sale bar must demonstrate this by "substantial evidence that is clear and convincing."[17] The standard to be applied in determining whether the grant of a patent is invalid based upon the on-sale bar was determined by the Supreme Court in *Pfaff v. Wells Electronics, Inc.*[18]

> The Court established two conditions that must be satisfied to begin the one-year statutory period for the on-sale bar: 1) the invention must be the subject of a commercial offer for sale; and 2) the invention must be ready to be patented. [footnote omitted] The [C]ourt then stated that the second condition 'may be satisfied in at least two ways': 1) by proof of a reduction to practice; or 2) by proof that the inventor developed drawings or other materials sufficient to permit one skilled in the art to practice the invention.[19]

The results of the *Pfaff* test may be harsh and serve as a warning to biotechnology companies to have a comprehensive intellectual property policy in place to avoid such catastrophic outcomes.

A further limitation is that a patent issued by the Patent Office is effective only within the territory of the United States.[20] The U.S. patent law does provide some protection against the import of nonpatented products produced abroad by a process patented in the United States.[21] However, without foreign patent protection the manufacture and sale of such products outside the territory of the United States cannot be prohibited.[22] To obtain patent protection in foreign countries, an application must be filed in each country where protection is desired.[23] The United

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14. *See* GRUBB, *supra* note 12, at 233-34.
15. *See* 35 U.S.C. § 101 (1994).
16. *See id.* § 102(b).
17. Finnigan Corp. v. International Trade Comm'n, 180 F.3d 1354, 1370 (Fed. Cir. 1999).
18. *See* Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 67-69 (1998).
19. Juan C. Gonzalez, *The On-Sale Bar to Patentability: The U.S. Supreme Court Sheds Some Light*, 40 J.L. & TECH. 83, 88 (2000).
20. *See* 35 U.S.C. § 271 (1994).
21. *See id.* § 271(g).
22. *See* MARTIN J. ADDMAN ET AL., CASES & MATERIALS ON PATENT LAW 813 (1998).
23. *See id.*

States is party to international agreements that facilitate this process.[24] Unlike the United States, most foreign countries offer no grace period for prior use or publication of the invention.[25] Foreign rights may be lost as the result of any prior commercial use or publication of the invention prior to filing of foreign patent applications.[26]

In a field as competitive as biotechnology, it is not unusual for there to be more than one claimant to the same invention. When applications by multiple applicants to the same invention are simultaneously pending, or a pending application interferes with an unexpired patent, it is the duty of the Commissioner of the Patent and Trademark Office to declare an interference.[27] In *Singh v. Brake*[28] the Federal Circuit overturned a Patent and Trademark Office Board of Patent Appeals and Interferences decision awarding priority of invention in a DNA construct to Anthony J. Brake.[29] The Federal Circuit determined that the decision of the Board was not supported by substantial evidence and remanded so that the Board could reweigh the sufficiency of the evidence and reach factual conclusions.[30] At issue was the requirement that an inventor's testimony be corroborated.[31] The Federal Circuit concluded that the inventor's laboratory notebook, not witnessed until several years after the fact, could provide corroboration of the inventor's testimony regarding conception but not reduction to practice.[32] The case illustrates the importance of keeping good, promptly witnessed, records of all aspects of research in biotechnology in order to support subsequent applications for patent protection.

Barton v. Adang[33] involved a three-way interference over priority of invention in a method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants.[34] The interference was declared between two pending applications, assigned to Agracetus and Monsanto, and an issued patent assigned to Mycogen Plant Science, Inc.[35] Shortly after the interference was declared, Monsanto purchased Agracetus, notified the Patent Office of common ownership, and in the notification declared that good cause existed to continue the three party interference.[36] The Patent Office determined that good cause to continue the three party interference did not exist and required Monsanto to elect between the two

24. *See* 35 U.S.C. § 351 (1994).
25. *See* ADDMAN, *supra* note 22, at 850-53.
26. *See id.*
27. *See* 35 U.S.C. § 135 (1994).
28. Singh v. Brake, 222 F.3d 1362 (Fed. Cir. 2000).
29. *See id.* at 1369.
30. *See id.* at 1371.
31. *See id.* at 1366.
32. *See id.* at 1368.
33. Barton v. Adang, 162 F.3d 1140 (Fed. Cir. 1998).
34. *See id.* at 1141.
35. *See id.*
36. *See id.* at 1142.

applications.[37] While finding that the Patent Office has discretion to decide whether to declare an interference or continue one once begun, the Federal Circuit found that in the absence of discovery Monsanto could not determine which application would be the best evidence to establish priority, and that this was "good cause" to continue the interference.[38] The implication of this decision is that the Patent Office could force Monsanto to elect an application once discovery was complete and the information needed to make the election had been obtained.[39]

Genentech, Inc. v. Chiron Corp.[40] arose from an interference involving claims to technology related to the production of human insulin in yeast.[41] The Federal Circuit addressed the complex issue of interpretation of a count in an interference.[42] The count in an interference is the matter for which the Patent Office has determined that priority is in issue.[43] As with determination of the scope of claims in an issued patent, the proper construction of the count is a question of law for the court.[44]

In *Kridl v. McCormick*[45] the Federal Circuit reviewed and upheld the award of priority by the Board of Patent Appeals and Interferences to McCormick and two fellow inventors, Barton and Swain.[46] The Federal Circuit noted that priority is a question of law subject to review de novo on appeal.[47] At issue in the interference was priority to an antisense recombinate DNA technology useful for giving plants resistance to certain viruses.[48] The case contains a good review of the law applicable to the corroboration required for testimony by inventors.[49] The complexity of priority claims in biotechnological inventions is illustrated in *Fiers v. Revel*,[50] an appeal from a three-way interference in which British, Israeli, and Japanese teams of inventors contested priority of invention in DNA that codes for human fibroblast beta-interferon.[51]

Patent protection is generally available for a term of twenty years from the date of filing the patent application.[52] During that period, the owner of the patent has the right to exclude all others from making, using, or selling any product or process

37. *See id.*
38. *See id.* at 1146.
39. *See id.*
40. Genetech, Inc. v. Chiron Corp., 112 F.3d 495 (Fed. Cir. 1997).
41. *See id* at 497.
42. *See id.* at 500-02.
43. *See id.* at 499.
44. *See id.* at 500.
45. Kridl v. McCormick, 105 F.3d 1446 (Fed. Cir. 1997).
46. *See id.* at 1447.
47. *See id.* at 1449.
48. *See id.* at 1446.
49. *See id.*
50. Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).
51. *See id.* at 1164-65.
52. *See* 35 U.S.C. § 1154(a)(2) (1994).

that contains or uses the patented technology.[53] A patent does not, however, confer a right to use; for example, use of a patented organism may be banned if it is too hazardous to the public health or the environment.[54] Any other person who makes, uses, or sells any part of that patented technology is an infringer.[55] An infringer is liable to the patent owner for damages even if the infringer was unaware of the patent or the infringement.[56] A court may treble damages and award attorney fees against one who knowingly infringed a patent.[57]

Patenting of living organisms poses special problems for the patent system. Section 112 of the Patent Act requires:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[58]

To enable the public to practice an invention embodied in a self-replicating organism, a deposit must be made in an acceptable depository.[59] Acceptable depositories may be either any International Depository Authority ("IDA") as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure or any depository deemed suitable by the U.S. Commissioner of Patents and Trademarks.[60] Anyone who intends to seek protection in countries in addition to the United States would be well advised to use the IDA to avail themselves of the provisions of the Budapest Treaty. *Chakrabarty* established that the Patent Office must grant patent protection to living organisms.[61] By interpretive rule, the Patent Office determined that section 101 of title 35 of the U.S. Code also required that it grant patent protection to inventions embodied in multicellular organisms, including animals.[62] The Federal Circuit rejected a challenge to the Patent Office's interpretation on grounds of standing.[63]

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53. *See* 35 U.S.C. § 271(a) (1994 & Supp. IV 1998).
54. *See* DONNER, *supra* note 1, at 9.
55. *See* 35 U.S.C. § 271(a) (1994 & Supp. IV 1998).
56. *See id.* § 271(e)(4)(C).
57. *See id.* § 271.
58. 35 U.S.C. § 112 (1994).
59. *See* U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENTING EXAMINATION PROCEDURE § 2404 (1998) [hereinafter MPEP].
60. *See id.* at § 2405.
61. *See generally* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (holding that a live human-made micro-organism is patentable subject matter).
62. *See* GRUBB, *supra* note 12, at 252.
63. *See* Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 939 (Fed. Cir. 1991).

The situation regarding the patenting of plants was complicated by the existence of the Plant Variety Protection Act.[64] The Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply, Inc.*[65] The defendants objected that Pioneer had obtained both patent protection under title 35 of the U.S. Code and certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn.[66] The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter under the U.S. patent statute.[67] The Federal Circuit rejected this argument noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts . . . to regard each as effective."[68]

With regard to gene patents, the Patent Office requires "the use of standard symbols and a standard format for sequence data in most sequence-type patent applications."[69] This is a departure from general Patent Office practice that allows the inventor to be his own lexicographer.[70]

The Patent Office has also recently clarified the utility requirements for gene patents under sections 101 and 112 of the patent statute,[71] and the written description requirement under section 112, paragraph 1.[72] As both of these clarifications govern internal practices, the Patent Office has determined that both of these changes are exempt from notice and comment rulemaking.[73] Nonetheless, these changes may have profound implications for some applicants. In clarifying the utility requirement, the Patent Office decided against developing a utility standard specifically for gene patents and stated that the utility must be "specific and substantial:"[74]

> The *prima facie* showing must contain the following elements:
>
> (1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

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64. *See* 7 U.S.C. § 2321 *et seq.* (1994).

65. *See* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 200 F.3d 1374, 1378 (Fed. Cir. 2000).

66. *See id.* at 1376-77.

67. *See id.*

68. Radzanower v. Touche Ross & Co., 426 U.S. 148, 155 (1976) (quoting Morton v. Mancari, 417 U.S. 535, 551 (1974)).

69. MPEP, *supra* note 59, § 2421.01 (1998).

70. *See* Elekta Instrument S.P.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000).

71. *See* 64 Fed. Reg. 71,440, 71,441 (1999).

72. *See* 64 Fed. Reg. 71,427, 71,427 (1999).

73. *See* 64 Fed. Reg. 71,440, 71,441 (1999).

74. *See id.*; *In re* Ziegler, 992 F.2d 1197, 1201 (Fed. Cir. 1993).

> (2) Support for factual findings relied upon in reaching this conclusion; and
>
> (3) An evaluation of all relevant evidence of record.
>
> (b) Where no specific and substantial utility is disclosed or known, a *prima facie* showing of no specific and substantial utility must establish that it is more likely than not that a person skilled in the art would not be aware of any well-established credible utility that is both specific and substantial.
>
> The *prima facie* showing must contain the following elements:
>
> (1) An explanation that clearly sets forth the reasoning used in concluding that there is no known well established utility for the claimed invention that is both specific and substantial;
>
> (2) Support for factual findings relied upon in reaching this conclusion; and
>
> (3) An evaluation of all relevant evidence of record.
>
> (4) A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.[75]

Statements of fact made by the applicant are treated as true unless one skilled in the art would doubt them.[76] A lack of utility is also the basis for a rejection based upon a failure to disclose how to use the invention under section 112, first paragraph (the enablement requirement).[77]

The Revised Utility Examination Guidelines are consistent with Supreme Court precedent.[78] The Supreme Court's rationale for requiring specific utility is the fear that an inventor's patent claims might occupy the entire field.[79]

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, [footnote omitted] without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress

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75. 64 Fed. Reg. 71,440, 71,442 (1999).

76. *See id.*

77. *See id.*

78. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 528-36 (1966) (discussing the specific utility requirement for patents).

79. *See id.* at 534-35.

> for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[80]

The Federal Circuit has clarified that "[t]he threshold of utility is not high: An invention is useful under section 101 if it is capable of providing some identifiable benefit."[81]

However, the disclosure in the patent application must be sufficient to enable one skilled in the art to practice the invention.[82] "[W]hether a patent specification adequately describes the subject matter claimed is a question of fact."[83] "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."[84] "Tossing out the mere germ of an idea does not constitute enabling disclosure."[85] While every aspect of a generic claim certainly need not have been carried out by an inventor or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.[86]

The specification of the patent need not contain sufficient detail to allow the public to practice the invention; however, it must contain information about those novel steps that are essential to allowing one skilled in the art to practice the invention.[87]

> It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.[88]

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80. *Id.*
81. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999).
82. *See* Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1365 (Fed. Cir. 1997).
83. *In re* Alton, 76 F.3d 1168, 1171-72 (Fed. Cir. 1996).
84. *Genentech*, 108 F.3d at 1366. *See also* Brenner v. Manson, 383 U.S. 519, 533-34 (1966) (stating, in context of the utility requirement, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.")
85. *Genentech*, 108 F.3d at 1366.
86. *See id.*
87. *See id.*
88. *Id.*

In *In re Wands*[89] the Federal Circuit set forth eight factors to be considered in determining whether undue experimentation is required:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[90]

Courts need not review all of these factors when deciding whether the invention has been enabled.[91] To complete its analysis of whether the disclosure has met the enablement requirement, the court must further determine the level of knowledge of one skilled in the art.[92] The disclosure in the patent application may substantially limit the scope of the claims.[93] "[C]laims may be no broader than the supporting disclosure, and therefore . . . a narrow disclosure will limit claim breadth."[94]

The unpredictability of the art is a key issue in determining the scope of claims allowable.[95] "The district court [in *Enzo Biochem, Inc. v. Calgene, Inc.*] . . . found that antisense was a highly unpredictable technology, a finding amply supported by the record."[96] The Patent Office and the courts have generally classified gene technology in the same category as chemistry, an inherently unpredictable art.[97]

As with the utility requirement, the Patent Office decided to develop neutral standards for the written description requirement that apply across all arts.[98] The written description must be sufficient that one skilled in the art could practice the invention.[99] In order to avoid confusion, the Patent Office has elected not to attempt to define the word "gene."[100] Taken together, these requirements will prevent

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89. *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988).

90. *Id.* at 737.

91. *See* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999). *See also* Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating, "it is not necessary that a court review all the Wands factors to find a disclosure enabling").

92. *See Enzo Biochem*, 188 F.3d at 1372-73.

93. *See* The Gentry Gallery, Inc. v. The Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998).

94. *Id.* at 1480.

95. *See Enzo Biochem*, 188 F.3d at 1372. *See also* Enzo Biochem, Inc. v. Calgene, Inc., 14 F. Supp. 2d 536, 550 (D. Del. 1998) (explaining that "when construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history").

96. *Enzo Biochem*, 188 F.3d at 1372.

97. *See* GRUBB, *supra* note 12, at 226. "The difficulty is that the inherent complexity of living systems is such that it becomes more difficult to ensure that these requirements are met where living organisms are involved . . .". *Id.*

98. *See* 64 Fed. Reg. 71,427, 71,428 (1999).

99. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

100. *See* 64 Fed. Reg. 71,427, 71,431 (1999).

applicants from obtaining patent protection on nucleotide sequences with no known applications other than as the subject of further research.[101]

Section 103 imposes the further requirement that the subject matter of the invention be non-obvious at the time the application for the patent was filed.[102] Subsection (b) of section 103 is directed specifically to biotechnological process inventions:

> (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if -
>
> (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and
>
> (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.
>
> (2) A patent issued on a process under paragraph (1) -
>
> (A) shall also contain the claims to the composition of matter used in or made by that process, or
>
> (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.
>
> (3) For purposes of paragraph (1), the term "biotechnological process" means -
>
> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to -
>
> (i) express an exogenous nucleotide sequence,
>
> (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
>
> (iii) express a specific physiological characteristic not naturally associated with said organism;
>
> (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
>
> (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).[103]

The history of the non-obviousness standard has been discussed in detail elsewhere by other authors.[104] The question of whether a claim in a patent is obvious

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101. *See* GRUBB, *supra* note 12, at 252.
102. *See* 35 U.S.C. § 103 (1994 and Supp. IV 1998).
103. *Id.* § 103(b).

is one of fact for a jury and may only be set aside if there is no substantial evidence to support it.[105] In *Sibia Neurosciences* a divided Federal Circuit found that claims to a cell-based screening method were obvious as a matter of law; the dissent protested that the court was substituting its judgment for that of the jury.[106] *In re Hiniker Co.*,[107] wherein the Federal Circuit affirmed a finding of obviousness by the Patent and Trademark Office Board of Patent Appeals and Interferences, illustrates the fact intensive nature of analyses into the obviousness of claimed inventions.[108] Unexpected results are one argument for non-obviousness of the claimed invention.[109] Whether the results of the claimed invention are unexpected is a question of fact.[110] The mere fact that a claimed invention is simple in nature will not make that invention obvious if it was not obvious to one skilled in the art at the time the invention was made.[111] Those reviewing claims for obviousness must avoid after-the-fact analysis.[112] The standard of review for the Federal Circuit when it reviews factual findings of obviousness or non-obviousness depends upon the route by which the issue came to the Federal Circuit.[113] In *Dickinson v. Zurko*,[114] a six to three decision, the Supreme Court held that the standard depends upon whether the decision was made by the Patent Office, an agency, or a federal district court.[115] In *Zurko*, the Supreme Court held that findings of fact made by the Patent Office are subject to review under the "arbitrary, capricious, [or] abuse of discretion, or . . . unsupported by substantial evidence" standard while factual findings of district courts are subject to review under the higher "clearly erroneous" standard.[116] The Supreme Court stated that hypothetically it would be possible for a decision to be clearly erroneous while supported by substantial evidence, although it stated that such cases would be extremely rare.[117]

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104. *See* David E. Wigley, Note, *Evolution of the Concept of Non-Obviousness of the Novel Invention: From a Flash of Genius to the Trilogy*, 7 ARIZ. L. REV. 581, 581 (2000).

105. *See* Sibia Neurosciences v. Cadus Pharm. 225 F.3d 1349, 1355 (Fed. Cir. 2000).

106. *See id.* at 1360 (Mayer, J., dissenting).

107. *In re* Hiniker Co., 150 F.3d 1362 (Fed. Cir. 1998).

108. *See id.* at 1367.

109. *See In re* Mayne, 104 F.3d 1339, 1343 (Fed. Cir. 1997).

110. *See id.*

111. *See* The Gentry Gallery v. The Berkline Corp., 134 F.3d 1473, 1478 (Fed. Cir. 1998).

112. *See id.*

113. *See id*

114. Dickinson v. Zurko, 527 U.S. 150 (1999).

115. *See id.* at 151, 160-65.

116. *Id.* at 152-53.

117. *See id.* at 162-63 (citing International Bhd. of Elec. Workers v. NLRB, 448 F.2d 1127, 1142 (D.C. Cir. 1971) (Leventhal, J., dissenting) for the proposition that Judge Leventhal wrongly believed, but corrected himself – "that he had found the 'case dreamed of by law school professors' where the agency's findings, though 'clearly erroneous,' were 'nevertheless' supported by 'substantial evidence').

Applicants for patent protection owe the Patent Office a duty of candor, good faith, and honesty.[118] When this duty is breached inequitable conduct has occurred.[119] Inequitable conduct during prosecution of the patent application may render the patent unenforceable.[120] "Inequitable conduct can consist of affirmative misrepresentations of material fact, submission of false material information, or the failure to disclose known material information during the prosecution of a patent, coupled with intent to deceive the [Patent Office]."[121] Whether inequitable conduct has occurred is a question of fact that must be proven by clear and convincing evidence.[122]

III. PLANT PATENTS

A special type of patent is available for new varieties of plants found in cultivated areas.[123] Section 161 provides:

> 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, subject to the conditions and requirements of this title. The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.[124]

These are called plant patents and are available for asexually reproduced plants.[125] Plants capable of reproducing by seed are also covered if they are capable of being asexually reproduced.[126] Plant patents cannot be obtained on tuber crops, such as Irish potatoes and Jerusalem artichokes.[127] The new plant must be a distinct variety.[128] No deposit is required for plants that are the subject of plant patents.[129]

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118. *See* Life Tech., Inc. v. Clontech Lab., Inc., 224 F.3d 1320, 1324 (Fed. Cir. 2000); Perseptive Biosystems, Inc. v. Pharmacia Biotech, Inc. 224 F.3d 1315, 1318 (Fed. Cir. 2000)
119. *See Life Tech*, 224 F.3d at 1324.
120. *See id.*
121. *Id.*
122. *See id.*
123. *See* 35 U.S.C. § 161 (1994).
124. *Id.*
125. *See id.*
126. *See* MPEP, *supra* note 59, § 1601 (2000).
127. *See id.*
128. *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1565 (Fed. Cir. 1995).
129. *See* MPEP, *supra* note 59, § 2403.2 (1998).

Nonetheless, the applicant may be required to provide a specimen of the plant.[130] Only a single claim is allowed in a plant patent.[131]

IV. CERTIFICATES OF PROTECTION UNDER THE PLANT VARIETY PROTECTION ACT

Certificates of Protection are available through the Plant Variety Protection Office of the U.S. Department of Agriculture.[132] This patent-like form of protection is available where:

> In general the breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is -
>
> (1) new, in the sense that, on the date of filing of the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety -
>
> (A) in the United States, more than 1 year prior to the date of filing; or
>
> (B) in any area outside of the United States -
>
> (i) more than 4 years prior to the date of filing, except that in the case of a tuber propagated plant variety the Secretary may waive the 4-year limitation for a period ending 1 year after April 4, 1996; or
>
> (ii) in the case of a tree or vine, more than 6 years prior to the date of filing;
>
> (2) distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application;
>
> (3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable; and
>
> (4) stable, in the sense that the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that

130. *See* MPEP, *supra* note 59, § 1607 (2000).

131. *See* 35 U.S.C. § 162 (1994). *See also* Nicholas J. Seay, *Intellectual Property Rights in Plants, in* INTELLECTUAL PROPERTY RIGHTS: PROTECTION OF PLANT MATERIALS 61, 63 (P. Stephen Baenziger et al. eds. 1993). "Each plant patent application is permitted only one claim that is specifically to the plant shown and described." *Id.*

132. *See* 7 U.S.C. § 2482 (1994).

> of varieties of the same category in which the same breeding method is employed.[133]

The term of a certificate of protection is twenty years for most crops and twenty-five years for trees, shrubs, and vines.[134]

V. INFRINGEMENT OF PATENTS

Infringement for both utility and plant patents is governed by the same law.[135] Infringement includes both acts of direct infringement and contributory infringement:

> (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.
> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.
> (d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.[136]

There are exceptions for certain acts involving biotechnology inventions:

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133. 7 U.S.C. § 2402 (1994 & Supp. V 1999).
134. *See id.* § 2483.
135. *See* 35 U.S.C. § 161 (1994).
136. 35 U.S.C. § 271 (1994 & Supp. IV 1998).

(e) (1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit -

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2) -

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product. The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement

> described in paragraph (2), except that a court may award attorney fees under section 285.[137]

The effect of this provision is to permit potential manufacturers of generic products to begin the process of regulatory review prior to the expiration of patents covering the product.[138]

The effect of a finding of infringement is draconian and potentially disastrous for the defendant in an infringement suit. Attorney fees may be awarded to the prevailing party;[139] typical attorney fees in an infringement suit run into seven figures for each side. The court in an infringement action may treble damages, as well as calculate them based upon a reasonable royalty, not the profits made by the infringer.[140]

Before finding infringement, the court must first determine the proper scope of the claims to be applied.[141] *Markman v. Westview Instruments, Inc.* is the leading Supreme Court opinion on the subject of claim interpretation.[142] *Markman* established that interpretation of claims is an issue of law "exclusively within the province of the court."[143] There is no "Seventh Amendment guarantee that a jury will determine the meaning of any disputed term of art about which expert testimony is offered."[144] Once the court determines the scope of the claims, the second question—whether infringement has occurred—is a question for the jury.[145]

Infringement may be either literal in that the accused device includes every limitation of the claim or an equivalent of each limitation under the doctrine of equivalents.[146] The doctrine of equivalents is an equitable doctrine that may be used to find infringement where the accused device does not literally infringe the claims but is nonetheless so similar to the claimed invention that fairness requires a finding of infringement.[147] "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."[148] Courts have struggled with the proper application of the doctrine of equivalents because it "conflicts with the definitional and public-notice functions of

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137. *Id.*
138. *See* DONALD A. GREGORY ET AL., INTRODUCTION TO INTELLECTUAL PROPERTY LAW 54-55 (1994).
139. *See* 35 U.S.C. § 285 (1994).
140. *See id.* § 284.
141. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 374 (1996).
142. *See, e.g., id.*; Schering Corp. v. Amgen, Inc., 222 F.3d 1347, 1351 (Fed. Cir. 2000).
143. *Markman*, 517 U.S. at 372.
144. *Id.*
145. *See id.* at 377.
146. *See* Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1572 (Fed. Cir. 1997).
147. *See* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 24-25 (1997).
148. *Id.* at 29.

the statutory claiming requirement."[149] The Supreme Court discussed these limitations in *Hilton Davis*.[150] Matter given up during the prosecution of the patent application cannot be reclaimed through the doctrine of equivalents.[151] Intent of the alleged infringer is irrelevant to the analysis under the doctrine of equivalents.[152] "An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element."[153] This test is particularly difficult to apply to inventions in genes and organisms and may limit the application of the doctrine of equivalents in infringement actions involving patents on such inventions.

Plant patents are governed by the same law as utility patents except where the statute indicates otherwise.[154] Therefore, the remedies for infringement are the same as for infringement of utility patents.[155] However, the analysis required to find infringement is different since plant patent protection is limited to a single "variety."[156] The asexual reproduction requirement restricts protection to a single plant—all protected specimens must have been asexually reproduced from the original plant.[157] For that reason it is insufficient to prove that an alleged infringing cultivar is similar to the patented variety. The scope of the single claim in a plant patent is always limited to asexual progeny of the original patented variety.[158] Infringement is proven by showing that the alleged infringing plant is an asexual progeny of the patented variety.[159] Independent creation is a defense to an allegation of infringement in a plant patent case.[160] Plant patents, therefore, provide weaker protection than utility patent protection.

Separate law governs infringement of a certificate of protection under the Plant Variety Protection Act.[161] Despite Congress's unfortunate use of the term "variety" in both the Plant Patent Act and the Plant Variety Protection Act, the Federal Circuit has concluded that the analyses of infringement under the two laws are quite different.[162]

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149. *Id.*
150. *See id.* at 28-34, 39-40.
151. *See id.* at 33.
152. *See id.* at 36.
153. *Id.* at 40.
154. *See* 35 U.S.C. § 161 (1994). "The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided." *Id.*
155. *See id.*
156. *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1569 (Fed. Cir. 1995)
157. *See id. See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that a live, human-made microorganism is patentable subject matter under 35 U.S.C. § 101).
158. *See Imazio Nursery*, 69 F.3d at 1569.
159. *See id.* at 1569-70.
160. *See id.* at 1570.
161. *See* 7 U.S.C. §§ 2541-2545 (1994).
162. *See Imazio Nursery*, 69 F.3d at 1568.

> It is true that both the Plant Patent Act and the [Plant Variety Protection Act] use the term "variety" and grant some form of intellectual property protection. However, the two statutes differ significantly in their purposes. The Plant Patent Act grants a plant patent to one who "invents or discovers and asexually reproduces any distinct and new variety of plant." 35 U.S.C. § 161. Conversely, one is entitled to plant variety protection under the [Plant Variety Protection Act] if he has sexually reproduced the variety and has otherwise met the requirements of 7 U.S.C. § 2402(a). The term "variety" in both statutes cannot be read divorced from the very different circumstances in which that term is used.[163]

Asexually reproduced plants are genetically identical to their parent whereas sexually reproduced plants are not.[164] For that reason the analyses of infringement under the two laws cannot be the same.

> Acts of infringement under the Plant Variety Protection Act include:
>
> (1) sell or market the protected variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;
>
> (2) import the variety into, or export it from, the United States;
>
> (3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety;
>
> (4) use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;
>
> (5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the variety;
>
> (6) dispense the variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received;
>
> (7) condition the variety for the purpose of propagation, except to the extent that the conditioning is related to the activities permitted under section 2543 of this title;
>
> (8) stock the variety for any of the purposes referred to in paragraphs (1) through (7);
>
> (9) perform any of the foregoing acts even in instances in which the variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or
>
> (10) instigate or actively induce performance of any of the foregoing acts.[165]

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163. *Id.*
164. *See id.*
165. 7 U.S.C. § 2541 (1994).

There are certain exceptions for contractors who have seed as the result of a breach of contract by the owner of the protected variety, private noncommercial uses, and state governments.[166] There is also a fairly broad saved-seed exemption for farmers who save their own seed for use on their own farms.[167] For varieties registered after the effective date of the 1994 amendments to the Plant Variety Protection Act, farmers may not sell seed for reproductive purposes to other farmers.[168] The Supreme Court's decision in *Asgrow Seed Co. v. Winterboer*[169] set the standard for pre-1994 amendment varieties; "a farmer is not eligible for the section 2543 exception if he plants and saves seeds for the purpose of selling the seeds that they produce for replanting."[170]

There are also research and intermediary exemptions.[171] These limitations and exceptions make the practical definition of infringement under the Plant Variety Protection Act much more limited than the definition under the Patent Act.[172] The definition of damages, including trebling, is the same as under the Patent Act;[173] however, the availability of attorney fees is limited to "exceptional cases."[174] The Supreme Court decision in *Asgrow Seed Co. v. Winterboer* is the leading case analyzing infringement under the Plant Variety Protection Act.[175]

VI. TRADE SECRET PROTECTION

A trade secret is information that has value to a business and is not generally known to the public.[176] The law of trade secrets is a matter of state law and varies from state to state.[177] Trade secrets are of potentially infinite duration since they last as long as secrecy can be maintained.[178] Most inventions will be held as trade secrets prior to obtaining patent protection.[179] To preserve trade secret status the owner of the trade secret must take affirmative steps to preserve the secrecy.[180] Confidentiality

166. *See id.*

167. *See* 7 U.S.C. § 2543 (1994 & Supp. V 1999).

168. *See* Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, §42, 108 Stat. 3136, 3142 (1994).

169. Asgrow Seed Co. v. Winterboer, 513 U.S. 179 (1995).

170. *Id.* at 188.

171. *See* 7 U.S.C. §§ 2544-2545 (1994).

172. *See supra* text accompanying notes 164-174.

173. *See* 7 U.S.C. § 2564 (1994); 35 U.S.C § 284 (1994).

174. *See* 7 U.S.C. § 2565 (1994).

175. *See* Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 185-85 (1995).

176. *See* BLACK'S LAW DICTIONARY 1494 (6th ed. 1990).

177. *See* Kewannee Oil Co. v. Bicron Corp., 416 U.S. 470, 479 (1974) (stating that states may grant trade secret protects and are not preempted by federal patent law).

178. *See* GREGORY, *supra* note 138, at 212-13.

179. *See id.* at 205-06.

180. *See* UNIF. TRADE SECRETS ACT § 1(4)(ii) (amended 1985), 14 U.L.A. 438 (1990). *See also* GREGORY, *supra* note 138, at 204 (stating that a trade secret is information that is valuable because it is maintained as a secret).

agreements with employees, collaborators, and sources of capital are a key component of convincing courts that affirmative efforts to preserve trade secrets have been made.[181]

Trade secret protection may also be a permanent alternative to patent or other formal protection for biotechnology inventions. Trade secret protection is particularly appropriate for process inventions where the process remains under the control of the owner. The pre-grant publication practices of some foreign patent offices may also indicate that trade secret protection is the better means for protecting certain biotechnology inventions since the pre-grant publication destroys the trade secret and there is no guarantee that a patent will ever be granted.[182]

VII. COPYRIGHT PROTECTION

"Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device."[183] GMOs have not been protected to date using copyright because the sequences incorporated into most GMOs are not original, in that the incorporated sequences were found in other organisms.[184] However, as the technology becomes more sophisticated there is no reason why artificial (and original) sequences of DNA might not be protected through copyright. The duration of copyright protection is much longer than patent protection.[185] In general the duration of a copyright "in a work created on or after January 1, 1978, subsists from its creation and . . . endures for a term consisting of the life of the author and 70 years after the author's death."[186] Where available, copyright exists in addition to patent protection, not as an alternative to it. However,

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181. *See generally* GREGORY, *supra* note 138, at 213 (discussing confidential relationships and stating, "[e]xpress confidentiality agreements, even with employees, provide a stronger basis for protecting trade secrets").

182. *See* GRUBB, *supra* note 12, at 100, 117-20. *See also* GREGORY, *supra* note 140, at 207 (stating trade secret protection is lost when the information becomes publicly known through disclosure by the trade secret holder).

183. 17 U.S.C. § 102(a) (1994).

184. *See* Fiest Publications v. Rural Telephone Serv., 499 U.S. 340, 345-46 (1991) (discussing generally the originality requirements for copyright protection).

185. *Compare* 17 U.S.C. § 302(a)-(c) (Supp. IV 1998) (establishing that, in general, a copyright "endures for a term consisting of the life of the author and 70 years after the author's death;" in the case of joint works "the copyright endures for a term consisting of the life of the last surviving author and 70 years after such last surviving author's death;" and "[i]n the case of an anonymous work, pseudonymous work, or a work made for hire, the copyright endures for a term of 95 years from the year of its first publication, or a term of 120 years from the year of its creation, which ever expires first"), *with* 35 U.S.C. § 154(a)(2) (1994) (establishing that a patent ends "20 years from the date on which the application for the patent was filed in the United States"), *and* 35 U.S.C. § 173 (1994) (establishing the term of a plant patent to be "fourteen years from the date of the grant").

186. 17 U.S.C. § 302(a) (Supp. IV 1998).

protection is weak because actual copying must be proven in order to prevail in an infringement action.[187] Copyright protection has the additional advantage of existence from the time that the original work is fixed in a tangible medium of expression.[188]

VIII. CONCLUSION

There are a variety of means available to protect inventions in GMOs and other biotechnologies; however, utility patent and trade secret protections have been the most important. Utility patent protection has become essential for convincing investors to fund biotechnology-based businesses. Plant patents and certificates of protection under the Plant Variety Protection Act have not played a significant role in providing protection for the intellectual property embodied in GMOs; however, these forms of protection may become more important as GMOs enter wider commercial production and useful variations of the original GMOs are observed. Copyright protection has not, to date, been employed to protect the intellectual property in GMOs; however, there is no theoretical reason that it could not be used in an appropriate circumstance. Trademark protection is used to protect the names under which GMOs are marketed; however, a discussion of trademarks is beyond the scope of this Article. Appendix A lists some useful intellectual property web sites.

APPENDIX A: INTELLECTUAL PROPERTY WEB SITES

- ✓ U.S. Patent and Trademark Office
  - o http://www.uspto.gov
- ✓ U.S. Copyright Office
  - o http://lcweb.loc.gov/copyright/
- ✓ USDA, AMS, Plant Variety Protection Office
  - o http://www.ams.usda.gov/science/PVPO/pvp.htm
- ✓ American Intellectual Property Law Association (The AIPLA is an organization of more than 10,000 attorneys who practice intellectual property law.)
  - o http://www.aipla.org/
- ✓ Intellectual Property Owners Association (The IPO is an organization of intellectual property owners.)
  - o http://www.ipo.org/
- ✓ Title 7 Agriculture, Chapter 57 Plant Variety Protection

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187. *See* 17 U.S.C. § 501(a) (Supp. V. 1999); Readers Digest Assoc., Inc. v. Conservative Digest, Inc., 821 F.2d 800, 805 (D.C. Cir. 1987); A.A. Hoehling v. Universal City Studios, Inc., 618 F.2d 972, 977 (2nd Cir. 1980); Central Point Software, Inc. v. Nugent, 903 F. Supp. 1057, 1059 (E.D. Tex. 1995); Arica Inst., Inc. v. Palmer, 770 F. Supp. 188, 190 (S.D.N.Y. 1991); Selle v. Gibb, 567 F. Supp. 1173, 1180 (N.D. Ill. 1983).

188. *See* 17 U.S.C. § 102(a) (1994).

- http://www4.law.cornell.edu/uscode/7/ch57.html
- ✓ Title 15 Commerce and Trade, Chapter 3 Trade-Marks
  - http://www4.law.cornell.edu/uscode/15/ch3.html
- ✓ Title 17 Copyrights
  - http://www4.law.cornell.edu/uscode/17/
- ✓ Title 35 Patents
  - http://www4.law.cornell.edu/uscode/35/